

The Feasibility of Research in Cancer Patients Close to Death and the Impact on Evaluating a Complex Intervention

Dr Clare Smith
BM (Hons) MRCP MA

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ABSTRACT:

In the UK approximately half of all cancer patients die in hospital despite evidence that most would prefer to die at home. Research into complex interventions (CIs) at the end-of-life (EoL) is limited. The Hospital2Home CI (H2H) is a patient centred, multidisciplinary service that includes a case conference (CC) and individualised care planning. The aim of H2H is to seamlessly transfer care from the cancer centre to the community where patient and their families want to be. Research into H2H in cancer patients has not been carried out.

The aim of this thesis was to determine the feasibility of evaluating H2H in cancer patients at the end of life. This thesis follows the Medical Research Council (MRC) framework for developing and evaluating CIs. It incorporates a mixed methods quasi-experimental design to evaluate the study design feasibility, intervention acceptability and to identify any potential benefits of H2H. It also includes a retrospective study of factors influencing place of death (FIPD), and a bereavement study of carer satisfaction with inpatient deaths. These provide context to H2H through providing learning about the wider end of life care experience of patients treated at a cancer centre.

The mixed methods feasibility study shows it is feasible and acceptable to enrol patients in the last few months of life and their carers in longitudinal research. It highlights key learning for studies involving participants at the end of life (EoL); multiple longitudinal research contacts, as frequently as every 2 weeks, are acceptable to patients and their carers, contact from the same researcher throughout is advocated to ensure low withdrawal rates, Preferred Place of Death (PPD) as a single primary outcome is not recommended due to high levels of missing data and reliance on carer proxy responses for patient symptom burden when the patient is too unwell to complete the assessment may be limited by similar carer drop out close to patient death.

In total, 184 patients were invited to participate in the feasibility study 83 (45%) were recruited with 43 carers. The primary outcome tested during this feasibility study was the achievement of PPD. Unadjusted analysis showed H2H 68.8% achieved PPD, Comparator group 47.8% achieved PPD. Potential benefits were also seen in symptom burden, QoL and satisfaction. .The retrospective study of FIPD observed community palliative care (CPCT) involvement and H2H were both independently associated with an increased likelihood of dying at home (CPCT OR 2.36 (1.68-3.31), H2H OR 1.97 (1.31-2.96). The bereavement study showed high levels of satisfaction with inpatient EoL care (Mean Famcare Score 81.7).

Qualitative interviews of 8 patients and 15 health care professionals (HCPs) observed that transition of care to community teams had important meaning, specifically loss of treatment, friendship and trust. Whilst patient participants were positive about the service, HCPs had concerns about community knowledge and service provision the views of community professionals and informal carers now need to be explored

The findings from this feasibility study provide key learning for the conduct of EoL care research. H2H is acceptable to patients with preliminary data suggesting potential benefits that require further evaluation in a definitive clinical trial.

Statement of Originality:

This thesis is based on an original idea by Professor Julia Riley and the author. The author's contribution included protocol design and approval, patient recruitment, data collection, database design, data analysis and primary authorship of this thesis. All data in this thesis are original.

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Publications and Posters Presentations

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- Wood J, **Smith C** End-of-life Care: preparing patients and families. Nature Reviews Urology 2010 Vol 7 p425-429

Posters presentations and Abstracts:

- Boyle L, **Smith C**, Stevens A-M, Riley J How good are we at predicting prognosis? Congruence between predicted prognosis and survival in a tertiary referral cancer centre EoL care service. 9th Palliative Care Congress, 14-16th March, Gateshead 2012
- Cave L, **Smith C**, Stevens A-M, Riley J, Hospital2Home: Outcomes of face to face CCs and a telephone conference between acute to community care? 9th Palliative Care Congress, 14-16th March, Gateshead 2012
- Owens M, **Smith C**, Steven A-M, Riley J .Can we work across the boundaries? Hospital and Community Services working together to support the patient's choice of PPD. 9th Palliative Care Congress, 14-16th March, Gateshead 2012
- Fry GL, Shanmuganathan M, Laftah Z, **Smith C**, Ross JR, Riley J. An audit of in-patient deaths in a tertiary cancer centre. 7th EAPC World Research Congress, Trondheim, Norway, 7-9th June 2012
- **Smith C**, Gough N, Kabir M, Popat S, Bosanquet N, Riley J. Factors influencing place of death for patients treated at a tertiary referral cancer centre. 7th EAPC World Research Congress, Trondheim, Norway, 7-9th June 2012
- **Smith C**, Bosanquet N, Riley J. Family satisfaction with EoL care in a tertiary referral cancer centre. 7th EAPC World Research Congress, Trondheim, Norway, 7-9th June 2012.
- **Smith C**, Riley J, Owens M Patient Led Case conferencing at the Interface between Acute and community care to facilitate Advanced care planning at the EoL Palliative Medicine 2010; 24:S99 No 307
- **Smith C**, Owens M, Bosanquet N, Riley J The Royal Marsden Hospital2Home Project Poster Palliative Care Congress March 2010 Bournemouth
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Abbreviations

ACP:	Advance Care Plan
AC:	All comparator study group
ADI:	Attrition due to illness
ADD:	Attrition due to death
AAR:	Attrition at random
AMS:	Anna Marie Stevens
AKPS:	Australian Kornosky Performance Scale
APM:	Association of Palliative Medicine
AUC:	Area Under the Curve
BSC:	Best Supportive Care
CC:	Case conference
CCG:	Clinical Commissioning Group
CHCP:	Community Health Care Professional
CI:	Complex Intervention
CPC:	Community Palliative Care
CPCT:	Community Palliative Care Team
CQOLC:	Carer Quality of Life in Cancer questionnaire
CRF:	Clinical record file
CRCT:	Cluster Randomised Controlled Trial
CS:	Clare Smith
CSRI:	Client Service Receipt Inventory
DN:	District Nurse
DoH:	Department of Health
EAPC:	European Association for Palliative Care
EoL:	End of Life
EoLC:	End of Life Care
EPR:	Electronic Patient Record
FIPD:	Factors influencing place of death
GI:	Gastrointestinal
HCP:	Health Care Professionals
H2H:	Hospital2Home
H2H SS:	Hospital2Home Specialist Sister
IMD:	Index of Multiple Deprivation
ILD:	Interstitial Lung Disease
IP:	Inpatient
IR:	Interquartile range
JK:	Jonathan Koffman
JR:	Julia Riley
LAD:	Last Assessment before Death
LSOA:	Local Super Output Area
MAR:	Missing at Random
MDT:	Multidisciplinary Team
MNAR:	Missing Not at Random
MRA:	Multiple regression analysis
MRC:	Medical Research Council
MSAS-SF:	Memorial Symptom Assessment Score- Short Form

MSAS-GDI:	Memorial Symptom Assessment Score – Global Distress Index
MSC:	Main site controls
MQOL:	McGill Quality of Life Questionnaire
NAO:	National Audit Office
ND:	Nigel Dodds
NHS:	National Health Service
NIHR:	National Institute for Health Research
NOK:	Next of Kin
OACCS:	Outcome Assessment and Complexity Collaborative Suite of Measures
ONS:	Office of National Statistics
OR:	Odds Ratio
PCA:	Principle Component Analysis
PCT:	Primary Care Trust
PI:	Principle Investigator
PIS:	Patient Information Sheet.
PoD:	Place of Death
POS:	Palliative Outcome Scale
PPC:	Preferred Place of Care
PPD:	Preferred Place of Death
PPS:	Palliative Performance Status
PROMS:	Patient Reported Outcome Measures
PSSRU:	Personal Social Services Research Unit
QoL:	Quality of Life
Qual:	Qualitative research
Quan:	Quantitative research
REC:	Regional Ethics Committee
RCT:	Randomised Controlled Trial
RMFT:	Royal Marsden Foundation Trust
RR:	Response rate
SD:	Standard Deviation
SSC:	Satellite Site Controls
SPC:	Specialist palliative care
SPCT:	Specialist palliative care team
TMSAS:	Total Memorial Symptom Assessment Score
TQOL:	Total McGill Score

1. Background: End of Life Care, Place of Death, Preferred Place of Death

1.1 Introduction

In the UK approximately half of all cancer patients die in hospital despite evidence that most would prefer to die at home. Research into CIs to achieve preferences at the end-of-life (EoL) is limited. This thesis presents a feasibility study to evaluate research methods used and to identify preliminary estimates of effectiveness of an EoL CI in cancer patients. It also presents retrospective and bereavement work to determine the wider EoL Care (EoLC) experience of cancer patients known to a tertiary referral centre.

In this chapter I will present the background to this thesis. I will discuss the current challenges in EoLC with reference to UK government policy. I will also present place of death (PoD) data for the UK and discuss the definitions of, and available evidence on PPC (PPC) and PPD (PPD). The use of PPD and actual PoD congruence as an outcome measure for EoLC will then be addressed. I will describe guidance for developing and evaluating CIs (CI) in health care, and detail the Hospital2Home CC intervention (H2H), an example of a CI designed to coordinate care at the end of cancer treatment. Finally, I will present the background work I undertook in preparation for this thesis. Formal assessment of H2H in terms of feasibility and effect on outcomes at the EoL has not been conducted in the UK. Therefore the work in this thesis forms the *feasibility and piloting* stage of the MRC guidance for developing and evaluating H2H[1].

1.2 End-of-life Care

1.2.1 Section introduction

The World Health Organisation defines palliative care as:

‘An approach that improves the QoL of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual’[2]

EoL care is:

‘Care that helps all those with advanced, progressive, incurable illness to live as well as possible until they die. It enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last phase of life and into bereavement. It includes management of pain and other symptoms and provision of psychological, social, spiritual and practical support’[3].

High quality EoLC requires a holistic palliative care approach. EoLC is an issue that is relevant to everyone [4]. Death is the only certain fact in life: it will happen to us all at some stage. Health care providers only have one chance to get it right for each patient and family. To provide context to the work in this thesis, this section will describe the current challenge for EoLC, alongside recent UK government initiatives to improve EoLC that have been developed over the last ten years.

1.2.2 EoL Care - What is the challenge?

Internationally it is recognised that many people are still dying without adequate palliative care. Therefore, there is an expectation that current EoLC services can

be substantially improved [5]. 'Much of the development of palliative care services has been focused on the goal of increasing the rate of home deaths' [6]. This is based on evidence that most people would prefer to die at home and thus that home death is ideal [7]. Home death rate and achievement of PPD are increasingly being used as quantifiable indicators in EoLC [8]. However in the developed world only a minority of people die at home [9].

In the United Kingdom (UK) approximately 500,000 people die each year [10] and, due to changing demographics, this is projected to rise to 590,000 by the year 2030 [11]. 48% die in hospital [3, 12, 13]. Deaths of people *over the age of 85* have risen by 7% in the last decade [14]. The challenge of place of death faced by health care services looks set to become even more significant, affecting a higher number of patients. The mismatch between where people want to die and actual place of death has been identified as a key deficiency in EoLC service provision [3]. To have choice and control over where death occurs is thought to be important for good quality of EoL [15] [16, 17].

There is a lack of robust evidence in EoLC service delivery [18], particularly in interventions to achieve good EoLC. The published literature draws only limited conclusions due to challenges in recruitment, study design and attrition [18-20]. Consequently, this area of service delivery remains poorly understood and continues to pose a significant challenge.

1.2.3 Initiatives and policy to improve EOLC in the UK

In the past, the priority given to EoLC was low. Over the past decade, resources have been directed to enable more people to die in their preferred place [4]. In the UK, the DoH has developed a number of initiatives to improve the quality of EoLC. In 2000, the National Cancer plan [21] recognised a need to provide more support for SPC services. Subsequently, in 2003, the DoH assigned £12 million to the three year NHS End-of-Life Care programme [22] with the aim to improve best practice. In 2008, The NHS Next Stage Review final report [23] recognised

EoLC as one of eight priority workstreams and the DoH (DoH) End-of-Life Care Strategy was published[3]. The strategy aims to provide high quality care for all regardless of diagnosis and care setting. A sum of £286 million was assigned over two years to improve services. The strategy emphasised a co-ordinated care pathway approach from recognition of EoL to care after death. The 1st annual report [24] published recognised that there was a gap in research into the optimum way to deliver EoLC, including what services work best and at what cost. In 2015, the Choice in EoL Care Programme board commissioned by the UK Government published 'What's Important to Me - a Review of Choice in EoL Care'[25]. The report highlighted that too many people do not receive good quality care that meets their individual needs and wishes at the EoL. A public engagement exercise revealed 7 important EoL choices – one of which was 'I want to be cared for and die in a place of my choice'. Also, in 2015, six national ambitions for palliative and EoLC were announced: each person is seen as an individual; each person gets fair access to care; maximising comfort and wellbeing; care is coordinated; all staff are prepared to help; each community is prepared to help[26].

One of the key themes of public policy in palliative care has been achievement of choice in PoD[16]. The NHS commissioning framework in the UK covers five domains. The fourth concerns experience with care and this domain includes two outcomes to improve the experience of care at the EoL. One of these is the proportion of cancer patients dying in place of choice[27]. Research into interventions to achieve patient preferences at the EoL is paramount to ensure services are developed appropriately and effectively.

1.3 Place of death (PoD)

1.3.1 Section introduction

Each year across the world, over 58 million people die. Global numbers of deaths are anticipated to rise to over 74 million by 2030[11]. PoD is of great

importance to patients, family members, HCPs and policy makers worldwide. Home is more than a physical space for patients and families[28]: it represents love, control, familiarity and normality. The interest in home death rates stems from an aim to increase preferences (including PoD) at the EoL. Alongside this is an assumption that home deaths may be cheaper than dying in an institution. PoD is used as a surrogate indicator for the quality of care delivered to terminally ill people[29] and has become a prominent outcome measure for palliative care services. However, the interplay between PoD and quality of death is complex[14]. 'Qualitative evidence indicates that patient attitudes to place of death are complex, uncertain, shifting and pragmatic' [30]. In this section I will describe trends in PoD data worldwide and more specifically in the UK. I will then discuss PoD in advanced cancer patients and factors influencing PoD. For UK data, Office of National Statistics (ONS) data are used. Appendix 6.1 details ONS definitions for PoD [13]. This PoD section provides context to the setting of this feasibility study.

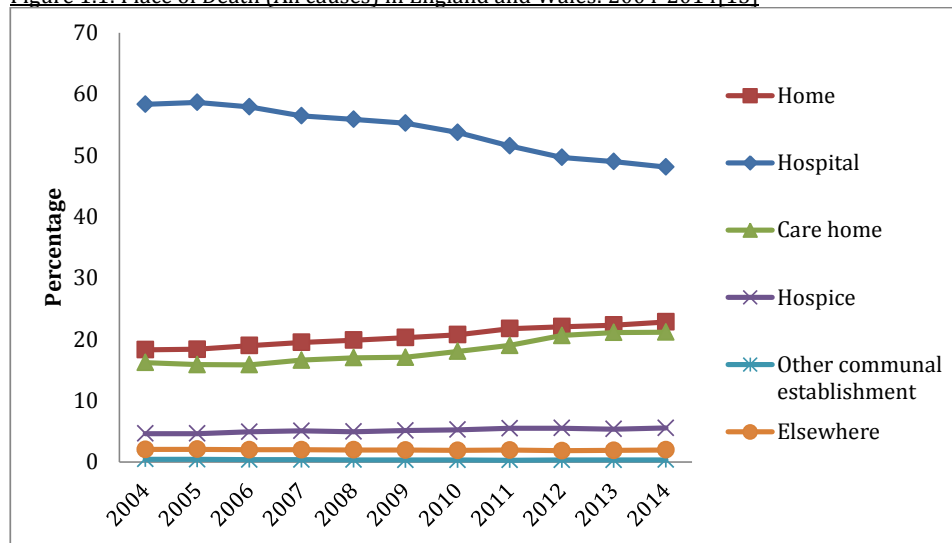
1.3.2 Place of Death

Trends towards institutionalised dying in the developed world were seen in the 1970s-2000s[31]. In the developed world, most deaths still occur in institutions. Studies from the USA, Western Australia and Belgium show hospital death rates of 49.5% [32], 48.7%[33], and 52-63% [29] respectively. These rates are similar to those seen in the UK, where in 2014 48.1% of all deaths occurred in hospital[13]. Some western countries have much lower hospital death rates. In the Netherlands between 31-35% of deaths occur in hospital[29]. However, although absolute proportions are broadly similar across most developed countries, the trends over time are quite different. The USA, Canada and Britain have seen a rise in home deaths over the past twenty years, whereas hospital deaths have increased in Italy, Greece, Japan, Taiwan and Portugal[34-37] [31],[38], and nursing home deaths have increased in Belgium and Australia[39, 40].

In 2008, Gomes et al[11] reported the concerning trend across England and Wales that home death rates had fallen from 31.3% in 1974 to 18.1% in 2003. The fall in home death rates was more marked for non-cancer patients compared to cancer patients (2003: Home deaths: 16.7% non-cancer, 22.1% for cancer patients). The importance of this trend on the health system is compounded by the projection that total UK deaths are set to rise from 500,000 to over 590,000 by 2030[11]. However, a descriptive study of PoD for adults dying in England and Wales between 2004-2010 found a reversal of trends in PoD with a slow and steady increase in the proportion of home deaths from 18.3% in 2004 to 20.8% in 2010[31]. Initially, as home deaths increased, a reduction of 4.5% was seen in the proportion of deaths occurring in NHS hospitals and nursing homes over the same time period. Despite this reversal of earlier trends of decreasing home deaths rates, hospital was still the PoD for the majority of people.

In the UK, PoD varies depending on the region of the country. In 2010, the National End-of-life Care Intelligence Network, commissioned by the DoH, published its first review of regional variations in PoD in England[14]. Based on the ONS data taken from death certification[10], it showed that over ten years (1998-2007) there was a 9% decrease in the number of total deaths per year. At the start of the work presented in this thesis (2009), 58% of people died in hospital and only 19% died at home [14]. These data varied depending upon where people lived within the UK, with hospital deaths highest in London (65.7%). London also had the lowest proportion of home deaths (17.6%). The percentage of people dying in a hospice showed wide variation across the UK, from 0.1% in Nottingham and Hillingdon to 13.3% in Milton Keynes. The trends in PoD for all causes over the last ten years from 2004-2014 are shown in Figure 1.1 below. The last published ONS data (2014)[13] showed 48.1% of all deaths occurred in hospital, 22.8% at home and 5.5% in a hospice.

Figure 1.1: Place of Death (All causes) in England and Wales: 2004-2014[13]



1.3.3 Place of death – cancer patients

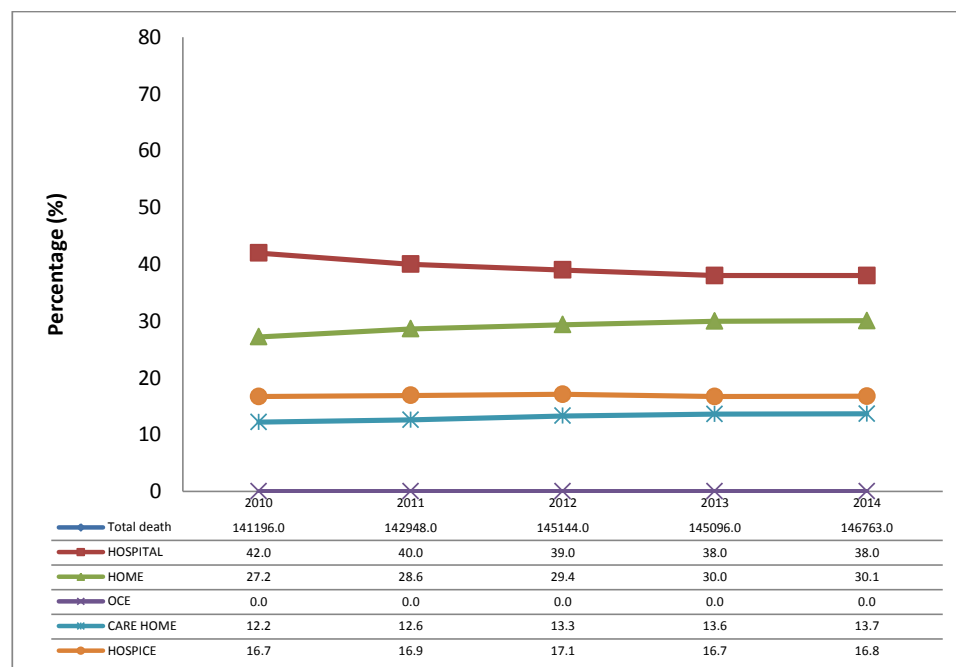
Worldwide, approximately 8 million people die of cancer each year and the number of cancer deaths is set to rise[41]. A large variation exists in PoD of cancer patients across the world: between 12% and 57% occur at home (South Korea and Mexico respectively). The lowest hospital death rate (26%) in cancer patients is seen in New Zealand compared to the highest (87%) in South Korea[9].

Patterns in PoD for cancer patients in the UK have been explored in depth by Higginson et al[42] in 1998 and subsequently by Gao et al[4] in 2013. Higginson et al[42] showed that the proportion of cancer patients dying at home in England and Wales between 1985 and 1994 reduced by a small amount. In the same time period, the number of hospital deaths also decreased, albeit more substantially (from 57.8% to 44.3%-47.3%). The reduction in hospital deaths corresponded with the proportion of deaths in non-NHS institutions increasing over the same time period as more hospice beds became available. In 1994, between 13.7-16.4% of cancer deaths occurred in voluntary hospice units.

Gao et al[4] followed on from Higginson's original research using ONS data and investigating the changing patterns in cancer PoD alongside factors associated with cancer PoD between 1993-2010. The final dataset included 2,281,223 adult deaths. Over the entire ten year period, overall 48% (95% CI 47.9%-48.0%) died in hospital, 24.5 % (95% CI 24.4%-24.5%) at home and 16.4% (95% CI 16.3%-16.4%) in a hospice[4]. A significant reduction in hospital deaths (-1.82% CI -1.81%-1.83%) occurred in 2005/2006 compared to previous years and hospital death rates continued to decline for cancer patients year on year up until the end of the analysis in 2010, when 41.9% occurred in hospital. This trend was matched by the opposite pattern in home and hospice deaths. Between 2006 and 2010, 25.8% of cancer deaths occurred at home and 17.4% in a hospice compared to 26.2% and 13.6% respectively between 1993 -1995. Figure 1.2[13] shows the PoD for cancer patients from 2010-2014. Home deaths are continuing to increase in the cancer population. The last published ONS data showed that 30.1% of people who died of cancer in England did so at home.

PoD is an important outcome because it has been linked to patient QoL as well as bereaved carer outcomes. Studies have shown that not only do cancer patients who die in hospital have a poorer QoL (QoL) compared to those who die elsewhere (namely home or hospice) but also their bereaved caregivers have a higher risk of developing an adverse grief reaction and psychiatric illness[43, 44].

Figure 1.2 Place of Death – Cancer patient 2010-2014



1.3.4 Factors influencing place of death

In order to inform and develop EoLC interventions, it is essential to understand the factors influencing PoD over time. PoD is influenced by interactions between three main groups of variables: individual, environmental and illness-related.[28]

A number of studies have elicited factors that affect PoD, including four systematic reviews by Gomes[28], Murray[45], Gill[46] and Costa[47] . Understandably, given difference in health service delivery, the impact of certain variables differs between countries [48]. Gomes's [28] systematic review included 58 original studies gathering results from over 1.5 million patients across 13 countries. Variables were categorised into 3 areas using a theoretical framework and 17 were found to have high-strength evidence for associations with PoD of cancer patients (See Figure 1.3b). The six factors most strongly associated with home death were low functional status, patient preference, home care and its intensity, living with relatives and extended family support. The review by Costa et al[47] considered variables influencing home death for advanced life-limiting illness of any cause. Costa considered 22 quantitative studies and 26 qualitative studies and found similar influential factors for home death to Gomes et al. However, more environmental factors were reported.

The available evidence from 2004 onwards and the four systematic reviews are summarised in Table 1.1 in relation to the 'three group theoretical framework' proposed by Gomes[28]. Figure 1.3a shows a combined forest plot of Gomes and Costa data (where more than one odds ratio was presented in Gomes et al's review, the lower is plotted). Odds ratios of one or more favour a home death. I will now discuss each group of variables.

1.3.4.1 Individual factors

Demographic variables:

Gomes et al[28]reported six high quality studies supporting the idea that good social conditions- including social class, deprivation and education- can positively influence the likelihood of a home death. However, two further high quality studies showed no effect. Since this review, these findings have been replicated by Gao et al 2013[4] and Dixon et al 2016[49]. Married status increased the likelihood of a home death. Kandor et al [50], Jeukaur and Escobar et al[51] replicated this finding. Gender was not a variable strongly associated with home death in the systematic review by Gomes et al; however, studies since 2004 have repeatedly shown male gender to increase the likelihood of dying at home. Some studies have shown an increased tendency for home death with increasing age [52], whilst others found the opposite trend[4, 49]. The evidence remains inconsistent across studies for the influence of age and gender on PoD.

Preference variables:

Gomes et al [28]reported an expressed preference for home death as one of the six factors most strongly associated with home death. Other preference variables in favour of a home death were confirmation of choice by nurses and agreement between patient and carer for a home death. Costa et al[47] found similar associations with numerous studies replicating the finding of expressed preference increasing the odds of a home death[49, 51, 53]. The odds ratio for expressed preference influencing home death reported by Costa et al was 2.13 (CI 1.58-2.87).

1.3.4.2 Illness factors

Costa et al found that a diagnosis of cancer as opposed to non-malignant disease increased the likelihood of a home death[54]. Within the different types of cancer diagnoses, Gomes et al[28] concluded that those with haematological malignancy were considerably less likely to die at home (OR 0.53 (CI 0.34-0.63))

compared to the reference category (colorectal cancer)[4]. Low functional status has also consistently been linked to home deaths (OR 2.05, CI 1.33-3.15)[28].

1.3.4.3 Environmental factors

Social support

The influence of social support on home deaths was through four variables. Firstly, Gomes et al found those living alone were less likely to die at home and the presence of both extended family support and caregiver preference for home death were associated with increased home deaths[28]. Costa et al again found similar social support variables in favour of home death with the addition of caregiver distress. Home deaths were more likely for patients whose caregiver had low distress levels during the stable phase of illness [47]. Evidence also suggests that proximity to hospital; previous admission and inpatient bed availability are all linked to a decrease in home deaths.

Other social support factors in favour of home deaths in multivariate analysis were the presence of more than one family caregiver (OR 2.28, CI 1.05-4.94) and support of the family physician (OR 2.23, CI 1.21-4.08).

Health Care Input

Gomes [28] reported that home care use and high home care intensity increased the likelihood of a home death. Costa et al[47] found that review by community SPCT and early referral to the community SPCTs were both associated with home deaths (Use of Home care OR 2.56 (CI 2.31-2.83), Early referral OR 2.2 (1.33-3.67)). Palliative care multidisciplinary home care teams also increased the odds of cancer patients dying at home (11.82 (95%CI 4.95-28.02)[55].

Figure 1.3a: Combined odds ratios for home death Gomes et al and Costa et al [28, 47]

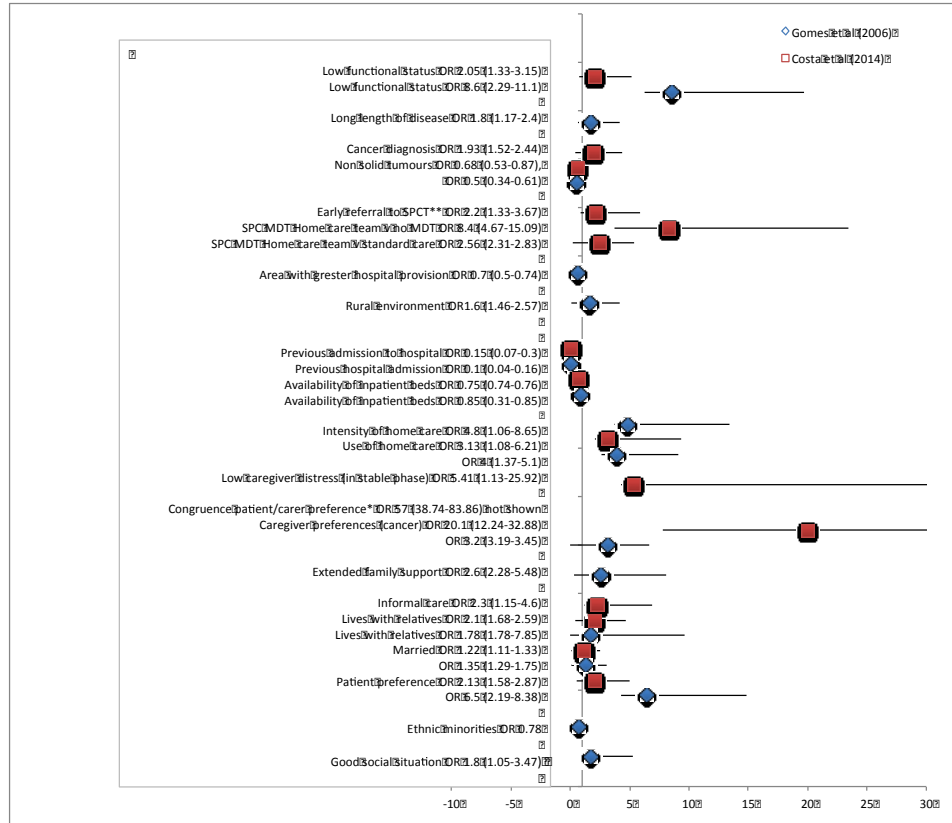


Figure 1.3b Adapted Gomes et al model of variations of place of death in relation to this work[28]

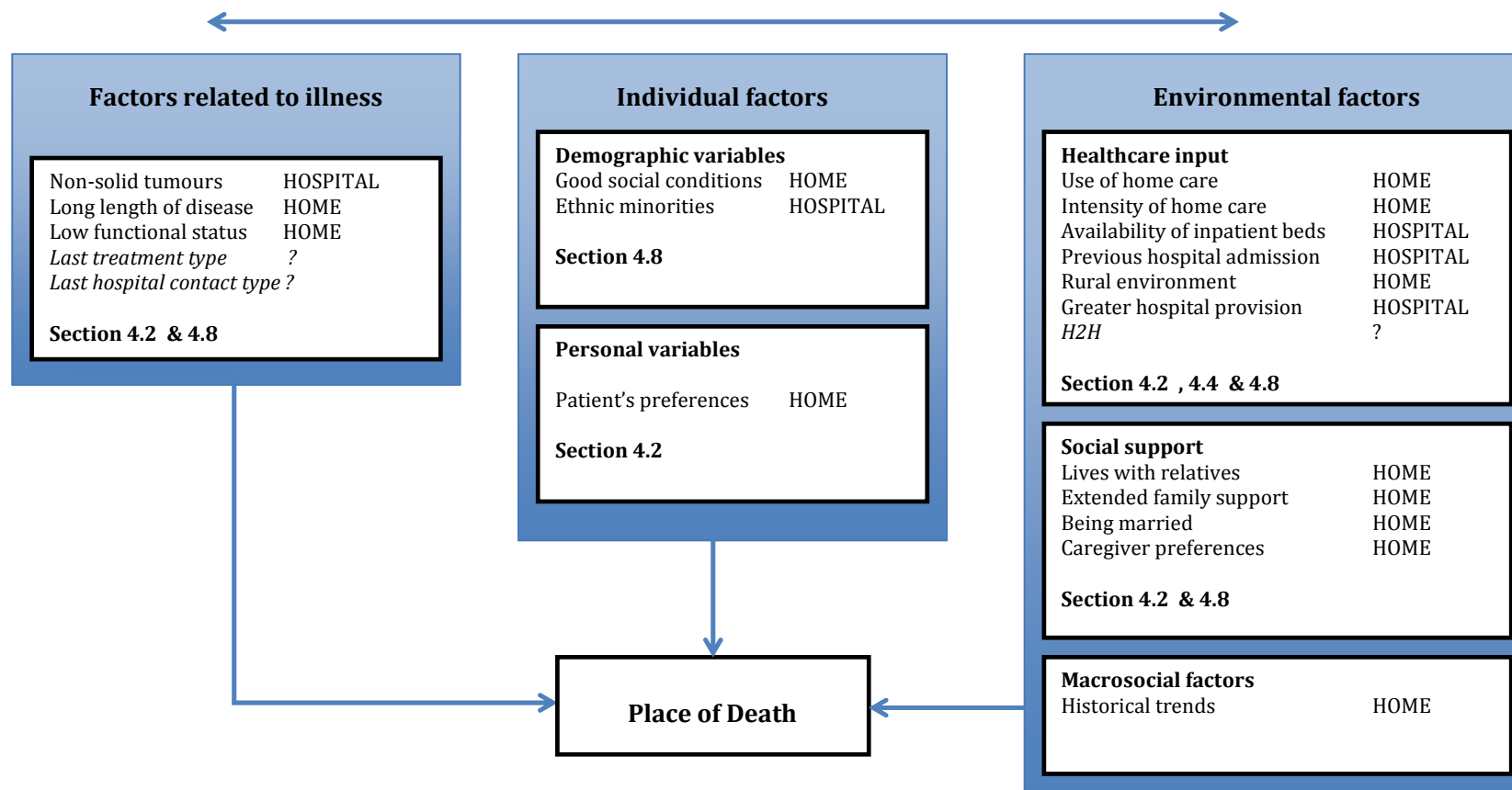


Table 1.1 Factors influencing place of death – Focus on cancer patients (2004-2014)

Death more likely at Home	Individual Factors									Illness			Environmental Factors												
	Age (increasing)	Gender (Male)	Marital Status (Married)	Good social situation (low deprivation)	Ethnicity	Education	Increasing Income	Patient preference	Experience of death/being informed	Cancer (solid tumours)	Long length of disease	Low Functional Status	Previous Hospitalisation (No)	Lives with relative/ caregiver (Yes)	Extended family support	Caregiver ability to cope/ distress	Caregiver preference	Increasing intensity of Home visits	Use of Home care	Review by CPCT MDT	Earlier referral to CPCT	Rural environment	Greater hospital provision (no)	Availability of inpatient beds (no)	
(* Indicates the study considered deaths from all causes, + indicates the study considered deaths from cancer only research., Escabar study – 'increased care needs' has been categorised under low functional status, -indicates a negative association with home death, ± indicates evidence for and against increased home deaths; ✓ indicates a positive association with home death. Chvetzoff found coordinating medical oncology home visits increased home)																									
Systematic reviews																									
Costa (2014) ^{†[54]}								✓		✓			✓	✓		✓	✓			✓	✓				
Gill et al (2013) ^{†[46]}																									
Murray et al (2009) ^{†[45]}	±	±	✓		✓		✓	✓	✓	✓		±	✓	✓		✓		✓	✓	✓		✓			
Gomes et al (2006) ^{†[28]}			✓	✓	✓			✓		✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓	
Original research (2004 onwards)																									
Dixon et al (2016) [†] [49]	-	✓		✓				✓		✓															
Cohen et al (2015) ^{†[9]}			✓							✓															
Kondo et al (2014) ^{†[50]}																							✓		
Gao et al (2013) ^{†[4]}	-		✓	✓						✓															
Ischikawa et al (2013) ^{†[53]}	✓	✓						✓				✓					✓	✓						✓	
Jeukar et al (2012) ^{†[51]}			✓					✓				✓						✓							
Escobar (2011) ^{†[56]}			✓							✓		✓			✓							✓			
Alonso-Barbarro (2011) ^{†[57]}													✓	✓					✓						
Carderas-Turanza (2011) ^[52]	✓									✓			✓												
Houttekier et al (2010) ^[58]																				✓					
Ahmed et al (2010)	✓															✓									
Lanzenby et al (2010) [†] [59]	✓	✓																							
Masucci et al (2010) [†] [60]		-												✓											
Houttekier et al (2009) ^[29]							✓							✓											
Brink et al (2008)		✓	✓									✓		✓											
Cardenas-Turanza (2007) ^[61]	✓	✓	✓			✓				✓															
Howat et al (2007) [†] [62]	-	✓											✓						✓						
Cohen et al (2006) [†] [63]						✓				✓				✓					✓						
Foreman et al (2006) ^[64]		✓										✓							✓						
Yun et al (2006) ^[65]		✓	✓			✓	✓			✓									✓						
Choi et al (2005) ^[66]			✓				✓							✓											
Chvetzoff et al (2005) [†] [67]												✓							✓						
Klinkenberg et al (2005) ^[68]														✓								✓			

1.3.5 Section summary

A clear understanding of factors that influence the PoD of cancer patients is essential to both the design and critical evaluation of new models of service delivery at the EoL [69]. Factors can be divided into three areas: environmental factors, illness factors and individual factors. Throughout the work in this thesis, this theoretical structure will be used as a framework for the evaluation of PPD and PoD. Family support, patient and family preferences are a clear recurring theme. The majority of studies[6, 70-73] show that, for the most part (up to 78%), patient and caregiver preferences for place of death agree. There is a complex network of factors and interactions that influence where people die. Any health service research should aim to consider all the possible factors mentioned.

1.4 Preferred Place of Care (PPC) and Death (PPD)

1.4.1 Section introduction

It is frequently said that people the world over wish to be cared for and to die in their home. Individual choice is highly valued in society. Autonomy is ranked first among equals in bioethical principles[33, 74]. Respecting the wishes of the dying has therefore become a fundamental characteristic of good EoLC[29]. Over the last twenty years, where people die has received a great deal of interest and is now extensively studied around the world[3, 75].

The National EoL Care Strategy in the UK recommends that HCPs actively involve patients and their carers in discussions about PPD in order to identify and meet their wishes[3]. In this section I will explain the definitions of PPC and PPD. Secondly, I will review current evidence regarding PPD and congruence between PPD and actual PoD.

1.4.2 Definitions – PPC and PPD

Over the past decade, two distinct terms have emerged in reference to respecting EoL preferences:

- *PPD*- The place in which the patient would wish to die;
- *PPC*- The place in which the patient wishes to be cared for.

The two are linked but entirely separate entities. One problem, both in clinical practice and when reviewing the early research literature, is that PPC and PPD are often asked interchangeably or asked within the same question (See Table 1.3 in Section 1.4.4 below). Agar et al[6] studied PPC and PPD longitudinally and reported that PPC and PPD were not synonymous. Levels of agreement between location for PPC and PPD were relatively low; moreover, the preference for each changed differently over time. The study showed that when patients were asked about PPC and PPD as separate questions 87% chose PPC to be home and 41% chose PPD to be home. If language for PPC and PPD is used interchangeably, the proportion of patients preferring a home death will be artificially inflated. This in turn will make the gap between recorded preferences and actual PoD larger than reality.

1.4.3 Preference for Place of Death

Around two thirds of the general population express a preference to die at home[7, 76]. Most people want to die at home, followed by inpatient hospice or SPC setting. Care homes and hospital are the least popular[27]. Over the past two decades there have been three systematic reviews of the literature examining PPD.

A systematic review published in 2000 appraised the research evidence concerning PPD from 1966-1999[12]. There were eighteen studies across the UK, US, Australia and Europe recording patient or general public preferences. Nine of these studies had major design flaws. However, the review did conclude that the preference for home death ranged from 49-100%[12]. Since this review,

numerous studies have replicated these findings [64, 66, 72, 77-82]. The findings from studies regarding the preference of patients with advanced illness have shown mixed results with a split between those identifying home as the preferred option and others concluding that hospice is the preferred choice (See Table 1.3 below). Studies specifically in the cancer population[66] or terminally ill [72] have found home death preferences from 50-61%.

In 2013, a systematic review by Gomes et al[76] considered 210 studies from 33 countries, 130 of which reported on a preference for dying at home. Fourteen studies were high quality and these reported on 6,463 people (1,400 patients, 836 carers and 4,227 members of the public)[76]. Overall, moderate strength evidence was found that the majority of people preferred to die at home. The results from 97 studies (75%) showed at least 50% of participants expressed a PPD for home (range 51-100%). The proportion of participants expressing home as PPD was more than 70% in 47 of the studies. The majority of patient studies were in the terminally ill (82/92) with 66 (72%) studies confirming that greater than 50% of patients wished to die at home. However, there was a wide range in preference from 18%-100%. Amongst the high quality studies, estimates for home preference ranged from 31-87%. The review also considered caregiver preference, which was evaluated in 36 studies. Twenty-two (61%) found the majority preferred their relatives to die at home.

In 2015, Hoare et al's systematic review[83] considered 61 articles containing quantitative results regarding PPD. This repeated the same findings as previous reviews: that the majority of general public, patients and caregivers prefer home for PoD. Again, there was a wide range of results for the preference of home in the patient group. Hoare reanalysed data, including the participants with missing data for PPD (i.e. not asked, no preference or not sure) in the denominator. The reanalysis results were considerably different. Only the general public subgroup had an overall median proportion of greater than 50% of participants preferring home. In the cancer population the inclusion of missing values meant that across all studies the overall median preference for home was 36%.

Table 1.2 below provides a summary of studies eliciting preferences for PoD in cancer patients. Overall, home still appears to be the PPD for the majority of cancer patients; however, this wish is not shared by all[84]. The table shows that the majority of cancer patients do prefer a home death but in some studies it is not an overwhelming majority (42.5%-91%). The studies with a high response rate for PPD (those with minimal missing data) broadly show lower preference rates for home death. It may be that those who do not want to die at home are reluctant to say so or HCPs are reluctant to ask.

A number of variables are likely to contribute to the documentation and choice of PPD. Certain patient groups are more likely to discuss and complete advanced care planning (ACP) including PPC and PPD and thus have a documented PPC and PPD of which HCPs are aware. A cancer diagnosis, as opposed to other diagnoses, has been positively associated with increased discussion of EoL issues and awareness of PPD[85]. Patients with a non-malignant disease are two thirds less likely to participate in ACP than cancer patients (0.29 respiratory disease, 0.16 cardiovascular disease). Those living in more deprived areas (0.73 CI 0.62-0.87) and from ethnic minority backgrounds (0.64 CI 0.44-0.94) are less likely to participate in ACP discussions regarding PPC and PPD[49].

The preference chosen varies with a range of patient, carer, environmental and social support factors[16]. PPD is influenced by the prior experience of the patient, depends on on-going experiences in locations of care [4, 12] and disease states. Moreover, older patients are less likely to chose home for fear of burdening their family and friends[86] and those from more deprived areas are also less likely to chose home[87]. Qualitative research [88] suggests that preferences are not necessarily a clear and positive choice for all.

Waghorn et al in 2011[87] examined the preference for EoLC in patients with advanced cancer. The results of this work (highlighted in green in Table 1.3) are particularly relevant because the study was conducted at the same tertiary referral cancer centre (RMFT) as the research in this thesis. Waghorn et al found

42.5% (51/120) of patients chose home as their PPD, and 67% (80/120) deemed it an acceptable location for death.

Table 1.2 Documentation of PPD (2006-2016) (where cancer only deaths can be extracted from the original data this is presented)

Study	Design	Population	% PPD response rate	% PPD Home	% PPD Hospice
Systematic review					
Hoare et al (2015)^[83]	Systematic review Number of studies (quant) 61	General population and patients		36% cancer patients	
Gomes et al (2013)^[76]	Systematic review, Number of studies 130	General public n=29,926, patients n=34,021		31-87 for patients	
Original research					
De Graaf et al (2016) ^[89]	Retrospective cross-sectional study, n=107	89% cancer/ Netherlands	94.4	91	91
Waghorn et al (2016) ^[90]	Prospective observational study n=120	100% cancer/ multicentre, know to SPCT	99	50	45.5
Arnold et al (2015) ^[91]	Retrospective case note review n=1127	Patients referred to a SPCT/single site	77	37	60
Ko et al (2014) ^[92]	GP mortality follow back study n=2048	100 % Cancer patients cross 3 European countries	873/2048 (42.6)	695/873 (79.6)	85/873 (9.8)
Brogaard et al (2013) ^[93]	Prospective longitudinal study n=96	100% cancer, Denmark	65	71	-
Hunt et al (2013) ^[27]	Bereaved relatives survey Cancer component n=407	100% cancer, Death in one year 2 districts in England	41.4	66.7	19.5
Ishikawa et al (2013) ^[53]	Retrospective survey of HCP, n=258	100% cancer/ Japan	96.9	49.2	-
Oxenham et al (2013) ^[16]	Retrospective audit n=196	Known to SPCT	81	52	43
Abel et al (2012) ^[94]	Retrospective EPR cohort study, n=839	Subset: 100% cancer/ single PCT study	56.4	53.4	26
Jeurkar et al (2012) ^[51]	Retrospective: EPR* cohort study n=7391	100% Cancer / hospice program	42.7	88.5	
Scholes et al (2012)	Retrospective: 3 month audit of patient known to SPT n=708	100% Cancer patients/ known to SPCT	60.2	43.2	
Smith et al (2012) ^[95]	Retrospective: EPR review n=1087 records, 207 deaths	53% cancer/ London	78	62	11
Meeussen et al (2011) ^[96]	Retrospective: follow-back study n=422	100% Cancer patients/National	51.9	-	
Waghorn et al (2011)^[87]	Prospective study n=120	100% cancer/ Tertiary referral centre	100	42.5	-
Holdsworth et al (2010) ^[97]	Retrospective case note audit n=298	100% cancer/ Three Hospice units	41.6	-	-
Walker et al (2010)	Prospective: observation study, n=41	88% cancer patients/ SPCT service	100	53.7	-
Van der Heide et al (2007) ^[98]	Interview with bereaved relatives n=63	100% cancer	50.8	78.1	
Hsieh et al (2007)	Prospective : Cohort survey and bereavement interview, n=46	100% cancer/ single hospital service	100	73.9	
Becarro et al (2006) ^[82]	Retrospective: Bereaved caregivers interview, n=1003	100% cancer /Italy – national	79.7	91.5	0.2

1.4.4 The reporting of PPD

Preferences across studies show considerable variation in the proportion of participants expressing home as their desired location for death. The reasons for such variation may be due to the population studied but also in part due to question asked to ascertain the preference from the patient.

The Population and Question asked

Surveys of the general public, that may include the very young and healthy, do not represent or accurately predict how people will feel or the choices they will make when faced with an advanced terminal illness. General population surveys tend to overestimate the preference for a home death. However, the question asked does not always differentiate between PPC and PPD. Therefore, where these are not separately discussed, an inflated preference for home death may be reported. Recent surveys which have included this differentiation indicate that participants often give a different response for place of care and death[30]. In addition to these issues, the context and framing of the questions will shape the nature of the response. Therefore, the heterogeneity and quality of studies in the literature makes firm conclusions difficult[30].

The way in which preferences are elicited and reported varies greatly[93] and there is often ambiguity in the question asked. In 2009, Agar et al[6] described the numerous methods of eliciting PPC and PPD in research studies. Gomes et al's[76] review of 210 studies found 66 that provided the exact question used to assess PPD. Again, questions were varied and 103 studies were not clear on how preferences were elicited. In the 97 studies that reported patient preferences for home death, the majority asked about PoD (n=76);however, 41 referred to place of care but quoted PPD statistics. Ten asked both PPC and PPD, and in 3 studies the question was unclear. A sample of different methods and questions used to elicit preferences is shown in Table 1.3. Gomes et al[76] reported that as the number of studies investigating PPD increased after the year 2000, so too did the

heterogeneity of study design, populations studied and the quality of the study. This has led to more heterogeneous findings with preference for home death ranging from 5%-100%. Data collection of such heterogeneity makes study comparison difficult and may exaggerate the range of results across studies.

Table 1.3 Data collection of PPD adapted from Agar et al and Gomes et al

Collection of method	Example	Examples of studies
Direct question to patient	<i>'In light of existing condition where would you best like to be cared for?'</i>	Hinton[99] Stajduhar et al[79]
	<i>'If your illness gets worse where would you rather be?'</i> and <i>'Where would you prefer to die?'</i>	Alonso-Babarro et al[57]
	Conditional on families ability to cope	Townsend et al[100]
	In ideal versus real circumstances <i>'Ideal place of death is.....'</i> <i>'If everything were possible, where would you choose to be cared for in the end stage of your illness?'</i>	Kwon et al McCall et al[88]
Direct question to caregiver: post-bereavement questionnaire or interview	<i>'Where did patient wish to die?'</i>	Abarshi et al[101]
Assessed by nursing or medical staff	Retrospective reporting by nursing staff and GPs	Neergaard et al[102]
From review of medical records		Walker et al[103]

The Data Presented

The reporting of preferences for PoD varies across studies and a substantial number of participants often do not specify a preference. The inclusion or exclusion of the group who do not respond can substantially affect the results reported. Transparency regarding the nature of this reporting is crucial. A high preference for a home death in a study with a low response rate to the question on PPD may be an inaccurate portrayal of the true preference of that population. For example, in Table 1.3 above, Ko et al[92] report a preference for home death of 79.6%; however, the study of 2048 participant deaths only had a PPD response rate of 42.3% (873). PPD was a missing value in 57.7% (1,175) of the population studied. The proportion choosing home from the entire population can be recalculated, as Hoare et al[83] suggest, to 33.9% (695/2026). PPD response rates should always be presented alongside preference data and ideally both derived preference rates should be presented:

(1) $PPD_{\text{Answered}} = \text{Proportion of patients preferring a location} / \text{All those who gave a preference}$

(2) $PPD_{\text{total population}} = \text{Proportion of patients preferring a location} / \text{Total population}$

(Total population = those who gave a preference + those who did not give a preference)

Change over time

A PPD elicited too far in advance of the terminal phase of illness may be inaccurate[6].

Gomes et al reported 15 studies (out of a total of 210) that measured change in preference over time. Most data (13/15) were collected prospectively with a change in preference seen for 20% of patients across all studies. However, the change in preference rates varied considerably between studies (2-80%) and therefore the overall evidence regarding whether preferences do change as death approaches was inconclusive. Auriemma et al[104] reviewed the evidence on stability of EoL preferences and found that in 71% (17/24) of studies, 70% or more patients had stable preferences over time. In the UK, studies of individual patient preferences have found that up to a quarter of terminally ill patients (10-24%) change their preference[105-107]. Evans et al [108] conducted a case note review of deceased patients known to a single SPCT. The results showed that 57% of patients had a preference change over time but the majority were from an unspecified PPD to a specific location for PPD. Fifteen percent changed their PPD from one location to another over the time known to the SPCT. This possibility for change in preference means the last preference documented is of most value as an outcome measure to minimise missing data on preference and ensure the most up to date information is used for PPD in study analysis.

1.4.5 Congruence between preferred and actual place of death

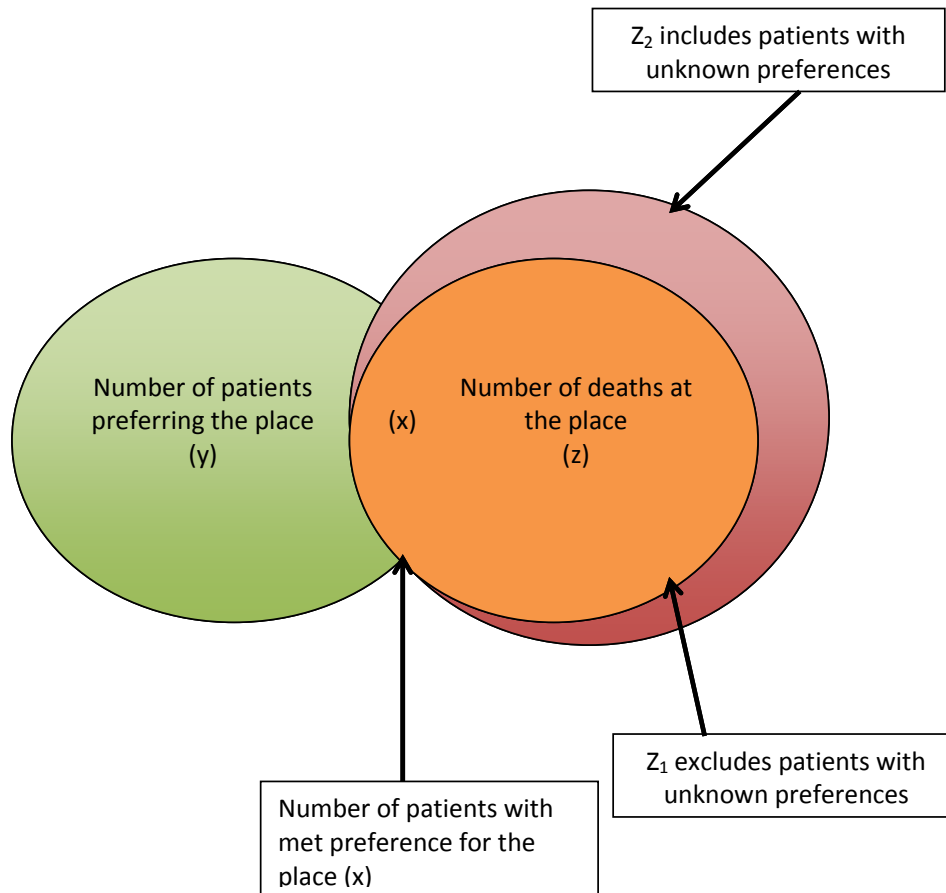
Congruence is the agreement between two variables, in this case a patient's stated PPD and actual PoD[109].

1.4.5.1 Congruence: Methods of reporting

There is considerable variation in how congruence between preferred and actual PoD are measured [93, 110]. Bell describes four different methods of reporting congruence in the literature. These are reproduced in Figure 1.4 below. The use of different methodology may contribute to the large differences in congruence reported across studies and hamper the comparison of results across studies for different services and interventions[109]. A review by Bell et al[110] found that congruence between PPD and actual PoD varied from 30% to 91%. If achievement or congruence of PPD is to be used as an outcome measure to compare interventions and palliative care services then a standardised approach should be used. Overall congruence and the use of the kappa agreement statistic have both been proposed as standard methods of reporting congruence to enable cross-study comparison[109]. **Overall congruence** is defined as the total number of patients whose preferences were met for all locations of death divided by the total number of patients with preferences in the study[109].

Bell's systematic review identified 12 studies that measured and reported congruence as a primary outcome; however, only 4 studies provided complete data on preferred and actual PoD for all four of the main locations [110]. Overall congruence between preferred and actual PoD (Method A in Figure 1.4) across all locations was between 30% and 90%, and the kappa statistics of agreement ranged from 0.11- 0.68[110]. The review highlighted not only the different methods of calculating congruence already described but also inconsistencies in how PPD was determined, which may have affected the results. In studies where preference was elicited close to death or after death, congruence with actual PoD was higher.

Figure 1.4: Definitions of congruence between PPD and Actual PoD[110]



Congruence:

Definition A: x/y – Met preference divided by preference for place

Definition B: x/z – Met preference divided by deaths at place

Definition C: x/z_2 – Met preference divided by deaths at place including patients with unknown or no preference

Definition D: Overall congruence – All met preferences for all places of death divided by preferences for all places in the study

Table 1.5 below summarises congruence studies in cancer patients from 2006-2016. Congruence A for each location and overall congruence are shown. For articles where data was missing if possible algebraic back calculations were performed using the reported percentages to determine the data for the table

1.4.5.2 Congruence between preferred and actual place of death in cancer patients

Bell's review found overall congruence between preferred and actual PoD ranged from 30-90%. A subsequent systematic review by Billingham[84] in 2013 reported on 26 studies concerning congruence with preferred and actual PoD. There was a substantial degree of heterogeneity across the studies. Overall congruence for home PPD was 62.3% for cancer patients and 68.4% for non-cancer patients. Considering congruence across all locations, a non-cancer diagnosis and preference for home death were associated with an increased risk of incongruence between preferred and actual PoD [weighted risk ratio for incongruence: non-cancer (1.23 95% CI 1.01-1.49), and home preference (1.17 95% CI 0.84-1.64)]. Table 1.4 is an update of this review for cancer patients. Overall congruence and kappa statistics have been calculated where the data were available from the original study paper.

Table 1.4. Congruence between preferred and actual place of death in cancer patients (2006-2016)

Study	Design,n	% PPD Home	Congruence (method A*, n (%))				Kappa statistic (95% CI)
			Overall (method D)	Home	Hospice	Hospital	
De Graaf et al (2016) ^{[89]*}	Retrospective cross-sectional study, n=107, 89% cancer patients	77/107 (72)	92/107 (91.4)	70/77 (91)	21/23 (91)	0	-
Burge et al (2015) ^[111]	Retrospective population based mortality follow back study, n=1316	-	315/606 (52)				0.29
Ko et al (2014) ^[92]	GP mortality follow back study n=2026	695/873 (79.6)	570/780 (73.1)	528/695 (75.9)	42/85 (52.9)	-	0.16 (0.08-0.23)
Brogaard et al (2013) ^[93]	Prospective longitudinal study n=73	33/48 (68.8)	21/48 (43.8)	16/33 (48.5)	5/12 (41.7)	0/2 (0)	0.25 (0.13-0.37)
Ishikawa et al (2013) ^{[53]*}	Retrospective survey of HCP, n=258	123/250 (49.2)	-	93/123 (75.6)	-	-	-
Hunt et al (2013) ^{[27]*}	Bereaved relatives survey Cancer component n=407	66.7	57.2	-	-	-	-
Oxenham et al (2013) ^[16]	Retrospective audit n=196	83/159 (52)	113/159 (71)	53/83 (63.9)	60/68 (88)	-	0.51 (0.38-0.64)
Jeuker et al (2012)	EPR ⁺ retrospective cohort study, n=7391	3153/3561 (88.5)	-	1735/3153 (55)	-	-	-
Scholes et al (2012)	3 month audit of patient known to SPT n=708	184/426 (43.2)	349/426 (81.9)	-	-	-	-
Smith C et al (2012)	Retrospective EPR review n=1087 records, 207 deaths 53% cancer	82/149 (55)	94/149 (63.1)	56/82 (68)	11/32 (34)	7/10 (70)	0.2 (0.02-0.37)
Meeussen et al (2011)[96]	Retrospective follow-back study, n=422	-	167/219 (76.3)	-	-	-	
Holdsworth et al (2010) ^[97]	Retrospective case note audit n=298	80/131 (61.1)	71/131 (54.2)	42/80 (52.5)	25/29 (86.2)	2/2 (100)	0.35 (0.22-0.47)
Walker et al (2010)	Prospective observation study, n=41	53.7	47.2	-	-	-	
Agar et al (2008)[6]	Prospective RCT, secondary data analysis, n=69	24/69 (34.7)	41/69 (59.4)	9/24 (37.5)	20/26 (76.9)	5/8 (62.5)	0.45 0.33 (0.14-0.52)*
Van der Heide et al (2007)	Interview with bereaved relatives n=63	25/30 (83.3)	25/30 (83.3)	20/25 (80)	2/2 (100)	3/3 (100)	0.60 (0.3-0.9)
Hsieh et al (2007)	Prospective cohort survey and bereavement interview n=46	34/46 (73.9)	20/46 (43.5)	8/34 (23.5)	-	12/12 (100)	
Becarro eta al (2006)[82]	Retrospective: Bereaved caregivers interview, n=1003	94	67.0	65.9	42.6	91.7	Unable to calculate

Studies are included in this table if the > 80% of the cohort had a cancer diagnosis. Studies included in Bell paper overall congruence and kappa taken from Bell paper, otherwise data used to calculate the kappa statistic taken from values in original papers for the 3 main locations, if numbers not given these were derived using the percentages given and algebraic calculations as per Bell paper. *3 main locations.

1.4.6 Factors influencing achievement of PPD

Although it cannot be concluded that home is the PPD for all, the overall majority would prefer a home death. It is therefore understandable that variables influencing congruence of PPD largely mirror factors known to increase the likelihood of a home death. These variables can be described using the Gomes et al[28] three factor model: individual, illness and environmental factors. Table 1.5 presents variables from the literature in these three categories that either increase or decrease congruence.

A literature review[109] examining reasons for congruence found that symptom control, physician support, hospice enrollment, family support and family caregiver ability most consistently affect congruence. Hunt et al[27] surveyed bereaved relatives of all causes of death in England regarding patient preferences at the EoL. The results showed patients with a cancer diagnosis were more likely to die in their preferred place (57.2% vs. 35.5% $p<0.01$), as were patients reported to have an official health-care record of their preference (83.5% vs. 32.4%, $p<0.01$).

Table 1.5: Summary of factors in the literature associated with congruence between PPD and actual PoD[109]

Factors associated with congruence PPD and actual PoD	Individual	Illness	Environmental
Increasing Congruence			
	PPD: Care home OR 7.7 (2.53-23.47)[112]		Physician Support[113] GP Palliative care 2.6 (1.2-5.5), 9.7 (2.4-39.9), 9.9 (3.7-26.6)*
	PPD: Hospice[6]		Family physician home visits [111, 114]
	Higher social class[115]		Rapid response team OR 2.1 (1.43-3)[112]
	Patient understands illness[116]		Palliative home care team[111]
	DNAR advance directive[117]		Provision of special equipment[115]
			More support service [118]
			Lives with caregiver OR1.5 (1.0-2.3)[112]
			Family caregiver ability[119]
			Family support[119]
Decreasing Congruence			
	PPD : Home [6, 82] OR 0.55 (0.36-0.83) ^[112]	Inability to control symptoms[118] [114]	Equipment not available
	Lower education levels[120]	Need for 24 hour nursing care[118]	Rehospitalisation[111, 119]
	Perceived family inability[118, 119]	Unclear prognosis [117]	Proximity to hospital[119] Hospital palliative care[121]
	Change of preference[118]	Gender[92]	Increased GP home visits (> 2 per week) OR 0.1 (0.01-0.9)
		Age[92]	

* Studied in 3 different countries in Europe, Italy, Belgium and Netherlands respectively

* Ko et al examined factors associated with fulfilling a preference for dying at home (as known to GP), values above one indicate an increased likelihood of a home death. + reference category was 0 GP contacts in 2nd, 3rd and 4th week before death

1.4.7 PPD Versus Home death as an Outcome measure

The rationale behind PoD as an important clinical outcome measure in EoLC is the supposition that quality and quantity of service provision determines PoD[27]. Thus, high quality service provision leads to an increased number of patients dying in their PPD (home). However, patient, family and disease related factors also significantly impact on PoD.

Home death rates are used as an outcome measure by which to compare services and care. High home death rates are presumed to indicate high quality palliative care. However, this implies that patients who die in another location must receive poor quality care[75, 97, 122]. The view of home as the optimal place to die is now being challenged and more focus is on achieving the patient's PPD or time spent in their PPC[75].

Some authors have stated that death in the preferred location is a more appropriate reflection of the quality of care than home death rates[84] [69]. The main criticism of home death as a quality indicator is that it implies a home death is the best option for everyone. This is not always the case. Calazani et al surveyed the general population across 8 European countries about their least preferred option for PoD[123]. The results showed that home was, in fact, the least preferred option for between 4.3% (Netherlands) and 21.8% (Portugal) of participants. Home may not be feasible let alone desirable when there is a high burden on caregivers, uncontrolled symptoms and suffering or inadequate resources for the individual patient's needs. Hunt et al [124] showed that bereaved relatives of those who achieved their PPD were more likely to report the patient was treated with dignity and respect (95.5% vs. 76.6% $p<0.01$), more likely to agree there was enough help with nursing care (84.8% vs. 65%, $p<0.01$) and that the patient's environment provided adequate privacy (93.0% vs. 67.9%, $p<0.01$). This suggests PPD is a more relevant surrogate outcome measure for quality of care than home deaths per se. It has been argued by some that meeting patient preference is the ultimate measure of success in palliative care[125]. PPD is relevant, measurable and unaffected by attrition due to death. Therefore, it appears to be a good choice of outcome measure in EoLC research.

1.4.8 Section summary

Overall, people prefer to die at home. However, a high proportion of patients in the developed world die in hospital. The discrepancy between the proportion of patients who prefer a home death and the number who actually achieve this is striking. Congruence between the two is a common outcome measure chosen to assess EoLC interventions. The interplay between PPD and achievement of this preference at the EoL is complex. Interventions that promote congruence between preferred and actual PoD are required[16]. Any intervention aimed at maximising congruence should also be evaluated for its effect on other EoLC outcome measures.

1.5 Other Outcome measures in EoL Care

1.5.1 Section introduction

PoD has become a key surrogate indicator of the quality of EoLC[3, 126]. However, although quality care at EoL does require attention to patient preferences[110], EoLC is multidimensional. Given the definition of EoLC, it is not surprising that possible outcomes are multiple. Over the years, clinicians, policy makers and researchers alike have all attempted to determine what constitutes a 'good death'. Often the emphasis is on death being pain-free, peaceful and dignified[12].

Agar et al[6] describe dying patients, carers and their palliative care providers as being engaged in constant complex calculations. They must assess wishes, options available, the ability to effectively symptom-manage in the home setting and the degree of current and likely future burden for carers and patient. Above all else, the goal amongst all of this is to maintain the dying person's comfort and dignity. It is unlikely, therefore, that one single outcome – death at home - will fulfil all these requirements. Hence PoD and PPD as isolated outcomes have limited real value; other outcome measures must be evaluated. If an intervention increases the rate of home death or achievement of PPD at the expense of symptom control, QoL and satisfaction, then the intervention has surely failed and cannot be recommended. I

would also argue that an intervention that promotes patient PPD at the expense of the carer's QoL should also not be recommended.

Measuring the efficacy of interventions to improve outcomes at the EoL is difficult[127]. Moreover, knowing the important outcomes to measure and how to measure can be a challenge. Given the definition of EoLC, an assessment of symptom control, QoL, carer QoL and satisfaction alongside service use, hospital admissions and care transitions all seem relevant to fully understand the impact of an intervention on EOLC.

1.5.2 What is an outcome measure? What makes a good outcome measure?

An 'outcome' is the 'change in a patient's current and future health status that can be attributed to the preceding healthcare'[128].

Outcome measurement is an important step in evaluating care provided[129]. It involves establishing a patient's health status and monitoring any changes that occur over time through the use of valid and reliable measures or tools[128]. This can be problematic in EoLC as the common outcome measures of symptom control and QoL often deteriorate as death approaches.

A systematic review[130] revealed over 300 quality indicators or outcomes developed for palliative care clinical practice. A number of these relate to PoD and PPD. There are two main groups of outcome measure: generic and specific. Specific measures are designed to assess a particular domain of care, QoL and experience of symptoms. Such measures that evaluate clinically important data and are responsive to change over time are important for research purposes[128]. The outcome measures chosen should reflect the care that is given by an intervention, and thus is likely to need broad scope to cover all outcomes[131]. EoLC outcome measures must be holistic to capture all outcomes -physical, psychological, social and spiritual-related to patient and informal carer for the population or intervention being studied. Three universally agreed key palliative care and EoLC outcomes are QoL, satisfaction with care and economic cost. In 2008, Zimmermann et al conducted a systematic review[131], the aim of

which was to appraise the available literature regarding the effectiveness of palliative care in terms of improving QoL, satisfaction with care and economic costs. The review found that research evidence to support palliative care interventions was sparse and limited by methodological issues. Outcome measurements used in other areas of health care were not appropriate for palliative care studies.

In 2016, the EAPC published a white paper containing recommendations on the use of outcome measures in palliative care[128]. These recommendations are applicable to both clinicians and researchers, and the overarching principles apply to EoLC. Table 1.6 highlights the recommendations of particular relevance to the work in this thesis. Although this research began before the publication of the EAPC recommendations, Table 3.9 in Section 3.7.3.4 details the assessment tools and outcome measure chosen in relation to the relevant EAPC recommendations (Recommendations 1-4, &6).

Table 1.6 Relevant EAPC recommendations (1-4 &6) for the evaluation of EoLC

Recommendation
(1) PROMs: validated in the relevant populations and sufficiently brief and straightforward to allow proxy reporting
(2) Use multidimensional measures that capture holistic nature of palliative care
(3) Use outcome measures to assess the needs of unpaid carers alongside the needs of the patient
(4) Use measures that have sound psychometric properties
(6) Use valid and reliable measures in research that are relevant to the research question and consider patient burden when using measures

The deterioration of a patient approaching the EoL and during the dying phase makes PROMs challenging to use particularly over time.

1.5.3 Symptom burden, QoL and Satisfaction with care

Interventions at the EoL should offer a multi-dimensional approach. Symptom burden is important to evaluate for two reasons. Firstly, any service or intervention aimed at providing good EoLC must involve impeccable assessment and management of symptoms as this is essential to providing compassion and maintaining dignity at the EoL. Secondly, other outcomes at the EoL may be linked to symptom control, and should be assessed in the context of a symptom assessment.

Research shows that freedom from pain is consistently ranked as a priority by patients in the ordering of important factors at the EoL[90]. Therefore, symptom burden is a crucial outcome measure to assess.

QoL is frequently selected as an outcome measure to evaluate the effectiveness of palliative care and EoLC. This is appropriate given the emphasis on QoL in clinical care. Although there is no clear definition of QoL in the literature, there is a clear distinction between health-related QoL and holistic QoL. QoL instruments that measure all domains-physical, functional, psychological and spiritual- are more likely to capture appropriate outcomes at the EoL than those which measure one single domain [127]. For patients approaching the EoL, Zimmermann[131] suggests there should be more emphasis on existential and spiritual issues, alongside assessing how effectively a service or intervention plans and communicates for the EoL phase. Carer QoL is also an important outcome measure in EoLC. The informal carer is often providing personal care and support in between HCP visits, as well as their own QoL being an important outcome measure of EoLC. Therefore, evaluation of EoLC must also include an assessment of the informal caregiver.

Satisfaction of patients and caregivers is another measure of quality of care. The assessment of satisfaction with care can be problematic, in view of ceiling effects of generally high satisfaction. However, Zimmerman reported that caregiver satisfaction was the one outcome showing consistent improvement in research studies of palliative care effectiveness. Informal carers often rate care less favourably than patients; therefore, their assessment can provide a useful outcome measure, although depending on the timing of the assessment, outcomes may be subject to recall bias (such as bereavement surveys)[131].

1.5.4 Cost of care, hospital admissions and care transitions at EoL

The desire to measure the cost and cost effectiveness of interventions at the EoL stems from the known high cost of care, particularly hospital-based care, in the last year of life. Less is known about the community costs of care. Studies exploring the health economics of EoLC are limited. The available evidence points towards hospital deaths being more expensive than home deaths[132], although very little is known about total community costs. “The full

breakdown of costs in palliative care is yet to be unveiled'[133]. Costs of EoLC are multiple: hospital costs; community costs; social services costs; costs to informal carer and family members. These are difficult to capture in totality.

In the UK, the National Audit Office report published in 2008 estimated that by reducing admissions in the last year of life by 10% and the length of stay by a quarter, the NHS could redistribute approximately £104 million into community services[134]. A Canadian study [135] has also shown that the cost of care gradually increases up to the last month of life, with a large part attributed to inpatient care. The breakdown of outpatient costs in this study concluded most is spent on homecare, with informal carer costs also increasing in the last 3 months. One study [136] found that the daily cost of hospital EoLC was, on average, 3 times more expensive than in the community setting. In the current climate, research into new interventions should evaluate their impact on other service use and cost. Services need to at best demonstrate a cost saving and at worst be cost neutral with improved patient outcomes compared to standard care.

Two other important outcomes in EoL that are linked to service use and cost are hospital admissions and transitions in care at the EoL. A reduction in unnecessary hospital admissions and a reduction in the number of care transitions at the EoL translate to more time spent in PPC and are therefore thought to indicate better quality EoLC. These outcomes should be evaluated alongside service use.

1.5.5 Section summary

Good EoLC demands a holistic approach where the needs of patients and the people around them are considered and addressed. This requires multiple disciplines and agencies. Whilst PPC and PPD are important outcomes, research into the quality and delivery of EoLC must collect outcomes that span all areas of care to give a true picture of the population or intervention being studied. EoLC service delivery is achieved through the use of CIs in palliative care, although evaluation of these interventions is lacking. A CI has been developed at the RMFT to coordinate holistic care for patients for whom the treatment plan is best supportive care only. The modelling and evaluation of this CI forms the basis of this research.

1.6 Complex Intervention evaluation

1.6.1 Section introduction

In this section, I will first define CIs. Secondly, I will describe the MRC guidance for CIs and MORE Care statement for developing and evaluating CIs in EoLC. Thirdly, I will describe the use of case conferencing as an example of a CI in palliative care and then describe the Hospital2Home CI (H2H) that will be evaluated in this thesis. Finally, I will present preliminary work that forms part of the *development and modelling* stage of the MRC guidance for H2H. This includes a retrospective service evaluation, H2H staff workshop and consultant oncologist survey. Results from this work will inform the design of the exploratory feasibility study – the main work in this thesis.

1.6.2 Definition of CI

A CI is a health service package containing multiple interacting components. These act independently or inter-dependently of each other but all are deemed necessary for the proper functioning of the overall intervention [137]. The Medical Research Council (MRC) 2008 guidance on developing and evaluating a CI highlights important characteristics that contribute to the complexity of an intervention and its evaluation:

1. The number of interacting components within the new intervention
2. The number of interacting components in the control intervention
3. The number and difficulty of behaviours required by those delivering or receiving the intervention
4. The number of groups or organisational levels targeted by the intervention
5. The number and variability of outcomes
6. The degree of flexibility or tailoring of the intervention permitted[1]

1.6.3 Evaluation of CIs

It is acknowledged that CIs present a number of problems for evaluators. In 2000, the MRC published a framework to guide researchers in developing robust methods of studying and appraising CIs. The framework was based on a five-step approach (Figure 1.5), consisting of a series of steps of investigation, phase 0-phase IV. The framework acknowledged that the early phases in the model may overlap.

In 2008, updated guidance was published to reflect expert opinion that, although the step-wise approach was useful, it did not reflect the true complexity of developing, evaluating and implementing a CI. One criticism was that there was not enough emphasis on the ***developmental and modelling*** and ***feasibility and pilot stages (exploratory phase)*** of appraising a CI. This led to inappropriate research studies of poorly defined CIs. The updated guidance recognised that each phase may not follow a linear or even cyclical sequence [1]. The interplay between phases could occur in both directions as depicted in the new model (Figure 1.6). The MRC guidance has been used as a framework for the work in this thesis. In 2015, Moore et al[138] published guidance on process evaluation of CIs highlighting that effect size data does not provide policy makers with information on how an intervention may be replicated in their specific context or if outcomes are reproducible. Thus trials at all phases of the MRC guidance should include data collection on process evaluation to assess fidelity, quality, clarify causal relationships and identify any contextual adaptations. Figure 1.6 is an adapted version of the MRC guidance considering the different methodology of the development and evaluation of H2H in cancer patients. Process evaluation data was collected as part of both the ***development*** and ***feasibility and piloting phases*** of the evaluation of H2H.

Figure 1.5: The Medical Research Council framework for evaluating CIs 2000[137]

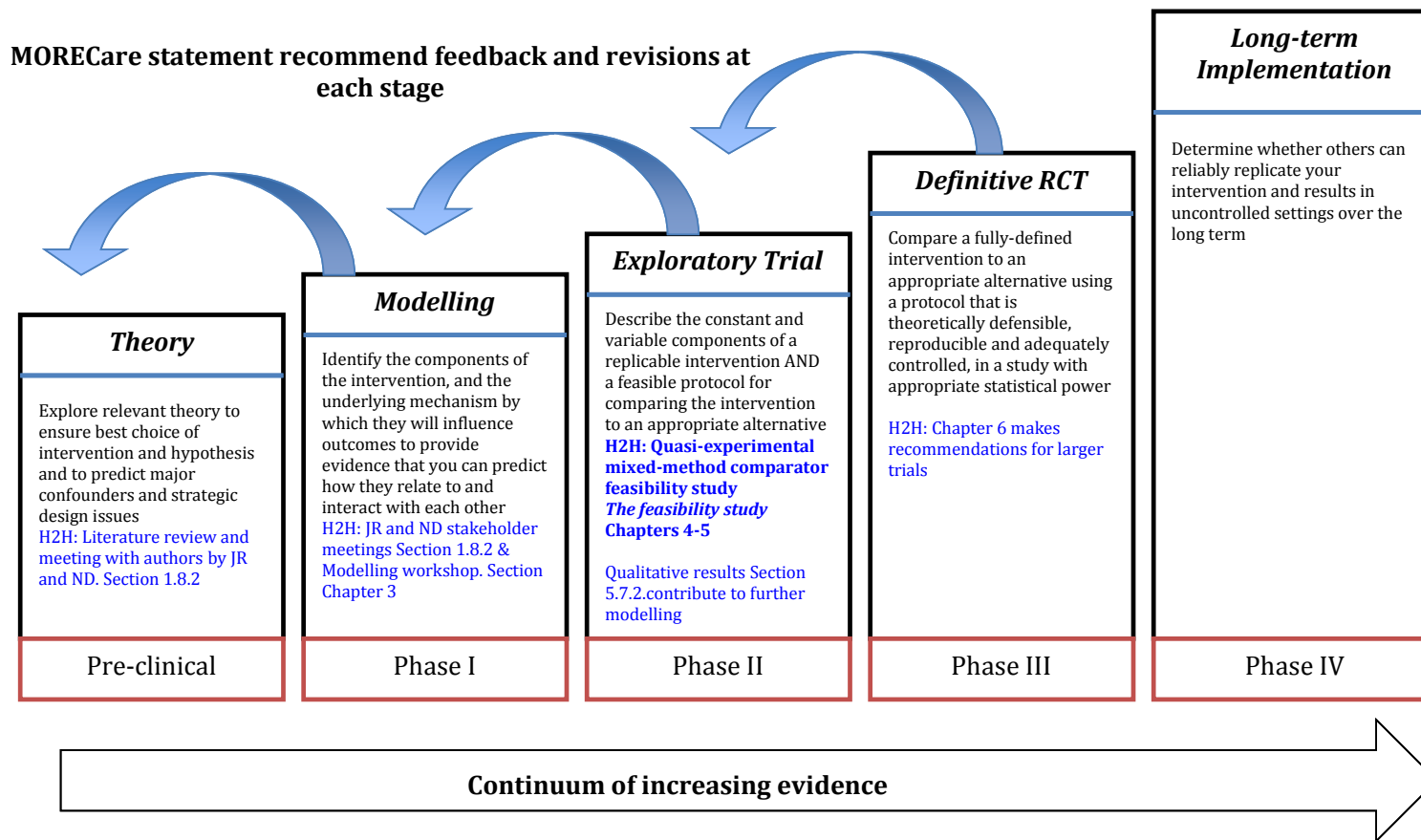
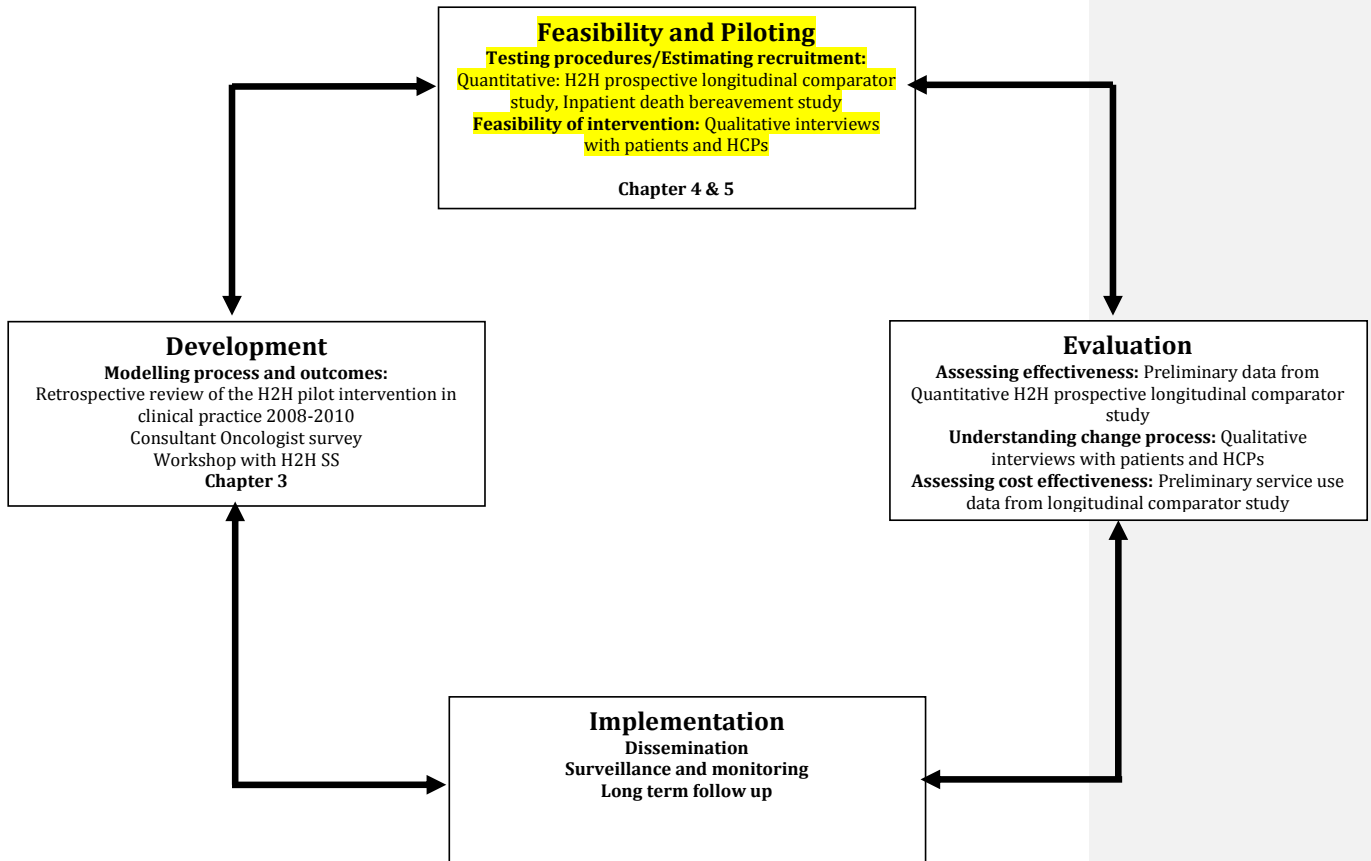


Figure 1.6:Adapted MRC model for developing and evaluating H2H.[1]



1.6.4 Evaluating CIs in EoL Care

Research in palliative care, and moreover EoLC, has challenges in all areas from study design, recruitment and consent through to attrition and follow up. In 2013, Higginson et al[139]published the MORE Care guidance. This guidance aimed to ‘identify, appraise and synthesise ‘best practice’ methods for research evaluating EoLC’. The result was a statement detailing 36 best practice solutions to improve study quality in EoLC research alongside a model of key steps in developing and evaluating EoLC interventions .The MORE Care statement was published after the end of recruitment to the H2H feasibility study and, therefore, the statement could not influence the H2H study design and conduct. However, the MORE Care

statement was used to guide the reporting and discussion of methodological issues and preliminary findings. The best practice statements are detailed in Appendix 7.1.2 with reference to this work.

1.7 Case Conferencing – An example of a CI

1.7.1 The Case Conference (CC) in palliative care- definition

A CC is a tool to coordinate care across a multidisciplinary team. It is used to share information about a patient's condition as well as to identify and discuss care needs and goals [140, 141]. It is a mechanism through which HCPs, patients and informal carers can address current issues and also begin to advance care plan. CC interventions can involve a face-to-face meeting in the presence or absence of the patient and carer or telephone/video conferencing. The membership of a CC varies depending on patient need and usually involves at least 3 disciplines and a written plan of care results[5].

1.7.2 Rationale for the use of the CC in the transition to end-of-life care

A CC intervention to coordinate the transition of care from the acute sector to community-led care should improve patient outcomes at EoL. Care frequently incorporates many disciplines- nursing, medical, allied health professionals and social work staff -, and co-ordination is crucial. Multiprofessional teams provide better palliative care than practitioners working in isolation[142, 143]. Research involving CHCPs identifies poor discharge planning and co-ordination as a barrier to patients dying at home[144]. Community health care providers also cite poor communication amongst health professionals as a primary factor that limits the ability to effectively and efficiently care for patients and their families.

Strategies that improve communication, such as CCs, are expected to improve the coordination of services and potentially patient-related outcomes even at the EoL[145]. Case conferencing is a unique opportunity to support GP involvement in MDT palliative care teams[5]. Cancer patients approaching the EoL should benefit substantially from a CC approach: needs are real,

imminent and often predictable to an expert[146]. Expert knowledge and clinical experience imparted to the patient, carer and community teams through a CC can identify future anticipated problems and direct the plan of care accordingly. CCs also have the potential to deliver an optimal and timely combination of GPs' contextual knowledge and specialist content knowledge[127]. This can reinforce the centrality of the GP role [5] which may be a crucial step in the transition of care from specialist centres to community-led teams.

Research into the palliative care CC originates in Australia where GPs were incentivised through remuneration to organise and participate in CCs with other HCPs.

Abernethy et al[5] conducted a cluster randomised control trial evaluating a face-to-face CC model. This study was evaluating three interventions: GP educational outreach visiting, structured patient and caregiver educational outreach visiting and case conferencing. Case conferencing was expected to improve patient outcomes by increasing communication among key providers and a more timely introduction of appropriate support. The primary outcome measure for this study was the period of time the patient had an PPS >60% (competent self care). Other outcome measures tested were hospital bed days, after hours medical visits, unplanned hospitalisations, resource utilisation, problems discussed during the CC, satisfaction, pain intensity, symptom scores and QoL and PoD. In this model, the patient and care giver were included in the conference and set the agenda, organised by the SPC nurse within one month of randomisation. The minimum attendees were patient, GP and SPC nurse (SPC).

Improvements were seen in performance status after CC and data regarding CC participation was encouraging, with three quarters of conferences involving three or more HCPs[147]. Secondary data analysis of PPD and actual PoD data for the total population (all arms of the study) showed overall congruence for 41/69 patients (59.4%, κ 0.45). Congruence for home death was 9/24 (37.5%)[6]. Data on congruence for the CC group alone has not been published.

Mitchell et al[127, 146, 148, 149] conducted a multi-centre RCT of a telephone CC model (the GP phoning into the routine SPCT meeting). The CC did not involve the patient or carer. The agenda was led by HCPS. Primary outcome measures were patient QoL and carer burden. The study did not reach sample size due to slow recruitment. The results show no change in the primary outcome measure of global QoL with the CC intervention compared to standard care.

However, data with death as a fixed time point showed five significant findings in favour of the CC intervention at 14 and 35 days prior to death in physical and psychological domains of QoL[148]. The study also showed improvements in two carer burden domains (impact on schedule and lack of family support) 5 weeks after CC.

A recent published feasibility RCT evaluating an adapted H2H in patients with interstitial lung disease in the UK found significant improvements in the Palliative Outcome Score (POS) from baseline to week 4 compared to standard care[150].

There is no previous research into H2H in the EoLC for cancer patients within the UK NHS. Similarly, the effect of the CC intervention on the primary outcome of PPD has yet to be studied.

1.8 The Hospital2Home (H2H) CI

1.8.1 Section introduction

The Hospital2Home CI centres on a CC aimed at improving the coordination of care between an oncology centre and community service providers.

This research was conducted at the Royal Marsden NHS Foundation trust (RMFT). The RMFT is a specialist tertiary referral oncology centre based in London. There is a dedicated SPCT at both sites. In 2004, an audit of emergency admissions found that symptom control alone accounted for 55% of cases. In 2005, of the 1,108 new patients referred to the palliative care team, 39% died in hospital. It was hypothesized that the reason for readmission of patients approaching the EoL was a breakdown of care due to inadequate sharing of information between the hospital and community. To improve the transition of care into the community, H2H was developed.

1.8.2 Development and Modelling

The identification of the evidence base for a CC approach along with the design of H2H was completed by Dr Julia Riley and Mr Nigel Dodds based on the Australian studies into CC[5, 148]. Consultation with Professor David Currow (part of the Australian team) and stakeholder

involvement (including local GPs, palliative care teams, oncology colleagues and carers) led to the pilot service design. The pilot service had been running for two years prior to this feasibility study.

1.8.3 Hospital2Home (H2H)

H2H is a patient centred, multidisciplinary service that includes a case conference (CC) and individualised care planning. The intervention centres on an MDT case conference involving the patient, their carer, hospital and community HCPs.

H2H is shown in Figure 1.8. It consists of the following interacting components.

1. **Education:** Oncologists are educated to refer patients with no further active oncological management to the H2H team (Referral criteria are outlined in Table 1).
2. **A H2H consultation:** The *H2H SS* (a palliative nurse employed solely for CC) meets the patient and their carer either on the hospital ward or in outpatients. The purpose is to draw up a patient-led agenda for the CC.
3. **H2H Fact finding:** The H2H SS spends time organising the CC, meeting and liaising with the oncology team and other specialists in the RMFT and outside to clarify management plans for any current problems and also an individualised care plan for future anticipated problems. This is based on the patient's agenda and the specialist team's knowledge of the individual patient's disease. It is shared with attendees at the CC. This step includes arranging additional procedures prior to discharge (such as portacath removal), organising for community-led monitoring and repeat prescriptions of complex medication that have routinely been prescribed from outpatients (for example low molecular weight heparin). It also involves reviewing and cancelling any unnecessary outpatients follow up appointments.
4. **The H2H CC (CC):** The H2H SS organises a suitable time and place, based on patient preference, for a CC with the community teams. This is usually in the patient's home. The patient, carer, GP, district nurse and CPC nurse are all invited. The patient can invite any other HCPs or carers that they feel are important to them. The H2H SS or GP chairs the meeting; time is taken to discuss current problems, anticipated problems and the action plan for these, as well as discussing the patient's EoLC preferences if appropriate. EoLC preferences, including PPC and PPD, are shared.
5. **Documented care plan:** At the CC, a care plan is drafted with a responsible professional for each item. The H2H SS distributes a copy of the care plan to the patient

and CHCPs involved in their care, including out of hours GP and ambulance services. The care plan template is available in Appendix 7.1.4. It is uploaded onto the RMFT electronic patient record.

6. **Specialist review:** Patient care plans are discussed at weekly H2H SPC MDT with SPC consultant input.

Table 1.7 Referral criteria for H2H

Referral criteria
Age over 18 years old
No further active oncology treatment available
Prognosis of less than one year
Discharge from the Royal Marsden Hospital

H2H parallels with the EoLC strategy recommended 6-step approach to individualised care planning. This 6-step approach is shown below with reference to H2H. H2H encompasses Steps 1-3, and acts as an enabler for community professionals to deliver high quality care during Steps 4-6..

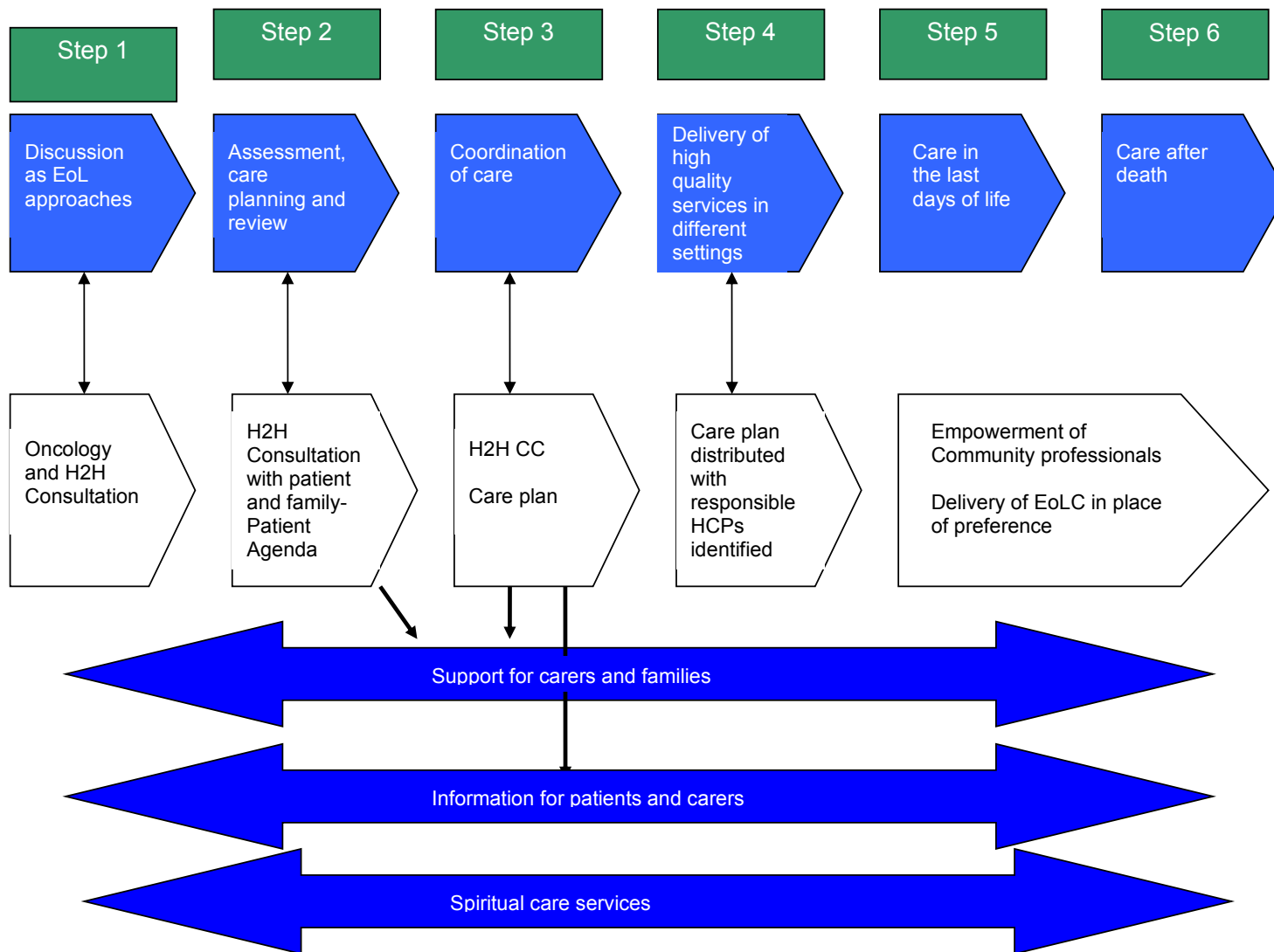
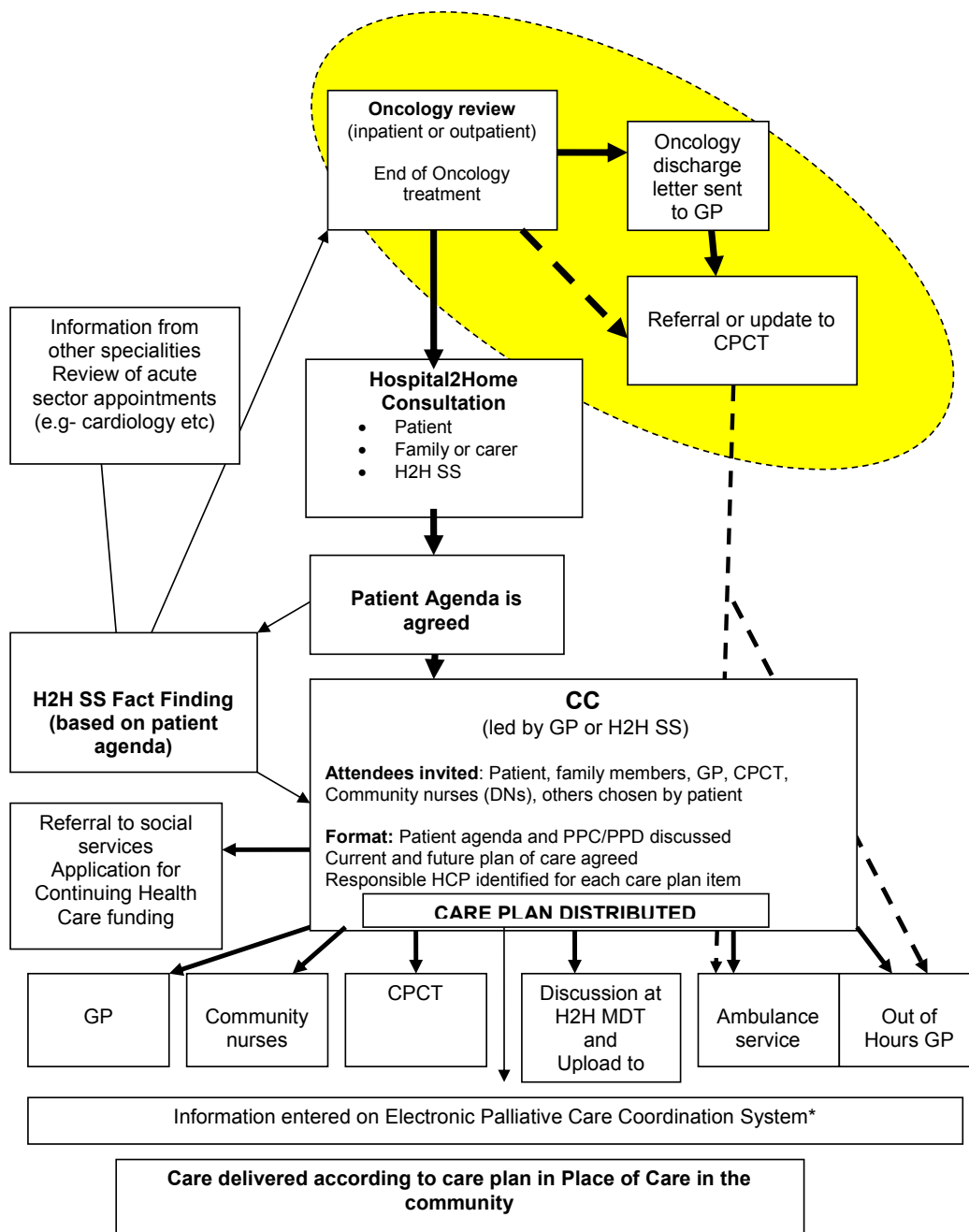


Figure 1.7: H2H and EoLC strategy



Yellow oval box includes all components of standard care *if available

Figure 1.8: The H2H intervntiooon

The complexity factors of an intervention described by the MRC guidance are summarised in Table 1.8 in relation to H2H and this exploratory feasibility work.

Table 1.8: What makes an intervention complex – H2H. Adapted from MRC guidance 2008

Factor of Complexity	Applicable to H2H?		Implications for evaluation/research
	Yes/No	Why	
Number of interacting components within the 'new' experimental intervention	Y	H2H involves multiple interacting components as per Figure 1.7. The components involve a number of different stakeholders across different care settings	Intervention standardised to allow confident reporting of what is delivered during a CC.
Number of interacting components within the control interventions	Y	Standard care involves referral to community SPC. The quality of this is location dependent, and how the CPCT interact with other community professionals impacts on standard care delivery	Heterogeneity in additional standard care in intervention and comparator group
Number and difficulty of the behaviours required by those delivering or receiving the intervention	Y	Highly relevant. - Referral to the service is dependent on the behaviours of oncologist - Acceptance of H2H is patient dependent - The quality of the CC is limited by the experience of the H2H SS and the attendance of CHCPs	Patient and HCP feedback about the service is an essential component of the feasibility study. There is a need for both qualitative and quantitative methodology Mixed methods research required
Number of groups or organisational levels targeted by the intervention	Y	Variety of stakeholders involved and targeted by H2H: - Patient, Carer, Oncologists, GP, District nurses, CPC - NHS and voluntary organisations	Participants of evaluation need to be from a variety of stakeholders Mixed methods research required
Number and variability of outcomes	Y	There are potentially a large number of outcomes for the intervention. Potential outcome measures related to patient, carer, HCPs and cost effectiveness.	Testing the feasibility of a variety of outcome measures is required to determine the most appropriate and observe for unforeseen effects of the intervention
Degree of flexibility or tailoring of the intervention permitted	Y	Essential factor. EOLC involves individualised care plans. Hence each CC is individualised, so too is the preCC work and aftercare	Describing the intervention in detail is complex Mixed methods research may be required

1.9 Chapter Summary

In the UK approximately half of all cancer patients die in hospital despite evidence that most would prefer to die at home. It has been argued that meeting patient preference is the ultimate measure of success in EoLC[125]. One of the key themes of public policy in EoLC has been achievement of choice in PoD[16]. Interventions that promote congruence between preferred and actual PoD are required[16] and should be robustly evaluated. Any intervention aimed at maximising congruence should also be evaluated for its effect on other EoLC outcome measures including symptom control, patient/carers QoL and satisfaction and cost.

There is sparse research evidence in EoLC service delivery[18]. The published literature draws only limited conclusions due to challenges in recruitment, study design and attrition[18-20]. A CI is a health service package containing multiple interacting components. EoLC service delivery is achieved through the use of CIs in palliative care, although evaluation of these interventions is lacking. Research in this area needs to first determine appropriate feasible outcome measures and study design prior to testing the benefits and harms of any new CI against standard care. In the RMFT a CI, H2H, has been developed to coordinate holistic care for patients for whom the treatment plan is best supportive care only. The aim of H2H was to improve patient outcomes at the EoL through ensuring a streamline transition of care from the specialist cancer centre to community led care. H2H is a CI centred on a CC involving patients, carers, cancer centre specialists and CHCPs. The MRC guidance recommends a phased approach to evaluating CIs and emphasises the importance of thorough testing at the feasibility and piloting phase. Formal assessment of H2H using methodology based on MRC guidance has not been conducted in the UK. The work in this thesis forms the **modelling** and **feasibility and piloting** phases of the MRC guidance for developing and evaluating H2H in cancer patients[1]. The findings from this work will inform the **evaluation phase** of the MRC guidance.

CHAPTER 2: AIMS AND OBJECTIVES

2.1 Aim

The aim of this thesis was to determine the feasibility of conducting a mixed methods longitudinal study of H2H and to explore the delivery and impact of H2H on cancer patient outcomes at the EoL.

There were 4 main aims:

- Aim 1:** To perform early process evaluation and modelling of H2H (*development and modelling* phase of MRC framework)
- Aim 2:** To determine the feasibility of evaluating H2H in a cancer population (*feasibility phase* of MRC framework)
- Aim 3:** To explore potential benefits of H2H compared to standard care in a cancer population
Null hypothesis: There is no difference in outcomes for participants receiving H2H and those receiving standard care alone.
(*feasibility phase* of MRC framework)
- Aim 4:** To understand the wider EoLC experience of cancer patients
(implications for future *development and modelling* of H2H)

To achieve these aims the work in this thesis follows the MRC framework for developing and evaluating CIs. The thesis is divided into two parts; Chapter 3 presents the methods and results of the *development and modelling phase* (Aim 1) and Chapter 4 and 5 present the methods and results of the *the feasibility and piloting stage* of the MRC framework for developing and evaluating CIs. The overall aims above were addressed by 4 individual objectives in the *development and modelling phase* and the 17 individual objectives in the feasibility and piloting stage. These objectives are outlined in Section 2.2 and 2.3 below.

2.2 Objectives

2.2.1 Objectives of the *development and modelling phase*

Aim 1: To perform process evaluation and modelling of the current H2H

The objectives of the *development phase* are outlined below:

Objective 1: To describe details of what is being delivered in 'real life' in H2H

Objective 2: To describe contextual adaptations to H2H

Objective 3: To evaluate the early implementation of H2H

Objective 4: To use the above work to further develop the service and inform the *feasibility and piloting phase* of this work – The H2H feasibility study

2.2.2 Objectives of the *feasibility and piloting phase*

The objectives of *feasibility and piloting* phase of this thesis are outlined below:

Aim 2: To evaluate the feasibility of evaluating H2H in a cancer population at the End of Life

Objective 5: To determine the feasibility of studying H2H in this setting by assessing inclusion and exclusion criteria, recruitment rates, retention and follow up rates and missing data (Aim 2)

Objective 6: To assess potential outcome measures for H2H intervention, and scrutinise the value of these outcome measures in this setting (Aim 2)

Objective 7: To determine if, in this population, the outcome measure of achieving PPD correlates with the patient reported outcome measure of QoL, and is therefore a feasible surrogate primary outcome measure (Aim 2)

- Objective 8:** To determine if proxy (carer) responses to patient symptoms and QoL tools match patient reports and therefore may be a feasible mechanism of minimising attrition due to illness as EoL approaches (Aim 2)
- Objective 9:** To describe views and perceptions of patients and professionals regarding transition to community-led care EoLC (Aim 2)
- Objective 10:** To describe patient and HCPS views and perceptions about H2H (Aim 2)
- Objective 11:** To describe potential facilitators and barriers to implementation of H2H (Aim 2)
- Objective 12:** To use the above work to inform further development, modelling and implementation of H2H (Phase I) (Aim 2)
- Objective 13:** To use all the above work to inform a future pilot study (Part 2 of Phase II) and larger evaluation trial (Phase III) of H2H intervention (Aim 2)
- Aim 3:** To explore potential benefits of the H2H compared to standard care in a cancer population
- Objective 14:** To explore preliminary hypothesis testing to provide an estimate of the effectiveness of H2H compared with standard care as measured by the achievement of PPD - **Primary outcome of effect (Aim 3).**
Null hypothesis: There is no difference in the proportion of participants achieving PPD with H2H compared to standard care alone.
- Objective 15:** To determine and compare the actual PoD of H2H group with standard care (Aim 3)
Null hypothesis: There is no difference in the proportion of participants dying at home, in hospice or in a hospice with H2H compared to standard care alone.
- Objective 16:** To determine and compare patient and carer symptom burden, QoL and satisfaction in H2H group compared to standard care (Aim 3)

Null hypothesis: There is no difference in patient and carer symptom burden, QoL and satisfaction with H2H compared to standard care alone.

Objective 17: To determine and compare service use after discharge from oncology services in H2H group compared to standard care (Aim 3)

Null hypothesis: There is no difference in service use after discharge from oncology services with H2H compared to standard care alone.

Objective 18: To determine and compare the number of patient days spent in their PPC in H2H group compared to standard care (Aim 3)

Null hypothesis: There is no difference in the number of days participants spend in their PPC with H2H compared to standard care alone.

Objective 19: To determine and compare the number of admissions and days spent in hospital/hospice in H2H group compared to standard care (Aim 3)

Null hypothesis: There is no difference in the number of admissions and days spent in hospital/hospice with H2H compared to standard care alone.

Aim 4: To understand the wider EoLC experience of cancer patients (implications for the feasibility of H2H and future *development and modelling* of H2H)

Objective 20: To determine and compare the bereaved family members' satisfaction with care in the H2H study with those family members of patients who died in the hospital (Aim 4)

Objective 21: To determine if the degree of satisfaction with care is related to any patient clinical, demographic, or preferences factors (Aim 4)

Objective 22: To determine other factors influencing PoD in the wider cancer population treated at the RMFT (Aim 4)

CHAPTER 3: DEVELOPMENT AND MODELLING PHASE

3.1 Introduction

The work in this thesis has been conducted in phases correlating to those of the MRC guidance. This chapter details the *development (modelling process and outcome)* work conducted, whilst the remainder of the thesis focuses on the *feasibility and piloting phase* of the guidance. This chapter presents the findings of the development phase the purpose of which is to answer Aim 1: To perform early process evaluation and modelling of H2H (*development and modelling* phase of MRC framework)

The objectives of this *development phase* are outlined in Chapter 2 and repeated here

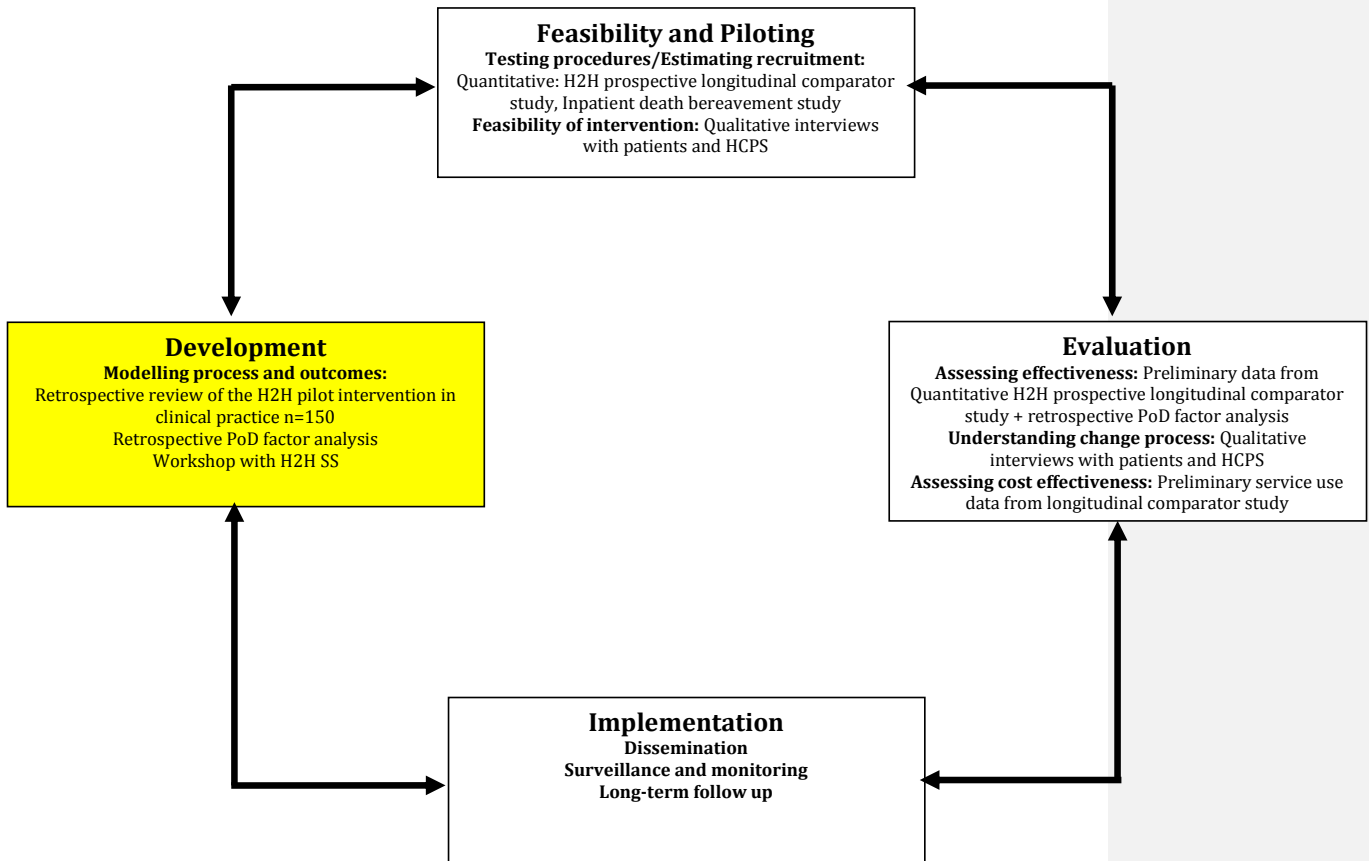
Objective 1: To describe details of what is being delivered in 'real life' in H2H

Objective 2: To describe contextual adaptations to H2H

Objective 3: To evaluate the early implementation of H2H

Objective 4: To use the above work to further develop the service and inform the *feasibility and piloting phase* of this work – The H2H feasibility study

Figure 3.1: H2H evaluation adapted from MRC guidance



3.2 Methods

The MRC guidance on evaluating CIs recognises the value of process evaluation as an important part of any CI study. Figure 3.1 above shows modelling process and outcomes as part of the **development phase**. Moore et al [138] advocate that trials at all phases of the MRC guidance should include data collection on process evaluation to assess fidelity and quality of the intervention, clarify implementation process, causal relationships and identify any contextual adaptations. Therefore to understand fidelity, how and what was being delivered in clinical practice, and evaluate possible early outcomes of H2H, I undertook three areas of early process evaluation; a workshop with the three H2H SSs to map the intervention, a retrospective service evaluation audit of the first 150 H2Hs and an audit of oncology consultants' understanding of EoLC and H2H. These three components constitute the **development** phase of the MRC

guidance focussing on process evaluation of the pilot service. The results enabled a clear understanding of H2H before embarking on the ***feasibility and piloting phase*** of the MRC guidance as well as providing important data to inform the design of the feasibility study.

Workshop outcomes and intervention mapping

The workshop took place in June 2010. It was a repeat of the modelling phase completed by JR and ND at the conception of H2H. The purpose of the workshop was to understand how the CI was being delivered in 'real life'; to describe any modifications that had occurred; and to ensure the CI, where possible, was standardised prior to the exploratory feasibility study.

I led the workshop with AMS and all 3 H2H SSs were in attendance. The workshop lasted 2 hours. The workshop had three components:

1. Each H2H SS described, in a detailed stepwise manner, the service they delivered
2. The current documentation, including referral forms and care plans, were reviewed and agreed as standard use. These documents are available in Appendix 7.1.2-7.1.4
3. The components of the modified H2H were determined and minimum standards were set.

Retrospective service evaluation

To further understand the delivery of H2H and early outcomes, I undertook a retrospective service evaluation of the first 150 face-to-face CCs. This was a review of the H2H clinical database and the hospital electronic patient record using an audit proforma tool.

Hospital Health Care Professional opinion survey

This final part of the ***modelling process and outcome phase*** was an electronic EoLC survey of consultant oncologists. The aim of the survey was to determine current knowledge about PPC and PPD, alongside eliciting any barriers and facilitating factors to the use of H2H to inform the exploratory feasibility study.

3.3 Results

3.3.1 Workshop outcomes and intervention mapping

The workshop highlighted two important changes that had occurred to the intervention as a result of clinical need. Firstly, face-to-face case conferencing was not always feasible and therefore a telephone CC model had been set up. The reasons for a telephone CC were explored in the workshop and are detailed in Table 3.1 below. The telephone CC involved all the same components of H2H except the face-to-face CC was replaced by H2H SS telephone contact with all CHCPs and the patient. Secondly, the H2H pilot service was initially targeted at inpatients; however, there was found to be increased clinical need from the outpatient departments and therefore referrals from outpatients were being accepted.

As a result of the workshop, the criteria for telephone case conferencing were established and minimum standards for face-to-face and telephone CC were agreed. I also created and shared an updated modified model of H2H. This is shown in Figure 3.1 below.

The workshop revealed that to ensure H2H was standardised and delivered as intended on-going quality measures were in place. These were discussed and documented to enable H2H to be reproduced at another centre.

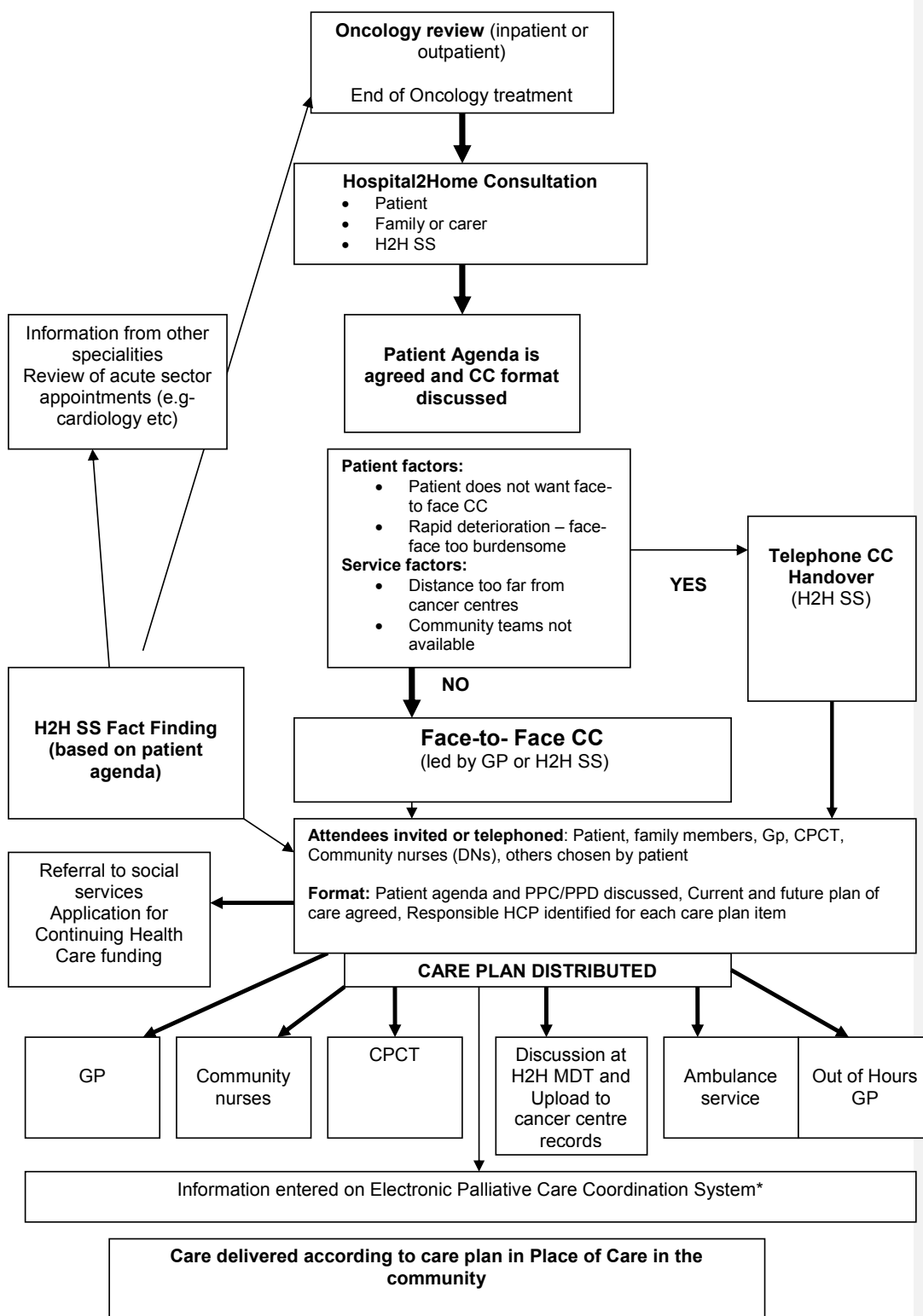


Figure 3.2: Modified Conceptual model of H2H

Table 3.1 Reasons for a telephone CC

Patient factors	Hospital2Home service delivery factors	CHCP factors
Choice	Service is at full capacity for face-to-face CC	Work commitments/ annual leave prevent organising a face-to-face conference within 2 weeks
Distance from patient home to hospital makes visiting impractical		
Deteriorating physical condition requires emergency palliative care discharge (a face-to-face CC is deemed too burdensome)		

The ongoing quality measures were:

- Mentoring and shadowing of H2H SS for any new staff members,
- Standardised documentation,
- A central post-CC database to document the lead SS, CC attendees and issues discussed for each H2H.
- Weekly database was analysis and case discussions in a H2H MDT meeting with a lead SPC consultant.

3.3.2 Retrospective Service Evaluation

The retrospective service evaluation audit included analysed data from the first 150 H2Hs. Patient demographics are shown in Table 3.2. The mean age of patients was 62 years old, 61.3% were female, 66% were married or had a partner and the majority (74.7%) were White British. The majority of patients (85.4%) had an identified informal carer and most of these lived with the patient (78%). In this cohort, 22% lived alone..The tumour groups most frequently using the service were Gastrointestinal (32.7%), Gynaecological (18%), Lung, Sarcoma and Urological cancers (10.7%), with 50.7% of patients receiving palliative chemotherapy as their last anti-cancer treatment. The estimated prognosis at the time of discharge was split equally between weeks (48%) and months (48.7%). Median PPS at discharge was 60 (range 20-80).

Table 3.2 Retrospective service evaluation: Demographics of patients who received a H2H (n=150) (continued on next page)

PATIENT DEMOGRAPHICS		n=150 (%)
AGE IN YEARS	Mean (SD)	62 (13.77)
	Median	63 (54-72)
	Range	(19-94)
GENDER	Male	58 (38.7)
	Female	93 (61.3)
ETHNICITY	White British	111 (74.7)
	Other	39 (25.3)
MARITAL STATUS	Married/Partner	99 (66)
	Other	51 (34)
LIVING ALONE	Yes	33 (22)
	No	117 (78)
INFORMAL CARER	Yes	137 (85.4)
	No	13 (14.6)
CARER RELATIONSHIP	No carer	13 (8.7)
	Spouse	93 (62)
	Adult Child	26 (17.3)
	Other	18 (12)
ACCOMODATION TYPE	House	114 (76)
	Flat	31 (20.7)
	NH	5 (3.3)
RECEIVING BENEFITS	Yes	129 (86)
	No	21 (14)
TYPE OF BENEFIT (n=129)	Disability living allowance	69 (53.5)
	Attendance allowance	59 (46.5)

ILLNESS FACTORS		n=150 (%)
CANCER DIAGNOSIS		
	Gastrointestinal	49 (32.7)
	Gynaecological	27 (18)
	Lung	16 (10.7)
	Sarcoma	16 (10.7)
	Urology	16 (10.7)
	Breast	11 (7.3)
	Skin (Melanoma)	5 (3.3)
	Head and neck	3 (2)
	Brain/CNS	2 (1.3)
	Unknown primary	2 (1.3)
	Other	3 (2)
LAST TREATMENT TYPE		
	No Treatment	11 (7.3)
	Chemotherapy	76 (50.7)
	Radiotherapy	44 (29.4)
	Surgery	11 (7.3)
	Hormones	8 (5.3)
ESTIMATED PROGNOSIS AT TIME OF DISCHARGE		
	Days	5 (3.3)
	Weeks	72 (48)
	Months/Year	73 (48.7)
PPS		
	<40	2 (1.3)
	41-60	71 (47.2)
	61-80	74 (49.2)
	>80	2 (1.3)

H2H was delivered in forty-two different primary care trusts (PCTs) around the UK. The median time from referral to CC was 3 working days (minimum 0 days, maximum 23 days), the majority occurring within 5 working days. The average length of a CC was 53 minutes (minimum 20 minutes, maximum 2 hours 15 minutes). Over 80% of CCs were attended by the minimum three community professionals requested: GP, CPCT and community nursing service. The patient was present at 96.7% of CCs. The main areas -, symptom control and psychosocial support - were discussed in over 85% of CCs; however, spiritual needs were rarely discussed (9.3%). PPC was discussed in all CCs with PPD discussed at 88.6% of CCs. Further details of the delivery of H2H are given in Table 3.3 below.

Table 3.3 Retrospective service evaluation: Delivery of the H2H CC

		n=150 (%)	
Average number of days after discharge	Mean (SD)	3.4 (3.02)	
	Median	3	
	Range	0-23	
Average length of CC (minutes)	Mean (SD)	52.4 (16.2)	
	Median	50 (40-60)	
	Range	20-135	
People present at CC	Patient	145 (96.7)	
	GP	124 (82.7)	
	Community/District Nurse	139 (92.7)	
	CPC	131 (87.3)	
	Carer	137 (91.3)	
Issues discussed at CC	Pain control	133 (88.7)	
	Other symptoms	147 (98)	
	Functional mobility	139 (92.7)	
	Psychological needs	131 (87.3)	
	Social needs	137 (91.3)	
	Spiritual needs	14 (9.3)	
	PPC	150 (100)	
	PPD	133 (88.7)	
If known, PPD choice (n=133)			
PPD (including not known) (%)			
	Home	84 (63.2)	(56)
	Hospice	45 (33.8)	(30)
	Hospital	0 (0)	(0)
	Nursing home	4 (3)	(2.6)
	Other location	0 (0)	(0)
	Not known		(11.4)

At the time of analysis, 148 patients had died. The median survival was 31 days (IQR 13-78, range 2-653 days). The early outcomes are detailed in Table 3.4. A high proportion of patients died at home (42.6%) or in a hospice (40.5%) with 10.8% dying in hospital. For those in whom PPD was known (n=130), overall congruence was 73.1%. For a home death, 69% achieved their wish (Table 1.13). Twenty-five percent of patients had one or more hospital admissions after the CC; the median length of stay was 3 days (range 1-25).

Table 3.4 Retrospective service evaluation: Early Outcomes of H2H (n=150)

		n=150 (%)
Survival (in Days)	<i>Mean (SD)</i> <i>Median (IQR)</i> <i>Range</i>	68 (96) 31 (13-78) 2-653
Place of death (n=148, 2 alive)	Home Hospice Hospital Nursing home Other location Not known	63 (42.6) 60 (40.5) 16 (10.8) 8 (5.4) 1 (0.7) 0 (0)
Overall congruence PPD achieved	Overall (for all locations) (n=130) If Home (n=82) If Hospice (n=44)	95 (73.1) 57 (69) 34 (77.3)
Patients with a hospital admission after CC		38 (25.3)
Hospital admissions days	Mean (SD) Median (IQR) Range	5.9 (6.38) 3 (1.5-9.5) 1-25

Table 3.5: Retrospective service evaluation: Congruence between actual and PPD (Congruence using Bell at al Method A)

PPD	Actual Place of Death, n (%)					
	Home	Hospice	Hospital	Nursing home	Other	Total
Home	57 (69)	19	5	0	1	82
Hospice	2	34 (77.3)	4	4	0	44
Hospital	0	0	0 (0)	0	0	0
Nursing Home	0	0	0	4 (100)	0	4
Overall congruence: 95/130, 73.1%, k 0.52 (95%CI 0.42-0.66) (moderate agreement)						

3.3.3 Hospital Health Care Professional opinion survey

An anonymous electronic EoLC survey was sent to 86 oncology consultants across RMFT; 21 returned the completed questionnaire. The response rate was low (24.4%). Table 3.6 details the results of the questionnaire. The majority of oncologists were aware of the terminology PPC and PPD and 70% felt it was very important for them to discuss PPC and PPD with their patients. Overall, the oncologists underestimated the EoLC needs at RMFT, with 55%

underestimating the total number of patients known to the trust who died each year and 77% underestimating the number of inpatient deaths per year.

71 % (16) of consultants had used H2H. Respondents gave reasons for not using the service as: unaware of the service (n=2); unsure who to contact (n=1); unsure of the referral criteria (n=1); and not involved in this aspect of patient care (n=1). The majority of consultants (83%) had a good experience of H2H, with none stating their experience was 'bad'. The consultants had multiple reasons for referring to the service: preventing unnecessary hospital admissions (n=13); security in knowing the patient preferences are being addressed (n=13); offering patients another form of care after active treatment (n=11); offering best supportive care (n=10); improving communication (n=7); and helping facilitate difficult conversations (n=6). However, three consultants felt the referral criteria were too strict: one was discouraged from using the service because they did not want to discharge patients from the hospital and one had concerns that the service may distress patients and families. Free text comments were also provided.

Table 3.6: Results of Hospital HCP opinion survey

	N (%)
Are you aware of the term PPC?	14 (70)
Are you aware of the term PPD?	16 (80)
Do you think PPC and PPD mean the same?	
Yes	1 (5)
No	17 (85)
No answer	2 (10)
How important do you think it is to ask your patients about PPC and PPD?	
Very important	14 (70)
Quite important	1 (5)
Not at all important	0 (0)
No answer	5 (25)
How many patients know to the RMFT die each year?	
<500	0 (0)
500-100	9 (45)
1000-2000	3 (15)
>2000	5 (25)
no answer	3 (15)
Approximately how many people die as an inpatient at RMFT	
<100	8 (38)
100-200	2 (10)
200-300	6 (32)
>300	2 (10)
no answer	2 (10)
Have you referred to H2H?	
Yes	15 (75)
What is your experience of the service?	
Good	12 (83)
Indifferent	1 (7)
Mixed	2 (13)
Bad	0 (0)
What prompt you to use H2H? (answer as many as apply)	
Offers best supportive care	10 (5)
Security in knowing patient preferences addressed	13 (65)
Helps facilitate conversations	6 (30)
Prevent unnecessary admissions	13 (65)
Able to offer the patient another form of care	11 (55)
Improves communication with community	7 (35)
What discourages you from using H2H?	
Do not want to discharge patient	1 (5)
Too strict referral criteria	3 (15)
May cause patient and family distress	1 (5)
Too difficult to discuss with patient	0 (0)
Patient should always come back to specialist centre	0 (0)

An example of positive feedback for H2H-

'My experience to date has been that this is an exceptional service in ensuring that patients continue to be well cared for following discharge. Patients welcome the service which they see as maximising communication between hospital and community teams and feel assured that they will continue to be well symptom controlled'

An example of potential barriers to the acceptability of H2H-

'Depends on the patient - Breast Unit practice is individualised care throughout. Co-ordination of all community services to support patient and family. Don't want to lose touch with patients and families who have built up a trust with us, often over many years, should problems arise that need further Marsden help. Often simply over the phone. Strong patient and family feed back on this one. Excellent service but the perception that patients and family cant keep in professional touch with their original team is a barrier to more referrals.'

Overall the results show that the intervention is acceptable to hospital clinicians. However, it may be possible that consultants were more likely to respond to the questionnaire if they had a positive experience of the service. The results illuminate polar opposite views regarding the service. This informed the design of the **feasibility and piloting phase** to include qualitative interviews with HCPs to explore perceptions of the service and transition to community-led care.

3.4 Chapter summary

This *development phase – modelling process and outcome* provided preliminary data on the delivery and fidelity of H2H and early outcomes. It answered Aim 1: To perform early process evaluation and modelling of H2H (*development and modelling* phase of MRC framework) prior to the exploratory feasibility study, and informed the design of the feasibility study.

The data from the workshop and the retrospective audit provided detail on the delivery in 'real life'. A clear model of the interacting components of the H2H was developed from the workshop and, the retrospective audit found the majority of CCs were delivered within 3 working days, average length was 53 minutes and were attended by at least 3 HCPs. This suggests that CHCPs were engaged and the format of H2H was broadly acceptable to patients, carers and CHCPs. The H2H SS workshop highlighted an increasing role for the H2H telephone CC that should be included in further feasibility work. The retrospective service evaluation audit found overall congruence between PPD and actual PoD to be 73.1%, $k=0.52$ (moderate agreement). This is an encouraging potential beneficial outcome of H2H however, the proportion of patients who achieve their PPD without H2H is not known. No conclusions can be made regarding the benefit H2H on PPD over and above standard CPCT follow up. This should be explored initially with a feasibility comparator study.

This **development phase** provided valuable insight into the demographics and outcomes of patients referred to H2H. These data informed the **feasibility and piloting phase** of evaluating H2H– The H2H feasibility study. The recommendations for the feasibility study were:

- The feasibility study should include both face-to-face and telephone CCs
- The feasibility study should evaluate whether the length of the CC is appropriate for patients and carers, and if the intervention causes distress
- A mixed methods design is most appropriate to enable qualitative and quantitative data to capture all potential outcomes of the intervention, to explore patient, hospital oncologists' and CHCPs' views on the intervention, barriers and facilitators. This will provide vital process evaluation data to understand more fully the feasibility of the intervention.
- A median survival of 31 days suggests a delayed RCT whereby one group receives H2H after a time period would not be ethical. For example, if the 'delay' group were randomised to receive H2H after 4 weeks it is likely that a large proportion of the group would never receive H2H due to death or being too close to death at 4 weeks to participate. This is addressed further in Section 4.4.
- PPD is documented in 88%; therefore, it is feasible outcome measure to consider.
- Survival time (median 31 days) requires the study schedule and analysis to concentrate data collection of patient outcomes to the first 4 weeks after study entry. Analysis that involves comparing baseline outcomes to a change at 4 weeks (28 days) will have considerable missing data due to drop out from death or illness. This requires any symptom control or QoL outcomes to be compared at 1 or 2 weeks from study entry.
- A larger piece of retrospective analysis should be conducted as part of ongoing to process evaluation work to understand the 'reach' of H2H in its current format.

The data presented in this chapter has provided insight into what is being delivered by H2H and how. The **feasibility and piloting phase** (Chapter 4&5) will include mixed methodology to build further on this early process evaluation work exploring the feasibility of H2H including reach, proposed mechanism of impact and the context of H2H in the cancer centre. Chapter 4 describes the methods whilst Chapter 5 details the preliminary results of feasibility and effectiveness. Chapter 6 is the discussion chapter considering the results in relation to developing future larger evaluation studies of H2H in cancer patients.

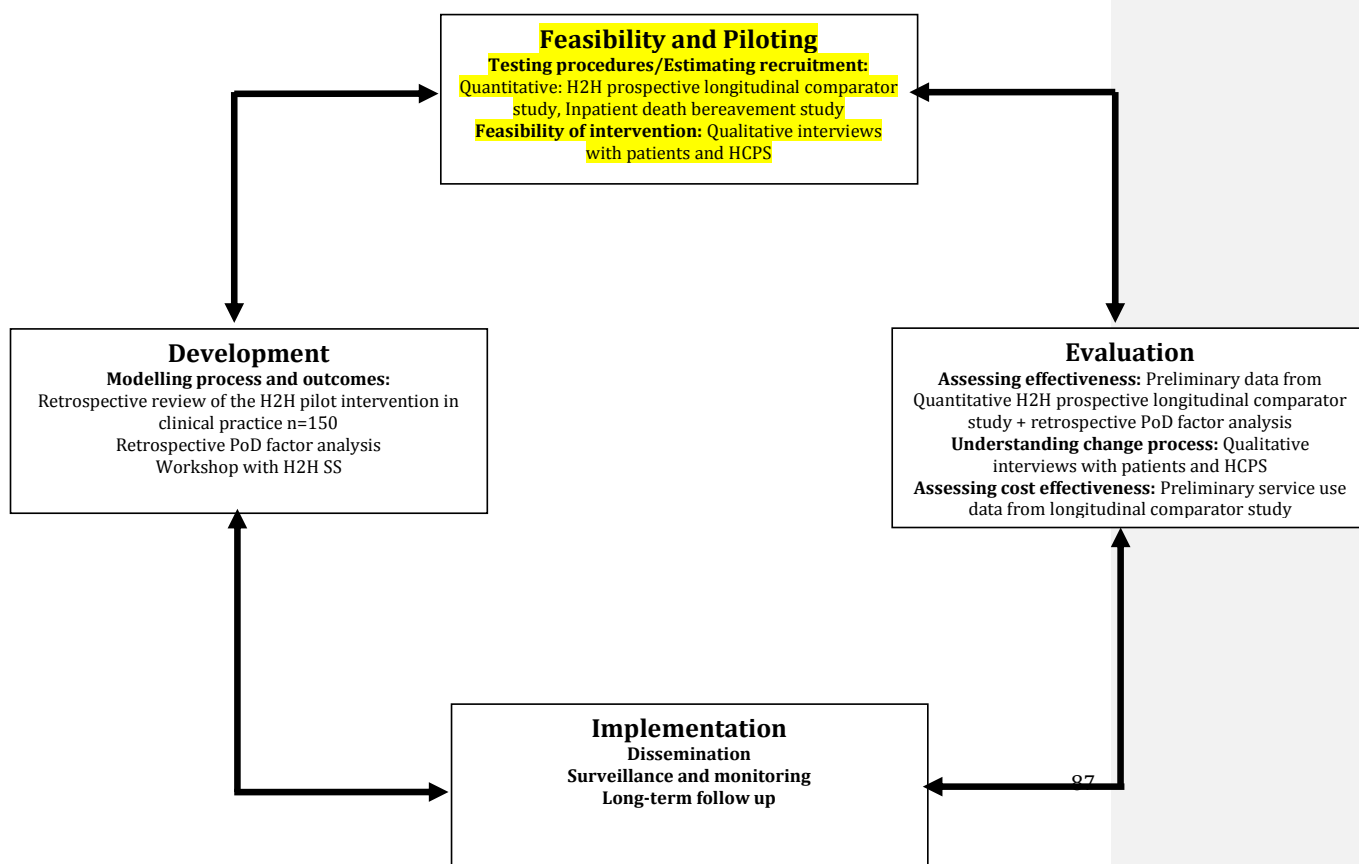
CHAPTER 4: FEASIBILITY AND PILOTING PHASE: METHODS

4.1 Introduction

This chapter describes the methods used in this feasibility study (Short title: The feasibility study). It describes the rationale for each method and how each component seeks to answer the study objectives.

The MRC guidance was used to inform and structure this work. Section 1.7 details the application of the MRC guidance on developing and evaluating CIs with respect to H2H. The work in the remainder of this thesis constitutes part of the *feasibility and piloting stage* of evaluation and contributes to some early *evaluation* data.

Figure 4.1: H2H evaluation adapted from MRC guidance



This chapter comprises the following sections:

- 4.2 Feasibility studies in EoLC research
- 4.3 The Use of mixed methods research
- 4.4 Setting
- 4.5 Overall Study Design
- 4.6 Acceptability and Feasibility
- 4.7 Ethical considerations in the H2H study
- 4.8 Quantitative component
- 4.9 Sample size calculation
- 4.10 Qualitative component
- 4.11 Bereavement component
- 4.12 Retrospective analysis- Factors influencing PoD
- 4.13 Ethics and R&D approvals

4.2 Feasibility studies in EoLC research

Research involving patients at the EoL is abound with potential ethical and logistical pitfalls.

Evaluating a CI at the EoL is particularly challenging.

Methodological challenges in both EoLC research and research evaluating CIs warrant detailed feasibility testing of study design and outcomes prior to a large scale trial of an EoL CI. It is unethical to enrol vulnerable participants in a large trial that has not been adequately designed and as a consequence produces results that are not interpretable or generalizable to the wider population[139, 151]. A full scale large evaluation trial without prior feasibility testing of the acceptability of the intervention and the proposed study procedures is at risk of failure. This makes feasibility testing of both the CI and study methodology essential. The MORE Care statement [139] emphasises the importance of the feasibility and piloting stages of evaluation. Feasibility studies should address the commonly cited challenges of EoL: ethical study design; identifying and gaining access to eligible research participants; estimating participant survival and accounting for unpredictable disease trajectories; the heterogeneity of the study population; minimising the potential burden of data collection alongside attending to issues of

consent and individual perceptions concerning study burden and acceptability. To inform future study design, feasibility studies of CIs are exploratory and descriptive and as such not able to provide a definitive answer/conclusion about the effectiveness of the CI.

The primary outcome of a feasibility study is to determine whether a larger definitive trial is likely to be successful in testing the intervention [152]. Feasibility studies are an opportunity to identify barriers to the research, alongside developing and testing strategies to address these barriers [152]. Wohleber et al [151] and the MORE Care statement [139] have both produced recommendations to address the challenges of conducting EoLC research in order to increase the quality of such research. These challenges are detailed in Table 4.1 considering H2H.

Table 4.1 Challenges for the feasibility study in EoL and CI intervention research [153] [151] [139]

EoL Research	Challenge/recommendation	H2H feasibility study
Acceptable study design	Allow plenty of time for planning and study design	Project advisory group and engagement with clinical staff when designing the study
High attrition	Plan for high attrition rates (attrition rates of 30-50% have been found in longitudinal studies [149])	Primary outcome chosen PPD – low attrition rates
	Seek to increase diversity in samples by using culturally appropriate material	Not possible in this feasibility study
	Consider implementing a 'silent opt out' where patients can decline to participate by inaction	Approach to participation by clinical team
Research information (PIS) may cause distress	Understand the specific target populations perceptions of their life expectancy or terminal status and word recruitment material accordingly to minimise distress/ increase recruitment	Patient representative advised on wording of patient information sheet and CRF
Valid Consent	Use formal competence assessment when possible	Researcher assessed capacity prior to recruitment – no formal tool used
	Use dual consent when proxy consent is required	Dual consent adopted. Carer consent sought separately to patient
	Use process consent in longitudinal studies	Consent reconfirmed at each longitudinal contact
	Deliver informed consent orally, with simple straightforward material for participants to keep as a reference	Informed consent was sought face to face by the researcher with a PIS (given in advance)
	Use oral, versus written, information while providing a concise written summary for future reference	Informed consent was sort face to face by the researcher with a PIS and timeline of future contact dates
Recruiting the correct participants	Include life expectancy as an inclusion/exclusion criteria to ensure participants will be able to complete the study and reduce gatekeeping	Inclusion Criteria: Life expectancy of > 2 weeks
Gate Keeping	Educate other involved professionals on research-related issues to minimise gatekeeping and maximise study recruitment	There were regular update meetings with clinical staff discussing positive verbal feedback from participants
	Understand participant preference to be approached by the medical professional most involved in their care	Approach to participation was by the clinical team first to allow the participant to invite the researcher to contact
Minimising Distress	Train data collectors to be alert to the signs of adverse effects – for example the emotional state of participants	I was the primary researcher – a palliative care doctor and therefore trained in being alert to adverse effects/distress
Data collection is burdensome	Use retrospective/routine data whenever possible to minimise the burden to patients	Clinical notes and contact with community staff used where possible
	Conduct pilot tests if there is a concern about the burden or feasibility of the planned study	This is a feasibility study and the outcomes of this study will address this important area for future studies.
CI Research		
Complexity between CI and context	Complex relationship and interactions between the patient recipient, provider, other services and organisations	Navigation of transition from specialist centre to community care at EoL is complex. H2H is delivered in this gap/at this junction. Qualitative work required into perceptions at this point of care
Complexity of control group	The comparator or control group is often complex and difficult to clearly define.	EoLC and community services in the in the UK are not standardised. The delivery of EoLC is through multiple agencies – NHS, voluntary and the informal carer
Possible multiple outcomes (positive and negative)		As discussed in Chapter 1 EoLC has multiple outcomes. Patient reported outcomes for symptom control/ QOL/ satisfaction requiring in depth assessment and Qualitative work to ensure important outcomes are not missed

The challenges in EoL research combined with the challenges of evaluating a CI meant that it was paramount to conduct a feasibility study in the appraisal of H2H. Specifically, Datta and Pettcrew [153] explain that the literature on CIs is thin on practical advice regarding how the challenges to implementing and evaluating CIs should be dealt with. Their review of the literature [153] reports that the complexity between the intervention and the context in which it is implemented is frequently an under-reported issue. The MRC guidance [1] notes that this

complexity may derive from interactions between patient, recipients and provider. Barriers to both implementation and evaluation should be considered when designing a feasibility study. Relevant data to enable reporting of these barriers should be collected. The recent literature review [153] into CIs found several studies describing a multiplicity of outcomes (both health and non-health) and this itself is a source of complexity. This requires that a range of outcome measures should be tested in the feasibility stage to ensure any larger evaluation trial will capture the relevant outcome measures for the intervention. This approach requires the researcher to consider both possible positive and negative outcomes of the CI.

H2H is a CI as described in Section 1.8.3. The intervention uses detailed discharge planning, including advance care planning, for patients at the end of oncology treatment. The aim is to enable the patient's preferences to be met, patients to remain in their PPC for as long as possible and to die in their PPD. These areas targeted by the intervention are complex in themselves. The navigation through this part of the cancer journey is influenced heavily by behaviours and interactions between patient, informal carer, the oncology team and the community providers. The outcomes related to H2H will be multiple including patient outcomes (QoL, symptom control, satisfaction) and carer outcomes (QoL, burden, satisfaction and health service use). There is also a possibility of negative outcomes. All these outcomes should be considered and tested alongside PPD (Primary outcome) as part of the ***feasibility and piloting*** exploratory phase of evaluating H2H.

The exploratory phase of the MRC guidance describes the use of both feasibility and pilot studies. There is debate in the literature surrounding the definitions of feasibility and pilot studies and differences between them[154]. For this work, I have adopted the NIHR definition of a feasibility study: a piece of research done before a main study in order to answer the question 'Can this study be done?'[155]. A feasibility study is a smaller study to estimate parameters of a potential future larger study[156]. It explores the practicality of the research design as well as testing whether a research question is appropriate for future study[157] [154]. Feasibility studies and pilot studies are different entities. Pilot studies are often described as miniature versions of the full scale study whereas a feasibility study to guide the design of a large RCT does not itself need to be randomised[155]. The MORE care statement [139] emphasises the importance of thorough feasibility testing. Hagen et al [152] highlighted the value of feasibility studies in palliative care and EoL research, where a key issue concerns the

acceptability of the study protocol in terms of burden versus benefit. A feasibility study is an essential step towards the design of a larger trial to evaluate H2H. It will provide insight and recommendations into the challenges of determining appropriate measurable outcomes, recruitment and estimating retention and attrition rates in the context of uncertain prognostic timelines at the EoL. It will also provide recommendations for minimising burden to study participation alongside insight into the complexity of the intervention including barriers to implementation and delivery. This feasibility study of H2H was exploratory and descriptive and as such not designed to provide a definitive conclusion about the effectiveness of H2H.

4.3 The use of Mixed Methods research

To satisfy the research aims and objectives set out in Chapter 2, I used *mixed methods*. Mixed methods research is the class of research where the researcher combines quantitative and qualitative techniques into a single study [158]. This section describes the rationale for the importance of a mixed methods study design to answer the study objective.

4.3.1 Defining mixed methods

In research, there are two main paradigms based on distinct philosophical perspectives. These are Positivism and Interpretivism. These two research paradigms are polar opposites. Positivism is thought of as the 'Quantitative Paradigm', with purists believing that the world and any social observations can and should be studied as entities [159]. The epistemological conviction is that knowledge is objective and is waiting to be studied and discovered. [159, 160]. Interpretivism can be thought of as the 'Qualitative Paradigm'. Purists in this field of inquiry believe that the world and any social observations depend on the individual person perceiving them. The epistemological conviction here is that knowledge is subjective based on interpretation, perception and context.

A comparison of methodologies is given in Table 4.2 below.

Table 4.2 Comparison of Quantitative and Qualitative research methodologies[161]

	QUANTITATIVE	QUALITATIVE
Paradigm	Positivism	Interpretivism
Design of study	Objective	Subjective
Aim of research	Test a set hypothesis and causal relationships	Unpick and understand an area of enquiry or concern
Sample	Probability based sample (sample size calculation)	Non-probability based sample (driven by saturation of experiences)
Data produced	Deductive: hypothesis driven, defined outcomes	Inductive: determines general concepts, relationships and patterns in experience
Type of Data	Surveys, Questionnaires RCTs, systematic reviews and meta-analyses	Interviews, focus groups, participant observations
Knowledge	Generalizable	Context based
Role of researcher	Objective, 'value free'	Subjective 'value-laden'

Many research questions are more fully answered through the amalgamation of these two research methodologies. Mixed methods occupy the 'middle ground' in the research methodology continuum. For the purpose of this study, *mixed methods* research is defined thus:

'The class of research whereby the researcher mixes or combines quantitative and qualitative research techniques, whether it be methods, approaches, concepts or language, into a single study'[159].

The approach of combining research methodologies is controversial: purists believe the two should never be mixed whilst other researchers take a more pragmatic approach recognising, particularly in health care, that one type of methodology may not alone be able to fully answer the research questions[162]. The fundamental principle of mixed methods research is that the researcher should collect multiple data using different strategies[163, 164]. The goal is to draw from the strengths and minimize the weaknesses of each type of research in one single study to provide a more accurate and detailed account of the area of interest.

4.3.2 Use and value of mixed methods in the H2H study- Rationale for study design

Mixed methods study design to evaluate a CI is recommended by the MORE care[139] statement and MRC guidance [1]. 'A mixture of quantitative and qualitative methods is likely to be needed to understand barriers to participation, estimated response rates and assess the feasibility of the intervention' [1]. Qualitative data is increasingly recognised as 'an essential

component of health service research'[165] providing rich insight into the acceptability of interventions and their social consequences which cannot be measured by a quantitative approach. This is particularly relevant to studying H2H. H2H is a CI at the EoL designed to encourage discharge from acute hospital services into community care. This includes advanced care planning. The literature on advanced care planning concludes that the success of advance care planning is multifactorial, relying on a number of interactions and perceptions held by patients and HCPS[166]. Therefore, a mixed methods design was essential to ensure the range of outcomes of H2H was evaluated. Brady et al [167] concluded that neither quantitative nor qualitative approaches would provide an adequate insight into the implementation of the CI from the perspective of all involved and capture the information needed in relation to both effectiveness and feasibility issues. The MRC published guidance[138] on process evaluation of CIs in 2015. This was after this study had completed data collection, however it advocates selecting a combination of methods; quantitative methods to measure key process variables along with effectiveness data, and qualitative methods to capture emerging themes in implementation, experiences of the intervention and unanticipated or complex causal pathways.

In this study, quantitative methods are used to determine the feasibility of the study design, outcomes measures and for preliminary hypothesis testing on the effectiveness of H2H. Qualitative methods are used to explore the acceptability and feasibility of the intervention in practice 'in the real world'.

Mixed methods were applied:

1. The quantitative component
 - a. A comparative longitudinal study of symptoms and QoL of patients (and their carers) who have been discharged from the acute oncology setting at the EoL, either through H2H or through standard care (The feasibility study QUAN)
 - b. Postal questionnaire of bereaved relatives to evaluate satisfaction with in-hospital (inpatient) EoLC (IP study)
 - c. Retrospective analysis of Factors influencing PoD
2. The qualitative component
 - a. In-depth semi-structured interviews to explore the experience surrounding discharging patients from oncology services from the perspective of patients

enrolled in H2H, oncology HCPS and specialist nurses delivering H2H (The feasibility study QUAL)

- b. Qualitative analysis of free text comments volunteered by respondents to the bereaved relatives postal questionnaire evaluating inpatient EoLC (IP study QUAL)

The mixed methods research approach requires careful consideration of a number of factors, both philosophical and practical. It is more time consuming and expensive than using either methods alone; however, when the research objectives warrant such an approach, a number of benefits applicable to this feasibility study have been cited and are summarised in Table 4.3

Table 4.3 Benefits of a mixed methods study design[168-170]

Benefit of a Mixed Methods approach	Description of Benefit	Application in the H2H feasibility study
Offer best opportunity to answer the research objectives	Different objectives may be best answered by different research approaches	Feasibility of data collection/outcomes measures/timelines – requires Quantitative work Feasibility and acceptability of the intervention – requires Qualitative work
Development: Can be used sequentially	Results of one method inform the development of the second method	Start of Qualitative component delayed to enable experience from data collection and interactions with participants in quantitative component to inform the topic guide
Maximise strengths	Reduce limitations of a single method	Data from both methods integrated in the discussion and recommendations for a larger study
Enables Triangulation	Convergence and corroboration of results, increase validity of findings	Qualitative work may corroborate quantitative survey on participants experience of H2H
Complementarity	Results from one method elaborate, enhance and clarify other results	Qualitative interviews may clarify quantitative findings or guide further work
Enhance depth of knowledge around a subject		Mixed methods was required to enable recommendations about remodelling of the intervention to improve acceptability and reach

I believe that EoLC can never truly be ‘value free’. Quantitative assessment alone of a service that aims to improve patient outcomes at the EoL is likely to underestimate outcomes or miss capturing valuable outcomes completely. Secondly, to design a study that relies solely on quantitative methodology would require total confidence that the primary quantitative outcome measure chosen was the main outcome for H2H. This is unlikely: outcomes are multi-factorial. Finally, this was the first study of a CC CI at transition from oncology specialist care to BSC and EoLC in the community. Therefore, it was important to collect rich data on the experiences of the CC from both the patient and HCP perspective to determine whether the CI was feasible in clinical practice. This necessitated a mixed methods approach.

4.4 Overall Study design

The study design for this exploratory feasibility study was a quasi-experimental longitudinal mixed methods comparator study. It comprised of an integrated mixed methods design with a dominant quantitative component and a smaller qualitative component.

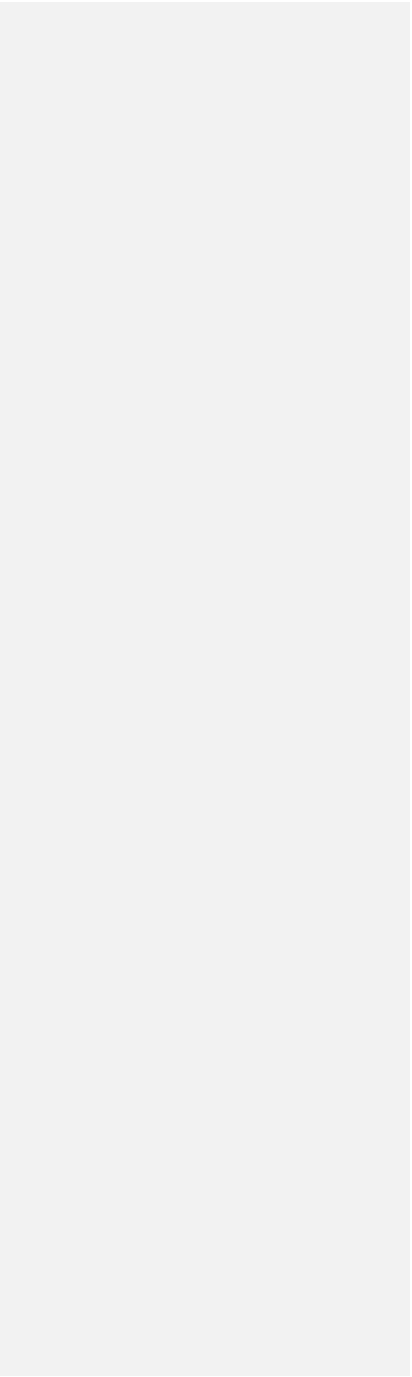
There were 4 components to the study:

- A longitudinal quasi-experimental quantitative comparator study
- Semi-structured face to face qualitative interviews
- A parallel inpatient bereavement satisfaction postal survey
- A parallel retrospective analysis of factors influencing PoD

Longitudinal data collection and qualitative interviews took place in parallel.

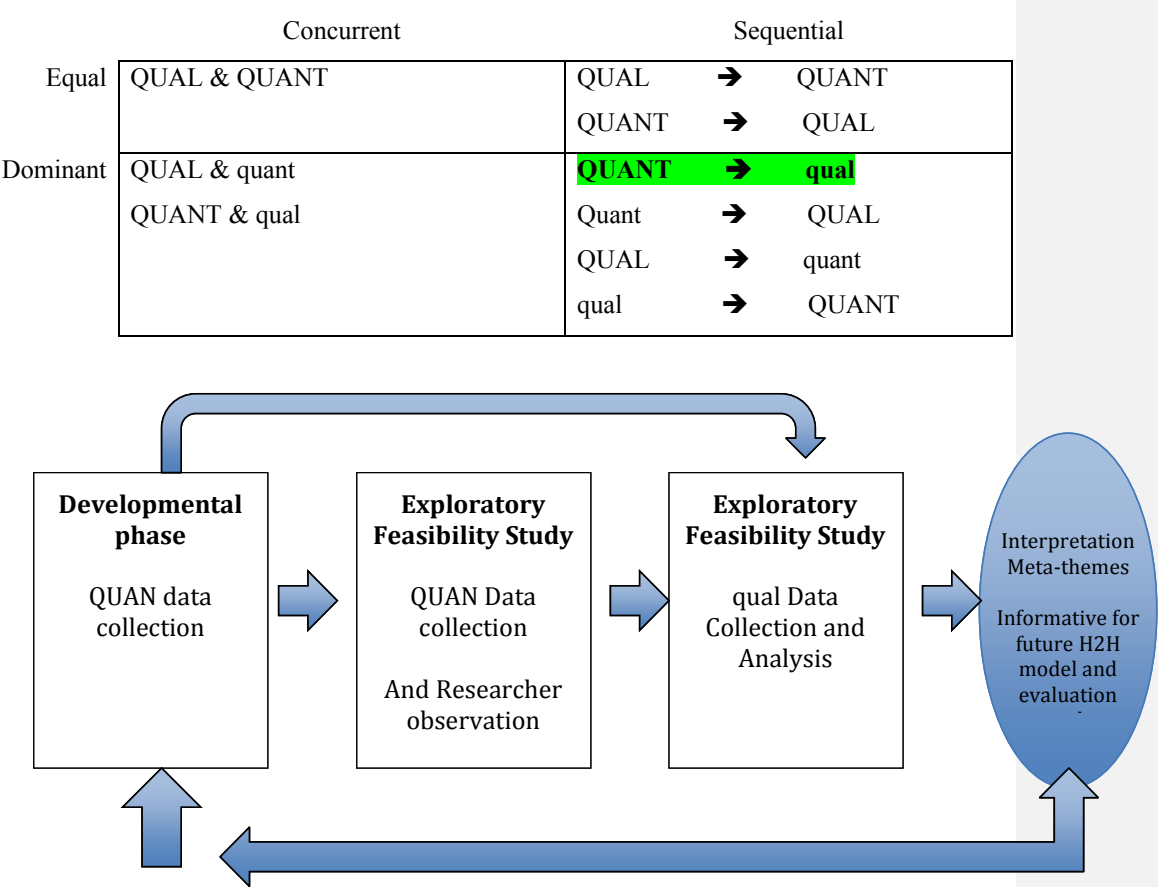
Figure 4.2 Overall Study design

REDRAW THIS FLOW DIAGRAM



The dominance and sequence of any mixed methods study needs to be established at the outset. Morgan[171] proposed his priority sequence model and this has been adapted into a decision matrix by Morse[172]. This offers possible combinations of sequence and dominance in mixed methods study design. The matrix is shown in Figure 4.3 below, with capital letters representing the dominant component of the study. The feasibility study was a **sequential embedded** study design with a **dominant quantitative** component (highlighted in green). This can be seen in Figure 4.2. The study began with the quantitative component. Observations from my interactions with participants and HCPs during recruitment and data collection for the quantitative study informed the design and enquiry of the qualitative component. There was overlap towards the end of the study period whereby both methods were being conducted concurrently.

Figure 4.3 Decision matrix and the feasibility study[172]



4.4.1 Integration of mixed methods

The integration of methods for this study has occurred during the **design** phase and **interpretation** phase of the study.

In the **design** phase, analysis of topics discussed with the researcher during the completion of the free text section of the QoL data collection tool and H2H acceptability questionnaire in the quantitative component of the study guided the lines of enquiry and topic guide for the qualitative component of the study. At the **interpretation** stage, results from the qualitative interviews were used to understand the experience of H2H and explore reasons for the outcomes of the longitudinal study through *triangulation* and *expansion*. The findings from each methodology are compared for look for convergence, divergence and complementarity in the data. Conflicting data from the two methodologies will be highlighted and discussed.

Table 4.4 shows how each research methodology contributes to answering the study objective set out in Chapter 2.

Table 4.4: Study objective and how each of method contributes to fulfilling the objective

Study Objective	Study Component
5) To determine the feasibility of studying H2H in this setting by assessing inclusion and exclusion criteria, recruitment rates, retention and follow up rates and missing data	QUAN
6) To assess potential outcome measures for H2H intervention, and scrutinise the value of these outcome measures in this setting	QUAN
7) To determine if, in this population, the outcome measure of achieving PPD correlates with the patient reported outcome measure of QoL, and is therefore a feasible surrogate primary outcome measure	QUAN
8) To determine if proxy (carer) responses to patient symptoms and QoL tools match patient reports and therefore may be a feasible mechanism of minimising attrition due to illness as EoL approaches	QUAN
9) To describe views and perceptions of patients and professionals regarding transition to community-led care EoLC	QUAL
10) To describe patient and HCPS views and perceptions about H2H	QUAL
11) To describe potential facilitators and barriers to implementation of H2H	QUAL
12) To use the above work to inform further development, modelling and implementation of H2H	QUAL + quan
13) To use all the above work to inform a future pilot study (Part 2 of Phase II) and larger evaluation trial (Phase III) of H2H intervention	QUAN + QUAL
14) To explore preliminary hypothesis testing to provide an estimate of the effectiveness of H2H compared with standard care as measured by the achievement of PPD	QUAN
15) To determine and compare the actual PoD of H2H group with standard care	QUAN
16) To determine and compare patient and carer symptom burden, QoL and satisfaction in H2H group compared to standard care	QUAN
17) To determine and compare service use after discharge from oncology services in H2H group compared to standard care	QUAN
18) To determine and compare the number of patient days spent in their PPC in H2H group compared to standard care	QUAN
19) To determine and compare the number of admissions and days spent in hospital/hospice in H2H group compared to standard care	QUAN
20) To determine and compare the bereaved family members' satisfaction with care in the H2H study with those family members of patients who died in the hospital	QUAN – IP Study
21) To determine if the degree of satisfaction with care is related to any patient clinical, demographic, or preferences factors	QUAN –IP Study
22) To determine other factors influencing PoD in the wider cancer population treated at the RMFT	QUAN-FIPD

4.4.2 Setting

The study was conducted at the Royal Marsden Hospital NHS Foundation Trust (RMFT). The RMFT is a specialist tertiary referral cancer centre based in London, England. Every year, approximately 2000 patients known to the RMFT die, nearly 350 of which die in the hospital itself. The RMFT operates from three sites: Chelsea, Sutton and within Kingston hospital, Kingston. Each site has a local catchment area, as well as receiving referrals from outside the local area. The RMFT has a H2H. The Kingston hospital team delivers the RMFT Kingston site palliative care service. There is no H2H for this site. Standard care discharge to community

services at the end of treatment is through a written letter to the GP and referral to the local SPCT.

4.4.3 Overview of Quantitative component- Rationale for a quasi-experimental study design

The MRC guidance [1, 173] asserts that randomised study designs (RCTs) are the most robust method to reduce bias when evaluating CIs. Randomization is beneficial because, on average, it tends to evenly distribute both known and unknown confounding variables between the intervention and control group. The MRC rationale for always considering randomisation in the study of CIs is summarised in Table 4.5 with specific reference to this H2H feasibility study. However, the guidance does acknowledge the need to use the 'best available method' to fit according to the limitations of the study context and ethical considerations. Non-RCT designs are important when randomisation is impractical or undesirable [174] and these are being increasingly used in EoLC research [175]. Quasi-experimental studies encompass a broad range of non-randomized intervention studies. These designs are frequently used when it is not logistically feasible or ethical to conduct a randomized controlled trial.

Table 4.5 Considerations in study design to evaluate the H2H

Problem/Consideration	Detail	Relevance to the H2H study
Timing and size of effect		
Likelihood of Selection Bias	Randomisation is a robust method of preventing selection bias	This is relevant. A Post-hoc adjusted analysis for the primary outcome to account for case mix is included. However this will only account for measured confounders
Feasibility and Acceptability of experimentation	Randomisation may be impractical if the intervention is already in widespread use	H2H had been in widespread use at the RMFT main site and therefore for this feasibility study randomisation was not possible and a comparator group was chosen
Cost	If an experimental study is feasible it needs to be decided whether the outcomes are worth the likely increased costs	Not relevant to this feasibility study

The choice not to randomize an intervention is based on one or more reasons: (1) ethical considerations, (2) difficulty of randomizing subjects or locations and (3) small available sample size[176]. After careful consideration of the MRC guidance and consultation with stakeholders [1], a conventional simple RCT randomising individual participants to H2H or standard care alone was considered impractical and undesirable for reasons outlined below.

1. Ethical considerations: A conventional randomised trial was not appropriate because H2H was fully integrated into the care of patients at the RMFT London sites and had become widely accepted in oncology and palliative care practice. Oncologists perceived benefit from the intervention and therefore it was unethical to deny patients at the main sites access to the service through introducing randomization.
2. Difficulty of randomisation and small sample size: Firstly, oncologists had developed views about the advantages of H2H and were reluctant to enrol patients through randomisation that may prevent them from receiving H2H[177]. Secondly, the study was focussing on cancer patients in BSC. The service evaluation (Section 1.8) showed the short survival of these patients, and there were concerns randomisation may have discouraged patients from participating. Thirdly, the sample size was predicted to be relatively small and thus the merits of randomisation preventing confounding factors influencing the outcome may have been minimal.

In some instances where conventional randomization of individual participants is deemed unethical, an alternative to a quasi-experimental study design is either the delayed randomization [18] or a cluster randomization approach. These two alternative approaches were also considered and discussed with stakeholders and the trial management team before deciding on the quasi-experimental study design. A summary of each approach in relation to this feasibility study are given below:

Delayed randomisation: In delayed randomisation all participants receive the intervention at some point in the study; however, individuals are randomised to receive the intervention at study entry or after a set time period from study entry (the delayed group). Delayed randomisation was not possible in this feasibility study for two reasons;

- The primary outcome is measured in both groups at a time point before the delivery of the intervention to the delayed group. This option was not feasible in this feasibility study because the primary outcome measure chosen to scrutinise was achievement of PPD. This can only be measured at one time point. Other secondary outcomes measures, which are amenable to delayed randomisation, were also tested in this feasibility study to determine the most appropriate outcome measure for a larger definitive trial.
- The retrospective process evaluation detailed in Chapter 3 found the median survival of patients receiving H2H was 31 days. It can be extrapolated from this that the survival of potential participants in this feasibility study would be similar, and therefore a large

majority of participants would have died by 1 month. Therefore even if a different outcome measure from PPD delayed randomisation is arguably still not possible and unethical in this population. For example if the intervention was offered at one month in the delay arm, the median survival informs us that a high number of participants in the delay arm would never receive the intervention due to ADI and ADD.

Cluster randomisation: In cluster randomisation, intact groups or clusters of individuals, rather than the individuals themselves, are randomised to receive the intervention or standard care[178]. All participants consenting to the study in the cluster randomised to the intervention receive the intervention and outcomes are measured on individuals within those clusters. The main advantage of this approach to randomisation is that it overcomes the difficulties of contamination between the intervention and standard care when both are delivered by the same group of professionals. Contamination is where processes and learning from the intervention are then knowingly or unknowingly delivered to the control/standard care group by HCPs. It is reasonable to suggest that most HCPs would find it difficult to provide two differing types of care, independently allocated, to patients in their care[178]. Although cluster randomisation addresses contamination concerns the main criticism of cluster randomisation is the possibility of selection bias. Puffer[179] described this occurring at the randomisation of the cluster whereby there is interference to ensure a particular cluster is allocated to the intervention and secondly, within clusters, individuals are more likely to refuse consent for the intervention than consent for data collection only which occurs in the standard care group. Cluster randomisation was considered for this feasibility study and discounted for the following pragmatic reasons

- Unable to randomly allocate clinic clusters – clustered by location (Chelsea, Sutton and Kingston) – without considerable cost and blocking from HCPs
- Contamination was likely to continue, despite cluster randomisation, due to the same oncology team reviewing patients at all sites.

A **pragmatic quasi-experimental mixed methods study** design was chosen for this feasibility study. The quantitative component of this mixed methods study was a quasi-experimental comparative longitudinal study of patients (and their carers) who had been discharged from oncology follow-up at the RMFT.

Quasi-experimental study designs can still aim to demonstrate causality between an intervention and an outcome[176]. A hierarchy of quasi-experimental study designs, shown in Table 4.6, has been proposed whereby, in general, the quality of the study design increases from A through to D. This feasibility study is category C1. The primary outcome of PPD precluded using category D (interrupted time-series design).

Table 4.6 Hierarchy of Quasi-experimental study design and the feasibility study adapted from Harris et al[176]

Category	Study design	Lowest quality
A	Quasi-experimental design without control groups	
B	Quasi-experimental design with use of control group but no pre-test	
C	Quasi-experimental design with use of control group but and pre-tests	
	1. Untreated control with dependent pre-test and post-test samples	THE H2H FEASIBILITY STUDY
	2. Untreated control with dependent pre-test and post-test samples using double pre-test	
	3. Untreated control with dependent pre-test and post-test samples using switching replications	
D	Interrupted time-series design	Highest quality

In a quasi-experimental study, participants are selected to the study group based on clinical setting, need or patient choice to receive the intervention [1, 173]. In this study, the selection to study group occurred in the following way:

- The H2H participants were referred to the service by their oncology team and then, after an initial consultation with the H2H SS, the patient participant chose whether or not to receive the intervention. This is an example of HCPS selection followed by self-selection.
- The comparator group consisted of patient participants from two sources:
 - a) Patients whose oncology care had primarily been from the RMFT main sites (Chelsea and Sutton) where the use of H2H had become standard practice but either the oncologist chose not to refer to the service or the patient declined the service. These patients received standard communication to community services at discharge. This is an example of either HCPS selection or self-selection.

- b) Patients whose oncology care had primarily been from the RMFT satellite site at Kingston Hospital, where H2H is not available, and discharge from oncology follow-up is via standard communication to community services. This is an example of site-selection.

Participants in the quantitative arm could also be participants in the qualitative arm. The quasi-experimental study design was prone to selection bias as individuals are more likely to refuse consent for the intervention than consent for data collection only (standard care group). Therefore we would expect the recruitment rate to be higher in the standard care arm. Selection bias may also occur when individuals approached to participate in the study are different from those not approached to participate. This may be deliberate and purposeful or due to gatekeeping of the patient deemed vulnerable. The purpose of this feasibility study is explore these concerns and their impact on study recruitment prior to a larger definitive trial.

4.4.4 Overview of Qualitative component

The qualitative component of the study was semi-structured face-to-face interviews with patient participants who had received H2H, consultant oncologists and the H2H SSs. This element of the mixed methods design was essential in understanding the context of the intervention and barriers to implementation. It also enabled a detailed evaluation of the fidelity and acceptability of the intervention building on results from the process evaluation and developmental phase (Chapter 3).

The start of the qualitative component was delayed until a year into the recruitment of the quantitative component. The rationale for delaying the qualitative component was to enable me to develop the topic guide for the qualitative interviews based on my field notes and observations whilst interacting with the H2H SS and oncologists in clinics and visiting patients in their own homes during recruitment to the quantitative study. Participants in the qualitative arm may also have participated in the quantitative study.

4.4.5 Overview of Parallel Inpatient Death Bereavement Study (IP study)

In parallel, over the same eighteen-month time period, bereaved relatives of patients who had died as inpatients at the RMFT were contacted to participate in a postal survey on EoL preferences, PPD and satisfaction with care.

Results from the Inpatient Study (Section 5.8) provide a parallel comparison of satisfaction with EoLC for those who died as an inpatient.

4.4.6 Overview of Retrospective Analysis of Factors influencing PoD

In a related analysis, I conducted a retrospective analysis of factors influencing PoD in patients known to the RMFT. This used binary logistic regression to assess factors from the literature[42, 47] alongside other illness and environmental factors, including the use of a H2H, to determine factors influencing PoD for patients treated at the RMFT. This section provides additional data on the significance of H2H in determining PoD in a larger population (n=1467).

4.5 Acceptability, Feasibility, Fidelity and Process Evaluation

There is lack of consensus and on-going debate about the use of the words ‘pilot’ and ‘feasibility’[154]. Some researchers use these words interchangeably; however, in this work I will draw on the NIHR definitions whereby feasibility work predates and informs pilot and larger evaluation studies. Feasibility studies ask whether the study can be done and address issues of uncertainty in preparation for a larger scale study. Hence, the output and results of feasibility studies focus on methodological issues.

Feasibility studies are pieces of research aimed at asking ‘can this study be done?’

The MRC guidance [1] highlights the importance of assessing the feasibility of the chosen evaluation methods. MORE Care endorses the significance of the feasibility and piloting stages in terms of testing the chosen evaluation methods and study design. It also emphasises the importance of developing both the feasibility of the evaluation methods and the feasibility of the intervention. ‘A detailed preparatory stage aims to maximise the likelihood of delivery of a definitive trial that is high in terms of both internal and external validity’ [180].

'Methodological research suggests that this vital preparatory work is often skimmed, leading to evaluations being undermined by problems of acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller-than-expected effect sizes' [1]. Although there is agreement in the research literature that feasibility testing is a crucial step in the development of a CI, there is no clear guidance on how feasibility should be tested and reported.

For the purpose of this study, feasibility will be judged using the 14 points detailed by Shanyide et al[181]. Table 4.7 lists these in relation to the H2H study and its components.

Table 4.7 Shanyide et al (22) Feasibility outcomes and the H2H study

Criteria	Addressed by the H2H study	Quantitative	Qualitative
Sample size	Yes	+	
Eligibility	Yes	+	
Recruitment	Yes	+	
Consent	Yes	+	
Randomisation procedures	No		
Blinding procedures	No		
Compliance/adherence to intervention	Yes	+	+
Acceptability of intervention	Yes	+	+++
Cost and duration of intervention	Yes	+	
Outcomes	Yes	+	
Selection of most appropriate outcomes	Yes	+	+
Retention	Yes	+	
Logistics of a multicentre trial	No		
How all components work together	Yes	+	+

Feasibility outcomes lend themselves to detailed descriptive analysis and scrutiny of the study process. In an attempt to define feasibility in this study, the success criteria in Table 4.8 will be reported in addition to a detailed descriptive analysis.

Table 4.8 Feasibility and acceptability success criteria – adapted from Stow et al [182]

Feasibility Objectives	Success Criteria
Recruitment	• > 20% of recruited pool • Each study site recruits >20% of eligible patients/carers • The target of 180 patient participants met in time available • >60-70% of eligible informal carers recruited
Eligibility criteria	• To study EoL, >60% die during the 3 month assessment period
Study design- choice of control group	• <10% of demographic variables are statistically significant across study groups
Retention of participants	• <10 % withdrawal from the study by choice
Intervention acceptability	• Positive response from patients and HCPs in qualitative interview • Delivery: >80% of CC last 30-60 minutes • > 70/80% of CC delivered within 3 working days of discharge if inpatient, 5 working days if outpatient • 100% of GPs and > 80/90% of other invited HCPs attend the CC
Feasibility and acceptability of the primary outcome piloted	• > 70% of PPD documented (rather than substituted in analysis)
Feasibility of assuming/using PPD as a proxy for QOL at the EoL	• Statistically significant difference in QOL score between participants who achieve their PPD and those who do not.
Feasibility and acceptability of the secondary outcomes piloted	• > 80% of data complete at each time point. Unknown values (blank or participant refusal) are considered missing.
Feasibility and acceptability of collecting longitudinal data in this study setting	• > 50% of participants complete 2 or more assessments
Feasibility of using the informal carer as a proxy response for patient data	• Agreement of patient and carer MSAS and MQOL scores on Bland=Altman plots

Process evaluation is a vital component of evaluating a CI. A CI that is highly effective in the context of a clinical trial but not possible to implement into clinical practice is of little use. Process evaluation has key functions including describing the intervention and its causal assumptions, describing the implementation process, determining what is delivered, the mechanism of any impact and contextual factors that may affect implementation and outcomes[138]. Chapter 3 began to provide data on what is delivered with H2H and how the oncologists perceive H2H. This was a platform from which it was decided what areas of process evaluation required further investigation in the feasibility study. **What is delivered** by H2H includes Fidelity, Dose, Adaptations and Reach. ‘Fidelity’ refers to whether the intervention was delivered as intended[138]. Data on the timing of the intervention, length of CC and whether the intervention was delivered as intended will be collected in the quantitative component of the study and judged based on the criteria in Table 4.9 below. The proportion of face-to-face H2H and telephone H2H will be reported to determine the ‘dose’ or quantity of H2H delivered. This will be interpreted with reference to the results of the service evaluation audit in Chapter 3 to gain additional insight into the sustainability of the intervention. The retrospective analysis of FIPD (Section 4.11 & 5.9) will provide insight into the ‘reach’ of H2H in the cancer centre. The acceptability of H2H to stakeholders (patients, carers, HCPs) will be investigated in this feasibility study through a combination of a short questionnaire at Week 1 in quantitative study and qualitative interviews with patients and oncologists. The findings of

acceptability and fidelity work will be used to describe the intervention to enable it to be reproduced in a larger trial, consider the context of the intervention suggesting any adaptations that may be required, and also to determine if the intervention is acceptable to stakeholders (patients, carers and HCPs) in real life.

Table 4.9 Fidelity measures for H2H

Fidelity measure	Criteria
Proportion delivered as face-to-face CC	> 75%
Time from discharge to CC	80% in < 3 working days
Length of CC	80% are between 30-60 minutes
Attendance at CC (%)	
Patient	90%
GP	100%
District nurses	75%
CPCIT*	75%
If in agreement, patient received copy of care plan	100%

4.6 Ethical considerations in the H2H study

Ethical concerns regarding both participants and the research team are of particular importance in palliative care research. Participants approaching the EoL are vulnerable; therefore, appropriate thoughtful study design is essential to balance the need for acquisition of knowledge in this under-researched area with the necessary care and precautions warranted by this vulnerable population[151]. The MORE Care statement [139] highlights this and recommends that studies are designed with this in mind.

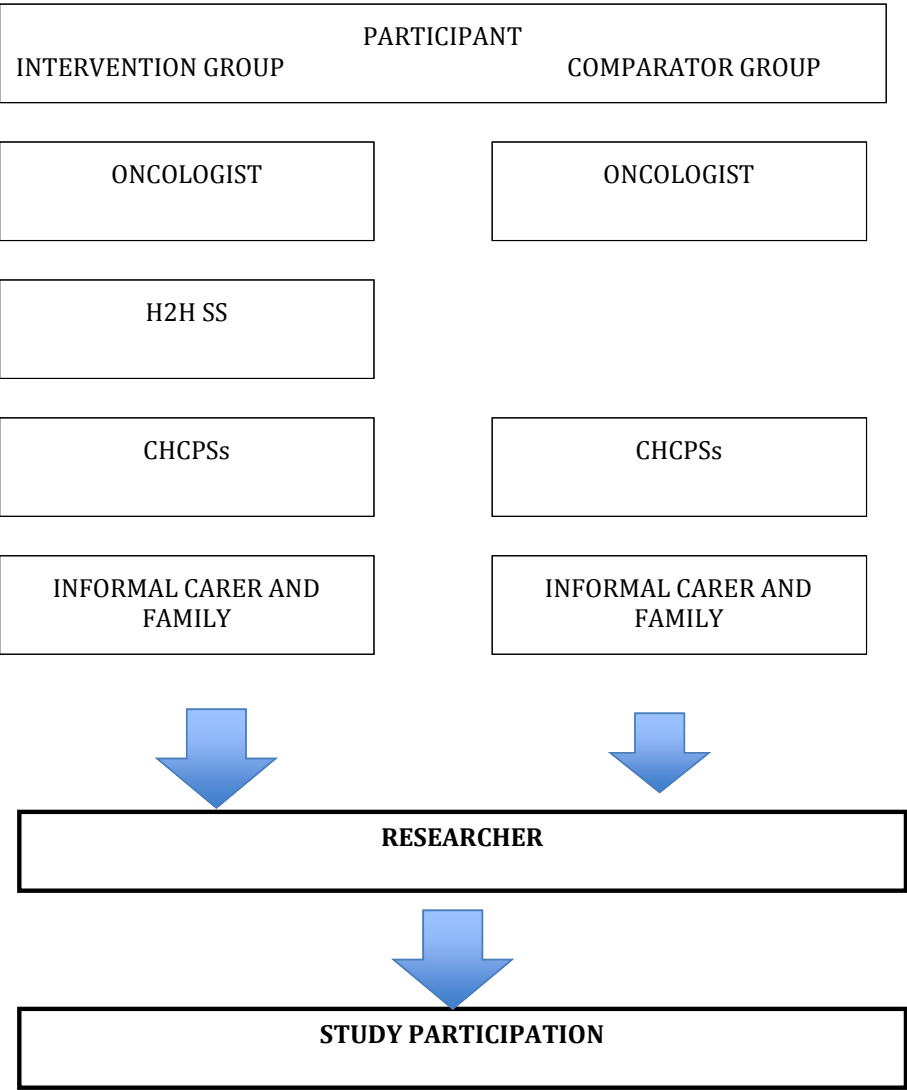
There are five main ethical issues to consider in this work:

- 4.6.1 Accessing and identifying eligible participants
- 4.6.2 Informed Consent
- 4.6.3 Burden, risk and adverse outcomes
- 4.6.4 Benefits of research
- 4.6.5 Risks to the researcher

4.6.1. Accessing and identifying eligible participants

In EoLC, gaining access to potential research participants can be a challenge[183]. This is because both clinicians and family members can be protective of eligible research participants and make decisions on their behalf[183, 184]. 'Family members may resent patients participating in research if it takes time away from them' [183] and they may also be protective of patient participants and not want them to be approached. This concept is known in the literature as gate-keeping. It was acknowledged that the H2H study might be prone to this problem. The potential layers of gate-keeping in each study group are shown in Figure 4.4. This highlights that eligible participants referred to H2H were exposed to an additional layer of possible gate-keeping from H2H SS team themselves.

Figure 4.4 Gate-keeping in the H2H study



In the attempt to minimise gate-keeping, the following strategies recognised in the literature [183] were utilised in the screening process for the feasibility study.

- Relationships with clinical staff were critical and important for on-going collaboration and communication
- Visible presence of the research team amongst clinical staff:
 - I attended weekly lung and GI outpatient clinics at both the RMFT main site and the Kingston satellite site. I also attended the weekly H2H team meetings. I found

that, on the occasions when I could not attend clinic, referral to the study did not occur.

- Principle investigator (PI) has a prominent role in interacting with clinical staff:
 - My primary supervisor, JR, was the PI for this study. JR was also part of the clinical service delivering palliative care in the hospital and the chair of the H2H clinical meeting.
- Take time to introduce the study to all clinicians who may be in contact with eligible participants:
 - At the beginning of the study and also at certain points throughout recruitment (such as doctor change over dates), I met with the oncology consultants, registrars and the H2H team to explain the study.
- Clinicians who have a relationship with the eligible study participant may be partners in the recruitment and enrolment:
 - Oncology consultants and registrars agreed to be partners and all participants were initially approached by them and given a PIS for the study.
 - H2H SS assisted with identifying eligible participants from their caseload and introduced the study to the patient and family member.
- Establishing a relationship with the family members of eligible participants:
 - At the initial telephone contact for the study I asked the patient participant to identify their closest informal carer and then asked to discuss the study with them to ensure they were fully informed.
 - The patient was encouraged to discuss the study with their family members before I visited them at home.
- Invitation to family members to be included in the research study:
 - The study design included the informal carer if they agreed to participate.

4.6.2 Informed Consent

Prospective Longitudinal mixed methods study (The feasibility study)

The initial approach to potential participants was by the clinical teams.

The study enrolled both patient and informal carer participants in parallel.

The clinical team and research teams were entirely separate to minimise any undue pressure on potential participants to agree to enter the study.

Participants were given sufficient time to consider entering the study (at least 24 hours) and also encouraged to discuss the study with their family.

If they agreed to enter, I had an informal discussion with the potential participant. This involved outlining the study again, and checking that both the patient and informal carers understood the information sheet. Specific attention was placed on explaining the purpose and nature of the research; what the research involved; its benefits, risks and burdens and also ensuring an understanding of the alternatives to taking part.

At the recruitment visit, I checked the patient's and informal carer's understanding of the information sheet. This included a verbal explanation of the study, answering any questions either participant had about the study. As part of this process, the following 4 points were highlighted.

1. *The longitudinal nature of the study.* This was to ensure the patient and carer were aware of their commitment to the study over the 3 month period and of the regular telephone contact involved.
2. *The voluntary nature of the study.* Participants were informed, both through the information sheet and verbally, that they could withdraw from the study without giving a reason. It was particularly important to convey that either patient participant or carer participant could withdraw with or without the other participant.
3. *The questionnaire.* It was highlighted to participants that the majority of questions asked by the researcher were from validated tools and that, given the nature of the study, some questions may make participants think about issues in their life outside of their health and could be difficult to answer.
4. *The illness trajectory.* The participants were advised that, due to the nature of their illness, circumstances may change and the patient participant may not be well enough to complete questionnaires. The informal carer consent also ensured, through verbal discussion and in the information sheet, that they were fully informed that the patient may or may not die during the study period and that study contact would end at this time until the 3 month bereavement questionnaire.

I answered any questions and a personalised flow chart of contacts was offered to the participants to keep along with the information sheet (Appendix 7.3.1, 7.3.2 & 7.3.6). It was impressed upon the informal carer that, if the patient agreed to enter the study, the informal carer was under no obligation to also participate. A decision not to participate would not affect the patient's current or future care in any way. The patient or informal carer participant could withdraw, with or without the other, at any time and did not need to give a reason.

This was a longitudinal study; therefore, at each contact the validity of the initial consent from participants was reconfirmed.

Inpatient Study: Bereaved relatives

The consent to participate in this arm of the study was through written consent by post. Bereaved relatives were identified from hospital records and an invitation letter, information sheet and reply slip were sent to these relatives at least 3 months after the patient's death (Appendix 7.3.18). An 'opt-in' model of consent was adopted for this study. Potential participants were given the option of returning the reply slip or making telephone contact. This gave consent for the study pack to be sent to them by post. If consent was obtained, the questionnaire was sent out by post, accompanied by a written consent form to return with the questionnaire.

4.6.3 Benefits of Research

The study was an observational study, with no change to standard care as a result of the participation. However, previous studies have shown that cancer patients approaching the EoL can feel positive towards participating in observational studies[185]. Perceived benefits include increased monitoring and attention for the participants themselves, and altruistic motives of improving care for others [186, 187]. With reference to the longitudinal nature of the study and serial contacts, Shipman et al [188] found that contact over time through serial interviews appeared to be a positive experience rather than a burden for those whose active treatment and follow up has ceased.

4.6.4 Burden, Risk and Adverse Outcomes to participants

Research interviews can be tiring and burdensome for patients if they are medically unwell. Shipman et al [188] sought to determine the views of advanced cancer patients on this issue using a 'mock' interview. The majority (13/15) of participants gave a time length of 30 or 45 minutes. All agreed to further follow up interviews. All research assessments and interviews in this study were organised at a time and location convenient to the patient and could be stopped at any time if the participant requested. Any assessment or interview could also be split into two parts over two consecutive days if the participant preferred. No participants chose to limit the interviews or assessments or split them over 2 days. I stopped one quantitative initial assessment early because it was clear the participant was too tired to continue. The participant survived for 3 days after the assessment.

EoL is a sensitive issue and I recognised that, for some participants or carers, the completion of questionnaire tools may have caused distress. For this reason, all the questionnaires being used were validated tools, and had previously been tested on populations similar to the study population.

Prospective Longitudinal mixed methods study: The feasibility study

It was routine practice that, after all quantitative and qualitative contacts, adequate time was taken to check the impact and effect of the assessment on the interviewee. If necessary, I directed participants to the appropriate source of health or social care professional. When I had a high level of concern about any participant, this was urgently discussed with the PI to decide the most appropriate course of action. All concerns of this nature were documented in the clinical record file for the patient or carer, and the frequency of these concerns audited. There was one occasion when answers to the MSAS-SF prompted me to refer the participant to their GP and palliative care team for assessment of suspected spinal cord compression.

Inpatient Study: Bereaved relatives

The postal questionnaire to bereaved relatives encouraged the participant to leave their contact details if they needed to discuss any issues raised by the research or if they felt they needed more support. Participants were then contacted by telephone and were either signposted to other services or a meeting was arranged with the PI to discuss the issues. The PI met with relatives on 3 occasions (3/88). In all cases, the bereaved relatives were seeking

more information around the circumstances of the death and there was not an issue with the research itself.

The project management group agreed a protocol for managing bereaved relative support in both the feasibility study and the IP Study. This is detailed in Appendix 7.3.23.

4.6.5 Risk to the Researcher

In EoL research it is recognised that research staff can experience similar 'burn out' to clinical staff, and the stress of interviewing terminally ill patients, observing their decline and eventual death builds up over time [189]. Therefore, monthly team meetings were scheduled so I could reflect and share concerns with the PI. Throughout the study, I had access to additional professional support if needed. The palliative care secretary who transcribed the qualitative interviews had access to the same support.

4.7 Quantitative Component

4.7.1 Design

The quantitative component of this mixed methods study was a quasi-experimental comparator longitudinal study of patients (and their carers) who had been discharged from oncology follow-up at the RMFT. These patients were from two groups:

- Patients who received H2H
- Patients whose primary oncology care was from the RMFT satellite site at Kingston Hospital where H2H was not available, and patients from the main site RMFT who did not receive H2H (due to clinician or patient choice) (AC (AC) group).

4.7.2 Participants

Participants in the study were patients (and their carers) with lung or gastrointestinal cancer known to the RMFT who were not eligible for active oncological treatments. For the purpose of the study, a patient with 'no further active oncology treatment' was defined as 'patients previously treated or assessed at the RMFT who have either progressive or stable advanced disease and in whom further chemotherapy or radiotherapy is not appropriate'. This specifically relates to chemotherapy or radiotherapy at doses aimed at slowing disease progression or improving survival. This definition includes patients who had never received any form of active anti-cancer treatment and also those who had chosen to stop treatment. Active anti-cancer treatment does not include palliative radiotherapy for symptom control (for example, a single fraction of radiotherapy for bone pain).

These participants were recruited from the RMFT main sites (Chelsea and Sutton) and from the RMFT satellite site at Kingston Hospital. All participants received standard discharge care (as detailed in Chapter 1) and participants from the main site may also have received H2H. Patient participants were therefore recruited from three groups (one intervention group and two comparator groups):

1. The intervention group: participants who have received either a face-to-face or telephone H2H.
2. Comparator group A (MSC): participants recruited at the RMFT main sites that did not receive the CC intervention.

3. Comparator group B (SSC): participants recruited from the RMFT satellite treatment unit at Kingston hospital where H2H was not available.

Two comparator groups were included to ensure any confounding factors could be accounted for. The Kingston group were chosen as a comparator due to similarities between the patient populations and treating oncologists.

Gastrointestinal (GI) and Lung tumours were chosen for pragmatic reasons:

- In the retrospective service evaluation of H2H (Chapter 3), GI cancer patients were the highest user group of H2H (34%) and Lung cancer patients the fourth highest user group (11%). It was not possible to enrol the second and third highest user groups of H2H (Gynaecological cancers 16%; Sarcoma 12%), as the RMFT does not treat Sarcoma or Gynaecological cancer patients at the Kingston site.
- The service evaluation showed the median survival of advanced GI and Lung cancer patients enrolled into H2H was 31 days (IR 12-78days) and 28 days (IR 13-50days) respectively. These data informed the longitudinal data collection points for the feasibility study.
- GI and Lung cancers are 2 of the 3 tumour groups treated exclusively across all three RMFT sites allowing for comparisons to be made. The third tumour group treated across all sites is prostate cancer. This cancer group was excluded from the study because possible treatments are varied including hormone therapy. Therefore, the end of oncological follow up is less clear in this population and their prognosis can be in the order of years, making EoL more difficult to define.

The patient participant's informal carer was also invited to enrol in the study.

It was decided to recruit caregivers alongside patients for the following reasons.

- Palliative care incorporates EoLC. It is a holistic discipline including the psychosocial support for the family and significant others. Therefore, any research into an EoLC CI needs to assess both patient and carer outcomes.
- Caregivers increasingly take the place of skilled staff in the delivery of often complex care at home [190, 191]

4.7.2.1 Inclusion and exclusion criteria

Patient participants:

Inclusion criteria

- Adult age 18 years or over
- Competent and able to give written consent
- Diagnosis of advanced (incurable) Gastrointestinal or Lung Cancer
- No active oncological management available

Exclusion criteria

- Too unwell to take part in serial interviews
- Lack capacity to consent
- Unable to understand and speak English
- Remaining as an inpatient in the hospital or being transferred to another inpatient facility (eg hospice unit) for terminal care
- Prognosis is less than 2 weeks

Informal carer participants:

Inclusion criteria

- Adult age 18 or over
- Able to understand and speak English
- Competent

Exclusion criteria

- Unable to understand and speak English
- Health problems limit the carer, making them too unwell to participate in serial assessments

4.7.2.2 Identification and recruitment of potential participants

Patient: Potential consecutive patient participants fulfilling the entry criteria were identified and assessed by the hospital oncology team, palliative care team and H2H team. The potential participants were approached about the study by the clinical teams and given a patient information sheet¹. This method of participant identification was chosen to maintain a clear boundary for the patient between the clinical team and the research team.

Informal Carer: The patient participant identified their primary informal carer. I asked the patient participant to name the person who spends the most time with them and provides

¹ The patient information sheet is available in Appendix 7.3.1

most of their daily care and support. It was the patient's decision whether to involve their informal carer in the study; in cases where no informal carer was identified, eligible patients were enrolled alone. Once the primary informal carer was identified, I discussed the study with them directly and then posted their information sheet to them to enable them to read it prior to the first assessment visit².

4.7.2.3 Recruitment and consent

I visited potential participants at their home to complete consent to the study and the first assessment. The participants completed written consent³ and were given a personalised flow diagram illustrating their scheduled contact dates for the duration of the study⁴. The informal carer could only participate if the patient had agreed to enter the study. The first time point questionnaire was then completed at this initial visit. After questionnaire completion, I checked the participants' feelings and views about the questions to ensure they would be willing to complete the questionnaire again at subsequent contacts. At each telephone contact I reconfirmed consent verbally prior to data collection. Although the validated tools used in the patient and carer questionnaire were designed to be completed independently, I chose to complete the questionnaires on behalf of participants face to face and over the telephone. The Abernethy study of case conferencing[145] adopted this approach after a pilot demonstrated the dying population found answering questions burdensome and this burden could be reduced by HCPS data collection.

4.7.3 The Longitudinal quantitative survey

4.7.3.1 Demographic and clinical data

Demographics data for both the patient and the informal carer were collected from the medical notes and as part of the initial assessment. Demographic information included age, gender, ethnicity, diagnosis, co-morbidities, carer co-morbidities, treatments, medications, social

² The informal carer information sheet is available in Appendix 7.3.2

³ The patient and informal carer consent forms are available in Appendix 7.3.4 & 7.3.5

⁴ The personalized flow diagram is available in Appendix 7.3.6

factors, and factors from the literature known to influence PoD[28]⁵. I also recorded the Palliative Performance Scale[192] at each assessment.

4.7.3.2 Primary outcome measure: PPD (PPD)

The primary outcome measure for the study was:

“The proportion (%) of patients achieving their PPD (Congruence)”

This preliminary outcome measure was chosen for the following reasons.

- Previous work and published literature confirms that patients, carers and the public[12] feel that dying in one’s place of choice is important to achieve where possible
- The National EoLC strategy in the United Kingdom[193] cites PPD as a clinical marker of good quality EoLC, and encourages clinicians to discuss and document this with patients where appropriate
- H2H routinely discuss and document PPD as part of a patient’s individualized care plan

PPD was recorded from the clinical teams’ notes, or was noted in the clinical record file if the participant offered this information during any of the study assessments. A decision was taken not to include PPD as a direct question asked to the patient or carer participants as part of the study schedule. This decision was taken because previous research[28]has shown the expression of a preference to impact on PoD and therefore the act of asking these questions could have directly influenced the outcome. Hence for the research to accurately reflect ‘real life’ and not to bias the achievement of the primary outcome in either group, PPD was obtained without direct questioning. In cases where PPD was not obtained during the study period it was obtained after death through a question in the carer post bereavement questionnaire or from the CPCT medical records.

The actual PoD was recorded from the clinical records, follow up with the community teams or from the informal carer during any of the routine contacts.

⁵ A full list of demographic information collected is available in the patient and carer clinical record file in Appendix 7.3.7 & 7.3.8

4.7.3.3 Secondary outcome data collection instruments

Patient questionnaire

Combinations of different outcome measures are often needed in palliative care research to ensure all outcomes, including unintended outcomes, of the intervention being studied are not missed. This must be weighed up against the burden on patients and resulting questionnaire fatigue that is common in EOLC research[128]. The patient questionnaire was used in this study to determine the secondary outcomes of the study including symptom prevalence, QoL and satisfaction. This enabled other possible relevant outcome measures for H2H to be scrutinised for development of a larger evaluation study.

The complete patient questionnaire⁶ consisted of 50 items. It was a combination of the McGill QoL questionnaire[194-196] and Memorial Symptom Assessment Scale short form [197]. There were an additional 16 items at Week 1 from the FAMCARE –Patient[198] satisfaction questionnaire, and if the patient had a CC, 8 questions on the acceptability of the CC.

Informal carer questionnaire

The evaluation of carer QoL is an important component of a palliative care holistic assessment and thus essential in evaluating any CI at the EoL.

The complete informal carer questionnaire⁷ consisted of 85 items. It was a combination of an adapted McGill QoL questionnaire[194-196], an adapted Memorial Symptom Assessment Scale short form[197], and the Caregiver QoL – Cancer questionnaire tool[199, 200]. There were an additional 20 items at Week 1 consisting of the FAMCARE[201] satisfaction questionnaire, and if the patient had a CC, 8 questions on the carer's experience of the CC. This allowed direct comparison between the patient and their carer's score of the patient's symptoms and QoL as well as assessing the carer's QoL.

The validated tools used are briefly described below. The tools chosen fulfilled the study secondary outcomes, were validated in the cancer population approaching the EoL and were relatively short to ensure they were not too burdensome to the patient or carer.

The rationale for the use of each tool is detailed in Table 4.10 below.

⁶ The complete patient questionnaire is available in the patient clinical record file in Appendix 7.6.7

⁷⁷ The complete carer questionnaire is available in the carer clinical record file in Appendix 7.6.8

Table 4.10: Rationale for choice of assessment tool used for each outcome measure

Outcome measure	Tool Used	Rationale for choice of Tool	EAPC recommendation
Patient Symptom Burden	MSAS-SF	Used in multiple cancer studies, enables thorough symptom assessment. Sufficiently brief Used in previous study of CC in Australia[145]	(1), (2), (4), (6)
Patient QOL	MQOL	Validated in EoLC. Assesses multiple QOL domains (not only health related QOL) Sufficiently brief but space for free comment Used in previous studies of CC in Australia[145, 146]	(1), (2), (4), (6)
Carer QOL	CQOL-C	Validated in carers of patients with cancer. Includes questions to assess the positive affects of caring as well as the burden. Used in a number of studies.	(1), (3), (4), (6)
Satisfaction with care	Patient – FAMCARE-P Carer- FAMCARE	Used in multiple studies. Sufficiently brief. Has a matching patient and carer validated tool.	(1), (3), (4), (6)
Service Use	2 weekly self designed form adapted from CSRI	No appropriate tool to capture all different service use in palliative care therefore I personally devised one based on the CSRI with input from the MDT.	

EAPC Recommendation
(1) PROMs: validated in the relevant populations - sufficiently brief and straightforward to allow proxy reporting
(2) Use multidimensional measures that capture holistic nature of palliative care
(3) Use outcome measures to assess the needs of unpaid carers alongside the needs of the patient
(4) Use measures that have sound and proven psychometric properties
(6) Use valid and reliable measures in research that are relevant to the research question and consider patient burdens when using assessment tools.

The MSAS and MQOL had previously been used in the Abernethy study of CCs in

Australia[145]. Mitchell et al used the MQOL as their primary outcome measure[127].

Permission to use each of the tools was granted by the original author, with the exception of the MSAS-SF, as it is universally available without requiring specific study permission. The tools used are described in more detail below.

- Memorial Symptom Assessment Scale Short form[197]

- This is a validated tool for assessing physical symptoms in cancer patients. It is a 34 point questionnaire in which the patient is asked to rate physical symptoms in terms of how much distress they cause, with a scale ranging from 'Not at all' to 'Very much'. It has been chosen to enable detailed data collection regarding physical symptoms and to determine the prevalence of symptoms in the population being studied.
- McGill QoL Questionnaire[194-196]
 - This is a validated patient-reported instrument that employs 16 items plus a single-item global scale, each with a 2-day time frame. QoL is rated on a 0-10 scale. Five domains (physical well-being, physical symptoms, psychological, existential, and support) were identified through principal component analysis, and each of the domains is scored as a separate sub-scale. An overall index score can be calculated from the means of the five sub-scales.
- FAMCARE [198, 201]
 - This is a 16-item tool for patients and a 20-item tool for carers, each with a 5-point Likert scale (1-very satisfied to 5- very dissatisfied) developed to assess the degree of satisfaction in the care of patients with advanced cancer and their families. It has proven content validity as well as good internal consistency and test-retest reliability.
- Caregiver QoL Index-Cancer (CQOLC) [199, 200]
 - This tool is a 35-item instrument, using a 5- point Likert scale (0-'not at all' to 4-'very much') developed for carers of cancer patients (including a validation study in a palliative care population). It is now a well-developed tool, which has been validated, and has demonstrated test-retest consistency.

Service use data collection tool

An adapted version of the Client Service Receipt Inventory[202]. This was designed after discussion with the palliative care multidisciplinary professional team. The researchers collected these data over the telephone from the patient, or their informal carer, every 2 weeks for the duration of the study.

4.7.3.4 Baseline and Follow up data collection

I visited the participants (patients and carers) at a time and place most convenient to them for the first assessment (this was normally the participant's own home). All subsequent contacts were via the telephone. Participants completed the validated questionnaires at initial assessment, a week later, then at 4 weeks and 12 weeks (Table 3.10). This time-line was chosen based on results of the retrospective service evaluation (Section 1.9) and this showed the median survival of patients after CC was 31 days (IR 13-78). Where possible, these contacts were completed within one week of the scheduled date. Patient and carer participants had a maximum of 4 parallel contacts with myself to complete questionnaires. The carers, or patients, were contacted via the telephone every two weeks for the duration of the study period (12 weeks) so the service use data collection tool could be updated.

All patient participants who had survived to 12 weeks did not have any further interviews but, with their consent, the community teams were asked to update the research team as to the date and PoD. Carers of patients who died during the 12 week follow up were contacted 3 months after the death to complete a post bereavement preference and satisfaction questionnaire. This time point was chosen to minimise distress from contact too close after death. For the purpose of the satisfaction questionnaire, the carer was asked to reflect on the whole experience of care from discharge to death. Symptom and QoL assessments were not done because 3 months was deemed too long for the carer to accurately recall patient symptoms and QoL.

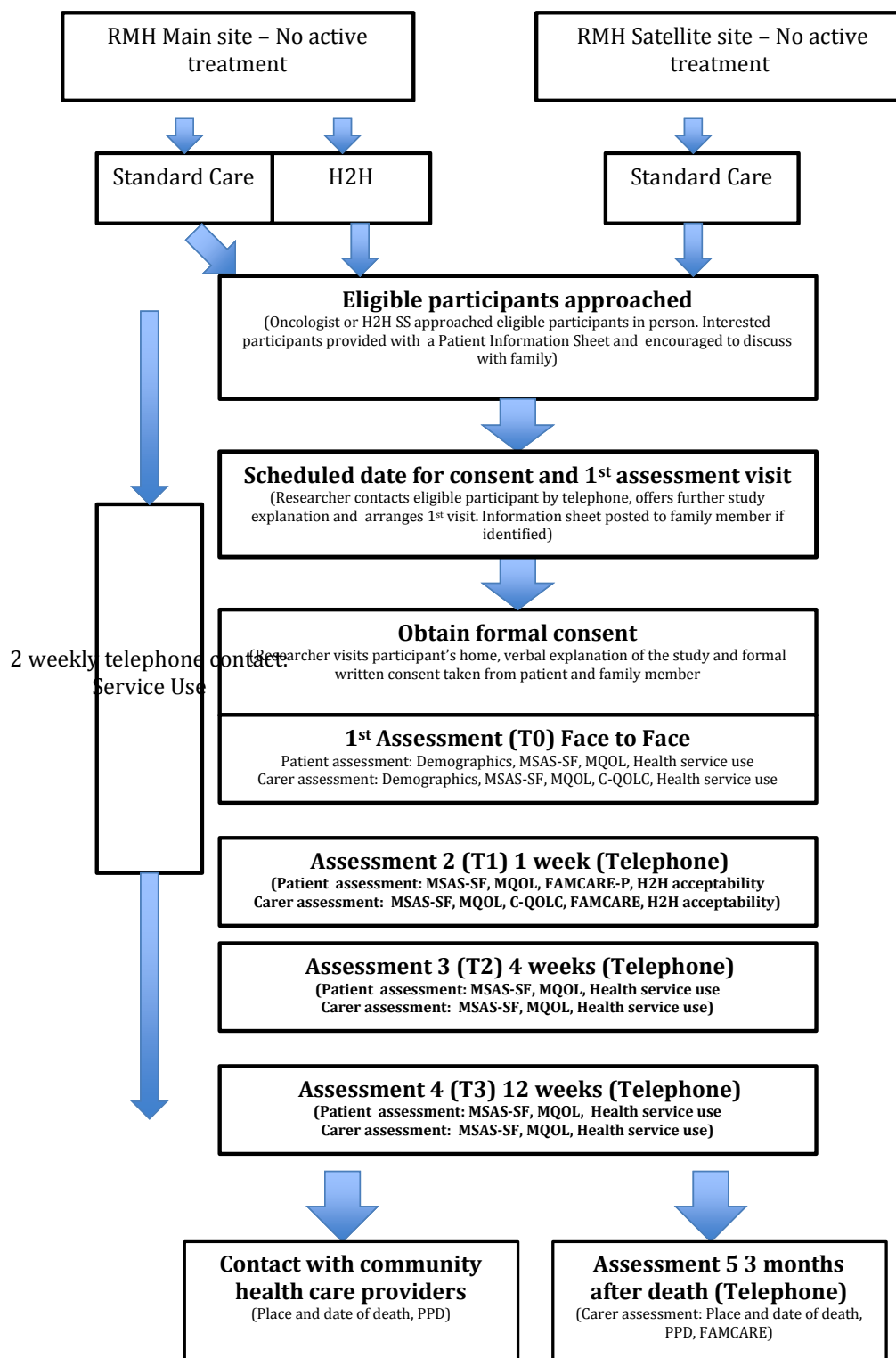


Figure 4.5: Study Schedule for the H2H quantitative feasibility study

Table 4.11 Data collection time points H2H study: quantitative component

			Study Week					
Reporter	Domain assessed	Assessment	Baseline (T0)	1 week (T1)	Every 2 weeks (Baseline – Week 12)	4 weeks (T2)	12 weeks (T3)	3 months after Death
Clinical record/ Patient		Demographic data	X					
	Achievement of PPD	PPD	X					X
		PoD	At any point across the study period					
Patient	Symptoms	MSAS-SF	X	X		X	X	
	QoL	MQOL	X	X		X	X	
	Satisfaction	FAMCARE-P		X				
	H2H acceptability	H2H 8 item tool		X				
Carer	Patient symptoms	MSAS-SF adapted	X	X		X	X	
	Patient QoL	MQOL adapted	X	X		X	X	
	Carer QoL	CQOLC	X	X		X	X	
	Carer satisfaction	FAMCARE		X				
	H2H acceptability	H2H 8 item tool		X				
Patient or Carer	Health service use	CSRI adapted	X		X			

MSAS-SF – memorial symptom assessment-short form, MQOL – McGill QoL questionnaire, CQOLC- Carer QoL Index-Cancer, FAMCARE, CSRI – Client Service Receipt Inventory.

4.7.4 Missing data

The primary outcome measure was achievement of PPD. For some patients, the preferred place had not been recorded although the actual PoD was known. In such cases, for analysis purposes it was assumed that the patient would have preferred to die at home. Missing data for secondary outcome data were minimised, by the researcher completing the questionnaires by telephone and reviewing all questionnaires for missing items, before the end of that contact to ensure data had not been accidentally missed.

4.7.5 Data entry and checking

Data were dual-entered into the RMFT 'CRSWeb' database. Data were extracted into a Microsoft Excel document and all primary outcome data were dual checked to identify any systematic errors in the data entry process. No systematic errors were identified for the primary outcome measure. This process was repeated for a random sample of 10% of secondary outcome data. No systematic errors were identified in the data for the symptom assessment, QoL and satisfaction. However, this process highlighted data entry error in the input of service use data. Therefore, all service use data were dual crosschecked and any data entry errors corrected. All individual values, total scores and subscales were explored descriptively to identify any outlier or out of range data entries. Outliers were checked again for data entry errors but none were identified. Data were then imported into SPSS Version 20 for analysis.

4.7.6 Analysis

This section describes the statistical analysis plan for the study. This analysis plan is split into two sections:

- 4.7.6.1 Preliminary hypothesis testing
- 4.7.6.2 Feasibility testing

Analysis compared H2H participants with all comparators (AC) (SSC+MSC).

3.7.6.1 Preliminary hypothesis testing

Primary outcome measure analysis plan

Objective: To compare the proportion of patients dying in their preferred place in H2H with standard care.

Null hypothesis: There is no difference in the proportion of patients achieving their PPD with H2H compared to standard care alone (All Comparator group).

Outcome measure: The proportion of participants (%) in each group that died in their documented PPD.

PPD was determined from four sources: the participant during the study; patient RMFT electronic record (including the H2H care plan); the bereaved carer and the CPCT after death. If more than one source had a documented PPD, the analysis used the last known (last dated) documented PPD.

All the sources were contacted for each participant and therefore if PPD was 'not known' this was because it was not documented by any HCPS during the participant's care and was also not known by the bereaved carer. For the purpose of analysis, it was assumed that these participants would have chosen 'home' in line with research evidence into PPD[12]. Two main analyses were performed: an unadjusted one as a baseline, using the chi-squared test statistic, and an adjusted one using binary logistic regression to allow for demographic difference between the groups.

Secondary outcome analysis plan

The secondary outcome measures in the study were split into patient outcomes, carer outcomes and service use outcomes. Cross-sectional and longitudinal data analyses were conducted.

Table 4.12 details each secondary objective, outcome measure and the statistical analysis plan used for patient, carer and service use outcomes.

For longitudinal analyses, the whole sample of participants was used. Therefore, because of attrition, the sample size at each time point reduced over time. This is made clear in all graphs or tables by specifying the number contributing to the descriptive measure at each time point.

Table 4.12 Secondary objectives and Patient outcomes measures analysis plan (continued on next page)

Objective (Null Hypothesis)	Outcome	Measure	Description	Statistical Analysis
Objective 15 To compare the actual PoD of H2H and AC participants <i>There is no difference in the proportion of patients dying at home, in hospital, in hospice with H2H compared to standard care alone (All Control group).</i>	PoD	PoD	PoD obtained from medical records or carer. Descriptive analysis of proportion dying in each of the four main locations: home, hospital, hospice, other.	Formal analysis using Chi squared (unadjusted) and binary logistic regression (adjusted) comparing proportion dying in hospital and dying out of hospital
PATIENT Objective 16 To determine and compare patient and carer symptoms, QoL and satisfaction in H2H and AC participants <i>There is no difference in patient and carer symptoms, QoL and satisfaction with H2H compared to standard care alone (All Control group).</i>	Prevalence of individual symptoms	MSAS-SF	Descriptive analysis of overall prevalence of the 32 individual symptoms measured in MSAS-SF, including 95% confidence intervals	Analysis A: The mean difference in scores between initial assessment and week 1. Analysis B: The mean difference in scores between initial assessment and last observation before death. Average overall changes were compared using T-test or Mann-Whitney U including 95% confidence intervals
	Average symptom distress from all symptoms	MSAS-SF	Summary Statistics (mean, standard deviation, median and range) for total MSAS score	
	Distress from physical symptoms	MSAS-SF	Summary Statistics (mean, standard deviation, median and range) for MSAS-PHYS score	
	Distress from psychological symptoms	MSAS-SF	Summary Statistics (mean, standard deviation, median and range) for MSAS-PSYCH	
	Average QoL	MQOL	Summary Statistics (mean, standard deviation, median and range) for Total MQOL score	
	Psychological QoL	MQOL	Summary Statistics (mean, standard deviation, median and range) for MQOL Psychological domain score	
	Existential QoL	MQOL	Summary Statistics (mean, standard deviation, median and range) for MQOL Existential domain score	
	Degree of Support	MQOL	Summary Statistics (mean, standard deviation, median and range) for MQOL Support domain score	Week 1 Total FAMCARE-P scores were compared using Mann Whitney U test
CARER Objective 16 To determine and compare patient and carer QoL and satisfaction in H2H and AC participants <i>There is no difference in patient and carer symptoms, QoL and satisfaction with H2H compared to standard care alone (All Control group).</i>	Satisfaction with care	FAMCARE	Summary Statistics (mean, standard deviation, median and range) for Total FAMCARE-P score	
	Overall Carer QoL	CQOL-C	Summary Statistics (mean, standard deviation, median and range) for Total CQOLC score	Analysis A: The mean difference in scores between initial assessment and week 1. Analysis B: The mean difference in scores between initial assessment and last observation before death. Average overall changes were compared using T-test or Mann-Whitney U including 95% confidence intervals
	Burden	CQOL-C	Summary Statistics (mean, standard deviation, median and range) for CQOLC Burden domain score	
	Disruptiveness	CQOL-C	Summary Statistics (mean, standard deviation, median and range) for CQOLC Disruptiveness domain score	
	Positive Adaptation	CQOL-C	Summary Statistics (mean, standard deviation, median and range) for the CQOLC Positive Adaptation domain score	
	Satisfaction with care	FAMCARE	Summary Statistics (mean, standard	Week 1 Total FAMCARE-P scores were

Objective (Null Hypothesis)	Outcome	Measure	Description	Statistical Analysis
			deviation, median and range) for Total FAMCARE score	compared using the Mann Whitney U test
LONGITUDINAL Objective 16 To determine and compare patient and carer symptoms, QoL and satisfaction in H2H and AC participants <i>There is no difference in patient and carer symptoms, QoL and satisfaction with H2H compared to standard care alone (All Control group).</i>	Population and individual patient profiles of symptom burden overtime	MSAS-SF GDI Total MSAS	Summary statistics (mean and median) at each time point are presented in tables and plots for the total population, H2H group and AC group. Error bars at each time point represent 95% confidence intervals (CI)* Individual patient and carer participant profiles for symptoms and QoL at each time point are shown in sets of mini graphs, vitagrams, for secondary outcome measures.	The summarizing multiple measurements technique described by Matthews et al [203] is used for preliminary formal longitudinal analysis. The summary measure chosen is Time-adjusted Area Under the Curve (AUC). Summary statistics (mean, standard deviation, median, range) for the time adjusted AUC in each group are reported. Average AUC summary statistic were compared using a two-sided t test or Mann Whitney U test including 95% confidence intervals The area under the curve has been standardized for time in the study (time-adjusted AUC)
	Population and individual profiles of QoL over time	Total MQOL	Summary statistics (mean and median) at each time point are presented in tables and plots for the total population, H2H group and AC group. Error bars at each time point represent 95% confidence intervals (CI)* Individual patient and carer participant profiles for symptoms and QoL at each time point are shown in sets of mini graphs, vitagrams, for secondary outcome measures.	
Objective 17 To determine and compare service use from all health care providers of patients in the H2H group and AC group <i>There is no difference in service use with H2H compared to standard care alone (All Control group).</i>	Health service use	Adapted Client Service Inventory Sum of all contacts over the study period (13 weeks)	Summary statistics (mean, SD, median and range) for community contacts over the study period are presented	Average contacts per group were compared using T-test or Mann-Whitney U including
Objective 18 To determine and compare the number of patient days spent in their PPC in the H2H model with standard care. <i>There is no difference in the number of days spent in PPC with H2H compared to standard care alone (All Control group).</i>	Cost of health service use at the EoL Sum of all contacts over the study period multiply PSSRU unit costs*	Adapted Client Service Inventory	Summary statistics (mean, SD, median and range) for community cost over the study period are presented Participants who died during the 3 month study period	Average costs (£) per group were compared using T-test or Mann-Whitney U including Participants who died during the 3 month study period
Objective 19 To compare number of admissions and days spent in hospital/hospice of patients who had a H2H compared with standard care. <i>There is no difference in the number admissions and days spent in hospital/hospice with H2H compared to standard care alone (All Control group).</i>	The proportion (%) of time spent hospital and/or hospice.	Adapted Client Service Inventory Days in Hospital/hospice/Days in Study	Sum of days in hospital or hospice. This was calculated as a proportion of the participant's total time in the study i.e. from discharge to death or 3 months follow up (91 days) Descriptive summary statistics are reported (numbers, proportions, mean, median, range)	The average proportion of time was compared across groups using independent t-test or Mann Whitney U test.

4.7.6.2 Feasibility testing

The analysis plan for the feasibility of the study design is detailed in Table 4.13 below. This analysis plan answers to Objectives 5-8..

Table 4.13 Feasibility objectives analysis plan and success criteria: quantitative component

Feasibility Objectives	Success Criteria	Analysis plan
Objective 5: Recruitment	> 20% of recruited pool - Each study site recruits >20% of eligible patients/carers - The target of 180 patient participants met in time available >50/70% of eligible informal carers recruited	Detailed descriptive analysis of recruitment rates per study group is presented and compared to the success criteria.
Objective 5: Eligibility criteria	To study EoL, >60/70% die during the 3 month assessment period	
Objective 5: Study design- choice of comparator group	<10% of demographic variables are statistically significant across study groups	Statistical comparison across study groups using either χ^2 test or Fisher's exact test for categorical variables and the Mann-Whitney test for non-parametric continuous or ordinal data is reported.
Objective 5: Retention of participants	<10 % withdrawal from the study by choice	Attrition and withdrawal rates are presented for each study group
Intervention acceptability and fidelity	- Positive response from patients and HCPs in qualitative interview - Delivery: >80% of CC last 30-60 minutes > 70/80% of CC delivered within 3 working days of discharge if inpatient, 5 working days if outpatient 100% of GPs and > 80/90% of invited HCPs attend the CC	Qualitative component of study
Objective 5 & 6 : Feasibility and acceptability of the primary outcome piloted	> 70% of PPD documented (rather than substituted in analysis)	Descriptive analysis is reported for documented PPD
Objective 5 & 6: Feasibility and acceptability of the secondary outcomes piloted	> 80% of data complete at each time point. Unknown values (blank or participant refusal) are considered missing.	Detailed descriptive analysis of individual missing items data is reported for each validated tool
Objective 5: Feasibility and acceptability of collecting longitudinal data in this study setting	> 50% of participants complete 2 or more assessments	Detailed descriptive analysis of attrition from secondary outcome data collection is reported for the total population and each study group
Objective 8: Feasibility of using the informal carer as a proxy response for patient data	Agreement of patient and carer MSAS and MQOL scores	Summary statistics and Bland-Altman plots are presented
Objective 7: Feasibility of assuming/using PPD as a proxy for QOL at the EoL	Statistically significant difference in QOL score between participants who achieve their PPD and those who do not.	Summary statistics are presented and these are compared using 2 sided t test or Mann-Whitney U test

4.7.6.3 Missing data

Missing data from the primary outcome (PPD) could occur if PPD was not known during the study. This is presented in the results section.

Missing data from secondary outcome data collection of symptom burden and QoL was expected due to deteriorating health (ADI) or death at time of contact (ADD). This terminal missing data is classed as an informative drop out because it is a change in the patient's QoL (i.e. deteriorating health/death) that prevents them from completing the later time point questionnaires. A description of the missing whole questionnaire and reasons for this missing data are reported. There are various methods of imputing data for dropouts[204, 205]; however, all of these have associated problems. Therefore, as symptom control and QoL are secondary outcomes, the imputing of data for dropouts was not adopted. Missing data and causes were analysed descriptively and reported, and this is taken into account when interpreting the findings.

Missing service use data did occur very close to death, as participants were too unwell to complete the assessments. The pattern and frequency of missing service use data is reported. Mean contacts per week were standardized for the number of weeks of data collection. Terminal missing service use data (ADI) is likely to be important in data interpretation as community care service use does become increasingly intensive up to the point of death.

Individual items may be missing within a questionnaire and this needs to be accounted for in the analysis of that questionnaire and calculation of the total score. The pattern and frequency of individual missing item data is reported.

4.8 Sample size calculation

This was an exploratory feasibility study and therefore the statistical analysis performed was descriptive and exploratory. Sample size calculations are difficult to determine and criticised in exploratory studies. This exploratory study was designed with the intention of testing the feasibility of the H2H complex intervention and also examining and testing the proposed research methods to inform the design of a larger definitive study of effectiveness.

One component to be tested was recruitment and attrition rates to inform the sample size calculation of a definitive trial. With this in mind, a pragmatic sample size was calculated based on the primary outcome -achievement of PPD - and the retrospective service evaluation and PoD of RMFT patients the year previous to the study (2008-2009). The sample size calculation was based on unproven estimates that at the start of the study the proportion who died in their preferred place under 'usual care' was 45%⁸, the proportion of patients referred/not referred to H2H was 70%/30%⁸ alongside the service evaluation data (Chapter 3) showing the proportion of patients who die in their preferred place in H2H was approximately 80%⁹. To detect a difference between groups of 25% at the 5% significance level with 80% power, a sample of 90 patients in each group was required.

For the purpose of this feasibility study, it was assumed that patients recruited would be close to death and therefore loss to follow up for the primary outcome measure of PPD was very unlikely. Hence increasing the study sample size to account for primary outcome attrition was not necessary. It was recognised that this sample size may not be reached throughout the time allowed for the study. However the emphasis of this study was not to determine the effect of H2H but to inform the feasibility of a larger trial. Therefore, the recruitment of as many participants as feasible would give valuable information on recruitment rates and attrition to inform the sample size calculation for a larger definitive trial. Therefore a pragmatic approach was taken to enrol as many participants as the time period (3 years) allowed or a total of 180 participants whichever came first.

⁸ Data taken from previous audit 2008/2009, actual number dying in PPD unknown as PPD not documented. This estimate was assuming all those dying at home or nursing home wanted to do so. Those dying in usual place of residence (presumed PPD) in 2010/2011 was 31% (See Section 5.9), hence the sample size calculation could have been lowered.

⁹ Data taken from Service evaluation Section Chapter 3.

4.9 Qualitative Component

4.9.1 Section Introduction

The qualitative component of this mixed methods feasibility study was parallel face-to-face, in-depth, semi-structured interviews with patients (n=8), oncology consultants (n=15) and H2H SS (n=3). The 'parallel' element of the study refers to the time line of data collection.

Interviews were conducted in parallel to quantitative data collection. However, there was a time lag between the start of the quantitative component of the feasibility study and the start of the qualitative interviews. This was intended. It was common in the patient participant's first assessment for the quantitative study that participants shared a lot of information regarding their feelings and experiences of care. This was outside the questions in the assessment tools and at the time I made field notes of these issues. A delayed qualitative start enabled me to use the experience in the quantitative data collection to inform the topic guide for the qualitative interviews. Qualitative interviews took place between July 2011 and July 2012.

4.9.2 Sampling

In line with previous qualitative research [206], it was expected that approximately 20 interviews with patients and 20 interviews with HCPS may be needed to enable thorough data extraction and analysis. Recruitment of a total of 40 participants was therefore planned. However, at the outset it was decided that, if during data collection theoretical saturation were reached early, recruitment would cease. Theoretical saturation can be explained as a point where no more new data can add additional insights into the research questions[207]. Consecutive participants who fulfilled the purposive criteria in each group were approached. Purposive sampling is a case orientated approach to participant selection[208]. It is a non-probability sampling method characterised by a deliberate effort to gain representative cases by including specific pre-determined groups in a sample[207]. The aim of qualitative research is to provide explanation and conceptual understanding of a research question through the in-depth study. It is not designed to test hypotheses. The aim of the qualitative research in this feasibility study was to explore the views and experiences surrounding discharge from

oncology services of both patients and HCPS to provide insight into the acceptability, feasibility and barriers to H2H. The qualitative interviews were designed to be exploratory in nature, with the aim of discovering patient and HCPS feelings and thoughts concerning the delivery of H2H. H2H is a unique service in the United Kingdom and therefore it was imperative to explore all possible patient outcomes (positive and negative) of such a service.

H2H acts at the interface between acute sector and community based care with the aim of optimising coordination and understanding between patient, carer and all services. With this in mind, a simple purposive sampling grid was devised for both patient and HCPS participants based on their prior experience of community services and H2H respectively.

4.9.2.1 Patient participants

Patient participants recruited to take part were consecutive patients who had experienced a face-to-face H2H (H2H) CC; were deemed well enough to be able to talk for 30-45minutes and who fulfilled the purposive criteria. Other study inclusion criteria included the ability to understand and speak English. Potential patient participants were excluded if they only received a telephone H2H; were unable to provide informed consent or had cognitive impairment. For patient participants, purposive sampling was based on exposure to CPCTs rather than demographic information per se. The evidence available informs us that patients who are known to a CPCT are more likely to have better outcomes (symptom control and number of hospital admissions)[209]. Therefore, patients known to a CPCT prior to H2H may have very different views and experiences from those not known to CPCT. For this reason, the criterion of whether a patient had had previous contact with CPC services was used for purposive sampling. Table 3.13 outlines the purposive criteria.

4.9.2.2 Oncology Consultants and H2H SS participants

The oncology consultant participants' purposive sampling was based on the frequency with which the oncologist referred to H2H. It was hypothesised that those using the service regularly and those who use it rarely may have polar perceptions and experiences of the

intervention. Therefore, the purposive sampling criteria separated consultant oncologists into those who regularly refer to H2H (refer more frequently than once a month), and those who do not regularly refer to H2H (refer less frequently than once a month). Table 4.13 outlines the purposive criteria for oncology consultants. All H2H SS employed at the time of the study were interviewed (n=3).

Table 4.14: Sampling matrix for in-depth interviews

Patients participants	Number of interviews
Known to CPCT ¹⁰	10
Not known to CPCT	10

Oncology Consultant participants	Number of interviews
Regularly refer to H2H ¹¹	10
Do no regularly refer to H2H	10

4.9.3. Consent

Section 4. 7 of this thesis details the overall ethical considerations of consent for this mixed methods feasibility study. The process of consent for the qualitative interviews is described here, highlighting areas of particular importance to this method of study.

4.9.3.1 Patient participants

After completion of a H2H, potential patient participants were initially approached about the study by the clinical team, normally by their allocated H2H SS. The clinical team gave any potential participants an information sheet¹². Subsequently, I contacted them by telephone to discuss the study and arrange an interview date if they were willing to participate.

¹⁰ To be 'known to CPC services' the patient must have met one of the CPCT, this was normally a CPC specialist nurse, prior to involvement of the H2H team

¹¹ Regularly refer to H2H was defined as referring to the service at least once a month.

¹² A copy of the patient information sheet for the qualitative interviews is available in Appendix 7.3.12

4.9.3.2 HCP participants

Potential HCP participants were identified from staffing records and contacted with a written invitation letter and information sheet¹³. The letter requested the HCP to reply by email or telephone to accept or decline an interview. If the HCP agreed to participate, I contacted them via email or telephone to arrange an interview date.

I visited potential participants who agreed to an interview at a time and place most convenient to them. All participants (patients and HCPS) consenting to an in-depth interview were asked to sign a consent form¹⁴. The consenting process included a verbal explanation of the study, answering any questions the participant had about the study. As part of this process, the following details regarding the study were highlighted.

- Likely length of interview. It was anticipated that the majority of interviews could last between 30-60 minutes. This was explained to the participant at the outset to ensure the patient participants felt well enough and to minimize interruptions to all interviews where possible.
- Tape-recorded. The fact that the interviews were being audiotape recorded was highlighted. Participants were also made aware that they could stop the interview at any time and withdraw their consent. In such an event, the audiotape recording would be erased immediately.
- Do not have to answer all questions. It was impressed upon the participants that if the interviewer asked a question they did not want to answer, the participant could ask to move on to the next question.

¹³ A copy of the HCP invitation letter and information sheet for the qualitative interviews is available in Appendix 7.3.15

¹⁴ A copy of the patient and HCP consent forms for the in-depth interviews is available in Appendix 7.3.13 & 7.3.16

4.9.4. Data collection

4.9.4.1 Demographic data

Demographic data for each patient participant were taken from the medical records and I recorded the participant's PPS [22] at the time of the interview. Demographic data included individual factors (age, gender, ethnicity), factors related to illness, and environmental factors[28]. Survival (in days) after interview was also calculated to provide further context to the interviews. Demographic data for each HCP were elicited by completion of short questionnaire prior to commencing the in-depth interview¹⁵. These data included gender, cancer specialty, number of years working in current role and frequency of referral to H2H.

4.9.4.2 Topic Guide

The in-depth interviews for all participants were semi-structured using a topic guide prepared to satisfy the objectives of the study. This topic guide was initially created based on my previous experience enrolling the first 30 patients into the quantitative arm of the study. I referred to the free text comments noted when completing the quantitative survey alongside research evidence to devise the areas of interest and importance for the qualitative interviews. A patient representative reviewed the topic guide. The topic guides are shown in Appendix 7.3.14 & 7.3.17. I ensured all areas were addressed in the course of the interview. The interviews broadly followed the topic guide. However, as the interviews were semi-structured, the participant led the path of the conversation and for this reason discussions were not exclusive to those on the topic guide and the guide was not always followed in order.

¹⁵ The demographic data questionnaire for HCPS is available in Appendix 7.3.17

Throughout all interviews, prompts were used to explore relevant areas in more detail and elicit further information. Earlier interview responses informed the emphasis of subsequent interviews. At the end of the interview, participants were asked if there was anything further they would like to add or anything important they felt had been missed.

I conducted all interviews and these were audiotape recorded. Field notes were not recorded as the interview was being conducted; however, after each interview, I took a 'time out' prior to travelling back to my place of work to record field notes regarding my immediate observations, feelings and thoughts surrounding the interview. These field notes were used in the analysis of the transcripts to provide further depth and insight into the concepts that emerged. The decision not to make notes during the interview exchange was made explicitly to maximize the verbal and non-verbal interactions between the participants and me. This ensured I could respond appropriately to both verbal and non-verbal cues and focus entirely on the participant's responses. Interviews were anonymised at transcription and transcribed verbatim. All names were changed to alternatives that matched in gender and ethnic origin.

I did not have any previous experience of conducting in-depth qualitative interviews. In preparation for this work, I attended a six-day workshop run by a senior qualitative researcher at Kingston University. My interview technique was tested on a fellow researcher and reviewed by supervisors, JR and JK. Alongside this, I read and re-read early interview transcripts to critique my interview technique, looking at my use of open questions and my ability to minimize interruptions and follow the topic guide whilst also responding to cues. This and the nature of qualitative interviews meant that I felt my interview technique improved over the course of the 24 interviews conducted.

4.9.5 Conduct of the interviews

The ethical conduct of research requires careful consideration of the target population being studied. For patient participants in these qualitative interviews, this included the terminal nature of their cancer alongside the sensitive issues and potential concerns that may emerge during the research interview. Interviewing terminally ill patients often requires discussing sensitive topics. This necessitates attention to key areas of the conduct of the qualitative

interview: sensitive and open questioning; researcher disclosure and rapport; correct timing of interviews; comfortable interview environment and addressing any distress inadvertently caused by the interview process [210]. These areas of conduct are cause for ethical concern and can also influence the richness and quality of data collection during the interview. I will now discuss each area of conduct and how I addressed these during the qualitative interviews.

4.9.5.1 Establishing a rapport and relationship

Rapport building is a crucial component of any research interview[210]. The topic guide broached sensitive issues and therefore it was imperative that I developed a good rapport with both patient and HCPSs in order to facilitate honest and open discussion. This study required quick rapport-building during a single encounter or based on one previous encounter with the patient participant if they had been involved in the quantitative arm of the study. Power imbalances, researcher neutrality and disclosure can all impact on rapport building.

Power relations exist in all social contexts and the qualitative interview is no exception. Power imbalances have an influence on rapport building.

- *Patient participant-researcher*: In the context of the dynamic between the researcher and the patient approaching the EoL, the researcher may be perceived as in a position of power due to expert knowledge, the vulnerability of the patient and the uncertainty of their illness [210, 211]. This is a particular concern where the researcher, like me, has a clinical background and this is disclosed to the patient. I felt it was important for me to be honest with all participants about my clinical background and therefore I disclosed this at the beginning of the interview process. However, I appropriately framed the interview encounter[212] emphasising my role as a researcher for the purposes of the interview, the confidentiality of the interview, that there were no 'right answers' to the semi-structured questions and also emphasising the participant's role as an expert in the topic of conversation. I hoped this clarity of role addressed any power imbalance patients may have felt. I was aware of other socio-demographic factors out of my control that may have influenced the power imbalance and rapport-building, namely gender, ethnicity and socioeconomic status[213]. Finally, the interviews were conducted at a time and place convenient to the participant. For all except one patient, the interviews occurred in their own home. Conducting the interviews in the patient's home enabled the patient to feel at ease, in control and the 'host' of the interview[210].

As well as the home environment addressing power relations, it also allowed me to connect with the patient before the start of the interview by a brief chat, discussing family photos and the surroundings. This has since been recognised as a positive factor in home interviews that may enhance the richness of the data collected[210].

- *HCP-researcher*: The power relations in the HCP –researcher dynamic were very different to those described above. The HCPS interviewed were senior oncology consultants, the majority with at least ten years experience. I was a junior doctor and research fellow. Through previous clinical work, I had worked alongside some of the consultants I interviewed. The power balance was towards the consultant oncologists due to their clinical position and the interview being conducted in their work office. This meant that they appeared to feel at ease and in total control of the interview. I feel my junior position and emphasis on confidentiality during the consent process allowed the oncologists and H2H SS to be honest and open regarding their views and experiences.

I recognised that the sensitive topics discussed required me to invest a bit of myself in the interview. Attempting to maintain neutrality throughout the interview and show no emotions or acknowledgement during difficult parts of the interview would have been counterproductive in establishing rapport. This may not have lead to a ‘good’ interview which would have impacted negatively on the quality of the data collection[210]. I was more than a passive player in the interview and responded accordingly to the feelings displayed by the patient or HCPS, showing empathy where necessary. However, I was very conscious of the need to be balanced and measured in my interactions in order to minimise influencing the interviewee responses. I feel my profession as a palliative medicine doctor and the advanced communication skills I have developed through taught courses and daily routine contact with terminally ill patients allowed me to establish a relationship with the patient participants with relative ease and respond appropriately in difficult situations if necessary. Some of the patient participants had also been involved in the quantitative component of the study. Thus, for these participants, I was a ‘familiar face’ and this too appeared to put the participant at ease.

4.9.5.2 Environment

It was important where possible to conduct the interviews alone, in an environment where the participant felt at ease, and without interruption. All the interviews, except one patient interview (Mark), were conducted alone with nobody else in the room. In Mark's case, his wife was present throughout the interview. The literature recognises that in this setting it may not be appropriate to separate the patient from their companion for the purpose of the interview; however, the data collected in the presence of a dominant companion may be different and this should be acknowledged[210]. In Mark's case, his wife was present but did not want to contribute her views to the interview itself. She occasionally helped Mark with word-finding difficulties he experienced from his brain metastases. Therefore, I did not feel Mark's views and feelings were altered due to his wife's presence. All interviews were conducted in the participant's place of choice; for the majority of patient participants (7/8), this was their own home and for the majority of HCPS (14/16), this was their work office. A total of 8 patient and 16 HCPS interviews were conducted. For the patient participant interviews, all except Diane's occurred in the patient's own home. Diane had been readmitted to the RMFT after her H2H. Diane's interview was conducted in a single room on an inpatient ward. Fourteen of the sixteen HCP interviews occurred in the professional's own office. The remaining two interviews, both with the H2H SS (Emma and Susan), occurred in a private meeting room at the RMFT. Every attempt was made to keep interruptions to a minimum during the interviews; however, two patient interviews had to be halted temporarily, one for a District nurse visit and the other for a telephone call. When this did occur, I recapped the last few minutes of the interview prior to the interruption and then the interviews recommenced. One HCP interview was interrupted very briefly for a delivery to the office (Dr Barrett) and another had to be stopped and rescheduled (Dr Smith). In the latter instance, the interview started from the beginning and both tape recordings were transcribed and analysed.

4.9.5.3 Interview Length

Before the interviews commenced, the participants were informed that the expected interview duration was approximately 30-45 minutes. However, participants were made aware that they could terminate the interview early if they wished. No participants (patient or HCPS) terminated the interview early. The duration of the interviews ranged between 23 and 65 minutes. In one patient interview (Mark), the researcher stopped the interview slightly

prematurely after Mark complained of feeling tired. However, the interview had lasted 32 minutes and the last question in the topic guide had been addressed.

4.9.5.4 Checking for undue distress and adverse effects of the interview

The study protocol included a strategy for dealing with inadvertent undue distress as a result of the interview or clinical concerns arising during course of the interview. This entailed signposting participants, notifying the patient participant's key professional in the community (usually the GP) and discussing any issues arising with the PI for the study (JR). However, no issues arose requiring action.

4.9.6 Analysis

The raw data for analysis consisted of the interview audiotape digital files, the interview transcripts and field notes. All interviews were transcribed verbatim. A palliative care secretary with previous experience of qualitative interviews transcribed all 24 interviews. All data files were stored on a secure database at the RMFT. The software package NVivo 10 was used to store and manage this data.

Data analysis used a constant comparison technique supported by a five step 'framework' approach[214] to categorise different patient and HCP attitudes and find associations between their experiences. The framework approach is a method of content analysis that uses five key stages: familiarisation, thematic analysis, indexing, charting and finally mapping and interpretation. This approach was chosen because it is systematic, transparent, auditable and comprehensive[161, 215]. It allowed me to use both inductive and deductive techniques to identify themes classified by study objectives and also identify important emerging additional themes from the transcripts. I approached these five steps in the following way.

4.9.6.1. Familiarisation of transcripts.

The familiarisation process entailed immersion in the raw data. I initially listened to the audiotapes. After listening to each audiotape, the corresponding interview transcript was read and re-read. I took notes on potential themes at this time and if necessary listened again to the audiotapes to clarify context. Although I conducted all the qualitative interviews, this process

was invaluable in allowing me to become engrossed in the data and familiarise myself with the data as a whole to gain an overview of its diversity and depth. Although the palliative medicine secretary transcribed all the interviews, I also transcribed two interviews independently. This allowed me to further familiarise myself with the data.

4.9.6.2 Identifying a thematic framework and indexing.

This process identified all the key concepts and themes by which the data could be examined[214]. The process of indexing and setting up a thematic framework was an iterative one. The step of familiarisation with the data alongside the study objectives and associated topic guide provided me with an initial framework of codes from which to start sorting and indexing the data. This helped me to organise all the data. The reading and re-reading of transcripts illuminated additional themes outside these initial codes. Therefore, additional codes were added and the overall framework was continually revised as codes were applied and interviews re-read. This initial process resulted in a large number of themes being recognized. Each of these themes were labelled as 'codes' in NVivo. These were then reviewed and the transcript sections for each theme re-read. Themes were then merged or categorized as sub-themes where appropriate. The themes and sub-themes were constantly modified and revised during this process. After much iteration, a final coding index for themes and sub-themes was established. This is outlined in Table 4.15 below:

Table 4.15 Thematic framework used in qualitative interviews

	Theme	Subtheme
1	Loss	Loss of Control
		Loss of Hope and treatment – Last consultation
		Loss of familiarity and trust
		Experiences of the last consultation
2	Transition Barriers	Understanding and Acceptance
		Attachment
		Follow up concerns
3	Transition Management	Preparation
		Phased gradual transition
		'Open door' approach
4	Community Care Anxieties	Lack of Knowledge and prior experience
		Inadequate Service Provision
5	Views on H2H	Maximal information sharing
		Visual integrated teamwork
		Acceptability and delivery limitations of CC model
		Concerns and suggested changes

NVivo was used to manage the data and index according to the coding theme.

All transcripts were re-read and indexed using this final hierarchy of codes. This ensured all data were coded and no data extracts were missed. Some extracts of data applied to multiple codes; these were coded as such. Deviant cases were included and discussed with supervisor JK. Each code in NVivo was then reviewed for patterns and associations. The emerging themes and sub-themes were regularly discussed with supervisor JK to challenge my interpretation in order to ensure the trustworthiness and authenticity of the data.

4.9.6.3 Charting

This involved using tables and figures to rearrange the data further according to the thematic reference to summarise the key subject areas. I used a combination of tables created in Microsoft Word and hand drawn figures to group the data. The data were then mapped to pull together key characteristics and identify relationships between themes. The charting process enabled me to gain further insight into the overall story of the transcripts and how experiences, views and attitudes shaped each theme.

4.9.6.4 Mapping and Interpretation

The mapping and interpretation step was an iterative process that involved me reviewing all the charts and notes created to look for patterns and explanations of the findings in the overall data. This involved looking for similar and contrasting perceptions and experiences across all interviews. I discussed findings with JK. This enhanced rigour by continually challenging my

interpretation of the data. Discussion of the emerging concepts ensured my own perceptions and views were not leading to a bias view of the data and that the views of the participants were being accurately and honestly represented. Divergent data were actively looked for and reported. Although each of the steps described in the analysis process is distinct from the next, the steps are highly inter-linked. I found that, during the data analysis, I moved back and forth between steps. Each step is intricately linked to the previous and subsequent step, each informing the other's analysis.

4.9.6.5. Reflection on personal perspectives

Myers states [216] 'Qualitative studies are tools used in understanding and describing the world of human experience. Since we maintain our humanity throughout the research process, it is largely impossible to escape the subjective experience, even for the most seasoned of researchers'.

In particular, the interpretation of codes and themes in overall analysis and how these themes are inter-linked relies heavily on the researcher's perspective. My personal knowledge and experience were used as tools to make sense of the data [217]. This must be recognized in the analysis stage of conducting qualitative research. For this reason I include here some key points about myself as the main researcher in order to provide context to the qualitative results.

- Work: I come to this research after working clinically in the palliative care team at the RMFT for over 12 months. During this time I have worked alongside oncology teams and the H2H team on a daily basis. In my professional life I have moderate experience of working with oncology teams, and I have held two junior doctor posts working in oncology before beginning my training as a palliative care doctor. The simple fact that I am a palliative care doctor by background rather than any other profession means I come to this research with my own ideas about the 'EoL experience' in the NHS and voluntary sector. I also have my own thoughts about the pros and cons of discharging people from oncology services and how this affects hope and denial and their coping strategies.
- Experience of loss and death. I have very little personal experience of death and dying. I have lost only grandparents at an appropriate age (in their 80's). None of them died from cancer but from chronic illnesses leading to gradual declines in health in old age

(dementia/COPD). Therefore, my interpretation of their deaths was that it was an expected outcome - old people die. It is the natural progression of life. This tame experience of death and dying in my personal life may affect my analysis of the transcripts for these cancer patients as, although I have a lot of clinical experience of death and dying from cancer, I have no personal experience on which to reflect during analysis.

4.9.6.6 Credibility and Rigour

The concepts of validity, reliability and rigour are well established in the quantitative research paradigm; however, the relevance of applying these directly to qualitative research is contested[218]. Patton[219] states that validity and reliability are two factors that any qualitative researcher should be concerned about while designing, analysing results and judging the quality of a study. The concepts of reliability, validity and generalisability have been redefined to relate to qualitative work [220]. Alternatively, the concepts of truth value, consistency or neutrality and applicability as a framework for credibility and rigour of qualitative work are cited[221].

Although there are no universally accepted terminology and criteria used to evaluate qualitative research [221], it was imperative for this work to incorporate strategies to enhance the credibility of the findings. The strategies employed are detailed in Table 4.16 below adapted from Noble and Smith [221].

Table 4.16 Credibility and Rigour in Qualitative Research and the H2H feasibility study [221]

Quantitative terminology applied to qualitative research	Alternative terminology associated with credibility of qualitative research	Strategies used in the H2H study qualitative interviews
Validity The precision in which findings accurately reflect the data	Truth value Recognition that multiple realities exist; - Researcher outlines personal experiences that may result in methodological bias - Clearly and accurately presents participants' perspectives	Reflexivity - My personal circumstances/experiences are detailed above and were taken into account during analysis - Regular debriefing with my supervisor and a fellow novice researcher to discuss and challenge my interpretation of the transcripts and uncover any biases and assumptions Representativeness of findings - Audio recordings of the data allowed me to revisit the spoken data again to check the emerging themes were an accurate reflection - Deviant cases were included - Inclusion of both patient and HCPS participants perspectives helped to produce a more comprehensive set of findings - Where possible full verbatim rich extracts from participants are used in the results to support findings so that the reader can also judge if final themes accurately reflect the participant views Respondent validation - The timeline of data collection meant that I was unable to use patient participants to check the transcripts and themes for as the majority had died before analysis was complete. Due to time constraints 'member checking' was not used for HCPSs
Reliability The consistency of the analytical procedures, including accounting for personal and research method biases	Consistency Relates to the 'trustworthiness' in which the methods are undertaken - Researchers decisions are clear and transparent - Independent researcher could arrive at similar/comparable findings	Trustworthiness of methods - I have given a transparent description of the research processes used in this work - The ethical considerations of the study were paramount to the integrity of the study. The consent process was robust (as described above), data stored in a manner that complied with data protection. All extracts anonymised and participant names changed to ensure confidentiality Engaging with other researcher to reduce bias - Supervisor (JK) read a sample of transcripts and independently recorded the core themes
	Neutrality Acknowledgement of the complexity of prolonged engagement with participants. Methods and findings are intrinsically linked to the researchers perspectives.	Emerging themes from the data were discussed with my supervisor (JK) in order to probe and challenge my interpretation of the data. Discrepancies were resolved by consensus
Generalisability The transferability of the findings to other settings and applicability in other contexts	Applicability Consideration is given to whether findings can be applied to other context, setting and groups	- The characteristics of the participants are compared to those of participants in the quantitative H2H study group to provide further context to the findings. - Although H2H is unique. The topic guide included more general questions regarding care at the end of oncology treatment to provide insight to other cancer centres/departments

4.10 Bereavement study component

4.10.1 Section Introduction

This part of the study was a mortality follow back study using a postal questionnaire of bereaved next of kin of patients who died as inpatients at the RMFT over an eighteen month period. Every year, over 2000 patients known to the RMFT die. Of these, around 350 patients die in the hospital across two hospital sites (Chelsea and Sutton). It is repeatedly reported that dying in hospital does not equate to a good death. To consider the context of H2H in more depth, it was important to determine the outcomes of patients who die in the cancer centre. Therefore this parallel comparator evaluation of bereaved relatives' satisfaction surrounding inpatient death was included in the study to compare experiences of people dying in hospital with H2H participants considered more likely to die at home. This provided context to the H2H and a 'real time' comparison of the experience of those dying in hospital.

4.10.2 Participants

Participants in the study were bereaved relatives of RMFT inpatients dying over the 18-month period from 1st August 2010-1st January 2012. These participants were identified over the 18-month period through the RMFT EPR. Participants were invited to participate if they were the documented next of kin of a patient who died as an inpatient during the study period.

4.10.2.1 Inclusion and exclusion criteria

Inclusion criteria

- Documented Next of Kin of a patient who died at the RMFT
- Adult Age 18 or over
- Participant able to understand and speak English

Exclusion criteria

- Contact details for the Next of Kin not available on the EPR
- Contact detail for the Next of Kin were outside the United Kingdom
- Relative died within a month of their initial cancer diagnosis
- Evidence on the EPR that the Next of Kin could not understand English

4.10.2.2 Identification and recruitment of potential participants

Consecutive participants fulfilling the inclusion criteria were identified from the RMFT electronic record. The potential participants were approached through an invitation letter sent by post with a study information sheet, an 'opt in' slip and a stamped addressed envelope¹⁶. The invitation letter was sent at least three months after the patient's death. If the potential participant sent back the 'opt in' slip or telephoned the research team agreeing to participate then the consent form and questionnaire were posted to them. All participants gave written consent to participate. This method of participant identification was chosen to allow the participant to consider the study free from any coercive influences and to minimize any potential distress receiving the postal questionnaire may have caused.

4.10.3 Non-participants

In order to understand any selection bias, data were collected on non-participants. Non-participants were potential participants who did not return an 'opt in' slip and those who initially agreed to participate but then did not return a completed questionnaire within the study period. Demographic data including age, gender, and diagnosis of the patient who died along with the gender and relationship of the next of kin were recorded. This was possible as all these data were available from the RMFT EPR.

4.10.4 The Clinical Record File

The clinical record file consisted of demographic and clinical data regarding the patient and participant and a postal self-completion questionnaire.

4.10.4.1 Demographic and clinical data

¹⁶ The invitation letter, 'opt in' slip and study information sheet is available in Appendix 7.3.18

Patient demographic data were collected from the EPR. Demographic information included age, gender, ethnicity, diagnosis, cancer treatments, length of disease along with next of kin gender and relationship.

4.10.4.2 Data collection instrument-Self-completion postal questionnaire

The postal questionnaire had a total of twenty-five questions and was split into three parts:

1. Preference statements: The first part of the questionnaire asked the bereaved carers their preferences regarding the patients PPD and if they had knowledge of the patient's preferences for PoD.
2. FAMCARE: The FAMCARE validated tool, is a 20-item self-completion questionnaire. Each item is scored on a 5-point Likert scale (1-very satisfied; 5- very dissatisfied). It was developed to assess the degree of satisfaction in the care patients with advanced cancer and their families received. It has good face and content validity as well as good internal consistency and test-retest reliability[222]. The questionnaire includes an item concerning satisfaction with time taken to diagnosis and therefore carers were asked to report on the whole care experience from diagnosis to death.
3. Free comments: The third part of questionnaire was a free comment section for the bereaved relative to provide any extra comments about the patient's care.

The questionnaire included the outcomes of PPD and satisfaction with care using the FAMCARE tool. Carer assessment of patient symptoms and quality of life along with carer quality of life were not included in the bereavement questionnaire. The reasons for limiting data collection to PPD and satisfaction are outlined below:

- PPD was an essential data collection item in bereavement to explore the importance of PPD as an outcome measure and assess change over time.
- Firstly, the bereavement questionnaire was 3-6 months after death and due to this time delay there was a concern regarding difficulties for carers to recall patient symptoms and quality life in the 2-3 days prior to death.
- Secondly, the tools used for patient symptoms, QOL and carer QOL have not been validated in bereavement.
- Thirdly, I had a concern about the possibility of the bereavement contact causing the carer distress and therefore I wanted to limit the length of the questionnaire.

4.10.5 Data entry

All data were anonymised and quantitative data (Preference statements and FAMCARE) were entered into a Microsoft Excel spreadsheet for data checking. These data were then transferred into SPSS (Version 20) for statistical analysis. The free text comments were anonymised, transcribed into Microsoft Word and then imported into NVivo (Version 10) for thematic qualitative analysis.

4.10.6 Participant and non-participant characteristics

Participants and non-participants were compared for similarities and differences in demographic and clinical variables. Descriptive analysis of demographic and clinical data of the patient and the bereaved relative are presented. A statistical comparison between participants and non-participants using either χ^2 test or Fisher's exact test for categorical variables is reported. The Mann-Whitney test for non-parametric continuous or ordinal data are also reported. This allows assessment of the representativeness of the sample to enable conclusions to be drawn about any selection bias impact on results and generalisability.

4.10.7 Missing data

Individual items were at times missing within a questionnaire and this needed to be accounted for in the analysis and calculation of the total score. The pattern and frequency of missing data are reported. The method to deal with individual missing items recommended by the authors of FAMCARE is to calculate a pro rata total score. This method was used here. It is an acceptable method as long as more than 50% of questions were answered. If more than 50% of questions were unanswered, the participant's questionnaire was excluded from the analysis. Descriptive analysis was used to define whether missing items were missing at random or there was a pattern to the missing data.

Prorated FAMCARE score =

$$\frac{(\text{sum of individual items}) \times 20}{\text{Total number of items answered}}$$

4.10.8 Analysis

The primary outcome of the study was to describe bereaved relatives' satisfaction with the care of the dying patient at RMFT. Therefore, the analysis for the primary outcome was largely descriptive. The FAMCARE scoring system has been reversed to ease interpretation so that high numbers correlate to high levels of satisfaction. The reversed scoring system is shown in Table 4.17 below. Principle component analysis followed by multiple regression was used to determine the association between demographic and preference factors and satisfaction scores.

Table 4.17: Reverse FAMCARE scoring system

Response	Score
Very dissatisfied (VD)	1
Dissatisfied (D)	2
Undecided (U)	3
Satisfied (S)	4
Very Satisfied (VS)	5

4.10.9 Analysis of Qualitative free text comments

The qualitative raw data for analysis consisted of free comments returned with the questionnaire. Thematic framework analysis was used as described in Section 4.9.6

4.10.10 Adverse events

The postal questionnaire encouraged the bereaved relative to highlight to the research team if they felt they required any further bereavement support. If this was the case, I then made contact to assess needs and signpost to specialist services where appropriate. I discussed all such cases with the PI for the study. A protocol was written to ensure bereavement concerns were managed in a timely standardised way. This is detailed in Appendix 7.3.22

4.11 Factors influencing Place of Death (PoD)

4.11.1 Introduction

A clear understanding of factors that influence the PoD of cancer patients is essential to both the design and critical evaluation of new models of service delivery at the EoL [69].

The primary objective of this part of study was to determine factors that significantly influence the PoD of patients known to the Royal Marsden NHS Foundation Trust (RMFT), a tertiary referral cancer centre, in the year 2010-2011 (Objective 22). This part of the study was a retrospective analysis of data held on the RMFT EPR system. Source data were obtained from the hospital EPR System (EPRS). The RMFT service evaluation committee approved the study.

4.11.2 Participants

Participants were patients of the RMFT who were known to have died between 1st April 2010 and 31st March 2011 inclusive. All potential patient participants were identified using a search of the EPR System.

Inclusion criteria:

- Adult patients over the age of 18
- Recorded as deceased 1st April 2010-31st March 2011

Exclusion criteria:

- PoD was outside the United Kingdom
- Last contact with RMFT was greater than six months prior to death
- Patient was seen as an opinion only and received their anti-cancer treatment outside RMFT
- The main cancer diagnosis being treated by the RMFT was a skin cancer

The rationale for exclusion criteria was a pragmatic one given the objective of the study. The RMFT would be unlikely to influence PoD for those patients in whom the last contact with RMFT was greater than six months prior to death, or in whom the RMFT gave an oncological opinion only. Data for all patients meeting the eligibility criteria were analysed.

4.11.3 Data checking and Analysis

Two researchers for all eligible patients were transferred into Microsoft Excel from the EPR System; data accuracy checked demographic and clinical information. Data were then imported into SPSS for statistical analysis. In cases where the primary outcome measure, PoD, was missing from the EPR, these data were obtained from GP records by telephone.

The primary end point for this study was PoD. For the purpose of analysis, PoD was divided into two binary categories: First analysis 1) Home, 2) Other location and Second analysis 1) Hospital, 2) Other location.

Forward stepwise binary logistic regression was used to determine the factors that statistically favour home or hospital death. The factors included in the analysis, along with the full study protocol, are available in Appendix 7.4.8. Factors included age, gender, ethnicity, performance status, marital status, Primary Care Trust (PCT) spend on palliative care, deprivation indices, cancer site, lead clinical team, hospital palliative care involvement, CPCT involvement, H2H team involvement, last anti-cancer treatment, time from last anticancer treatment to death, type of last contact with RMFT and time from last contact with RMFT to death.

Each factor was tested individually and all factors found to have a p value of ≤ 0.20 on the univariate analysis were used in the multivariate analysis to determine independent predictors of PoD. For the multivariate analysis, a p value of <0.05 was considered statistically significant. The categories used for each factor, along with the SPSS coding, are detailed in Appendix 6.3.8.

Descriptive statistics were used to report results of patients dying in five main locations (home, hospice, hospital, nursing home and elsewhere) in 2010-2011.

4.11.4 Outcome measure: PoD

The categorization of the PoD relies on the accuracy of the source data (the RMFT EPR) or the GP records (when PoD was missing from the source data).

The descriptive statistics used to report the proportion of patients dying in each main location used the ONS definitions:

- Home: death occurred in the participant's own residence, a relative's residence or a local authority or private residential home.
- Nursing home: death occurred in an NHS or private nursing home.
- Hospital: death occurred in an NHS, non-NHS, acute, community or psychiatric hospital.
- Hospice: death occurred in a freestanding hospice inpatient facility.
- Elsewhere: death occurred in another location not encompassed by any of the definitions of home, nursing home, hospital or hospice. For example, death in an ambulance or in a public place.

The primary outcome for the logistic regression analysis was binary: First analysis: Home or other location; Second analysis: Hospital or other location. Other location as an outcome was a summation of all locations listed above excluding the location of interest.

4.11.5 Rationale for factors chosen for analysis

A total of twenty-one factors were evaluated as part of the univariate analysis. The rationale for the factors chosen was twofold. Firstly, as detailed in Table 1.2, factors that were identified in the recent meta analysis [28] to influence home deaths in cancer patients were included in the analysis. Secondly, through discussion with the study advisory group, additional factors specific to the setting of the RMFT were included. These factors can be divided into three categories: personal factors, illness factors and environmental factors. Each of these categories and the factors therein are detailed in Table 4.18; factors in **bold** were unique to this analysis.

All factors except deprivation and palliative care spend were derived direct from the source data with continuous variables being grouped into categories and each group assigned a reference category as detailed in Appendix 7.3.23.

Table 4.18: Factors included in the univariate analysis of PoD.

Individual Factors	Environmental Factors	Illness Factors
Age[52, 53]	Living alone[28, 45]	Performance Status[28, 53]
Gender[49, 53]	IMD Deprivation Quintile[28, 49]	Treatment Site
Ethnicity[28, 45]	PCT Spend/Death Quartile	Cancer Diagnosis[28, 49]
Marital Status[28, 45]	Known CPCT[45]	Survival from diagnosis[28]
	H2H	Last appointment type
		Survival from last appointment
		Last treatment type
		Last treatment intent
		Survival from last treatment
		Number of admissions[28, 45]
		Known to Hospital PCT

***Bold text** factors were RMFT specific factors not tested elsewhere

A deprivation score was assigned to each participant based on his or her postal code. There are a number of different deprivation indices in use in health care research. In this instance, the Index of Multiple Deprivation (IMD 2010) index was used to assign participants a deprivation score by linking their postal code to a Local Super Output Area (LSOAs) generating a deprivation score, rank and quintile. The deprivation scores for participants in this study were generated by A Pring, Senior Analyst at the South West Public Health Observatory employing computer software used in his recent work for the National EoLC Intelligence Network [2] 'Deprivation and Death: Variation in Place and Cause of Death'. This also enabled the results to be directly compared to this published work.

The factor 'palliative care spend' was derived from linking the participant's Primary Care Trust (PCT), available from source data, to data held by the DoH on PCT palliative care spend in the year 2010[223]. Palliative care spend per PCT was available as pounds (£) per population head and also as pounds per death (£). Each of these denominators were ranked into quartiles, and a quartile assigned to each participant.

4.12 Ethics and R&D approvals

Ethics approval was received from the London Research Ethics Committee (REC number: 10/H0718/24). Approval was also sought from the Royal Marsden Foundation Trust (RMFT) Research and Development committee and the RMFT sponsored the study. Appendix 7.3.24 includes the approval letters from the North London REC ethics committee and research and development committee at RMFT.

CHAPTER 5: FEASIBILITY AND PILOTING PHASE: RESULTS

5.1 Recruitment, participant characteristics, follow up and survival

Objective 5: *To determine the feasibility of studying the H2H in this setting by **assessing inclusion and exclusion criteria, recruitment rates, retention, follow up rates and missing data***

This section describes the context of the study findings. This includes the demographic and clinical characteristics of the total study population and each study group. In this section, I report recruitment rates, follow up and attrition rates, survival of each study group and finally recruitment and participant characteristics in the qualitative component of the study. These data are then revisited in the section summary 5.1.5 to describe the feasibility findings of the study design.

The data are presented in five subsections:

- 5.1.1. Quantitative results: Recruitment, follow up and attrition
- 5.1.2 Quantitative results: Characteristics of the study groups
- 5.1.3 Quantitative results: Death, Prognosis and survival
- 5.1.4 Qualitative interviews: Recruitment and participant characteristics
- 5.1.5 Section Summary: Feasibility of study design

5.1.1. Quantitative results: Recruitment, follow up and attrition

5.1.1.1 Recruitment

Overall, 234 patients met the inclusion criteria of gastrointestinal or lung cancer with no further oncological treatment options available. One hundred and forty seven were identified at the main site (MS) and 87 at the satellite site (SS). All these patients were assessed by a clinician, given a PIS and referred to me for recruitment. Eighty-three patients were recruited into the quantitative arm of the study.

Figure 5.1 illustrates the recruitment of patient participants into the study.

Of the 234 potential participants screened for the study, eight (3.4%) were excluded because the inclusion criteria for the study were not met (due to lack of capacity or an estimated prognosis of less than 2 weeks). Twenty-five (10.7%) died before contact, whilst 13 (5.6%) had been admitted to hospital or hospice between discharge from the RMFT and contact. Four (1.7%) were not contactable by phone.

The remaining 184 patients were invited to participate; 101 declined (40 felt too unwell, 61 preferred not to participate) and 83 (45%) were successfully recruited. Table 4.1 gives further detail of recruitment at the main site and satellite site respectively. This shows a MS recruitment rate of 35.7% compared with 59.7% at the SS. The recruitment rate at the SS was over 20% higher than the MS, with a lower proportion admitted elsewhere (hospice/hospital) before study contact (2.3% SS compared to 7.5% MS participants).

Potential participants at the SS received standard care alone (n=41) and made up the majority (84%) of the AC group (AC). Potential participants recruited at the main site were referred to H2H or received standard care alone. This was clinician choice or patient choice, and therefore a small number (n=8, 16%) became part of the AC group. All analyses compare H2H participants with all those not receiving the intervention (AC group).

Figure 5.2 gives recruitment rates per month over the study period. Over the 3-year period (August 2010-July 2013), there was a steady recruitment rate of between 2-5 participants per month (mean 2.3, median 2). This was considerably lower than the 8 participants per month required to ensure the target sample size of 180 patient participants was met over the 2-year period. The study was extended by an extra year to maximise recruitment however the target sample size was not met.

When a patient participant was successfully recruited, the patient was invited to identify a carer to participate alongside them. Carer consent was sought separately to patient consent. Of the 83 patient participants recruited, 55 identified a carer and 43 of these were successfully recruited (78%).

Figure 5.1. CONSORT recruitment figure for H2H quantitative feasibility

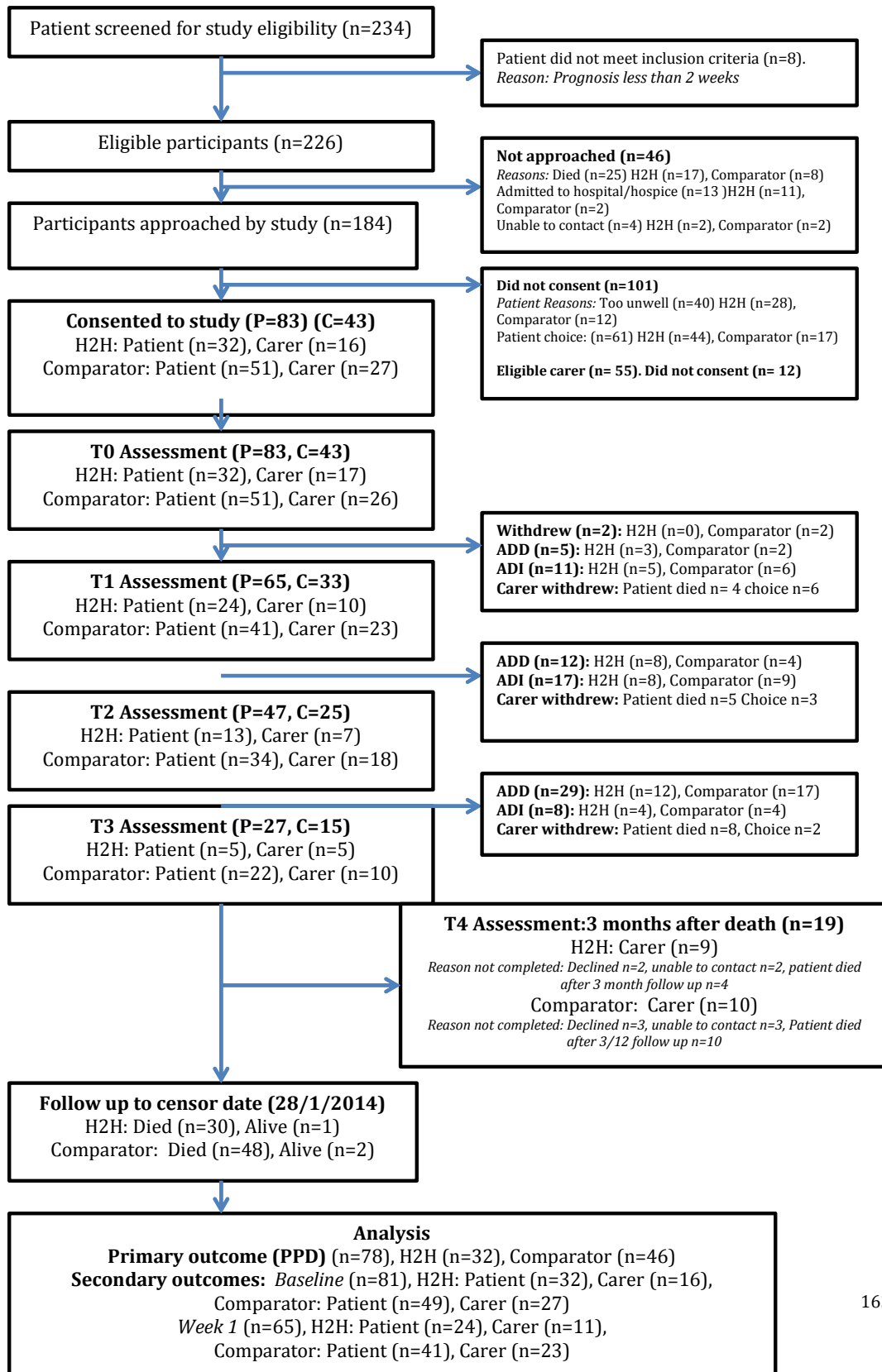
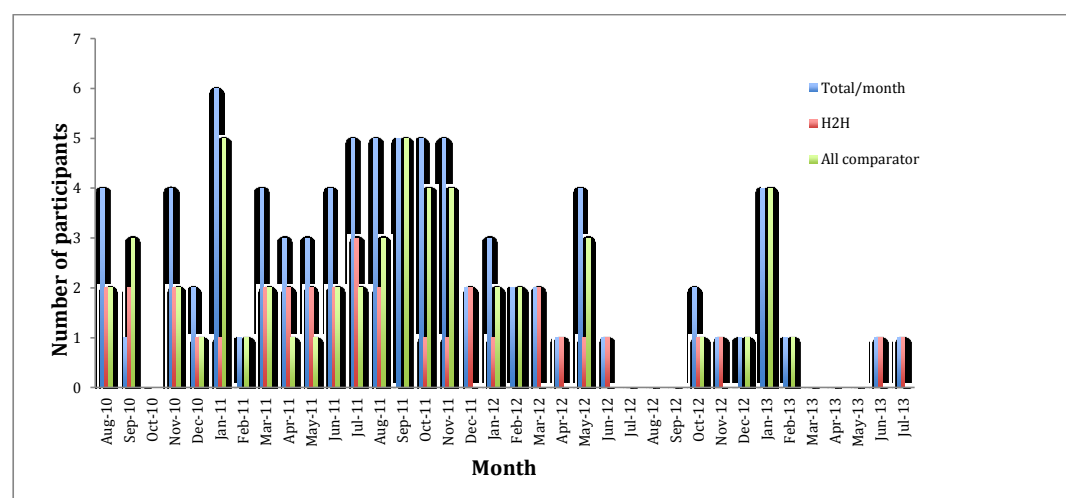


Table 5.1. Recruitment to study by location and study group

Identified for the study	Total n (%)	Main Site n (%)	Satellite Site n (%)
Identified as appropriate for study	234	147 (62.8)	87 (37.2)
Not eligible	8 (3.4)	5 (3.4)	3 (3.4)
Died before contact	25 (10.7)	17 (11.6)	8 (9.2)
Admitted to Hospital/hospice before contact	13 (5.6)	11 (7.5)	2 (2.3)
Unable to contact	4 (1.7)	2 (1.4)	2 (2.3)
Invited to participate	184 (78.6)	112 (76.2)	72 (82.8)

		Total n (%)	Main Site n (%)	Satellite Control site n (%)
Invited to participate		184	112 (60.9)	72 (39.1)
Recruited to study		83 (45.1)	40 (35.7)	43 (59.7)
		<i>H2H</i>	<i>32 (80)</i>	
		<i>MS control</i>	<i>8 (20)</i>	
Declined to participate	Total	101 (54.9)	72 (64.3)	29 (40.3)
	Too unwell	40 (21.7)	28 (25.0)	12 (13.8)
	Patient Choice	61 (33.2)	44 (39.3)	17 (19.5)
Carer invited to participate		55		
Carers recruited to study		43 (78.2)		

Figure 5.2 Recruitment rates per month.



5.1.1.2 Follow- up and attrition

The median length of follow-up of participants was 76 days (range 3-1015 days): H2H – 45.5 days (range 3-900) and AC 111 days (range 3-1015).

The primary outcome measure was PPD. There was minimal loss of follow up for this primary outcome. The reasons for loss of follow up for the primary outcome were withdrawal from the study or still alive at the end of study follow up period (censored 28/01/2014). Two patients withdrew from the study: one from each study group. Each of these withdrew after the initial assessment. Three patient participants were alive at study censor: one from the H2H study group and two from the AC group. Therefore, the total number of participants included in the primary outcome analysis was seventy-eight.

The low withdrawal rate-n=2 (2.4%)- from the study reflects the detailed explanation of the study during the consent process and suggests the study schedule and assessments were not overly burdensome. The two participants both withdrew between initial assessment and week 1 follow up. The reason for withdrawal in both cases was time constraints. These participants are excluded from all analysis.

Secondary outcome data were collected through longitudinal questionnaires. Loss to follow up due to being too unwell (ADI) or due to death (ADD) were the most common causes of loss of secondary outcome data. The total number of participants alive at each data collection time point and loss of follow up to secondary outcome data are given in detail in Section 5.3.2

5.1.2 Quantitative results: Characteristics of the study groups

The study was not randomised; therefore, in order to evaluate the feasibility of this quasi-experimental design and inform the validity of preliminary results, this section compares the demographics and clinical variables for the study populations. In the design of this feasibility study, the analysis plan was to compare H2H to AC participants (Main site controls + Satellite site controls).

Table 5.2 gives a comparison of clinical and demographic variables for H2H and AC participants.

The two study groups had broadly similar demographic characteristics. The two study group participants had a similar mean age of 70.3 (SD 12.5) years and 75 (SD 9.5) years for the H2H and AC groups respectively. Almost all participants were White British in ethnic origin. Most participants were married or living with a partner (H2H 78%, AC 73.5%). Over 60% at each site (H2H 62.5%, AC 65.3%) were known to the CPCT prior to discharge.

Illness characteristics including extent of disease, number of metastasis, number of cancer treatments and last treatment type were all comparable across both groups. Although not statistically significant, the AC study group had a higher proportion of participants with lung cancer compared to the H2H group (Lung cancer H2H 40%, AC 57%). The PPS (PPS) also showed variation across the study groups. PPS was lower, indicating a poorer health state, in the H2H group compared to the AC group with a higher proportion of H2H participants with a PPS less than forty at recruitment (PPS < 40 H2H 18.8%, AC 2%). Survival from diagnosis was not statistically different across the study groups; however, survival from study entry was statistically shorter in the H2H study group. H2H group median survival was 45.5 days compared 111 days in the AC group ($p=0.003$).

The comparison of H2H and AC participants does highlight three patient variables that are statistically significant across the two study groups: ethnicity, home-ownership and survival from discharge. H2H study participants were less likely to own their own home ($p=0.02$), more likely have an ethnicity other than White British ($p=0.02$) and had a significantly shorter survival ($p=0.02$) than AC participants. Although some statistically significant outcomes may not be clinically relevant, ethnicity, home-ownership status and survival have all been linked to

an increased likelihood of dying in hospital and less likelihood of dying at home[28]. Since the majority of patients prefer to die out of hospital, it must be considered that in the exploratory analysis of this feasibility study these patient variables may make the H2H participants less likely to achieve their PPD (primary outcome for the study). The exploratory primary outcome analysis attempts to account for this by employing multivariate analysis to determine any confounding factor influence on PPD.

Table 5.2 Demographic and clinical variables of A) Total Population, B) H2HStudy Group and C) AC Group
(continues onto next page)

PATIENT DEMOGRAPHICS	A) Total Population	B)H2H (n=32)	C) AC Group (AC) (n=49)	Statistics comparing B) &C)
AGE IN YEARS				
Mean (SD)	73.2 (10.9)	70.3(12.5)	75.0 (9.5)	Mann Whitney U test
Median	76	71.5	77	Z= -1.71
Range	(36-89)	(36-89)	(43-89)	p= 0.09
GENDER				
Number (%)				
Male	63 (77.5)	29 (90.6)	34 (69.4)	$\chi^2= 3.89$
Female	18 (22.5)	3 (9.4)	15 (30.6)	p= 0.05 (cc)
ETHNICITY				
Number (%)				
White British	77 (95.1)	28 (87.5)	49 (100)	Fisher's Exact Test p=0.02
Other	4 (4.9)	4 (12.5)	0 (0)	
MARITAL STATUS				
Number (%)				
Married/Partner	61 (75.3)	25 (78.1)	36 (73.5)	$\chi^2=0.05$
Other	20 (24.7)	7 (21.9)	13 (26.5)	p=0.83 (cc)
LIVING ALONE				
Number (%)				
Yes	27 (33.3)	9 (28.1)	18 (36.7)	$\chi^2=0.32$
No	54 (66.7)	23 (71.9)	31 (63.3)	p=0.57 (cc)
INFORMAL CARER				
Number (%)				
Yes	60 (74.1)	27 (84.4)	33 (67.3)	$\chi^2=2.10$
No	21 (25.9)	5 (15.6)	16 (32.7)	p=0.15 (cc)
CARER RELATIONSHIP				
Number (%)				
No carer	42 (51.9)	17 (53.1)	25 (51.0)	$\chi^2=6.26$
Spouse	31 (38.3)	15 (46.9)	16 (32.7)	p=0.10
Adult Child	6 (7.4)	0 (0)	6 (12.2)	
Other	2 (2.5)	0 (0)	2 (4.1)	
EXTENDED FAMILY SUPPORT				
Number (%)				
Yes	56 (69.1)	21 (65.6)	35 (71.4)	$\chi^2=0.09$
No	25 (30.9)	11 (34.4)	14 (28.6)	p=0.76 (cc)
ACCOMODATION TYPE				
Number (%)				
House	56 (69.1)	18 (56.3)	38 (77.6)	$\chi^2=4.82$
Flat	18 (22.2)	11 (34.4)	7 (14.3)	p=0.09
Other	7 (8.7)	3 (9.4)	4 (8.2)	
HOME OWNER				
Number (%)				
Yes	67 (82.7)	22 (68.8)	45 (91.8)	$\chi^2=5.69$
No	14 (17.3)	10 (31.3)	4 (8.2)	p=0.02
KNOWN TO CPC				
Number (%)				
Yes				
No	52 (64.2)	20 (62.5)	32 (65.3)	$\chi^2=0.00$
	29 (35.8)	12 (37.5)	17 (34.7)	p=1.0 (cc)

ILLNESS FACTORS	(A) Total Population	(B) H2H	(C) AC group	Statistic comparing B) & C)
CANCER DIAGNOSIS <i>Number (%)</i> Lung Gastrointestinal	41 (50.6) 40 (49.4)	13 (40.6) 19 (59.4)	28 (57.1) 21 (42.9)	$\chi^2= 1.5$ $p= 0.22$ (cc)
EXTENT OF DISEASE <i>Number (%)</i> Local disease Metastatic disease	22 (27.2) 59 (72.8)	5 (15.6) 27 (84.4)	17 (34.7) 32 (65.3)	$\chi^2= 2.66$ $p= 0.1$ (cc)
NUMBER OF SITES OF METASTASIS Mean (SD) Median Range	1.3 (1.1) 1 (0-5)	1.53 (1.1) 1 (0-5)	1.08 (1.06) 1 (0-4)	Mann Whitney U test Z=-1.9 $p=0.06$
TOTAL NUMBER OF CANCER TREATMENTS Mean (SD) Median Range	2.05 (1.86) 2 (0-9)	2.41 (2.3) 2 (0-9)	1.82 (1.5) 2 (0-5)	Mann Whitney U test Z=-0.87 $p=0.38$
LAST TREATMENT TYPE No Treatment Chemotherapy Radiotherapy Surgery	19 (23.5) 49 (60.5) 10 (12.3) 3 (3.7)	7 (21.9) 20 (62.5) 4 (12.5) 1 (3.1)	12 (24.5) 29 (59.2) 6 (12.2) 2 (4.1)	$\chi^2= 0.14$ $p=0.99$
OTHER COMORBIDITIES <i>Number (%)</i> Yes No	57 (70.4) 24 (29.6)	20 (62.5) 12 (37.5)	37 (75.5) 12 (24.5)	$\chi^2= 1.00$ $p=0.32$ (cc)
ESTIMATED PROGNOSIS <i>Number (%)</i> Weeks Months/Year	15 (18.5) 66 (81.5)	5 (15.6) 27 (84.4)	10 (20.4) 39 (79.6)	$\chi^2=0.06$ $p=0.80$
PPS <i>Number (%)</i> <40 41-60 61-80 >80	7 (8.6) 22 (27.2) 43 (53.1) 9 (11.1)	6 (18.8) 9 (28.1) 15 (46.9) 2 (6.2)	1 (2.0) 13 (26.5) 28 (57.2) 7 (14.3)	$\chi^2=7.78$ $p=0.05$
SURVIVAL FROM DIAGNOSIS (DAYS) Mean (SD) Median Range	677.6 (755) 415 (32-3990)	615.9 (664.8) 372 (68-3636)	717.9 (812.3) 432 (32-3990)	Mann Whitney U test Z=-0.35 $p=0.73$
SURVIVAL FROM DISCHARGE (DAYS) Mean (SD) Median Range	177.1 (222.3) 83 (7-1023)	105.3 (187) 45.5 (3-900)	193.2 (234.2) 111 (3-1015)	Mann Whitney U test Z=-2.94 P<0.01

5.1.3 Quantitative results: Death, survival and predicting study eligibility

5.1.3.1 Death and survival

The statistically significant discrepancy in survival between the two groups is likely to be highly clinically relevant and will influence the interpretation of further exploratory analyses of the primary and secondary outcomes. Therefore, this subsection gives more detailed analysis of survival across the study groups.

The study was censored on the 28th January 2014. At this time, seventy-eight patient participants had died and three remained alive (1 H2H participant, and 2 AC participants). Table 5.3 gives detail of the 12-week survival of the total population and each study group. Overall, 57% of the total study population died in the 12 weeks secondary outcome assessment period. The H2H group had significantly fewer participants alive at 12 weeks than the AC group ($p=0.02$). Twenty-eight percent of H2H participants were alive at 12 weeks compared to 53% of AC participants ($p=0.02$). H2H participants were closer to the EoL during the collection of secondary outcome data than the AC group.

Table 5. 3 Twelve week survival of all subgroups, H2H, AC group and subgroups: main site (MSC) comparator and satellite site comparator (SSC)

SURVIVED TO 12 WEEKS	Total Population (n=81)	(A) H2H Group (n=32)	(B) AC Group (n=49)	C) Main Site (MSC) (n=8)	D) SC group (n=41)	Statistics comparing (A) & (B)
	(n, %)					
Yes	35 (43)	8 (28)	26 (53.1)	4 (50)	22 (53.7)	$\chi^2=5.2$ df 1 p=0.02
No	46 (57)	23 (72)	23 (46.9)	4 (50)	19 (46.3)	

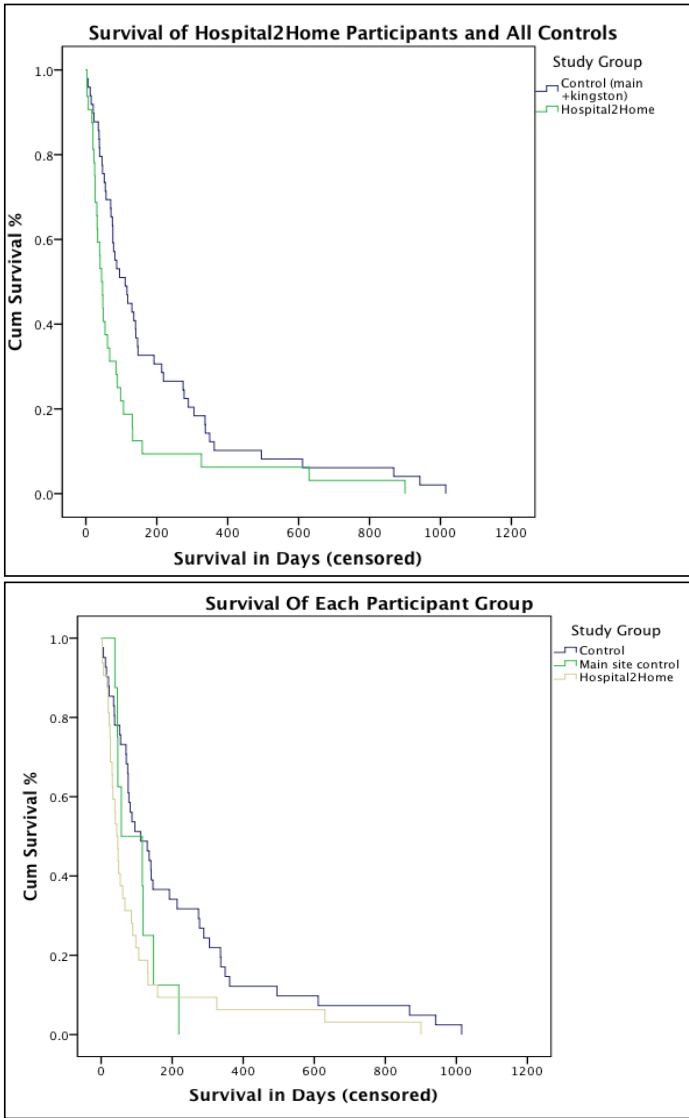
* Continuity correction quoted as 2 x 2 table

Overall, 96% of participants died during the study period up to the censor date (28/1/2014). Examination of the overall survival of each subgroup- H2H, main site controls (MSC) and SSC- demonstrates that the H2H participants had a significantly lower median survival (45.5 days) than the AC group (111 days) ($p=0.003$) (Table 5.4 & Figure 5.3). Figure 5.3 shows that survival is also significantly shorter than either comparator subgroup (MSC 86.5 days, and SSC 111 days).

Table 5.4: Censored Survival (Days) of each study group

Survival (in days)	H2H (A) n=32	AC (B) n=49	MSC n=8	SSC n=41	Statistical comparison (A) & (B)
Mean	105.3	193.2	98.6	211.6	Mann-Whitney U test 479.5 z=-2.94 p <0.01
SD	187	234.2	63.5	251.0	
Median	45.5	111	86.5	111	
Range	3-900	3-1015	39-219	3-1015	

Figure 5.3 Kaplan-Meier survival curves for the H2H study group and AC group



5.1.3.2 Quantitative results: Predicting Prognosis and Study Eligibility

An inclusion criterion for this feasibility study was an estimated prognosis of greater than 2 weeks. At study entry, the referring clinician was asked to predict the participant's prognosis, categorised as days, weeks or months.

Table 5.5 shows the accuracy of hospital HCPS at estimation of prognosis. An accurate prognosis was as follows.

- Days = Survived 7 days or less
- Weeks = Survived between 8- 31 days
- Months = Survived between 32- 365 days

Prognosis was accurately predicted in 71.6% of the total population. However, although not significant, the H2H study group prognosis was predicted with less accuracy than that of the AC group (59.4% and 79.6% respectively, $p=0.09$).

Table 5.5 Accuracy of Oncologist Prognosis at the time of recruitment to the study

PROGNOSIS ACCURATELY PREDICTED	Total (n=81)	(A)H2H (n=32)	(B) AC group (n=49)	MSC (n=8)	SSC (n=41)	Statistics comparing (A) & (B)
	(n, %)					
Number (%)						
YES	58 (71.6)	19 (59.4)	39 (79.6)	5 (62.5)	34 (82.9)	$\chi^2= 3.00$ df 1 $p= 0.09$
NO	23 (28.4)	13 (40.6)	10 (20.4)	3 (37.5)	7 (17.1)	

* Continuity correction quoted as 2 x 2 table

5.1.4 Recruitment to the Qualitative interviews

Thirteen patients were approached to participate in the qualitative interviews. Five declined to be interviewed: three felt too unwell, two declined due to time constraints. Fifteen oncology consultants were approached to participate of whom 13 agreed to be interviewed. This was a response rate of 62% for the patient group and 87% for the consultant oncology group. All three H2H SS agreed to be interviewed.

There were difficulties with patient recruitment. However, despite the small number of patient participants, data saturation was reached at 6 patients and 10 oncology consultants and therefore recruitment was stopped before the 20 patient and 20 HCPS interviews.

The patient participants had a median age of 70 years (62-91), five were male, five were living alone and only two were married with three widowed and three patient participants single. At the time of the in-depth interview, six had metastatic disease whilst two had locally advanced disease. The median PPS (PPS) of participants was 50 (50-90). A median PPS of 50 indicates that these participants were mainly sitting or lying down for most of the day and requiring considerable assistance with self-care. Thus, at the time of interview the burden of cancer was having a significant impact on the participants' daily life. Five patient participants were known to the CPC services. The median survival from interview to death was 34 days. Four participants died in the month following their interview. The participant with the shortest survival was Mark, who died 11 days after he completed his qualitative interview. The longest survivor was John, who lived for 100 days (3.2 months) after interview. Nine of the oncology consultants interviewed were male, and ten had at least ten years experience as an oncology consultant. Eight regularly referred to H2H.

Table 5.6 gives detail of the patient participant characteristics and compares these to the participants in the quantitative component of the study. Demographics were broadly similar, except fewer participants in the qualitative interviews were married. Also, as participants with any cancer diagnosis could participate in the qualitative interviews, the range of cancer diagnoses was different.

Table 5.6 Qualitative results: Patient participant characteristics comparison with quantitative H2H participants

Patient Characteristic		n of patients (%)	Participants in quantitative H2H study group (%)
Gender	Male	5 (62.5)	90.6
	Female	3 (37.5)	9.4
Age	Median	69.5	71.5
	(min,max)	(62,91)	(36,89)
Self-assigned ethnicity	White British	7 (87.5)	87.5
	White Other	1 (12.5)	12.5
Marital Status	Married	2 (25)	78.1
	Single	3 (37.5)	21.9
	Widowed	3 (37.5)	
Living Alone	Yes	5 (62.5)	28.1
Cancer diagnosis	Lung	2 (25)	40.6
	Gastrointestinal	2 (25)	59.4
	Gynaecological	3 (37.5)	0
	Urological	1 (12.5)	0
Extent of disease	Locally advanced	2 (25)	15.6
	Metastatic	6 (75)	84.4
Length of disease	Median in days (min, max)	465 (242, 3590)	372 (68, 3636)
PPS	Median (min, max)	50 (50, 90)	
Survival after interview	Median in days (min, max)	34 (11, 100)	-
Known to CPCT	Yes	5 (62.5)	62.5

Table 5.7 Qualitative results: Oncology consultant characteristics

Characteristic		n of oncologists
Gender	Male	9
	Female	4
Field of Oncology	Medical Oncology	8
	Clinical Oncology	5
Number of Years as Oncology Consultant	< 5 years	3
	5-10 years	0
	10-15 years	5
	> than 15 years	5
Regularly refer to H2H	Yes	5
	No	8

5.1.5 Section summary: Feasibility of study design

5.1.5.1 Recruitment and retention in a longitudinal study

The results in section 5.1 provide insight into Aim 2 'To determine the feasibility of evaluating H2H in a cancer population (*feasibility phase* of MRC framework)'. These data inform the research methods for the definitive trial. Specifically, the data here addresses Objective 5.

Objective 5: To determine the feasibility of studying the H2H in this setting by assessing inclusion and exclusion criteria, recruitment rates, retention, follow up rates and missing data

The recruitment rates for this study are shown in detail in Section 5.1.1.1 This was an exploratory feasibility study, and as such sample size calculations are of questionable value. However in order to give this feasibility study a recruitment target a sample size calculation based on achievement of PPD was used as a guide (This is detailed in Section 4.8). The overall target for recruitment over the two-year study period was 180 participants. The second success criteria for study recruitment was that at least 20% of the eligible pool of potential patient participants would be recruited to the study at each site[186], and that 70% of informal carers would be recruited. The total number of patients screened for the study (given a PIS) was 234 although due to the reasons detailed in Figure 5.1 fifty patients were not then approached by myself as the researcher. The main reason for this was death before contact. 184 patients were approached, of these 83 were recruited (recruitment rate 45%, MS recruitment rate 35.7%, SS recruitment rate 59.7%). The two main reasons for not participating were; feeling too unwell and patient choice. Fifty-five patient participants identified an informal carer, 43 (78%) were recruited. The overall target sample size for this study was **not met** although the success criteria for recruitment rates were **met**. The recruitment target (n=180) was not reached. The study had an overall screen to recruitment rate of 45%. This is an important finding to inform methods for the definitive trial as it indicates the need for high resources or a change in inclusion criteria (to include those without consent) to improve the likelihood of meeting recruitment targets. The implications of the recruitment rates and participant survival on the feasibility of the study and sample size of a larger definitive trial are discussed in Chapter 6

The eligibility criteria for the study included a prognosis of at least 2 weeks. It was assumed that most participants would be approaching the EoL and die during the study follow up. Over the three and a half year study period until censor date (28/01/2014) 78 participants had died. It was expected that the majority would die during the first 12 week follow up, and therefore secondary outcome data would reflect symptom burden, QoL and service use at EoL. The criterion for evaluating if the correct population were studied was that > 60% died during the first 12 weeks follow up. Overall, 58% of the total study population died in the first 12 weeks. This is just below the feasibility criteria set. Across groups, 72% of H2H participants died during the 12 weeks period compared to 55% of AC participants. H2H participants were closer to the EoL during the collection of secondary outcome data than the AC group.

This study was not randomised and therefore feasibility criteria were set with regards to the potential differences in demographic and clinical parameters between study groups. The choice of comparator group was deemed feasible if 10% or less of the demographic, illness related or environmental variables were statistically different across the groups. Three patient variables (3/20, 15%) were significantly different across study groups meaning the feasibility success criteria were **not met**. Some statistically significant outcomes may not be clinically relevant nonetheless the three variables; ethnicity, home-ownership status and survival have all been linked to increase likelihood of dying in hospital[45]. The H2H group had more participants from ethnic minority backgrounds, less homeowners and shorter survival than the AC group. Therefore, to mitigate for this, adjusted analysis was performed for the PPD. Overall, the broadly similar distribution of demographic and clinical variables across the two study groups suggests study groups are largely comparable. This is important for any early effectiveness findings reported in this exploratory feasibility study as it was not randomised and is a comparison of outcomes for two pre-existing groups of participants. It is important to highlight that the survival between the two study groups is significantly different and this needs to be taken into account when interpreting the results of both the primary and secondary outcomes. H2H study participants had a significantly shorter prognosis than AC participants (median survival H2H 45 days, AC 111 days $p<0.01$). The significance of the shorter survival may be linked to other factors (not known or not collected) that contribute to complexity and encourage referral to H2H. The results of the qualitative interviews with oncologists to be presented in Section 5.7.2 highlight complexity - physical or social - as a

reason to be more likely to refer to H2H. This 'complexity' was not measurable and thus not accounted for in the primary and secondary outcome exploratory analyses.

Finally retention of participants in this longitudinal feasibility study was good. There was a low withdrawal rate, only 2 participants withdrew (2.4%). This confirms patients approaching the EoL are willing to participate in longitudinal research and that the study schedule was acceptable. The feasibility success criterion of less than 10% withdrawal was **met**.

5.1.6.2 Feasibility of a mixed-method embedded qualitative design

The qualitative component of the study was slow to recruit. The target number of 20 patient interviews was not met. HCP interviews stopped at 16 participants due to data saturation. It was difficult to recruit patients who had participated in a CC to the interviews. The main reason for this was that the potential participants approached felt too unwell to undertake a 30-45 minute interview. Indeed I chose to end one qualitative interview early due to patient fatigue. At study design it was envisaged that participating in both the quantitative component and the qualitative component of this feasibility study may be too burdensome for patients and therefore the inclusion criteria for the qualitative interviews was not confined to patients recruited to the quantitative study. A broader inclusion criterion of any patient receiving a face to face CC was employed. However, despite this, recruitment was slow. Although all quantitative participants were approached for the qualitative interviews only two of the 8 patient participants in the qualitative interviews were also participants in the quantitative study. Quantitative participants were approached for the qualitative interviews at week 1 of the quantitative study. This time point was chosen to limit the burden of the initial visit however attrition due to illness or death was high at week 1 (25%) limiting the number of potential participants for the qualitative interviews. Recruiting to the qualitative interviews from outside the quantitative study recruits was reasonable in this feasibility study to understand the broader experience of H2H. However, these findings suggest that an embedded mixed method design with patient qualitative interviews will not be feasible in a larger definitive trial. The recommendation therefore is that embedded interviews with carers and community HCPs will be more feasible in the definitive trial. This is considered further in the discussion chapter (Chapter 6)

No participant found the qualitative interview experience distressing, and most patient participants commented that they had found it helpful and therapeutic to tell their story[210]. The HCPS participants also described the interview as therapeutic and giving them time to reflect on their current practice. Dr Peel typified this:

CS: *"How have you found this interview?"*

Dr Peel: *"Interesting..mmm...thought provoking....I think it's just been interesting because it's made me think about what, why and how we do things. Its left me feeling like there still is quite a lot we can do to improve things"*

5.2 Quantitative Analysis: Primary Outcome – Achievement of PPD (PPD)

5.2.1 Section Introduction

This section presents the primary outcome measure of this feasibility study. The results consider the feasibility of PPD as an outcome measure, compare the proportion of participants in each study group who achieve their PPD and also describe the PoD of participants in the study. This section answers Objectives 6, 13&14.

Objective 6: *To assess potential outcome measures for H2H intervention, and scrutinise the value of these outcome measures in this setting*

Objective 14: *To explore preliminary hypothesis testing to provide an estimate of the effectiveness of H2H compared with standard care as measured by the achievement of PPD*

Comment [CM1]: These objectives need changing

Objective 15: *To describe and compare the actual of PoD of H2H intervention group with standard care.*

The data in this section is presented in five subsections:

- 5.2.2 Feasibility of PPD as an outcome measure
- 5.2.3 Achievement of PPD
- 5.2.4 Achievement of PPD considering confounding factors
- 5.2.5 PoD
- 5.2.6 PoD considering confounding factors
- 5.2.7 Section summary

5.2.2 Feasibility of PPD as an outcome measure in EOLC research

This subsection addresses Objective 6 of the study:

Objective 6: *To assess potential outcome measures for H2H intervention, and scrutinise the value of these outcome measures in this setting*

5.2.2.1 Collection of PPD and missing data

In this feasibility study **Achievement of PPD** (Congruence) was the tested primary outcome measure. In order for PPD to be a useful outcome measure it must be both measurable and relevant to the area of study[128]. For reasons discussed in Chapter 1 Section 1.4 PPD is highly relevant to the study of H2H, this section details whether it was reliably measurable as an outcome measure

Achievement of PPD as a primary outcome measure requires two pieces of data collection to be complete:

1. PoD
2. Documented PPD

1. PoD: Three participants were alive at the study censor date (28/1/2014). For the remaining 78 patients 'PoD' had no missing data

2. Documented PPD

PPD was not asked directly as part of the data collection in the clinical record file (CRF). This decision was made for two reasons;

- Study ethics- at consent participants were not made explicitly aware that they might die during the study therefore to ask PPD if this had not been discussed by their clinical team may have caused undue distress.
- Evaluation of the intervention- this feasibility study observed outcomes in two groups of patients. Evidence has shown that an expressed preference for a home death increases the likelihood of dying at home [28]. Therefore asking PPD as part of the routine research assessment could have changed the clinical outcome for participants. This would have made comparisons between the groups more difficult, potentially reducing any effect size seen from H2H, and impacting on the validity of the study.

In practice I often developed a good rapport with the patient and occasionally the participant voluntarily discussed PPD. This was recorded in the CRF. PPD was also recorded from 3 other sources;

- RMFT EPR (including the H2H care plan),
- Post bereavement questionnaire with the carer
- CPCT records after death.

The source of PPD is given in Table 5.8

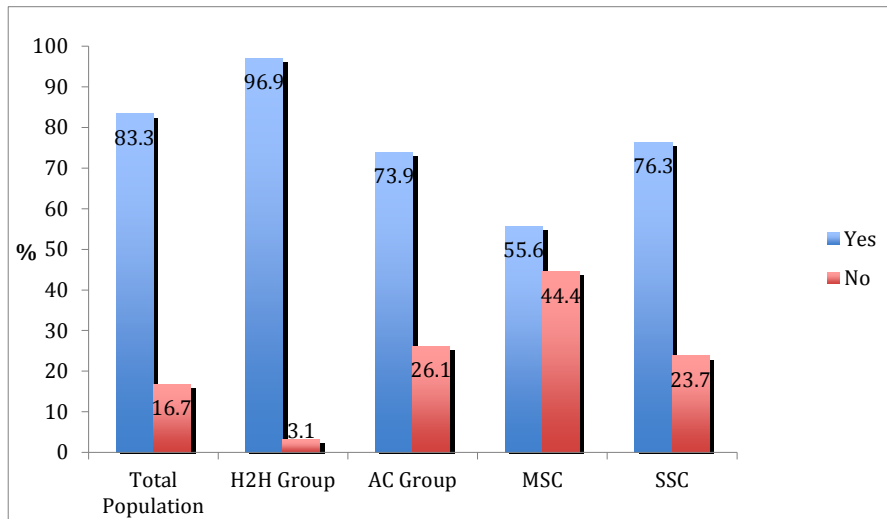
Sixty five of the 78 participants (83.3%) who died had a PPD documented by the end of the study.

Table 5.8 Source of Documented PPD

Source of PPD	n=78 (%)
CPCT	22 (28.2)
Medical notes	16 (20.5)
Patient	4 (5.1)
Bereaved relative	9 (11.5)
Greater than 1 source	14 (17.9)
Overall Documented PPD	65 (83.3)
Not Known (Missing value)	13 (16.7)

Overall, 88.3 % of the total population had a PPD documented (Figure 5.4 and Table 5.8). H2H participants were statistically ($p=0.02$) more likely to have a documented PPD. Ninety-seven percent of H2H participants had a documented PPD compared to 73.9% of AC participants (62.5% MSC, 75.7% SSC).

Figure 5.4 Documentation of PPD: Total population, H2H and AC study groups (%)



5.2.2.2 Documented PPD

The chosen PPD are detailed in Table 5.9 and Figure 5.5. Fifty-six percent (55.6%) of the total population expressed a wish to die at home and 24.7% in a hospice.

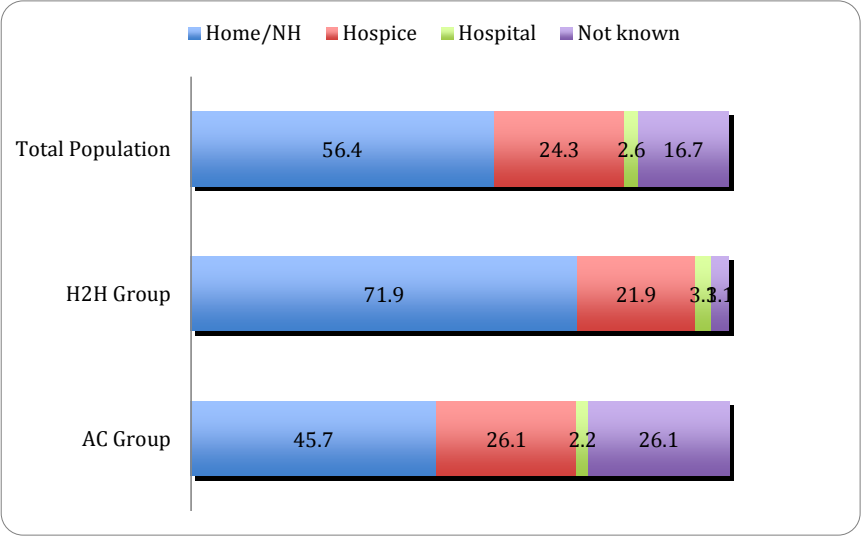
A greater proportion of the H2H participants wished to die at home compared with the AC group (71.9% versus 44.7%).

When each comparator group was considered separately, 80% of MS controls had a PPD of home. However, only 58% of SSC participants expressed a wish to die at home, with a high proportion wishing for a hospice death (38.7%).

The difference in choice of PPD may have an impact on the primary outcome as hospice beds are a limited resource. The possible reasons for the difference in chosen location across the comparator groups include:

- A higher proportion of unknown PPD in the SSC group
- There may be strong hospice links in the community area around the SSC.

Figure 5.5 Preferences for PoD: Total population, H2H and AC study groups (%)



Overall, 83.3% (65/78) of the total population had a PPD documented. Therefore the feasibility criterion that greater than 70% of participants had a documented PPD **was met**. For statistical analysis all 78 deaths were included in the analysis and where PPD was missing a preference for home was substituted. 16.7% of participants had a substituted PPD as 'home'. This substitution occurred for 3 H2H participants (9%) and 10 AC participants (26.1%). Given the research evidence[83] this approach to missing data was appropriate. Nonetheless, the level of missing for PPD in the AC group was high and when known a high number of AC participants chose hospice as their PPD. A proportion of the AC participants with a missing value for PPD may also have chosen hospice and therefore our approach of substituting missing values with a PPD of home may have underestimated the number of participants in the AC group achieving their preference. The validity of the documented PPD is questionable depending on how the information was derived and the time point that the information was noted. The decision not to ask PPD during the research assessment meant that I could not influence how the preference was elicited from the patient. The method of assessing this in the H2H group was standardised with separate questions for PPC and PPD. This was not the case in the AC group and may have influenced the patient responses. PPD can also change as death approaches[93] [224]. H2H participants were closer to death than AC controls. Therefore, it could be that their choice of PPD was less likely to change, making the documented PPD more accurate.

5.2.3 Exploratory preliminary outcome data: Congruence: Achievement of PPD (PPD)

This subsection explores the potential benefits of the H2H intervention and addresses objective 14 of this feasibility study:

Objective 14: *To explore preliminary hypothesis testing to provide an estimate of the effectiveness of H2H compared with standard care as measured by the achievement of PPD*

Table 5.9 details the proportion of participants achieving their PPD (PPD) in each group with unadjusted statistical comparison using Chi squared test statistic. The table gives the result of repeat analysis with the assumption that if PPD was not known it was expected to be home. i.e. substituting all 'not known' PPD for 'home'. The total number of participants in the analysis

was 78. (One H2H participant and two AC participants were still alive at the date of study censor).

This exploratory analysis shows the proportion of participants achieving their first or second choice PPD was higher in the H2H group compared to the AC group (68.8% v 47.8% respectively, $p=0.02$). Over 20% more participants in the H2H group achieved their PPD than the AC group. When inputting 'home' as the PPD for those in whom it was not known (PPD_a) the proportion of participants achieving their PPD_a remains 15% higher in the H2H group (68.8%) compared to AC controls (52.2%).

Table 5.9 Documentation and overall achievement (congruence) of PPD across the study groups

PPD <i>Number (%)</i>	Total population n=78	H2H (A) n=32	Comparator			Statistical analysis comparing (A) & (B)
			AC (B) n=46	Main Site n=8	Satellite Site n=38	
Documented / PPD response rate (PPD RR)						
Yes	65 (83.3)	31 (96.9)	34 (73.9)	5 (62.5)	29 (76.3)	$\chi^2=5.61$, p=0.01
No	13 (16.7)	1 (3.1)	12 (26.1)	3 (37.5)	9 (23.6)	
Location						
Home	44 (56.4)	23 (71.9)	21 (45.7)	4 (50)	17 (44.7)	
Hospice	19 (24.4)	7 (21.9)	12 (26.1)	1 (12.5)	11 (28.9)	
Hospital	2 (2.6)	1 (3.1)	1 (2.2)	0 (0)	1 (2.6)	
Not known	13 (16.6)	1 (3.1)	12 (26.1)	3 (37.5)	9 (23.7)	
If Yes, Location	n=65	n=31	n=34	n=5	n=31	
Home	44 (64.7)	23 (74.2)	21 (56.8)	4 (80)	17 (58.6)	
Hospice	19 (27.9)	7 (22.6)	12 (32.4)	1 (20)	11 (37.9)	
Hospital	2 (2.9)	1 (3.2)	1 (2.8)	0 (0)	1 (3.5)	
PPD Achieved						
1st Choice						
Yes	37 (47.4)	15 (46.9)	22 (47.8)	3 (37.5)	19 (50)	$\chi^2=8.98$, p=0.01
No	28 (35.9)	16 (50)	12 (26.1)	2 (25)	10 (26.3)	
Not known	13 (16.7)	1 (3.1)	12 (26.1)	3 (37.5)	9 (23.7)	
1st or 2nd Choice						
Yes	44 (56.4)	22 (68.8)	22 (47.8)	3 (37.5)	19 (50)	$\chi^2=7.46$, p=0.02
No	21 (26.9)	9 (28.1)	12 (26.1)	2 (25)	10 (26.3)	
Not known	13 (16.7)	1 (3.1)	12 (26.1)	3 (37.5)	9 (23.7)	
PPDa Achieved						
Yes	47 (60.3)	22 (68.8)	25 (54.3)	3 (37.5)	22 (57.9)	$\chi^2=1.64$ p=0.15
No	31 (39.7)	10 (31.2)	21 (45.7)	5 (62.5)	16 (42.1)	

Continuity correction quoted for 2 x 2 tables, PPDa- PPD with assumptions

Table 5.10 Congruence Table: PPD (First and second choice combined) and actual PoD by location and study group, for those with known preferences (n=65)

On a diagonal in **bold** are values are where PPD and actual PoD are congruent.

PPD (1 st and 2 nd choice)	Actual PoD, Total population n= 65 (%)			
	Home	Hospice	Hospital	Total
Home	23 (57.5)	8	9	40
Hospice	3	19 (86.4)	0	22
Hospital	0	1	2 (66.7)	3
Total	26	28	11	65
Overall congruence: 44/65, 67.7% kappa 0.46 (95% CI 0.29-0.63)				

PPD (1 st and 2 nd choice)	Actual PoD							
	H2H group (n=31) (PPD RR 96.9%)				AC group (n=34) (PPD RR 73.9)			
PPD (down)	Home	Hospice	Hospital	Total	Home	Hospice	Hospital	Total
Home	12 (63.2)	1	6	19	11 (52.4)	7	3	21
Hospice	2	8 (80)	0	10	1	11 (91.7)	0	12
Hospital	0	0	2 (100)	2	0	1	0 (0)	1
Total	14	9	8	31	12	19	3	34
Overall congruence: 22/31, 71%, kappa 0.53 (95% CI 0.28-0.77)					Overall congruence: 22/34, 64.7%, kappa 0.39 (95% CI 0.16-0.63)			

5.2.4 Exploratory preliminary outcome data: Achievement of PPD (adjusted for demographic and illness factors)

This section presents the results of achievement of PPD when adjusted for demographic and illness factors. This is essential to inform this exploratory analysis because the study was a non-randomised feasibility study. Table 5.11 gives the results of univariate analysis of demographic and illness factors on achievement of PPDa using Chi-squared test statistic.

The factors with a p value of < 0.2 (highlighted in red) on univariate analysis were then used in multivariate analysis (Principal component analysis followed by multiple logistic regression) (Table 5.13 & 5.14). The outcome *Achievement of PPD with assumptions (PPDa)* was used for this analysis.

Table 5.11: Univariate analysis of the influence of demographic and illness factors on achievement of PPD
(continued on the next page)

PATIENT DEMOGRAPHICS	A) Total Population n= 78		B)PPDa Achieved n= 46	C) PPDa Not Achieved n=32	Statistics comparing B) &C)		
					χ^2	df	p
STUDY GROUP							
H2H (H2H)	32 (41)		22 (68.8)	10 (31.2)	2.17	1	p=0.14
All Control Group (AC)	46 (59)		24 (52.2)	22 (47.8)			
PPD KNOWN							
Number (%)							
Yes	65 (83.3)		43 (66.2)	22 (33.8)	8.36	1	p=0.004
No	13 (16.7)		3 (23.1)	10 (76.9)			
AGE IN YEARS							
Number (%)							
Less than 60	8 (10.3)		6 (75)	2 (25)	3.19	2	p=0.21
60-79	42 (53.8)		27 (64.3)	15 (35.7)			
80 and older	28 (35.9)		13 (46.4)	15 (53.6)			
GENDER							
Number (%)							
Male	62 (79.5)		38 (61.3)	24 (38.7)	0.66	1	p=0.42
Female	16 (20.5)		8 (50)	8 (50)			
ETHNICITY							
Number (%)							
White British	74 (94.9)		44 (59.5)	30 (40.5)	0.14	1	p=0.71
Other	4 (5.1)		2 (50)	2 (50)			
MARITAL STATUS							
Number (%)							
Married/Partner	60 (76.9)		38 (63.3)	22 (36.7)	2.02	1	p=0.16
Other	18 (23.1)		8 (44.4)	10 (55.6)			
LIVING ALONE							
Number (%)							
Yes	25 (32.1)		12 (48.0)	13 (52.0)	1.82	1	p=0.18
No	53 (67.9)		34 (64.2)	19 (35.8)			
INFORMAL CARER							
Number (%)							
Yes	60 (76.9)		37 (61.7)	23 (38.3)	0.77	1	p=0.38
No	18 (23.1)		9 (50)	9 (50)			
EXTENDED FAMILY SUPPORT							
Number (%)							
Yes	55 (70.5)		34 (61.8)	21 (38.2)	0.62	1	p=0.43
No	23 (29.5)		12 (52.2)	11 (47.8)			
ACCOMODATION TYPE							
Number (%)							
House	54 (69.2)		35 (64.8)	19 (35.2)	2.45	1	p=0.18
Flat/Other	24 (30.8)		11 (45.8)	13 (54.2)			
HOME OWNER							
Number (%)							
Yes	65 (83.3)		39 (60)	26 (40)	0.17	1	p=0.68
No	13 (16.7)		7 (53.8)	6 (46.2)			
KNOWN TO CPC							
Number (%)							
Yes	52 (66.7)		31 (59.6)	21 (40.4)	0.03	1	p=0.87
No	26 (33.3)		15 (57.7)	11 (42.3)			

ILLNESS FACTORS	(A) Total Population n=78		(B) PPD Achieved n=46	(C) PPD Not Achieved n=32	Statistic comparing B) & C)		
					χ^2	df	p
CANCER DIAGNOSIS							
Number (%)							
Lung	39 (50)		18 (46.2)	21 (53.8)	5.37	1	p=0.02
Gastrointestinal	39 (50)		28 (71.8)	11 (28.2)			
EXTENT OF DISEASE							
Number (%)							
Local disease	21 (26.9)		8 (38.1)	13 (61.9)	5.13	1	p=0.02
Metastatic disease	57 (73.1)		38 (66.7)	19 (33.3)			
NUMBER OF SITES OF METASTASIS							
Number (%)							
None	21 (26.9)		8 (38.1)	13 (61.9)	5.44	2	p=0.07
1-2	49 (62.8)		32 (65.3)	17 (34.7)			
3 or more	8 (10.3)		6 (75)	2 (25)			
TOTAL NUMBER OF CANCER TREATMENTS							
Number (%)							
None	19 (24.4)		9 (47.4)	10 (52.6)	1.44	2	p=0.49
1-2	31 (39.4)		19 (61.3)	12 (38.7)			
3 or more	28 (35.9)		18 (64.3)	10 (35.7)			
LAST TREATMENT TYPE							
Number (%)							
No Treatment	18 (23.1)		9 (50)	9 (50)	0.82	3	p=0.85
Chemotherapy	47 (60.3)		29 (61.7)	18 (38.3)			
Radiotherapy	10 (12.8)		6 (60)	4 (40)			
Surgery	3 (3.8)		2 (66.7)	1 (33.3)			
OTHER COMORBIDITIES							
Number (%)							
Yes	55 (70.5)		28 (50.9)	27 (49.1)	5.29	1	p=0.02
No	23 (29.5)		18 (78.3)	5 (21.7)			
ESTIMATED PROGNOSIS							
Number (%)							
Weeks	15 (19.2)		8 (53.3)	7 (46.7)	0.24	1	p=0.62
Months/Year	63 (80.8)		38 (60.3)	25 (39.7)			
PPS							
Number (%)							
<40	7 (8.9)		7 (100)	0 (0)	8.35	3	p=0.04
41-60	22 (28.2)		15 (68.2)	7 (31.8)			
61-80	43 (55.1)		22 (51.2)	21 (48.8)			
>80	6 (7.8)		2 (33.3)	4 (66.6)			
SURVIVAL FROM DIAGNOSIS (DAYS)							
Number (%)							
Less than 6 months	13 (16.7)		8 (61.5)	5 (38.5)	0.44	3	p=0.93
6-12 months	22 (28.2)		12 (54.5)	10 (45.5)			
1-2 years	21 (26.9)		12 (57.1)	9 (42.9)			
Greater than 2 years	22 (28.2)		14 (63.6)	8 (36.4)			
SURVIVAL FROM STUDY RECRUITMENT (DAYS)							
Number (%)							
Less than 3 months	47 (60.3)		31 (66)	16 (34)	3.96	2	p=0.14
3-6 months	15 (19.2)		9 (60)	4 (40)			
Greater than 6 months	16 (20.5)		6 (37.5)	10 (62.5)			
Baseline MSAS- GDI Score							
Mean (SD)	1.25 (0.66)		1.32 (0.61)	1.16 (0.73)	1.04	1	p=0.31
Median (Range)	1.16 (0-3.3)		1.16 (0.3-3.3)	1.15 (0-3.2)			

The factors that have a significance value of <0.2 on univariate analysis for achievement of PPD are as follows.

- **Patient Demographic factors:** Study group, PPD known, Marital Status, Living alone and Accommodation.
 - *Study group:* A greater proportion of the H2H study group achieved their PPD compared to the AC group, 68.8% and 52.2% respectively ($p=0.14$).
 - *PPD known:* 66.2% of those whose PPD were known achieved their preference compared to 23.1% in those with an unknown PPD ($p=0.004$).
 - *Marital status:* Married participants were more likely to achieve their PPD than others (63.3% and 44.4% respectively, $p=0.16$).
 - *Living Alone:* Participants living alone (48%) were less likely to achieve their PPD than those living with others (64.2%) ($p=0.18$).
 - *Accommodation type:* A lower proportion of those in a flat or other accommodation (45.8%) achieved their PPD than those living in a house (64.8%) ($p=0.18$).
- **Illness factors:** Diagnosis, extent of disease, number of sites of metastasis, other co-morbidities and survival from recruitment.
 - *Diagnosis:* Those participants with a gastrointestinal malignancy were more likely to achieve their PPD than those with Lung cancer (71.8% compared to 46.2%, $p=0.02$).
 - *Extent of disease:* A higher proportion of those with metastatic disease died in their PPD (66.7%) compared to those with local disease (38.1%, $p=0.02$).
 - *Number of metastasis:* Participants with a larger number of sites of metastases were more likely to die in their PPD ($p=0.07$).
 - *Co-morbidities:* Participants with no other co-morbidities were more likely to die in their PPD (78.3%) than those with other co-morbidities (50.9%, $p=0.02$).
 - *Performance Status:* The better the participant's performance status, the less likely they were to achieve their PPD ($p=0.04$).
 - *Survival:* As survival from study recruitment increased, the likelihood of achieving PPD decreased ($p=0.14$).

Table 5.12: Factors influencing achievement of PPDa with a p value < 0.2 on univariate analysis

Demographic Factors	Illness Factors
Study Group	Diagnosis
PPD known	Extent of Disease
Marital Status	Number of sites of metastasis
Living Alone	Other Comorbidities
Accommodation Type	Performance Status
	Survival from recruitment

The variables, excluding study group, in Table 5.12 were used in Principal Component Analysis (PCA) to determine relationships between the variables. The resulting factors generated from PCA alongside study group were then used in multiple logistic regression to determine which, if any, were related to achievement of PPD after adjustment for the other factors.

The ten variables found to be significant to a value of <0.2 on univariate analysis were subject to principal component analysis (PCA) using SPSS version 20. The Study Group was not included in this analysis as it is the variable of interest, and was analysed as an individual variable in the following step of multiple logistic regression. PCA was chosen in preference to multiple regression as the sample size (n=78) is smaller than the sample size recommended for multiple regression (minimum 90 participants for 6 variables). The suitability of data for factor analysis (PCA) was assessed. First, inspection of the correlation matrix revealed a number of coefficients of 0.3 and above. The Kaiser-Meyer-Olin value was 0.57. This does not exceed Kaiser's recommended value of 0.6 but is acceptable. The Bartlett's Test of Sphericity reached statistical significance (p=0.000), supporting the factorability of the correlation matrix. Exploratory PCA (Table 5.13) revealed 4 components with Eigenvalues exceeding 1 explaining 26.45%, 17.31%, 12.97% and 10.60% of the variance respectively. In total these 4 components cumulatively explained 67.34% of the variance. An inspection of the scree plot revealed a clear break after the fourth component. This reinforced the decision to retain 4 components in the analysis based on the Eigenvalues exceeding 1.

The four-component solution explained a total of 67.34% of the variance (as explained above). To aid in the interpretation of these four components, oblimin rotation was performed. This rotation solution was chosen to account for any cross correlation between components. The rotated solution revealed the presence of a simple structure, as defined by Thurstone[225], with all four components showing strong loading and all variables loading substantially on only one component.

Table 5.13 gives the detail of the pattern and structure matrix for PCA with Oblimin Rotation of Four Factor Solution for these variables.

Table 5.13 Pattern and Structure Matrix for PCA with Oblimin Rotation of Four-factor Solution for Demographic and Illness Factors

Item	Pattern Coefficients					Structure Coefficients				Communalities
	Component 1	Component 2	Component 3	Component 4		Component 1	Component 2	Component 3	Component 4	
Number of Metastasis	-0.947	0.127	0.122	-0.113		-0.920	0.104	-0.152	-0.220	0.891
Stage of Disease	-0.951	0.091	0.046	-0.038		-0.939	0.058	-0.225	-0.146	0.894
Cancer Diagnosis	0.482	0.228	0.166	-0.109		0.482	0.259	0.286	-0.072	0.325
Marital Status	-0.067	0.879	-0.211	0.212		-0.069	0.851	-0.198	0.100	0.816
Living Alone	0.084	-0.777	0.111	0.078		0.093	-0.779	0.126	0.174	0.641
Accommodation Type	0.126	0.557	0.386	-0.114		0.245	0.580	0.423	-0.127	0.532
PPD Known	0.051	0.081	-0.762	0.129		-0.183	0.056	-0.746	0.064	0.578
Survival from Recruitment	0.041	-0.098	0.748	0.214		0.272	-0.104	0.774	0.285	0.661
PPS	-	0.025	0.511	0.580		0.214	-0.024	0.557	0.617	0.643
Other comorbidities	0.084	0.031	-0.057	0.861		0.163	-0.053	0.033	0.863	0.753

These 4 components are distinct from each other and can be categorised clearly into 4 areas. In the analysis that follows these components have been labelled to correspond with the variables they represent as follows

- Component 1: Disease Factors
 - Number of metastasis, stage of disease, cancer diagnosis
- Component 2: Social Factors
 - Marital status, living alone, accommodation type
- Component 3: EOLC Factors
 - PPD known and survival
- Component 4: Health Factors
 - Other comorbidities, PPS

The final step in the analysis was to determine whether any of these four factors or the study group had a significant impact on the achievement of PPD after adjustment for the other factors. To determine this, these factors were subject to Multiple Logistic Regression Analysis. This Multiple Logistic Regression Analysis used the binary outcome of PPD Achieved (0=No, 1=Yes). The model contained the 4 factors derived from PCA (continuous regression scores) and the Study Group (AC =0, H2H =1)

The full model containing all predictors was statistically significant, χ^2 (5, N=78) =18.04, $p=0.003$, indicating that the model was able to distinguish between participants who achieved their PPD and those who did not. The model as a whole explained between 20.7% (Cox and Snell R square) and 27.8% (Nagelkerke R squared) of the variance in achievement of PPD, and correctly classified 75.6% of cases.

Table 5.14 details the multiple logistic regression statistics for the four factors and Study Group in determining achievement of PPD. This shows that in this exploratory feasibility study only one of the independent variables, Health Factors, made a unique statistically significant contribution to the model: Odds ratio 0.56 (95%CI 0.32-0.99), $p=0.05$. H2H odds ratio was 1.12 (reference category: No H2H). This suggests a potential benefit of H2H on achieving PPD but the finding is not independently significant ($p=0.84$) with wide confidence intervals (95%CI 0.36-3.5) and requires further investigation in a definitive trial.

Table 5.14 Factors affecting Achievement of PPD, Binary Logistic Regression Coefficients (n=78)

Factor/Regressor	β	Standard Error	Wald	df	Odds Ratio	95% CI for Odds Ratio	p
Disease Factors	-0.472	0.275	2.945	1	0.62	0.36-1.07	0.09
Social Factors	0.489	0.270	3.276	1	1.63	0.96-2.77	0.07
EOLC Factors	-0.540	0.301	3.225	1	0.58	0.32-1.05	0.07
Health Factors	-0.578	0.288	4.033	1	0.56	0.32-0.99	0.05
Study Group (0=AC, 1= H2H)	0.117	0.582	0.041	1	1.12	0.36-3.52	0.84
Constant	0.337	0.339	0.985	1	1.40		

5.2.5 Place of Death

This subsection addresses **Objective 15:** *To describe and compare the actual of PoD of H2H intervention group with standard care.*

Overall, 37.2% of the total study population died at home, with a large proportion dying in a hospice (42.3%) and 28.1 % dying in hospital. The figures for home and hospice deaths are higher than the national average for cancer deaths in the same year (28.4% and 16.9% respectively ONS 2011). In parallel with this, hospital death rates (28.5%) in this study were considerably lower than the ONS figures (48%).

Table 5.15 details PoD for each study group. Over 10% more deaths occurred at home in the H2H group compared to the AC group (43.8% compared to 32.6%). Hospital death rates were also higher in the H2H study group (28.1% H2H, 15.2% AC group) and of note is the high rate of hospice deaths (52.6%) in the AC group. This early exploratory analysis shows differences between the 2 study groups which require careful consideration and further evaluation in a larger definitive trial.

Table 5.15 PoD: Total population, H2H and comparator groups

PoD <i>Number (%)</i>	Total population n=78	H2H (A) n=32	Comparators			Statistical analysis comparing (A) & (B)
			AC (B) n=46	MSC n=8	SSC n=38	
Home	29 (37.2)	14 (43.8)	15 (32.6)	2 (25)	13 (34.2)	$\chi^2= 4.72^*$ p= 0.09
Hospice	33 (42.3)	9 (28.1)	24 (52.2)	4 (50)	20 (52.6)	
Hospital	16 (20.5)	9 (28.1)	7 (15.2)	2 (25)	5 (13.2)	
Home	29 (37.2)	14 (43.8)	15 (32.6)	2 (25)	13 (34.2)	$\chi^2= 0.58^*$ p= 0.32
Other location	49 (62.8)	18 (56.3)	31 (67.4)	6 (75)	25 (65.8)	

* continuity correction quoted as data 2x 2 table

5.2.6 Place of Death (adjusted for individual, illness and environmental factors)

This section presents the outcome of PoD when adjusted for individual, illness and environmental factors. Table 5.16 shows the results of univariate analysis, using Chi-squared test statistic, on the binary outcome of death at home or other location. The factors with a p value of < 0.2 (highlighted in red) on univariate analysis were retained and used in multivariate analysis (Multiple logistic regression) (Table 5.17).

Table 5.16: Univariate analysis of the influence of individual, illness and environmental factors on PoD (Home vs. Other location) (continued on next page)

VARIABLES	A) Total Population n= 78	B) Home n=29	C) Other location n=49	Statistics comparing B) &C)		
				χ^2	df	p
STUDY GROUP						
H2H	32 (41)	14 (43.8)	18 (56.3)	0.58	1	0.32
All Control Group	46 (59)	15 (32.6)	31 (67.4)			
INDIVIDUAL						
PPD KNOWN						
Number (%)						
Yes	65 (83.3)	26 (40)	39 (60)	1.41	1	0.24
No	13 (16.7)	3 (23.1)	10 (76.9)			
AGE IN YEARS						
Number (%)						
Less than 60	8 (10.3)	4 (50)	4 (50)	1.66	2	0.44
60-79	42 (53.8)	17 (40.5)	25 (59.5)			
80 and older	28 (35.9)	8 (28.6)	20 (71.4)			
GENDER						
Number (%)						
Male	62 (79.5)	22 (35.5)	40 (64.5)	0.37	1	0.55
Female	16 (20.5)	7 (43.8)	9 (56.3)			
ETHNICITY						
Number (%)						
White British	74 (94.9)	28 (37.8)	46 (62.2)	0.28	1	0.60
Other	4 (5.1)	1 (25)	3 (75)			
MARITAL STATUS						
Number (%)						
Married/Partner	60 (76.9)	28 (46.7)	32 (53.3)	12.31	1	p=0.00
Other	18 (23.1)	1 (5.6)	17 (94.4)			
ENVIRONMENTAL						
LIVING ALONE						
Number (%)						
Yes	25 (32.1)	7 (28.0)	18 (72.0)	1.36	1	p=0.24
No	53 (67.9)	22 (41.5)	31 (58.5)			
INFORMAL CARER						
Number (%)						
Yes	60 (76.9)	22 (36.7)	38 (63.3)	0.03	1	p=0.86
No	18 (23.1)	7 (38.9)	11 (61.1)			
EXTENDED FAMILY SUPPORT						
Number (%)						
Yes	55 (70.5)	24 (43.6)	31 (56.4)	3.51	1	p=0.06 (0.12)
No	23 (29.5)	5 (21.7)	18 (78.3)			
ACCOMMODATION TYPE						
Number (%)						
House	54 (69.2)	25 (46.3)	29 (53.7)	6.76	1	p=0.01 (0.03)
Flat/Other	24 (30.8)	4 (16.7)	20 (83.3)			
HOME OWNER						
Number (%)						
Yes	65 (83.3)	24 (36.9)	41 (63.1)	0.01	1	p=0.92
No	13 (16.7)	5 (38.5)	8 (61.5)			
KNOWN TO CPCT						
Number (%)						
Yes	52 (66.7)	18 (34.6)	34 (65.4)	0.44	1	p=0.51
No	26 (33.3)	11 (42.3)	15 (57.7)			

ILLNESS FACTORS	A) Total Population n= 78		B)Home n=29	C) Other location n=49	Statistics comparing B) &C)		
					χ^2	df	p
CANCER DIAGNOSIS							
Number (%)							
Lung	39 (50)		13 (33.3)	26 (66.7)	0.49	1	p=0.48
Gastrointestinal	39 (50)		16 (41.0)	23 (59.0)			(0.64)
EXTENT OF DISEASE							
Number (%)							
Local disease	21 (26.9)		5 (23.8)	16 (76.2)	2.30	1	p=0.13
Metastatic disease	57 (73.1)		24 (42.1)	33 (57.9)			(0.22)
NUMBER OF SITES OF METASTASIS							
Number (%)							
None	21 (26.9)		5 (23.8)	16 (76.2)	2.38	2	p=0.30
1-2	49 (62.8)		21 (42.9)	28 (57.1)			
3 or more	8 (10.3)		3 (37.5)	6 (62.5)			
TOTAL NUMBER OF CANCER TREATMENTS							
Number (%)							
None	19 (24.4)		5 (26.3)	14 (73.7)	1.36	2	p=0.51
1-2	31 (39.7)		13 (41.9)	18 (58.1)			
3 or more	28 (35.9)		11 (39.3)	17 (60.7)			
LAST TREATMENT TYPE							
Number (%)							
No Treatment	18 (23.1)		5 (27.8)	13 (72.2)	1.53	3	p=0.68
Chemotherapy	47 (60.3)		20 (42.6)	27 (57.4)			
Radiotherapy	10 (12.8)		3 (30)	7 (70)			
Surgery	3 (3.8)		1 (33.3)	2 (66.7)			
OTHER COMORBIDITIES							
Number (%)							
Yes	55 (70.5)		20 (36.4)	35 (63.6)	0.53	1	p=0.82
No	23 (29.5)		9 (39.1)	14 (60.9)			(1.00)
BASELINE PPS							
Number (%)							
<40	7 (9.0)		6 (85.7)	1 (14.3)	9.07	3	p=0.03
41-60	22 (28.2)		6 (27.3)	16 (72.7)			
61-80	43 (55.1)		16 (37.2)	27 (62.8)			
>80	6 (7.7)		1 (16.7)	5 (83.3)			
ESTIMATED PROGNOSIS							
Number (%)							
Weeks	15 (19.2)		5 (33.3)	10 (66.7)	0.12	1	p=0.73
Months/Year	63 (80.8)		24 (38.1)	39 (61.9)			
SURVIVAL FROM DIAGNOSIS (DAYS)							
Number (%)							
Less than 6 months	13 (16.7)		4 (30.8)	9 (69.2)	1.67	3	p=0.64
6-12 months	22 (28.2)		9 (40.9)	13 (59.1)			
1-2 years	21 (26.9)		6 (28.6)	15 (71.4)			
Greater than 2 years	22 (28.2)		10 (45.5)	12 (54.5)			
SURVIVAL FROM STUDY RECRUITMENT (DAYS)							
Number (%)							
Less than 3 months	47 (60.3)		19 (40.4)	28 (59.6)	0.55	2	p=0.76
3-6 months	15 (19.2)		5 (33.3)	10 (66.7)			
Greater than 6 months	16 (20.5)		5 (31.3)	11 (68.8)			
BASELINE MSAS-GDI							
Mean (SD)	1.25 (0.66)		1.39 (0.69)	1.17 (0.64)	0.5	1	p=0.17*
Median (Range)	1.16 (0-3.34)		1.31 (0.5-3.34)	1.12 (0-3.22)			

The data show that 43.8% of participants in the H2H group died at home compared to 32.6% of the AC group. Although more participants in the H2H group died at home, this did not reach statistical significance ($\chi^2=0.58$, df1, $p=0.32$). Therefore, the p value of 0.32 means that *study group* was not retained as a factor in the multiple regression analysis for PoD.

The following factors were retained and used in Multiple Regression Analysis ($p<0.2$):

1. Marital Status ($p=0.00$)
 - A higher proportion of married or with a partner participants died at home compared to those single, widowed or divorced.
2. Extended Family Support ($p=0.06$)
 - A higher proportion of those who had extended family support died at home compared to those without such support.
3. Accommodation Type ($p=0.01$)
 - A higher proportion of those living in a house died at home compared to those living in other types of accommodation.
4. Extent of Disease ($p=0.13$)
 - A higher proportion of participants with metastatic disease died at home compared to those with local advanced disease.
5. Baseline PPS ($p=0.03$)
 - Those with a lower baseline PPS were more likely to die at home
6. Baseline symptom distress (measured by MSAS-GDI) ($p=0.17$)
 - The average symptom distress score of those dying at home was higher than those dying in another location

Multiple Logistic regression was used to determine if any of these 6 factors had an impact on the achievement of a home death after adjustment for the other factors. This Multiple Logistic Regression Analysis used the binary outcome of PoD (1=Home, 0= Other Location).

The full model containing all predictors was statistically significant, χ^2 (5, $N=78$) =27.72, $p<0.01$, indicating that the model was able to distinguish between participants who achieved a home death and those who did not. The model as a whole explained between 30.2% (Cox and Snell R square) and 41.4% (Nagelkerke R squared) of the variance in achievement of home death, and correctly classified 75.3% of cases.

Table 5.17 details the multiple logistic regression statistics for the individual variables. In this exploratory analysis, the independent variables that made a unique statistically significant contribution to the model were:

1. Marital Status (Odds ratio 11.03, (95%CI 1.05-115.7), $p=0.05$)
 - Participants who were married or had a partner were 11 times more likely to die at home than those who were single, widowed or divorced.
2. Accommodation type (Odds ratio 6.77 (95%CI 1.29-35.6), $p=0.02$)
 - Participants who lived in a house were nearly 7 times more likely to die at home than those living in other types of accommodation

Table 5.17 Factors affecting Achievement of Home Death, Binary Logistic Regression Coefficients (n=78)

Variable	Label	β	Standard Error	Wald	df	Odds Ratio	95% CI for Odds Ratio	p
Disease Stage	0=Locally Advanced, 1= Metastatic	0.69	0.68	1.05	1	2.00	0.53-7.50	0.3
Marital Status	0= Other, 1= Married/Partner	2.40	1.20	4.00	1	11.03	1.05-115.79	0.05
Extended Family Support	0=No, 1=Yes	0.89	0.72	1.52	1	2.42	0.59-9.89	0.22
Accommodation Type	0=Flat/Other, 1=House	1.91	0.85	5.10	1	6.77	1.29-35.61	0.02
Baseline MSAS-GDI	Increasing value	-0.06	0.51	0.01	1	0.94	0.35-2.57	0.9
PPS	<40 (Ref)				3	1		
	40-60	-3.10	1.70	3.30	1	0.05	0.00-1.27	0.07
	60-80	-3.15	1.68	3.51	1	0.04	0.00-1.16	0.06
	>80	-4.13	2.18	3.61	1	0.02	0.00-1.14	0.06
Constant		-4.95	1.38	12.86	1	0.01		0.00

5.2.7. Section Summary

The preliminary primary outcome of effect in this feasibility study was to compare the proportion of patients achieving their PPD between the study groups. The purpose of which was to to make recommendations on the suitability of PPD as an outcome measurement at the EoL and provide early exploratory data on whether H2H changes the likelihood of achieving PPD.

Place of death was known for all participants with no missing values. Overall PPD was documented in 83% of participants. It was therefore missing in 17% of cases. More H2H participants had a PPD documented compared to the AC group (96.9% and 73.9% respectively, $X^2=5.61$, $p=0.02$). In this feasibility study missing PPD was handled by substituting 'home' for

all missing PPD values. However, during this study the importance of hospice as a PPD became apparent (22.6%% in H2H and 32.4%% in AC group) and therefore the utility of substituting home for all missing values is questionable and not a valuable technique to use in a larger definitive trial. This issue makes PPD a difficult outcome measure to recommend as the primary outcome for a definitive trial because of the risk of potentially high levels of missing data (26.1% in the AC group). This feasibility study used clinical sources to collect PPD and as such has not tested the use of a standardised research question to collect this outcome measure. The level of missing data may be reduced if such a question was included.

Exploratory unadjusted analysis reveals achievement of 1st or 2nd choice PPD was higher in the H2H group (68.8% compared to 45.7% AC control, $X^2=7.8$, $p=0.02$). The strategy adopted here for dealing with missing documented PPD was to substitute all missing PPDs for a preference of home across both study groups. Analysis of this outcome (PPDa) showed 68.8% ($n=22/32$) of H2H participants achieved PPDa compared with 52.2% ($n=24/46$) of AC participants. Using this approach, over 15% more H2H participants achieved PPDa compared to AC participants. Exploratory analysis adjusting for possible confounding variables illustrates that only 'Health Factors' independently impacted on achievement of PPDa (Odds Ratio 0.56, $p=0.05$). Study group did not make an independent contribution to achievement of PPDa. However this is a feasibility study and as such is not adequately powered to detect a difference between the groups. The trend that more H2H participants achieve their PPD than comparators warrants further study in a larger definitive trial.

The study population as a whole had a higher out of hospital death rate compared to national cancer death figures for 2011. Overall, 79% died out of hospital. Analysis of study groups revealed more H2H participants dying at home (43.8%) compared to the AC group (32.6%). Conversely, a larger proportion of AC participants died in a hospice, 52.2%, compared with 28% of H2H participants. Over 10% more H2H participants died in hospital (25% of H2H participants, 15.2% of AC participants). These differences in PoD were not statistically significant. In this exploratory work adjusted analysis revealed married participants or those living with a spouse were nearly eleven times more likely to die at home than other study participants ($p=0.05$), and those living in a house were nearly 7 times more likely to die at home than those living in other accommodation ($p=0.02$).

This section has contributed to the *feasibility and piloting phase* of the MRC framework for evaluating complex interventions by scrutinising PPD and PoD as possible outcomes measurements. It has highlighted the following considerations for a definitive trial that are considered further in the discussion chapter of this thesis;

- Missing data – 26% of the AC group had no documented PPD in clinical records. Three possible reasons for this need to be considered if PPD is to be used as an outcome measure in a definitive trial.
 - A substantial proportion of participants' PPD will never be known
 - A substantial proportion of participants have no preference
 - Clinical records alone are not a sufficient data source. Therefore the definitive trial must be designed to incorporate a standardised question on PPD in the research assessment tools
- Limitations of outcome measurement based on patient preference
 - The emphasis on home as the chosen PPD was different across the groups (H2H PPD home 74.2%, AC PPD home 56.8%) leading to PPD amounting to a comparison of different location outcomes whereby other external factors may influence the outcome such as availability of hospice beds, or quality/intensity of available home support
 - Preference can change overtime and therefore repeated standardised recording of PPD is necessary in a definitive trial.
- Early exploratory analysis suggests H2H may have a positive effect on achievement of PPD and this warrants further study of H2H in a larger definitive evaluation study

5.3 Quantitative Analysis: Symptom burden, QoL and Satisfaction

5.3.1 Section Introduction

This section presents the secondary outcome measurements of symptom burden, QoL and satisfaction in this feasibility study. The results consider the feasibility of collecting this longitudinal outcome data to inform research methods for a definitive trial, and also compare the symptoms and QoL in each study group to determine early potential benefits and/or negative outcomes of the H2H intervention. Specifically, Objectives 5, 6 and 16.

Objective 5: *To determine the feasibility of studying H2H in this setting by assessing inclusion and exclusion criteria, recruitment rates, retention and follow up rates and missing data (Aim 2)*

Objective 6: *To assess potential outcome measures for H2H intervention, and scrutinise the value of these outcome measures in this setting*

Objective 16: *To describe and compare patient and carer symptom burden, QoL and satisfaction in H2H intervention group compared with standard care*

MSAS-SF, MQOL and CQOL-C scores are presented at baseline and week 1 before change scores are presented for each of the outcome measures. Given the differences in survival across the two groups, an exploratory analysis comparing change scores from T0 to last observation prior to death is also then presented. Patient and carer satisfaction scores for the total populations and each study group are then compared and discussed. Lastly, MSAS-SF and MQOL longitudinal trajectories for group populations and individual participants are then addressed. These data are presented in the following subsections:

- 5.3.2 Feasibility of secondary outcomes and study schedule
- 5.3.3 Exploratory secondary outcome analysis
 - 5.3.3.1 Symptom burden MSAS-SF individual items: overall and within groups (T0 n=81)
 - 5.3.3.2 Symptom burden MSAS-SF scores at baseline and week 1.
 - 5.3.3.3 QoL MQOL individual items: overall and within groups (T0 n=81)
 - 5.3.3.4 QoL MQOL scores at baseline and week 1.
 - 5.3.3.5 Carer QoL CQOL-C individual item scores: overall and within groups
 - 5.3.3.6 Carer QoL scores at baseline and week 1
 - 5.3.3.7 Last observation before death MSAS-SF and MQOL scores
 - 5.3.3.8 Cross-sectional change in symptom, QoL and carer QoL scores: Baseline to Week 1 (n=81)
 - 5.3.3.9 Satisfaction scores (FAMCARE) Week 1
 - 5.3.3.10 Longitudinal symptom scores (MSAS-SF) over time
 - 5.3.3.11 Longitudinal QoL scores (MQOL) over time

- 5.3.3.12 Summary symptom and QoL scores over time (AUC)
- 5.3.4 Section Summary

5.3.2 Feasibility of secondary outcomes and study schedule

This sub-section addresses the feasibility of the study (Objective 5) with reference to follow up rates and missing data.

Objective 5: To determine the feasibility of studying the H2H in this setting by assessing inclusion and exclusion criteria, recruitment rates, retention, **follow up rates and missing data**

The results from detailed descriptive analysis of follow up and missing data give information as to the acceptability of the secondary outcome tools chosen and the study schedule.

MORE care guidance[139] suggests classifying attrition in EoLC research into the following categories

- Attrition due to illness (ADI)
- Attrition due to death (ADD)
- Attrition at random (AAR).

This classification will be used to describe whole questionnaire missing data in this feasibility study. Missing data can also be classified as terminal missing data and intermittent missing data. ADD is terminal missing data whereas ADI can be either terminal or intermittent missing data.

Missing data for the secondary outcomes was either; whole questionnaire missing or individual questionnaire item missing (individual item non response).

Whole questionnaire missing

Overall, with the exception of one participant, whole questionnaires were only missing if the participants were too unwell to participate (ADI) or had died at that time point (ADD). This reflects that data collection methods were effective and that the tools used were acceptable and not too burdensome. The total number of patient participant questionnaires for completion over the 3-month study period was 332 (based on all 83 participants completing all

4 time points). The whole questionnaire was missing in 112 (33.7%) of these 332 occasions. The total number of carer participant questionnaires for completion over the 3-month study period was 172 (based on all 43 carers completing all time points). The whole questionnaire was missing in 56 (32.6%) of these 172 occasions. ADD was expected during this study. Therefore Table 5.18 details the percentage of missing questionnaires for those participants remaining in the study (still alive at each time point). The success criteria set for this feasibility outcome was that 80% of questionnaires would be complete. The table shows that at baseline (T0) 100% were complete, at week 1 (T1) 85.5%, 4 weeks (T2) 73.5% and at 12 weeks (T3) 75.8% were complete. Therefore for time points T2 and T3 the success criteria were **not met**. However only one participant chose not to complete questionnaires, the remainder were too unwell (ADI). Overall for the whole study period 85.9% of possible assessments were complete therefore the success criteria were **met**.

Figure 4.18 and 4.19 give further detail of the missing questionnaires at each time point for patient participants in the H2H and AC group respectively, along with reasons for missingness. I have adapted the MORE Care classification for this feasibility study and further classified ADI into 2 subcategories:

- ADI-Admission – Attrition due to illness, patient admitted to hospital/hospice
- ADI – Attrition due to illness, patient at home but too unwell to complete questionnaire

These figures show how the categories of attrition (ADD, ADI and ARR) affect subsequent data points. The categories of attrition due to death (ADD), attrition due to illness (ADI) and attrition at random (ARR) describe the reason for missingness whilst the figures below (Figure 5.6 H2H attrition and 5.7 AC attrition) give a visual representation of how these causes of missing affect the data. The figures clearly show the two main patterns of missing data: intermittently missing and terminal missing data. Terminal missing data were much more frequent than intermittent missing data. Terminal missing data occurs when after a certain time point several episodes of missing data occur for the same participant. A formal missing data analysis was not undertaken. However, descriptive analysis and Figures 5.6 & 5.7 show terminal missing data were associated with the participant being too unwell (ADI), admitted to hospice/hospital (ADI-A) or dying (ADD) during the 12 week study period. For example, see the missing data from participant 2, 4, and 37. A comparison of the figures demonstrates that terminal missing data were more frequent in the H2H study population than the AC group reflecting the difference in survival between the groups.

An important pattern observed in this feasibility study was that once data was missing due to illness or admission then all subsequent data points were missing. This indicates that these participants were close to the EoL and highlights that neither study group had periods of ADI in the middle of data collection. Once the participants had been lost to follow up due to illness no further data were collected. Terminal missing data were therefore informative in this study.

That said, seventy eight percent (65/83) of patient participants completed 2 or more time point assessments. The success criteria for collecting longitudinal data (>50% complete 2 or more time points) were **met**.

This suggests longitudinal research in this study population was feasible and acceptable.

Individual item missing

The number of individual missing items in the completed patient questionnaires was low. There was under 1% of individual missing items at all-time points except Week 1 (1.7%). This reflects the acceptability of the validated tools chosen and the techniques I used to minimise missing data items. After initial assessment, the questionnaires were completed over the telephone and this allowed me to ensure no questions were accidentally missed. It is important to acknowledge that the Week 1 time point had an additional component to the questionnaire, the FAMCARE-P satisfaction tool and the H2H acceptability questionnaire. This made the Week 1 questionnaire longer than all other time points with the addition of an extra 24 questions for patients. The FAMCARE-P was the last component of the telephone questionnaire at week 1 and accounts for the majority of total missing data items (68/80). The high level of missing data from the FAMCARE-P questionnaire is because after each section of the telephone questionnaire I checked with the participant their willingness to continue the assessment. Three participants declined to complete the FAMCARE-P section of the telephone questionnaire due to fatigue. This accounts for 48 individual missing items. Across the remaining patient questionnaires (MSAS-SF +MQOL+FAMCARE-P) the top 3 missing items were:

1. MSAS-SF: 'Problems with sexual interest and activity' not answered on 8 occasions across all time points.
2. FAMCARE-P: 'how satisfied were you with referral to specialists' missing in 7 cases.
3. MQOL: 'in the past 2 days the world has been...(an impersonal unfeeling place, or caring and responsive to my needs)' not answered on 5 occasions.

The number of individual missing items in the carer questionnaire was also low overall, 1.1% across all time points.

Table 5.18 Attrition, whole questionnaire missing and individual item missing data

Time point	Number of participants at time point (Patient participant alive)	Number of missing questionnaires (% at that time point)	Number of items available to answer	Number of missing items (% of items available to answer)
Patient participant				
T0	83	0	4150	11 (0.3)
T1	76	11 (14.5)	4810	80 (1.7)
T2	64	17 (26.5)	2350	19 (0.8)
T3	33	8 (24.2)	1250	7 (0.6)
Overall	256*	36 (14.1)	12560	117 (0.9)
Carer participant**				
T0	43	0	3655	31 (0.9)
T1	39	6 (15.3)	3465	50 (1.4)
T2	34	9 (26.5)	2125	22 (1.0)
T3	26	11 (42.3)	1275	10 (0.9)
Overall	142	26 (18.3)	10520	113 (1.1)

* Indicates number of available patient assessments over the 12 week study period,** indicates the total number of available carer assessments over the 12 week study period, excluding ADD participants

Table 5.19 Patient and Carer missing data and reason for each study group

a) Patient

Time point		T0	T1	T2	T3
Completed assessment	Total Population	83	65	47	27
	H2H	32	24	13	5
	AC	49	41	34	22
Withdrew	Total Population	0	2	2	2
	H2H	0	0	0	0
	AC	0	2	2	2
Died (ADD)	Total Population	0	5	17	46
	H2H	0	3	11	23
	AC	0	2	6	23
ADI	Total Population	0	11	17	8
	H2H	0	5	8	4
	AC	0	6	9	4

b) Carer (Total population n=43)

Time point	T0	T1	T2	T3
Completed assessment	43	33	25	15
Withdrew	0	1	0	0
Patient Died (C-ADD)	0	4	9	17
Withdrew Patient unwell (C-ADI)	0	5	9	11

Figure 5.6 H2H study group: Follow up and attrition for secondary outcome data – symptoms and QoL

H2H Study ID	Time point			
	T0	T1	T2	T3
2			ADI-Admission	
4		ADI-Admission		
7				ADD
9			ADD	
10			ADI	
13				
21			ADI-Admission	
22		ADI		
23				
25		ADD		
27				
28			ADI-Admission	
30				ADD
31			ADD	
35		ADD		
36				ADD
37			ADD	
39				
42			ADI	
52		ADI-Admission		
56				ADD
58				ADD
59			ADD	
60				
65				ADI-Admission
66			ADD	
67			ADI-Admission	
69		ADI-Admission		
72				ADD
74		ADD		
82				ADI
83			ADI	

ADI- too unwell to complete questionnaire, ADD- Died, ADI-Admission- Admitted to hospice/hospital
T0- Initial Assessment, T1- Week 1, T2- 1 Month, T3- 3 Months

Figure 5.7 AC study group: Follow up and attrition for secondary outcome data- symptoms and QoL

All Controls		Time point			
Study ID	T0	T1	T2	T3	
1				ADI	
3				ADD	
5				ADI-Admission	
6				ADD	
8					
11	WITHDREW				
12					
14					
15			ADD		
16			ADI-Admission		
17			ADI-Admission		
18					
19					
20					
24					
26					
29		ADI-Admission			
32					
33					
34					
38					
40				ADD	
41				ADD	
43					
44				ADD	
45					
46		ADI			
47				ADI-Admission	
48				ADD	
49		ADD			
50		ADI-Admission			
51				ADD	
53					
54		ADI-Admission	ADI-Admission		
55				ADI	
57					
61					
62					
63		ADI			
64				ADD	
68			ADD		
70		ADD			
71					
73				ADD	
75	WITHDREW				
76		ADI-Admission			
77			ADI-Admission		
78			ADD		
79					
80					
81					

ADI- too unwell to complete questionnaire, ADI-Admission- Admitted to hospice/hospital, ADD-Death
T0- Initial Assessment, T1- Week 1, T2- 1 Month, T3- 3 Months

5.4.3 Exploratory secondary outcome analysis

5.4.3.1 Symptom burden MSAS-SF individual items: overall and within study groups

5.4.3.1.1 Baseline Symptoms –MSAS-SF

The MSAS-SF was used to assess symptom burden in this feasibility study. Participants were asked to score distress from each individual symptom over the previous 2 days on a numerical rating scale (0- not at all distressed, 4-severe distress). Table 5.20 and 5.21 give details of baseline physical symptom and psychological prevalence for the total population. At baseline, the most prevalent physical symptom in the total population was Lack of Energy (89% of participants experienced this symptom with 48% rating it as severe). Feeling Drowsy was the second most prevalent symptom (75.9%), and 69.9% of the total population experienced pain. Pain was ranked severe by 18% of the participants. Shortness of Breath was also a common symptom in this study population, experienced by 66.3% of the population and severe for 22.2%. The most prevalent psychological symptom in the total population was worrying (45.8%) with 16% worrying frequently or almost constantly.

Table 5.20 Total population Baseline prevalence and severity of physical symptoms (MSAS-SF) n=81

Symptom	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Difficulty concentrating	35 (42.2)	(31-53)	6 (7.2)	(2-13)	0
Pain	58 (69.9)	(60-80)	15 (18.0)	(10-27)	0
Lack of energy	74 (89.2)	(82-96)	39 (48.0)	(37-59)	0
Cough	44 (52.0)	(41-63)	8 (9.8)	(3-17)	1
Changes in skin	30 (36.1)	(25-46)	6 (7.2)	(2-13)	0
Dry mouth	47 (56.6)	(47-69)	15 (18.5)	(10-27)	0
Nausea	20 (24.1)	(15-34)	5 (6.0)	(1-12)	0
Feeling drowsy	63 (75.9)	(66-85)	19 (23.5)	(14-33)	0
Numbness/tingling in hand and feet	34 (41.0)	(31-53)	14 (17.3)	(9-26)	0
Difficulty sleeping	37 (44.6)	(35-57)	12 (14.8)	(7-22)	0
Feeling bloated	33 (39.8)	(29-50)	10 (12.4)	(5-20)	0
Problems with urination	17 (20.5)	(11-29)	8 (9.8)	(3-17)	0
Vomiting	6 (7.2)	(2-13)	0 (0.0)	(0)	0
Shortness of breath	55 (66.3)	(56-77)	18 (22.2)	(13-31)	0
Diarrhoea	23 (27.7)	(18-38)	8 (9.8)	(3-17)	0
Sweats	24 (28.9)	(18-38)	8 (9.8)	(3-17)	0
Mouth sores	6 (7.2)	(2-13)	0 (0.0)	(0)	0
Problems with sexual interest and activity	14 (16.9)	(9-27)	6 (7.4)	(2-13)	3
Itching	21 (25.3)	(16-36)	4 (4.9)	(0-10)	0
Lack of appetite	40 (48.2)	(38-61)	19 (23.5)	(14-33)	0
Dizziness	19 (22.9)	(14-33)	4 (4.9)	(0-10)	0
Difficulty swallowing	19 (22.9)	(14-33)	6 (7.4)	(2-13)	0
Changes in the way food tastes	36 (43.4)	(32-54)	16 (19.8)	(11-29)	0
Weight loss	39 (47.0)	(37-59)	12 (14.8)	(7-23)	0
Hair loss	16 (19.3)	(11-29)	3 (3.7)	(0-8)	0
Constipation	30 (36.1)	(26-48)	12 (14.6)	(7-22)	0
Swelling of arms or legs	25 (30.1)	(19-40)	9 (12.8)	(3-16)	0
'I don't look like myself'	26 (31.3)	(22-42)	11 (13.6)	(6-21)	0

Table 5.21 Total population Baseline prevalence and severity of psychological symptoms (MSAS-SF) n=81

Symptom	Overall prevalence		Frequency of Severe Symptoms (distressing the participant 'frequently' or 'almost constantly')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Feeling sad	32 (38.6)	(27-49)	7 (8.6)	(2-15)	0
Worrying	38 (45.8)	(35-57)	13 (16.1)	(8-24)	0
Feeling irritable	37 (44.6)	(33-56)	8 (9.9)	(3-17)	0
Feeling nervous	17 (20.5)	(12-30)	3 (3.7)	(0-8)	0

Table 5.22 Comparison of Baseline physical symptom prevalence in H2H study group and AC group

Symptom	H2H (n=32)					All controls (n=49)				
	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals		Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Difficulty concentrating	19 (59.4)	(41-77)	3 (9.4)	(-1-20)	0	16 (32.7)	(19-46)	3 (6.1)	(0-13)	0
Pain	25 (78.1)	(63-93)	6 (18.7)	(4-33)	0	31 (63.3)	(49-77)	9 (18.4)	(7-30)	0
Lack of energy	27 (84.4)	(71-98)	20 (62.5)	(45-80)	0	45 (91.8)	(84-100)	19 (38.8)	(25-53)	0
Cough	18 (56.3)	(38-74)	1 (3.1)	(-3-9)	0	24 (49.0)	(34-63)	6 (12.6)	(3-22)	0
Changes in skin	9 (28.1)	(12-45)	1 (3.1)	(-3-9)	0	20 (40.8)	(27-55)	5 (10.2)	(2-19)	0
Dry mouth	21 (65.6)	(48-83)	8 (25.0)	(9-41)	0	26 (53.1)	(39-68)	7 (14.3)	(4-24)	0
Nausea	10 (31.3)	(14-48)	3 (9.4)	(-1-20)	0	10 (20.4)	(9-32)	2 (4.0)	(-2-10)	0
Feeling drowsy	27 (84.4)	(71-98)	10 (31.3)	(14-48)	0	34 (69.4)	(56-83)	9 (18.4)	(7-30)	0
Numbness/tingling in hand and feet	17 (53.1)	(35-71)	6 (18.8)	(4-33)	0	17 (34.7)	(21-49)	8 (16.3)	(6-27)	0
Difficulty sleeping	17 (53.1)	(35-71)	4 (12.6)	(0-25)	0	20 (40.8)	(27-55)	8 (16.3)	(6-27)	0
Feeling bloated	13 (40.6)	(23-59)	6 (18.8)	(4-33)	0	19 (38.8)	(25-53)	4 (8.1)	(2-16)	0
Problems with urination	8 (25.0)	(9-41)	6 (18.8)	(4-33)	0	8 (16.3)	(6-27)	2 (4.1)	(-2-10)	0
Vomiting	3 (9.4)	(0-20)	0 (0.0)	0	0	3 (6.1)	(0-13)	0 (0.0)	0	0
Shortness of breath	20 (62.5)	(45-80)	7 (21.9)	(7-37)	0	34 (69.4)	(56-83)	11 (22.4)	(10-35)	0
Diarrhoea	8 (25.0)	(9-41)	4 (12.6)	(0-25)	0	15 (30.6)	(17-44)	4 (8.1)	(0-16)	0
Sweats	10 (31.3)	(14-48)	5 (15.7)	(2-29)	0	13 (26.5)	(14-39)	3 (6.1)	(0-13)	0
Mouth sores	1 (3.1)	(-3-9)	0 (0.0)	0	0	5 (10.2)	(1-19)	0 (0.0)	0	0
Problems with sexual interest and activity	8 (25.0)	(9-41)	3 (9.4)	(-1-20)	0	6 (13.0)	(3-23)	3 (6.5)	(0-13)	3
Itching	10 (31.3)	(14-48)	2 (6.3)	(-3-15)	0	11 (22.4)	(10-35)	2 (4.0)	(-1-10)	0
Lack of appetite	20 (62.5)	(45-80)	10 (31.3)	(14-48)	0	20 (40.8)	(27-55)	9 (18.4)	(7-30)	0
Dizziness	10 (31.3)	(14-48)	0 (0.0)	0	0	9 (18.4)	(7-30)	4 (8.2)	(0-16)	0
Difficulty swallowing	10 (31.3)	(14-48)	5 (15.7)	(2-29)	0	9 (18.4)	(7-30)	1 (2.0)	(-2-6)	0
Changes in the way food tastes	16 (50.0)	(32-53)	8 (25.0)	(9-41)	0	19 (38.8)	(25-53)	8 (16.3)	(6-27)	0
Weight loss	19 (59.4)	(41-77)	3 (9.4)	(-1-20)	0	19 (38.8)	(25-53)	9 (18.4)	(7-30)	0
Hair loss	6 (18.8)	(4-33)	1 (3.1)	(-3-10)	0	10 (20.4)	(9-32)	2 (4.1)	(-1-10)	0
Constipation	16 (50.0)	(32-68)	5 (15.7)	(2-29)	1	14 (28.6)	(15-42)	7 (14.2)	(4-24)	0
Swelling of arms or legs	11 (34.4)	(17-52)	4 (12.5)	(0-25)	0	13 (26.5)	(14-39)	4 (8.2)	(0-16)	0
'I don't look like myself'	13 (40.6)	(23-59)	2 (6.3)	(-3-15)	0	13 (26.5)	(14-39)	9 (18.4)	(7-30)	0

Table 5.23 Comparison of Baseline line psychological symptom prevalence in H2H study group and AC group

Symptom	H2H (n=32)					All controls (n=49)				
	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals		Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Feeling Sad	14 (43.8)	(26-62)	2 (6.3)	(-3-15)	0	17 (34.7)	(21-49)	5 (10.2)	(1-19)	0
Worrying	17 (53.1)	(35-71)	5 (15.6)	(2-29)	0	20 (40.8)	(27-55)	12 (16.3)	(6-27)	0
Feeling irritable	19 (59.4)	(41-77)	4 (12.5)	(0-25)	0	17 (34.7)	(21-49)	4 (8.2)	(0-16)	0
Feeling nervous	7 (21.9)	(7-37)	1 (3.1)	(-3-10)	0	10 (20.4)	(9-32)	2 (4.1)	(-2-10)	0

The comparison of symptoms across the two study groups is reported in Table 5.22 & 5.23. The trends were similar to the total population. Lack of energy was more prevalent in the AC group

(experienced by 91.8% of the All control group and 84.4% of the H2H group). However, the severity of this symptom was different across the study groups. 62.5% of H2H participants described lack of energy as severe, compared to 38.8% of AC participants. Feeling drowsy occurred more in the H2H group compared to the AC group (69.4% and 84.4% respectively). Pain was also more prevalent in H2H participants at baseline (78.1% in H2H participants and 63.3% in AC participants), although the prevalence of severe pain was similar across the two groups (H2H 18.7%, AC 18.4%). The prevalence of psychological symptoms was higher in the H2H study group. Fifty nine percent felt irritable and 53 % worried compared to 34.7% and 40.8% respectively in the AC group. This difference in physical and psychological symptom burden may be due to the H2H participants being closer to death than the AC group at baseline. However patient safety is an important consideration in the feasibility of H2H, therefore the higher prevalence of worry in the intervention group should be explored further in a larger trial.

5.4.3.1.2 Week One Symptoms (n=65)

Individual physical and psychological symptom prevalence at Week1 are presented in Appendix 7.4.3. The physical symptom burden at Week 1 had increased compared to baseline with six symptoms experienced by over fifty percent of participants: Lack of Energy (84.4%), Feeling Drowsy (70.3%), Pain (67.8%), Dry Mouth (54.7%), Shortness of Breath (57.8%) and Lack of Appetite (51.6%). At Week 1, the three most commonly experienced symptoms were the same as baseline: Lack of Energy, Feeling Drowsy and Pain. Lack of Energy was the most prevalent physical symptom in the total population, experienced by 84.4% with 40.6% rating this symptom as severe. Feeling Drowsy was the second most prevalent symptom (70.3%). Sixty-eight percent (67.8%) of the total population experienced pain, and this was severe for 29.7%. Shortness of Breath was also a severe symptom for many (57.8%) and over half of those who experienced Shortness of Breath rated it as severe (31.2%). Lack of Appetite was a more common symptom in the total study population at week 1 compared to baseline, experienced by 51.6% of the population, severe for 18.7%.

The most prevalent psychological symptom in the total population changed from baseline and was no longer Worrying. The most prevalent psychological symptom was Feeling Sad (n=35, 54.7%) with worrying also a concern for half of participants (n=32, 50%). Although Feeling sad was experienced by over half of participants at Week 1, less than 10% (9.4%, n=6) judged this as severe.

The comparison of week 1 physical and psychological symptoms in the two study groups is shown in Appendix 7.4.3. The number of symptoms prevalent in over half of participants was greater for the H2H group (8 symptoms) compared to the AC group (6 symptoms). The physical symptom burden at Week 1 had increased in both groups compared to baseline. The eight symptoms experienced by over 50% of H2H participants were Lack of Energy (79.2%), Feeling Drowsy (75%), Pain (70.8%), Difficulty Concentrating (62.5%), Shortness of Breath (58.3%), Difficulty Sleeping (54.2%), Dry Mouth (50%) and Lack of Appetite (50%). The six symptoms experienced by over fifty percent of AC participants were Lack of Energy (87.5%), Feeling Drowsy (67.5%), Pain (65%), Dry Mouth (57.5%), Shortness of Breath (57.5%) and Lack of Appetite (52.5%). The three most prevalent symptoms were unchanged from baseline in each group: lack of energy, feeling drowsy and pain. With the exception of Lack of Energy, these symptoms were more prevalent in H2H participants compared to AC participants.

Psychological symptoms were more prevalent in the H2H group than the AC group. This was true of all categories except Worrying. The most prevalent psychological symptoms in the H2H group at Week 1 were *Feeling irritable* (58.3%) and *Feeling Sad* (58.3%). The most prevalent psychological symptoms in the AC group were *Feeling Sad* and *Worrying* (52.5%). *Worrying* was more of a concern for the AC participants than the H2H participants (52.5% and 45.8% respectively) with this worry judged as severe by 15% of the AC group compared to 8.3% of the H2H group. This is a change from baseline where over ten percent more H2H participants (53%) experienced worrying compared to AC participants (40.8%).

5.4.3.1.3 Symptom burden MSAS-SF scores at baseline and week 1

The MSAS-SF subscale scores for baseline and week 1 are detailed in Table 5.24. The subscales are split into four domains: Global Distress Index (MSAS-GDI), Physical Symptoms (MSAS-Phy), Psychological Symptoms (MSAS-Psy) and Total Score (TMSAS). The numerical scale ranges from 0-4, zero indicating no distress and four indicating severe distress. For the total population, the highest scoring subscale at baseline was the Global Distress Index (mean 1.24 (SD 0.66)). At baseline, physical symptoms were causing more distress to participants than psychological symptoms (mean 1.13 (SD 0.63) and 0.83 (SD 0.72) respectively). In both study groups, physical symptoms (MSAS-PHYS mean H2H 1.3, AC 1.03) caused more distress than psychological symptoms (MSAS-PSYCH mean H2H 1.0, AC 0.72) at baseline. In this exploratory analysis H2H participants experience more distress across all subscales compared to AC participants at baseline. This may be because distress increases closer to death.

At Week 1, the Global Distress Index (mean 1.27 (SD 0.65)) remains the highest scoring subscale and this is relatively unchanged from baseline. Physical symptoms were still causing more distress to participants than psychological symptoms (mean 1.03 (SD 0.59) and 0.90 (SD 0.79) respectively).

There was a trend in this feasibility study for H2H participants to experience more distress in all subscales compared to AC participants at Week 1. In both groups, physical symptoms (mean H2H 1.1, AC 0.99) caused more distress than psychological symptoms (mean H2H 1.05, AC 0.83). The MSAS-GDI subscale score had reduced from baseline for H2H participants (Baseline mean 1.44, Week 1 mean 1.31) whilst it had increased in AC participants (Baseline mean 1.11, Week 1 1.24). The importance of these changes clinically requires further investigation in a larger trial. In both groups, the distress caused by physical symptoms had reduced from baseline to week 1, whilst psychological distress had increased over this time period.

Table 5.24 MSAS-SF Subscale Scores at Baseline and Week 1

MSAS Scores	Total Population						H2H Group						AC (AC) Group					
	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M
Baseline (T0) n=81																		
MSAS- GDI	80	1.24	0.658	1.16	0-3.34	1	31	1.44	0.628	1.34	0.2-3.3	1	49	1.11	0.650	1.06	0.0-3.2	0
MSAS- Phys	80	1.13	0.629	1.10	0-2.87	1	31	1.31	0.583	1.20	0.0-2.8	1	49	1.03	0.639	1.07	0.0-2.9	0
MSAS-Psych	81	0.83	0.718	0.67	0-3.17	0	32	1.00	0.732	0.83	0.0-3.2	0	49	0.72	0.694	0.53	0.0-2.9	0
Total MSAS	77	0.89	0.501	0.84	0.1-2.48	4	31	1.01	0.488	0.87	0.2-2.4	1	45	0.81	0.498	0.73	0.1-2.5	4
Week 1 (T1) n=65																		
MSAS- GDI	62	1.27	0.68	1.26	0-1.3.2	19	23	1.31	0.78	1.28	0.1-3.2	9	39	1.24	0.62	1.24	0.2-3.0	10
MSAS-Phys	62	1.03	0.59	0.97	0.1-2.5	19	24	1.10	0.69	1.03	0.1-2.5	8	38	0.99	0.52	0.90	0.1-2.5	11
MSAS-Psych	63	0.90	0.79	0.68	0-4.0	18	23	1.05	0.87	0.90	0.1-4.0	9	40	0.83	0.74	0.67	0-2.9	9
Total MSAS	57	0.83	0.46	0.73	0.1-2.0	24	22	0.91	0.56	0.76	0.1-2.0	10	35	0.77	0.39	0.72	0.2-1.8	14

	H2H Group (A)	AC Group (B)	Statistical Analysis comparing A) & B)		Mean difference across study groups (95% CI)
	Mean (SD)	Mean (SD)	T Test	P value	
T0 MSAS Subscales					
MSAS-GDI	1.44 (0.628)	1.11 (0.650)	-2.26	0.03	-0.33 (-0.63, -0.040)
MSAS-Phys	1.31 (0.583)	1.03 (0.639)	-1.97	0.05	-0.28 (-0.56, 0.00)
MSAS-Psych	0.83 (0.82)*	0.53 (0.70)*		0.04	<i>567.5, z=-2.1</i>
Total MSAS	0.87 (0.43)*	0.73 (0.52)*		0.05	<i>513.5, z=-1.9</i>
T1 MSAS Subscales					
MSAS-GDI	1.31 (0.789)	1.24 (0.616)	-0.412	0.68	-0.07 (-0.43, 0.29)
MSAS-Phys	1.10 (0.687)	0.99 (0.524)	-0.66	0.51	-0.10 (-0.41, 0.21)
MSAS-Psych	0.90 (0.87)*	0.67 (0.87)*		0.24	<i>378.5, z=-1.2</i>
Total MSAS Score	0.76 (0.68)*	0.72 (0.71)*		0.49	<i>342.5, z=-0.70</i>

*M -missing- missing values are calculated from total number of participants at T0, hence include ADD +ADI and participants unable to complete the whole questionnaire, and individual missing values.

T0 Baseline, T1 Week 1 Normal data is presented as mean (standard deviation) otherwise median (interquartile range) (indicated by *) is shown. The mean difference between the study groups has been calculated for normal distributed data and presented with confidence intervals (CIs); otherwise the Mann Whitney U test has been used (indicated by italics)

5.4.3.2 QoL MQOL individual items: overall and within study groups

5.4.3.2.1 Baseline QoL

The McGill QoL (MQOL) questionnaire was used to assess patient QoL throughout the study. The scale is from 0-10 with zero indicating a poor QoL and ten indicating excellent QoL. Table 5.25 gives detail of the average MQOL individual items scores at baseline for the total population and each study group. The two high scoring items on MQOL were 'I feel supported: (0=not at all, 10 = completely)' mean score 8.9 (SD 2.2) and 'when I thought about my life, I felt that my life to this point has been: (0=completely worthless, 10=very worthwhile)' mean score 8.35 (2.2). The items with the lowest QoL score for the total population were 'I have felt that I have: (0=no control over my life, 10=complete control over my life)' mean 6.09 (SD 3.2) and 'I felt good about myself as a person' (0=completely disagree, 10=completely agree) mean score 6.09 (2.6).

The overall QoL score 'considering all parts of life' was similar across both groups (H2H mean 6.28 (SD 2.6), AC 6.57 (SD 2.5)). In the H2H group, the two individual items with the highest QoL scores were 'I have been depressed: (10=not at all, 0= extremely)' mean 8.66 (SD 2.5) and 'I feel supported: (0=not at all, 10=completely)' mean 8.59 (SD2.83). The highest scoring individual items in the AC group were 'when I thought about my life, I felt that my life to this point has been: (0=completely worthless, 1=very worthwhile)' mean 8.86 (SD1.53) and 'I have been depressed: (10=not at all, 0= extremely)' mean 8.73 (2.2). The lowest QoL score in both groups relates to physical health: 'I have felt (0=physically terrible, 10=physically well) H2H mean 5.59 (2.47), AC 6.78 (2.21).

Table 5.25: Baseline QoL Individual Item scores: Total population, H2H and AC study groups

MQOL Item	Total						H2H						AC					
	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Considering all parts of my life-physical, emotional, social, spiritual and financial- the quality of my life has been (0= very bad, 10 = excellent)	81	6.46	2.510	7.00	0-10	0	32	6.28	2.606	7.00	0-10	0	49	6.57	2.466	7.00	0-10	0
Over the past two days, I have felt: (0= physically terrible, 10= physically well)	81	6.31	2.282	6.00	0-10	0	32	5.59	2.474	6.00	0-10	0	49	6.78	2.210	7.00	2-10	0
Over the past two days, I have been depressed: (10=not at all, 0= extremely)	81	8.70	2.283	10.00	0-10	0	32	8.66	2.471	10.00	0-10	0	49	8.73	2.177	10.00	2-10	0
Over the past two days, I have been nervous or worried: (10= not at all, 0=extremely)	81	8.33	2.510	10.00	0-10	0	32	8.09	2.775	10.00	0-10	0	49	8.49	2.337	10.00	0-10	0
Over the past two days, how much of the time did you feel sad? (10=never, 0=always)	81	8.32	2.392	10.00	0-10	0	32	8.22	2.352	9.00	0-10	0	49	8.39	2.439	10.00	0-10	0
Over the past two days, when I thought of the future, I was (10= not afraid, 0= terrified)	81	7.68	2.991	9.00	0-10	0	32	8.22	2.685	10.00	0-10	0	49	7.33	3.152	9.00	0-10	0
Over the past two days, my life has been: (0= utterly meaningless and without purpose, 1=very purposeful and meaningful)	79	6.89	2.797	8.00	0-10	2	31	5.74	2.955	5.00	0-10	1	48	7.63	2.446	8.00	0-10	1
Over the past two days, when I thought about my whole life, I felt that in achieving life goals I have: (0=made no progress whatsoever, 1=progressed to complete fulfilment)	79	7.62	2.162	8.00	0-10	2	32	7.53	2.540	8.00	0-10	0	47	7.68	1.889	7.00	4-10	2
Over the past two days, when I thought about my life, I felt that my life to this point has been: (0=completely worthless, 1=very worthwhile)	81	8.35	2.198	9.00	0-10	0	32	7.56	2.793	8.00	0-10	0	49	8.86	1.528	10.00	5-10	0
Over the past two days, I have felt that I have: (0=no control over my life, 10=complete control over my life)	80	6.09	3.203	7.00	0-10	1	32	5.59	3.120	5.00	0-10	0	48	6.42	3.25	7.00	0-10	1
Over the past two days, I felt good about myself as a person (0=completely disagree, 10=completely agree)	81	6.09	2.575	8.00	0-10	0	32	7.41	2.872	8.00	0-10	0	49	7.57	2.389	8.00	0-10	0
To me, the past two days were: (0= a burden, 10= a gift)	81	7.75	2.777	8.00	0-10	0	32	7.47	3.090	8.00	0-10	0	49	7.94	2.569	9.00	0-10	0
Over the past two days, the world has been: (0= an impersonal unfeeling place, 10=caring and responsive to my needs)	79	7.86	2.469	8.00	0-10	2	31	7.55	2.976	8.00	0-10	1	48	8.06	2.088	8.00	4-10	1
Over the past two days, I have felt supported: (0=not at all, 10= completely)	81	8.90	2.211	10.00	0-10	0	32	8.59	2.838	10.00	0-10	0	49	9.10	1.686	10.00	3-10	0

5.4.3.2.2 Week One QoL

The average scores for individual items of the MQOL at Week 1 are shown in Appendix 7.4.3. The average overall score 'considering all parts of life' was 6.34 (SD 2.5). The highest scoring item on MQOL was the same as baseline 'I feel supported: (0=not at all, 10 = completely)' with minimal change in the mean score. The second highest scoring item was 'I have been nervous or worried (0=extremely 10=not at all)' mean score 8.43 (SD2.3). The item with the lowest QoL score for the total population at week 1 was unchanged from baseline 'I felt physically (0=terrible, 10=well)' mean score 6.13 (2.2).

The overall score 'considering all parts of life' was again similar across both groups (H2H mean 6.34 (SD 2.5), AC 6.41 (SD 2.7)). In the H2H group, the two individual items with the highest QoL scores were 'I have been nervous or worried: (10=not at all, 0=extremely)' mean 8.35 (SD 2.7) and 'when I thought of the future, I was (10= not afraid, 0= terrified)' mean 8.3 (SD 2.5). The highest scoring individual items at week 1 in the AC group were different from baseline and were 'I have felt supported (0=not at all, 10=completely' mean 8.73 (SD2.0) and 'I have been nervous or worried: (10= not at all, 0=extremely)' mean 8.48 (2.1). The lowest QoL score in both groups was unchanged from baseline: 'I have felt (0=physically terrible, 10=physically well) H2H mean 6.13 (2.4), AC 6.13 (2.1). The score is identical across both study groups at week 1, although for the H2H group this represents an improvement (+0.54) from baseline, whereas the AC group has seen a decrease in physical QoL from baseline (-0.65). These overall trends are encouraging for H2H; however, such small differences may not be clinically relevant and the trends seen would need to be explored in a larger definitive trial.

5.4.3.2.3 MQOL scores at baseline and week 1

The baseline and week 1 MQOL subscales for the total population, H2H and AC groups are given in Table 5.26. The MQOL assessment tool is used to measure five separate areas of QoL at the EoL (zero represents the lowest QoL and ten excellent QoL). In the total population, the area of QoL with the highest score was Support (mean 8.40) and the area with the lowest score was Physical Wellbeing (mean 6.31). Overall, across all areas of QoL, participants scored their QoL as high with all domains scored over 5, and a mean total MQOL score of 7.53.

The comparisons of scores across the two study groups revealed that, in most areas of QoL, H2H participants scored their QoL lower than the AC participants at baseline. The domain with the highest QoL score at baseline was psychological QoL for H2H participants (mean 8.30) and Support QoL for AC participants (mean 8.57). The lowest scoring domain in both groups was Physical Wellbeing (H2H mean 5.59 (SD 2.5), AC mean 6.78 (SD 2.2)). Physical Wellbeing (H2H mean 5.59, AC mean 6.78) and Existential QoL (H2H mean 6.83, AC mean 7.76) show the greatest difference across the groups at baseline. AC participants score these domains higher than H2H participants at baseline.

The Week 1 MQOL subscales show that, for the total population (n=65), the area of QoL with the highest score was Psychological QoL (mean 7.94 (SD 2.2)) and the area with the lowest score remained Physical Wellbeing (mean 6.13 (SD 2.2)). Overall, across all areas of QoL, participants rate their QoL high with all domains scoring over 5 and a mean total MQOL score of 7.50. However, compared to baseline, all areas of QoL except physical symptoms had a reduction in mean scores. In all domains, this reduction was less than one point on the 0-10 scale and therefore may not be clinically relevant. The comparison of scores across the two study groups revealed differences at Week 1 compared to baseline. At Week 1, the physical QoL scores for H2H participants increased compared to baseline (Baseline 7.19, Week 1 8.28) and the Total MQOL score also increased (Baseline 7.22, Week 1 7.66). These increases indicate an improvement in QoL from baseline to Week 1 in the H2H group. At Week 1, H2H participants score their QoL higher than AC participants in three of the five domains. This is a change from baseline. The Total MQOL score was also higher for H2H participants compared to ACs (H2H 7.66, AC 7.42) at week 1. The domain with the highest QoL score at week 1 was

physical symptom QoL for H2H participants (mean 8.28) and Support QoL for AC (mean 8.57). The lowest scoring domain in both groups remained Physical Wellbeing (H2H mean 6.13, AC mean 6.13). These differences in groups are noteworthy and suggest patient QoL is an important outcome measure to include in a larger definitive trial.

Table 5.26 Comparison of MQOL domain scores for the total population, H2H participants and AC participants.

MQOL Subscales	Total Population						H2H Study Group						AC (AC) Study Group					
	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Baseline (T0) n=81																		
Physical S	79	7.16	2.452	7.33	0-10	2	31	7.19	2.672	7.67	1.3-10	1	48	7.15	2.328	7.33	0-10	1
Physical WB	81	6.31	2.375	6.0	0-10	0	32	5.59	2.474	6.0	0-10	0	49	6.78	2.210	7.0	2-10	0
Psychological	81	8.26	2.116	9.0	0-10	0	32	8.30	2.229	9.5	0-10	0	49	8.23	2.061	9.0	1.5-10	0
Existential	77	7.39	1.948	7.67	0-10	4	31	6.83	2.208	7.33	0-9.8	1	46	7.76	1.673	8.0	4.2-10	3
Support	79	8.40	2.140	9.0	0-10	2	31	8.13	2.757	9.0	0-10	1	48	8.57	1.634	9.0	3.5-10	1
Total MQOL	73	7.53	1.506	7.73	2-10	8	29	7.22	1.703	7.6	2-9.3	3	44	7.72	1.345	7.8	5.0-10	5
Week 1 (T1) n=65																		
Physical S	58	7.86	2.243	8.33	1.7-10	23	20	8.28	2.158	9.17	1.7-10	12	38	7.64	2.282	8.17	2.3-10	11
Physical WB	63	6.13	2.20	5.00	0-10	18	23	6.13	1.514	7.0	0-10	9	40	6.13	2.115	5.0	0-10	9
Psychological	63	7.94	2.174	8.75	0-10	18	23	8.26	2.377	9.25	0-10	9	40	7.76	2.057	8.0	2.3-10	9
Existential	62	6.96	2.116	7.08	1-10	19	23	6.64	2.582	7.0	1-10	9	39	7.14	1.797	7.17	3.5-10	10
Support	60	7.92	2.287	8.25	0-10	21	21	7.60	3.003	8.5	0-10	11	39	8.57	1.634	8.0	3-10	10
Total MQOL	54	7.50	1.588	7.49	1.7-10	25	18	7.66	1.992	7.99	1.7-10	14	36	7.42	1.368	7.21	4.4-10	13

M -missing- missing values are calculated from total number of participants at T0, hence include ADD +ADI and participants unable to complete the whole questionnaire, and individual missing values.

T0 Baseline, T1 Week 1 Normal data is presented as mean (standard deviation) otherwise median (interquartile range) (indicated by *) is shown. The mean difference between the study groups has been calculated for normal distributed data and presented with confidence intervals (CIs): otherwise the Mann Whitney U test has been used (indicated by italics)

	H2H Group (A)	All Control Group (B)	Statistical Analysis comparing A & B)		Mean difference across study groups (95% CI)
T0 MQOL Subscales	Mean (SD)	Mean (SD)	T Test	P value	
<i>Physical Symptom Score</i>	7.19 (2.672)	7.15 (2.328)	-0.08	0.9	-0.5 (-1.18, 1.08)
<i>Physical Well-being Score</i>	6.00 (2.0)*	7.00 (3.5)*		0.05	585.5, z=-1.94
<i>Psychological Score</i>	9.50 (3.0)*	9.00 (3.0)*		0.83	761.5, z=-0.22
<i>Existential Score</i>	6.83 (2.208)	7.76 (1.673)	2.12	0.04	0.94 (0.05, 1.82)
<i>Support Score</i>	9.00 (2.5)*	9.00 (2.5)*		0.91	733, z=-0.12
<i>Total MQOL Score</i>	7.60 (2.5)*	7.75 (2.4)*		0.30	546.5, z=-1.03
T1 MQOL Subscales					
<i>Physical Symptom Score</i>	9.17 (3.3)*	8.17 (4.4)*		0.33	322.5, z=-0.97
<i>Physical Well-being Score</i>	7.00 (3.0)*	5.00 (3.0)*		0.97	457.0, z=-0.04
<i>Psychological Score</i>	9.25 (3.0)*	8.00 (3.2)*		0.22	375.0, z=-1.22
<i>Existential Score</i>	7.00 (2.7)*	7.17 (2.5)*		0.72	423.5, z=-0.37
<i>Support Score</i>	8.50 (3.3)*	8.00 (3.0)*		0.92	403.0, z=-0.10
<i>Total MQOL Score</i>	7.66 (1.992)	7.42 (1.368)	-0.53	0.6	-0.24 (-1.17, 0.68)

5.4.3.3 Carer QoL CQOL-C individual item scores: overall and within study groups

The carer QoL was measured throughout the study using the Carer QoL-Cancer (CQOL-C) validated tool[199].

This subsection will present the individual item scores overall and for each study group at baseline and week 1, followed by the subscale scores and statistical analysis comparing the groups at each time point. Individual item scores range from 0-4, with 0 indicating 'not at all' agreeing with the item statement and 4 indicating 'very much' agreeing with the item statement. When interpreting the raw data scores, caution is required: for some items, a high score will indicate less burden and better QoL whilst in other items, a high score indicates more burden and a lower QoL.

e.g. 'It bothers me that my daily routine is altered ' (0=Not at all, 4 =Very much)

e.g. I have a more positive outlook on life since my loved one's illness (0=Not at all, 4=Very much)

The subscale scores have been calculated, transposed where necessary and then transformed into a comparable scale of 0-100. A score of one hundred indicates excellent QoL.

5.4.3.3.1 Baseline Carer QoL

The individual item scores for the total population at baseline are given in Table 5.27. The highest scoring individual item at baseline for the total population was 'it upsets me to see my loved one deteriorate (0=not at all, 4=very much)' mean 3.51 (SD 1.03), whilst the item with the lowest score was 'I am concerned about our insurance coverage' (0=not at all, 4 =very much)' mean 0.05 (SD 0.22). The most frequent missing item was 'I am satisfied with my sex life (0=not at all, 4= very much)'. This item was not answered by 15 (35%) carer participants.

Table 5.28 gives detail of the individual item scores at baseline for the H2H study group and the AC study group. The study groups display similar trends to the total population. The item with the highest agreement in each group is 'It upsets me to see my loved one deteriorate (0=not at all, 4=very much)' H2H mean 3.5 (1.1) and AC mean 3.52 (1.01). 'I am concerned about our insurance coverage (0=not at all, 4= very much)' is the item with the lowest agreement in each study group (H2H mean 0.25 (SD 1.0) and AC mean 0.0 (SD 0.0)).

Table 5.27 Total Population Baseline Carer QoL (CQOL-C) individual item scores (n=43)

Item	Total Population (n=43)				
	N	Mean (SD)	Median	Range	Missing
During the past 7 days: (0=Not at all, 4 =Very much)					
It bothers me that my daily routine is altered	43	0.77 (1.15)	0.0	0-4	0
My sleep is less restful	43	1.61 (1.62)	1.0	0-4	0
My daily life is imposed upon	43	0.72 (1.12)	0.0	0-3	0
I am satisfied with my sex life	28	2.46 (1.95)	4.0	0-4	15
It is a challenge to maintain my outside interests	42	1.81 (1.47)	2.0	0-4	1
I am under a financial strain	43	0.37 (0.87)	0.0	0-4	0
I am concerned about our insurance coverage	43	0.09 (0.61)	0.0	0-4	0
My economic future is uncertain	43	0.65 (1.25)	0.0	0-4	0
I fear my loved one will die	43	3.10 (1.54)	4.0	0-4	0
I have a more positive outlook on life since my loved one's illness (4=Not at all, 0=Very much)	41	2.98 (1.57)	4.0	0-4	2
My level of stress and worries has increased	43	2.56 (1.45)	3.0	0-4	0
My sense of spirituality has increased (4=Not at all, 0 =Very much)	43	3.26 (1.27)	4.0	0-4	0
It bothers me, limiting my focus to day-to-day	43	0.70 (1.19)	0.0	0-4	0
I feel sad	42	2.71 (1.27)	3.0	0-4	1
I feel under increased mental strain	43	1.72 (1.52)	2.0	0-4	0
I get support from my friends and neighbours (4=Not at all, 0 =Very much)	43	1.14 (1.34)	1.0	0-4	0
I feel guilty	42	0.67 (1.28)	0.0	0-4	1
I feel frustrated	42	1.33 (1.46)	1.0	0-4	1
I feel nervous	43	1.21 (1.26)	1.0	0-4	0
I worry about the impact my loved one's illness has had on my children or other family members	43	2.0 (1.51)	2.0	0-4	0
I have difficulty dealing with my loved one's changing eating habits	43	0.98 (1.46)	0.0	0-4	0
I have developed a closer relationship with my loved one (4=Not at all, 0=Very much)	43	2.60 (1.65)	4.0	0-4	0
I feel adequately informed about my loved one's illness	43	0.98 (1.18)	1.0	0-4	0
It bothers me that I need to be available to chauffeur my loved one to appointments	41	0.05 (0.22)	0.0	0-1	2
I fear the adverse effects of treatment on my loved one	42	1.17 (1.50)	0.0	0-4	1
The responsibility I have for my loved one's care at home is overwhelming	43	0.86 (1.30)	0.0	0-4	0
I am glad that my focus is on getting my loved one well (4=Not at all, 0=Very much)	39	1.31 (1.66)	0.0	0-4	4
Family communication has increased (4=Not at all, 0=Very much)	43	1.42 (1.55)	1.0	0-4	0
It bothers me that my priorities have changed	43	0.35 (0.87)	0.0	0-4	0
The need to protect my loved one bothers me	43	0.70 (1.21)	0.0	0-4	0
It upsets me to see my loved one deteriorate	43	3.51 (1.03)	4.0	0-4	0
The need to manage my loved one's pain is overwhelming	42	1.05 (1.56)	0.0	0-4	1
I am discouraged about the future	41	1.22 (1.48)	0.0	0-4	2
I am satisfied with the support I get from my family (4=Not at all, 0 =Very much)	43	0.42 (0.98)	0.0	0-4	0
It bothers me that other family members have not shown interest in taking care of my loved one	43	0.40 (1.03)	0.0	0-4	0

Table 5.28 Comparison of Baseline Carer QoL (COOL-C) individual item scores (n=43) for H2H and AC participants (n=43) (Continued over the next page)

Item	H2H Study Group (n=16)					All Control Group (n=27)				
	N	Mean (SD)	Median	Range	Missing	N	Mean (SD)	Median	Range	Missing
<i>During the past 7 days: (0=Not at all, 4 =Very much)</i>										
It bothers me that my daily routine is altered	16	0.63 (0.89)	0.0	0-3	0	27	0.85 (1.29)	0.0	0-4	0
My sleep is less restful	16	1.81 (1.76)	2.0	0-4	0	27	1.48 (1.55)	1.0	0-4	0
My daily life is imposed upon	16	0.25 (0.58)	0.0	0-2	0	27	1.00 (1.27)	0.0	0-3	0
I am satisfied with my sex life	12	2.67 (1.96)	4.0	0-4	4	16	2.31 (1.99)	4.0	0-4	11
It is a challenge to maintain my outside interests	16	1.56 (1.59)	1.0	0-4	0	26	1.96 (1.40)	2.0	0-4	1
I am under a financial strain	16	0.63 (1.20)	0.0	0-4	0	27	0.22 (0.58)	0.0	0-2	0
I am concerned about our insurance coverage	16	0.25 (1.0)	0.0	0-4	0	27	0.0 (0.0)	0.0	0-0	0
My economic future is uncertain	16	1.00 (1.55)	0.0	0-4	0	27	0.44 (1.01)	0.0	0-4	0
I fear my loved one will die	16	3.00 (1.67)	4.0	0-4	0	27	3.15 (1.49)	4.0	0-4	0
I have a more positive outlook on life since my loved one's illness (4=Not at all, 0=Very much)	16	3.19 (1.47)	4.0	0-4	0	25	2.84 (1.65)	4.0	0-4	2
My level of stress and worries has increased	16	2.56 (1.59)	3.0	0-4	0	27	2.56 (1.40)	3.0	0-4	0
My sense of spirituality has increased (4=Not at all, 0 =Very much)	16	2.81 (1.56)	3.5	0-4	0	27	3.52 (1.01)	4.0	0-4	0
It bothers me, limiting my focus to day-to-day	16	0.56 (0.96)	0.0	0-3	0	27	0.78 (1.31)	0.0	0-4	0
I feel sad (0=Not at all, 4 =Very much)	15	3.07 (1.10)	4.0	1-4	1	27	2.52 (1.34)	2.0	0-4	0
I feel under increased mental strain	16	1.50 (1.55)	1.5	0-4	0	27	1.85 (1.51)	2.0	0-4	0
I get support from my friends and neighbours (4=Not at all, 0 =Very much)	16	1.06 (1.34)	0.5	0-4	0	27	1.19 (1.40)	1.0	0-4	0
I feel guilty	16	0.31 (0.87)	0.0	0-3	0	26	0.89 (1.45)	0.0	0-4	1
I feel frustrated	16	1.13 (1.50)	0.0	0-4	0	26	1.46 (1.45)	1.0	0-4	1
I feel nervous	16	1.06 (1.39)	0.0	0-4	0	27	1.30 (1.20)	1.0	0-4	0
I worry about the impact my loved one's illness has had on my children or other family members	16	2.56 (1.63)	3.0	0-4	0	27	1.67 (1.36)	2.0	0-4	0
I have difficulty dealing with my loved one's changing eating habits	16	1.38 (1.71)	0.0	0-4	0	27	0.74 (1.26)	0.0	0-4	0
I have developed a closer relationship with my loved one (4=Not at all, 0=Very much)	16	3.00 (1.67)	4.0	0-4	0	27	2.37 (1.62)	2.0	0-4	0
I feel adequately informed about my loved one's illness (4=Not at all, 0 =Very much)	16	0.88 (1.36)	0.0	0-4	0	24	1.25 (1.65)	0.0	0-4	3

	H2H Study Group (n=16)					All Control Group (n=27)				
Item	N	Mean (SD)	Median	Range	Missing	N	Mean (SD)	Median	Range	Missing
During the past 7 days: (0=Not at all, 4 =Very much)										
It bothers me that I need to be available to chauffeur my loved one to appointments	15	0.00 (0.00)	0.0	0-0	1	26	0.08 (0.27)	0.0	0-1	1
I fear the adverse effects of treatment on my loved one	16	0.69 (1.30)	0.0	0-4	0	26	1.46 (1.56)	1.0	0-4	1
The responsibility I have for my loved one's care at home is overwhelming	16	0.75 (1.24)	0.0	0-4	0	27	0.93 (1.36)	0.0	0-4	0
I am glad that my focus is on getting my loved one well (4=Not at all, 0=Very much)	15	1.40 (1.72)	1.0	0-4	1	24	1.25 (1.65)	0.0	0-4	3
Family communication has increased (4=Not at all, 0=Very much)	16	1.44 (1.67)	1.0	0-4	0	27	1.41 (1.50)	1.0	0-4	0
It bothers me that my priorities have changed	16	0.13 (0.50)	0.0	0-2	0	27	0.48 (1.01)	0.0	0-4	0
The need to protect my loved one bothers me	16	0.88 (1.36)	0.0	0-4	0	27	0.59 (1.12)	0.0	0-4	0
It upsets me to see my loved one deteriorate	16	3.50 (1.10)	4.0	0-4	0	27	3.52 (1.01)	4.0	0-4	0
The need to manage my loved one's pain is overwhelming	16	0.56 (1.15)	0.0	0-4	0	26	1.35 (1.72)	0.0	0-4	1
I am discouraged about the future	15	0.93 (1.33)	0.0	0-4	1	26	1.39 (1.55)	1.0	0-4	1
I am satisfied with the support I get from my family (4=Not at all, 0 =Very much)	16	0.31 (1.01)	0.0	0-4	0	27	0.48 (0.98)	0.0	0-4	0
It bothers me that other family members have not shown interest in taking care of my loved one	16	0.19 (0.75)	0.0	0-3	0	27	0.52 (1.16)	0.0	0-4	0

5.4.3.3.2 Week 1 Carer QoL

At Week 1, the items that participants agree most with remain the same as baseline with only a slight decrease in score at week 1 (See Appendix 7.4.3). 'It upsets me to see my loved one deteriorate (0=not at all, 4= very much)' had a total population mean score of 3.31 (SD 1.45). The item with the lowest agreement was also the same as baseline. 'I am concerned about our insurance coverage (0=not at all, 1=very much)' had a mean score of 0 (SD 0). The most common missing item at week 1 was still 'I am satisfied with my sex life (0=not at all, 4 =very much)'. This was missing for 13/33 participants (39%).

Table 5.29 gives the CQOL-C subscale scores for the Total population, H2H and AC groups at baseline and Week 1. The CQOL-C assessment tool allows for scoring of carer QoL in four different domains: burden, disruption, positive adaptation (Pos Adapt) and financial burden, as well as a total QoL score. The overall score for each subscale was transformed into a 0-100 score, with higher values indicating a better QoL.

In the total population, the domain with the lowest carer QoL score at baseline was the burden score. This had an average score of 50 (mean 50.5 (SD 20.14)). The area with the highest QoL score, and hence causing least concern, was financial burden (mean 90.7 (SD 16.39)). The mean total CQOL-C score was 63.38 (SD 12.87). When comparing the two study groups, these patterns remain. Both study groups score low on the burden subscale (H2H mean 51.17, AC mean 50.10) with financial concerns also having a minimal impact on QoL (H2H mean 84.38, AC 94.4). Although the financial burden in each group was low, the H2H group score ten points less than the AC group, indicating more financial burden for H2H participants. The total CQOL-C scores were very similar across the groups (H2H mean 63.25, AC group mean 63.48).

5.4.3.3.3 Carer QoL scores at baseline and Week 1

At week 1 in the total population (n=33 carers), the domain with the lowest carer QoL score was again the burden score. This had an average mean score of 51.5 (SD 21.77). This was a slight improvement from baseline. The area with the highest QoL score, and hence causing least concern, remained financial burden (mean 94.19 (SD 13.42)). The mean total CQOL-C score was 67.22 (median 11.76) - an increase from baseline. When comparing the two study groups at week 1, there are differences in scores across the domains. The lowest scoring domain, and therefore the domain with the poorest carer QoL, is carer burden for the AC group (mean 48.52 (SD 23.27)). However, in the H2H study group, this domain scores over 10 points higher (mean 59.69 (SD 15.32)). The lowest scoring area in the H2H study group was the Positive Adaptation domain (mean 54.02 (SD 23.18)). Financial burden was the lowest area of concern (scoring the highest of all the domains) for both groups at week 1 (H2H mean 89.17 (SD 21.53), AC mean 96.38 (SD 7.46)). The total CQOL-C scores at week 1 were very similar across the groups (H2H mean 69.11, AC mean 66.68) in this preliminary analysis.

Table 5.29 Baseline (T0) and Week 1 (T1) comparison of Carer QoL (CQOL-C) subscale scores for Total Population, H2H and AC study groups

	Total Population						H2H Study Group						AC Study Group					
	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M
T0 CQOLC (n=43)																		
<i>Burden</i>	39	50.51	20.14	50.00	3-88	4	15	51.17	16.53	50.0	18-88	1	24	50.10	22.44	52.5	3-85	3
<i>Disruptive</i>	41	79.70	17.01	82.14	39-100	2	15	82.14	13.96	82.14	50-100	1	26	78.30	18.65	83.93	39-100	1
<i>Pos Adapt</i>	38	54.79	16.26	53.57	18-86	5	15	55.71	17.85	53.57	18-82	1	23	54.19	15.52	53.57	25-86	4
<i>Financial</i>	43	90.70	16.39	100.0	33-100	0	16	84.38	22.54	91.67	33-100	0	27	94.44	10.07	100.0	67-100	0
<i>Total</i>	26	63.38	12.87	62.14	35-86	17	11	63.25	9.89	62.14	48-81	5	15	63.48	15.03	62.14	35-86	12
T1 CQOLC (n=33)																		
<i>Burden</i>	30	51.50	21.77	53.75	5-95	13	8	59.69	15.32	63.75	40-80	8	22	48.52	23.27	50	5-95	5
<i>Disruptive</i>	29	79.68	17.34	82.14	39-100	14	7	88.27	11.97	89.29	68-100	9	22	76.95	18.10	76.79	39-100	5
<i>Pos Adapt</i>	29	57.76	15.83	57.14	29-89	14	8	54.02	23.18	48.21	29-89	8	21	59.18	12.45	57.14	32-86	6
<i>Financial</i>	33	94.19	13.42	100.00	33-100	10	10	89.17	21.53	100.00	33-100	6	23	96.38	7.46	100.00	75-100	4
<i>Total</i>	16	67.22	11.76	66.79	49-89	15	6	69.11	12.21	67.14	58-84	10	10	66.68	12.05	66.79	49-89	13

	H2H Group (A)	AC Group (B)	Statistical Analysis comparing A) & B)		Mean difference between study groups (95% CI)
	Mean (SD)	Mean (SD)	T Test	P value	
T0 CQOL Subscales					
<i>Burden</i>	51.67 (16.53)	50.10 (22.44)	0.15	0.89	1.08 (-14.2-16.3)
<i>Disruptive</i>	82.14 (17.86)*	83.93 (39.29)*		0.67	179.00, z=-0.44
<i>Positive Adaptation</i>	55.71 (17.85)	54.19 (15.52)	-0.39	0.70	-2.62 (-16.78-11.55)
<i>Financial</i>	91.67 (25.00)*	100.0 (8.33)*		0.08	155.50, z=-1.73
<i>Total CQOL-C Score</i>	63.25 (9.89)	63.48 (15.03)	0.05	0.96	0.24 (-9.87-10.34)
T1 CQOL Subscales					
<i>Burden</i>	59.69 (15.32)	48.52 (23.27)	-1.25	0.22	-11.16 (-29.4-7.07)
<i>Disruptive</i>	88.27 (11.97)	76.95 (18.10)	-1.54	0.14	-11.32 (-26.4-3.76)
<i>Positive Adaptation</i>	54.02 (23.18)	59.18 (12.45)	0.60	0.57	5.17 (-14.51-24.84)
<i>Financial</i>	100.00 (18.75)*	100.00 (0.0)*		0.47	101.00 z=-0.73
<i>Total CQOL-C Score</i>	67.14 (23.04)*	66.79 (20.18)*		0.71	24.50, z=-0.37

NB: Scores have been transposed so higher scores indicate a better Carer QoL. Scores have also been transformed into a 0-100 scale for easier comparison. *M -missing- missing values are calculated from total number of participants at T0, hence include ADD +ADI and participants unable to complete the whole questionnaire, and individual missing values. T0 Baseline, T1 Week 1 Normal data is presented as mean (standard deviation) otherwise median (interquartile range) (indicated by *) is shown. The mean difference between the study groups has been calculated for normal distributed data and presented with confidence intervals (CIs); otherwise the Mann Whitney U test has been used (indicated by italics)

5.4.3.4 Last assessment before death MSAS-SF and MQOL scores

In those who died during the 12 week follow up period, an additional analysis comparing last assessment before death (LAD) across the study groups was performed. This was examined because of the significantly different survival across the study groups. The results are shown in Table 5.30 below. This analysis excluded participants who died after the 12 week follow up; therefore, the total number included was 46 (H2H n=23, AC n=23). The median time from last assessment to death was broadly the same: 9 days in the H2H group and 8 days in the AC group. Therefore, comparisons of the data are worthwhile. For this population subset, there was no significant difference between baseline MSAS or MQOL scores across the groups. The results show the average MSAS-GDI and Total MSAS scores at LAD were all higher in the H2H group compared to the AC group, indicating more symptom distress at the last assessment prior to death. The AC group Total MQOL score was marginally higher than the H2H group at LAD.

Table 5.30 Statistical comparison of MSAS-SF scores, MQOL scores and survival at baseline and last observation prior to death. (n=46)

a) Symptom burden: MSAS-SF Scores for those who died in 12 week follow up (n=46)

	H2H Group (A)	AC Group (B)	Statistical Analysis comparing A & B		Mean difference across study groups (95% CI)
	Mean (SD)	Mean (SD)	T Test	P value	
T0					
MSAS-GDI	1.33 (0.85)*	1.15 (0.98)*		0.10	188.50, z=-1.66
Total MSAS	0.99 (0.52)*	0.87 (0.87)*		0.31	198.50, z=-1.02
Total MQOL	6.65 (1.75)	7.29 (1.15)	1.42	0.16	0.64 (-0.27-1.56)
Last Observation before Death					
MSAS-GDI	1.59 (0.65)	1.38 (0.58)	-1.20	0.24	-0.21(-0.58-0.15)
Total MSAS	0.89 (0.60)	0.84 (0.57)		0.27	214.00, z=-1.1
Total MQOL	6.63 (1.73)	6.91 (1.03)	0.65	0.52	0.28 (-0.58-1.13)

b) Survival from recruitment and Time (in days) from last observation to death

	H2H		AC	
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)
Survival (recruitment to death)	34.96 (20.94)	32 (3-89)	48.22 (26.73)	47 (3-95)
Time (days) from last observation to death	23.39 (17.13)	21 (82)	34.35 (20.56)	35 (3-82)

5.4.3.5 Cross-sectional change in symptom, QoL and carer QoL scores: Baseline to Week 1 (n=65) and Last assessment prior to death (n=46)

The change in scores from baseline to week 1 was the chosen outcome measure to assess the effect of H2H intervention on symptom burden and QoL compared to standard care (AC group). The average change in MSAS-SF, MQOL and CQOL-C scores are presented in Table 5.31. These early results show the H2H group had a reduction in global distress (MSAS-GDI) from baseline to week 1 compared to the AC group (MD -0.25, $p=0.03$). This effect size was small and not likely to be clinically relevant. Small improvements were also seen in all other subscales. Of importance is that in this exploratory study the H2H intervention did not appear to have a negative impact on patient or carer symptom and QoL outcomes. There were no clinical or statistical changes in MSAS-SF or MQOL subscales from baseline to last assessment before death.

Table 5.31 Cross-sectional change in outcome scores across the study groups from baseline to week 1

Outcome	H2H	AC	H2H versus AC			
			MD (95% CI) <i>MWU test</i>	p value	Clin Sign	H2H Trend
	<i>n=23</i>	<i>n=39</i>				
MSAS-GDI change _{T1-T0}	-0.15 (0.55)	0.10 (0.36)	-0.25 (0.02-0.48)	0.03	Yes(?)	Improve
	<i>n=22</i>	<i>n=33</i>				
Total MSAS change _{T1-T0}	-0.16 (0.36)	-0.04 (0.26)	-0.12 (-0.05-0.29)	0.16	No	Improve
	<i>n=17</i>	<i>n=34</i>				
Total MQOL change _{T1-T0}	0.14 (0.99)	-0.17 (0.92)	0.31 (-0.87-0.25)	0.27	No	Improve
	<i>n= 4</i>	<i>n= 12</i>				
Total CQOLC change _{T1-T0}	2.14 (12.50)	1.38 (5.36)	<i>20.50, z=-0.43</i>	0.67	No	Improve
	<i>n=8</i>	<i>n=20</i>				
CQOL burden change _{T1-T0}	6.56 (15.00)	0.50 (10.50)	6.06 (-4.15-16.28)	0.23	No	Improve
	<i>n=23</i>	<i>n=23</i>				
MSAS-GDI change _{LA-T0}	0.00 (0.37)*	0.00 (0.44)*	<i>221.0, z=-0.95</i>	0.34	No	No diff
	<i>n=22</i>	<i>n=22</i>				
Total MSAS change _{LA-T0}	0.00 (0.33)*	0.00 (0.26)*	<i>205.5, z=-0.86</i>	0.39	No	No diff
	<i>n=20</i>	<i>n=22</i>				
Total MQOL change _{LA-T0}	0.00 (0.31)*	-0.17 (0.83)*	<i>164.5, z=-1.40</i>	0.16	No	No diff

MSAS-SF scores: increase in score indicates increase in symptom distress, MQOL increase in score indicates improved QOL, CQOLC higher score indicates better/enhanced carer QOL and FAMCARE/FAMCARE-P higher score indicates greater satisfaction with care
MD mean difference, AC group. T0 Baseline, T1 Week 1 and LA Last Assessment prior to death. Normal data is presented as mean change (standard deviation) otherwise median change (interquartile range) (indicated by *) is shown. The mean difference between the study groups has been calculated for normal distributed data and presented with confidence intervals (CIs), otherwise the Mann Whitney U test has been used (indicated by italics)

Analysis of whole groups can mask individual changes in participant outcomes. An analysis of the proportion of participants in each study group experiencing a decrease or increase in scores was conducted to explore this for changes from baseline to week 1. The proportion of

those in each study group with an increase, decrease or no change in MSAS-GDI, Total MSAS and Total MQOL at Week 1 compared to baseline were calculated. The results of this are given in Table 5.32 below. The results (highlighted in green) show that over 10% more of the H2H study group had a decrease in symptom distress compared to the AC group. This is encouraging and provides data that symptom control is likely to be an important outcome measurement in the larger definitive trial. This is explored further in the longitudinal data analysis below.

Table 5.32 Change in symptom and QOL score from baseline to Week 1.

Outcome measure	Percentage (95% CI)							
	Decrease		Stable		Increase		Missing	
	H2H	AC	H2H	AC	H2H	AC	H2H	AC
MSAS-GDI	40.6	32.7	3.1	8.2	28.1	38.8	28.1	20.4
Total MSAS	43.8	30.6	0	6.1	25.0	30.6	31.3	32.7
Total MQOL	28.1	38.8	3.1	2.0	21.9	28.6	46.9	30.6

MSAS-SF scores: increase in score indicates increase in symptom distress, MQOL increase in score indicates improved QOL.

5.4.3.6 Patient and Carer Satisfaction (FAMCARE)

Satisfaction with care received was assessed using the FAMCARE validated tool and data collected from the patient (FAMCARE-P16) and carer (FAMCARE) at Week 1. This subsection reports the satisfaction of patients and carers at Week 1. The results answer study objective 16

Objective 16: *To describe and compare patient and carer symptom burden, QoL and satisfaction in H2H intervention group compared to standard care*

FAMCARE assessment tool measures patient and carer satisfaction. Each item was scored from 1-5, five indicating very satisfied. Individual item scores are presented for the total population and each study group, and these are followed by a comparison of total FAMCARE scores. The carer participants were also approached in bereavement to repeat the FAMCARE tool and this work is presented in Section 5.8 of this chapter.

The results are presented in the following subsections:

- 5.4.3.6.1 Satisfaction with Care FAMCARE individual item scores: overall and within groups
- 5.4.3.6.2 Total FAMCARE scores: overall and within study groups

5.4.3.6.1 Satisfaction with Care FAMCARE individual item scores: overall and within study groups

The total patient population, H2H and AC group FAMCARE –P16 and FAMCARE individual item average scores are detailed in Table 5.33. Further descriptive analyses of individual item scores are presented in Appendix 7.4.3. Overall, no single item had an average score of less than 3 indicating that all participants, irrespective of study group, were satisfied with care. Patient participants in each study group were most satisfied with ‘the way family is included in treatment and care decisions’ (H2H participants (mean 4.5), AC participants (mean 4.4)). H2H participants were also very satisfied with ‘the way tests and treatments were performed’ (mean 4.5). The lowest scoring element of care in each study group was ‘information given about side effects’ (H2H mean score 3.9, AC mean score 3.6). Carer participants in each group were most satisfied with ‘the way tests and treatments were performed’ (H2H carer participants (mean 4.27), AC carer participants (mean 4.35)). The lowest scoring area of care for H2H carer participants was ‘information regarding prognosis’ (mean score 3.82). The two individual items of particular interest when evaluating H2H intervention were ‘coordination of

care' and 'family conferences held to discuss the patient's illness'. The H2H patient and carers both scored the coordination of care item higher than the AC group (Patient: H2H mean score 4.3, AC 3.9 Carer: H2H mean score 4.36, AC 3.81). H2H carer participants also scored the family conference item higher than AC carer participants (H2H mean 3.82, median 4, AC mean 3.24, median 3). Interestingly, the lowest scoring area of care for AC carer participants was 'family conferences'; therefore, it was the individual item with the greatest difference in scores between study groups. This data suggest a potential important benefit of H2H intervention over and above standard care.

Table 5.33 Comparison of Patient and carer FAMCARE satisfaction individual item scores at Week 1 for H2H and AC study groups

FAMCARE Individual Items		H2H Study Group						AC Study Group					
Item <i>How satisfied are you with.....*</i>		Mean	SD	% Dissatisfied		% Satisfied		Mean	SD	% Dissatisfied		% Satisfied	
				1+2	1	4+5	5			1+2	1	4+5	5
Doctors attention to your description of symptoms	Patient	4.3	0.9	4.8	0.0	81.0	52.4	4.2	0.9	5.0	2.5	80.0	42.5
	Carer	4.1	0.8	0.0	0.0	72.7	36.4	3.8	1.6	23.8	19.0	66.7	52.4
How thoroughly the doctor assesses your symptoms	Patient	4.2	1.0	4.8	0.0	71.4	52.4	4.0	1.0	10.0	0.0	72.5	37.5
	Carer	4.2	0.6	0.0	0.0	90.9	27.3	4.2	1.1	9.5	4.8	81.0	57.1
Information about how to manage pain	Patient	4.4	0.9	4.5	0.0	81.8	59.1	3.7	0.9	2.8	0.0	50.0	22.2
	Carer	4.2	0.8	0.0	0.0	81.8	36.4	3.7	1.1	15.0	15.0	50.0	35.0
Information given about side effects	Patient	3.9	0.9	4.5	0.0	63.6	31.8	3.6	1.0	7.9	2.6	47.4	21.1
	Carer	3.8	1.0	9.1	0.0	63.6	27.3	4.2	1.0	9.1	0.0	77.3	50.0
Speed at which symptoms are treated	Patient	4.1	1.0	4.5	4.5	81.8	36.4	3.9	1.0	10.0	2.5	67.5	30.0
	Carer	4.1	0.7	0.0	0.0	81.8	27.3	3.8	1.4	23.8	9.5	66.7	42.9
Information given about your tests	Patient	4.3	0.9	4.5	0.0	81.8	54.5	3.7	1.2	17.9	10.3	71.8	25.6
	Carer	4.1	0.7	0.0	0.0	80.0	30.0	4.1	1.1	10.0	10.0	80.0	40.0
The way tests and treatments are performed	Patient	4.5	0.9	4.5	0.0	86.4	63.6	4.2	0.9	5.3	2.6	89.5	39.5
	Carer	4.3	0.7	0.0	0.0	90.9	36.4	4.4	1.1	10.0	5.0	90.0	60.0
The way tests and treatments are followed up your doctor	Patient	4.1	1.1	14.3	0.0	71.4	47.6	4.1	1.1	10.5	2.6	78.9	42.1
	Carer	4.3	0.7	0.0	0.0	90.9	36.4	4.0	1.3	20.0	5.0	70.0	50.0
Information provided about your prognosis	Patient	4.0	0.9	4.8	0.0	71.4	33.3	3.8	0.9	5.0	0.0	62.5	22.5
	Carer	3.8	1.2	18.2	0.0	63.6	36.4	3.9	1.1	19.0	0.0	71.4	33.3
Answers from health professionals	Patient	4.4	1.1	9.5	4.8	85.7	66.7	4.1	0.9	5.3	0.0	78.9	34.2
	Carer	4.3	0.9	0.0	0.0	72.7	54.5	4.0	1.2	9.1	9.1	72.7	40.9
Referrals to specialists	Patient	4.3	0.8	0.0	0.0	81.0	52.4	4.0	1.0	8.8	2.9	76.5	35.3
	Carer	4.4	0.9	9.1	0.0	90.9	54.5	3.6	1.4	26.3	10.5	63.2	36.8
The availability of the doctor to answer your questions	Patient	4.1	1.1	5.0	5.0	75.0	45.0	3.9	1.0	12.5	0.0	67.5	30.0
	Carer	4.4	0.7	0.0	0.0	90.9	45.5	4.1	1.1	14.3	0.0	76.2	47.6
The availability of nurses to answer your questions	Patient	4.2	1.1	9.5	4.8	81.0	52.4	4.1	0.8	0.0	0.0	77.5	35.0
	Carer	4.2	0.9	0.0	0.0	72.7	45.5	3.9	1.1	9.5	4.8	71.4	33.3
The way the family is included in treatment and care decisions	Patient	4.5	0.8	0.0	0.0	80.0	65.0	4.4	0.8	0.0	0.0	84.2	52.6
	Carer	4.2	0.6	0.0	0.0	90.0	27.3	4.1	0.9	4.8	4.8	81.0	38.1
Coordination of care	Patient	4.3	0.8	4.8	0.0	90.5	47.6	3.9	1.0	7.5	2.5	65.0	30.0
	Carer	4.4	0.7	0.0	0.0	90.9	45.5	3.8	1.4	19.0	0.0	61.9	42.9
Availability of doctors to your family	Patient	4.1	0.8	0.0	0.0	75.0	30.0	3.8	1.0	7.9	0.0	57.9	28.9
	Carer	4.1	0.7	0.0	0.0	80.0	30.0	3.8	1.4	23.8	9.5	76.2	38.1
Pain relief	Carer	4.4	0.8	0.0	0.0	81.8	36.4	4.1	1.0	5.0	0.0	65.0	35.0
Availability of a bed	Carer	3.7	1.1	9.1	0.0	45.5	36.4	3.9	1.1	5.0	5.0	60.0	35.0
Family conferences	Carer	3.8	0.9	0.0	0.0	54.5	27.3	3.2	0.9	17.6	0.0	29.4	11.8
Time to diagnosis	Carer	4.1	1.0	9.1	0.0	72.7	45.5	3.3	1.6	33.3	27.8	61.1	27.8

5.4.3.6.2 Total FAMCARE scores: overall and across study groups

The total FAMCARE scores were calculated pro rata (as described in Section 4.10.6) and, for ease of comparison between patient and carer results, the FAMCARE-P scores were converted into a score from 0-100. Zero indicated very dissatisfied and one hundred represented very satisfied. The average FAMCARE score for H2H patient participants was mean 84 (SD 13.93), median 87.5 and for the AC group was 78.13 (SD 11.81), median 78.13. These early results show the H2H study group were more satisfied with care than the AC group ($p=0.03$). The H2H participants' median total satisfaction scores were nearly 10 points higher than AC participant scores. This is likely to be clinically relevant. The comparison of carer scores at Week 1 showed similar trends. The average FAMCARE score for the H2H group was mean 81.9 (SD 7.27), median 83 compared to a mean score of 72.1 (SD 20.8), median 77 in the AC group. These results in conjunction with the patient score are likely to be clinically relevant. Carers scored satisfaction lower than patient participants across all individual items, and this translates into lower FAMCARE scores.

Comment [CM2]: ADD INTO SUMMARY SECTION TO PULL INTO DISCUSSION

Table 5.34 Comparison of Total FAMCARE scores for patient and carers in the H2H and AC study groups

Week 1	H2H Study Group						AC Study Group						Statistical analysis	
	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M		p
FAMCARE P-16	22	84.0	13.93	87.5	51-100	2	40	78.5	11.81	78.13	51-100	1	291.5* $z=-2.19$	0.03
FAMCARE Score	11	81.9	7.27	83.0	67-90	0	22	72.1	20.80	77.00	13-100	0	MD - 9.77 (-19.89-0.35)	0.06

Famcare P-16 score is out of a total of $5 \times 16 = 80$, to allow easy interpretation and comparison to carer scores this has been rescaled to be out of a total of 100. M- missing

*Normality testing of the data for FAMCARE-P gave the Kolmogorov-Smirnov statistic of 0.084, $p=0.2$ for the AC group. However, the H2H group test statistic was 0.193 with a p value of 0.032 suggesting a violation of the assumption of normality. Therefore, the Mann Whitney U test was used in preference to the 2-sided T-test.

5.4.3.7 Longitudinal Symptom scores (MSAS-SF) overtime

5.4.3.7.1 MSAS-SF GDI Population Profiles

Figure 5.8 gives the total population mean MSAS-GDI scores over the duration of the study. Higher values represent increased severity of symptoms and distress (with 4 the highest score possible). The figure and table show that for the total population there is minimal variation in global distress (MSAS-GDI) across the four time points of the study. The variation seen is a small decrease in scores over time (Baseline (T0) mean 1.24, Week 12 (T3) mean 1.18). This indicates that participants experience marginally less distress from their symptoms over time. However, it is important to note that the cohorts at each time point are not the same. There is a high dropout rate due to death (46 deaths by week 12) and this is likely to have an impact on the trend seen. It may be that those participants who are still alive and able to complete assessments were individuals with low distress scores at baseline and individuals with higher distress (MSAS-GDI) scores have been removed from the later time point cohorts due to death.

Figure 5.9 and Table 5.35 give the comparison of mean MSAS-GDI scores between the study groups over time. In the H2H group, there is a small reduction in MSAS-GDI scores over the study period by 0.5 on a 0-4 scale, indicating less distress as the study progresses. The AC group shows minimal change over the study period. However, H2H participants had marginally higher scores, and therefore more global distress, than the AC group up to week 4 (T2). For participants remaining at week 4 (T2) and week 12 (T3), the AC group had higher maximum MSAS-GDI scores compared to H2H participants (T3 AC 2.60, T3 H2H 1.28). H2H participants may have had their symptoms more proactively controlled than AC participants. It is important to reiterate for these population profiles that the cohorts are not identical at each time point due to dropouts from death. Therefore, based on this data, it cannot be confidently concluded that H2H participants experience less symptom distress over time. In order to establish accurate trends, the individual patient profiles in each group must be examined longitudinally through descriptive analysis and summary statistic analysis.

Figure 5.8 Total Population Mean MSAS-GDI Score over time

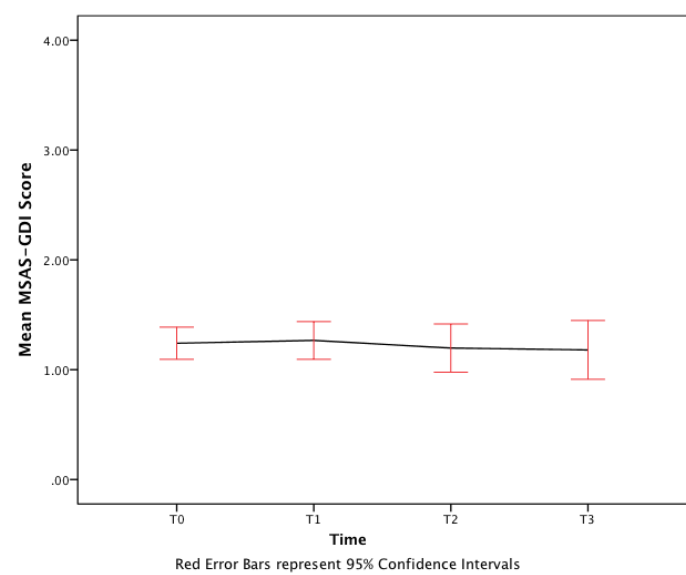


Figure 5.8 Comparison of mean MSAS-GDI Scores over time for H2H study group and AC Group

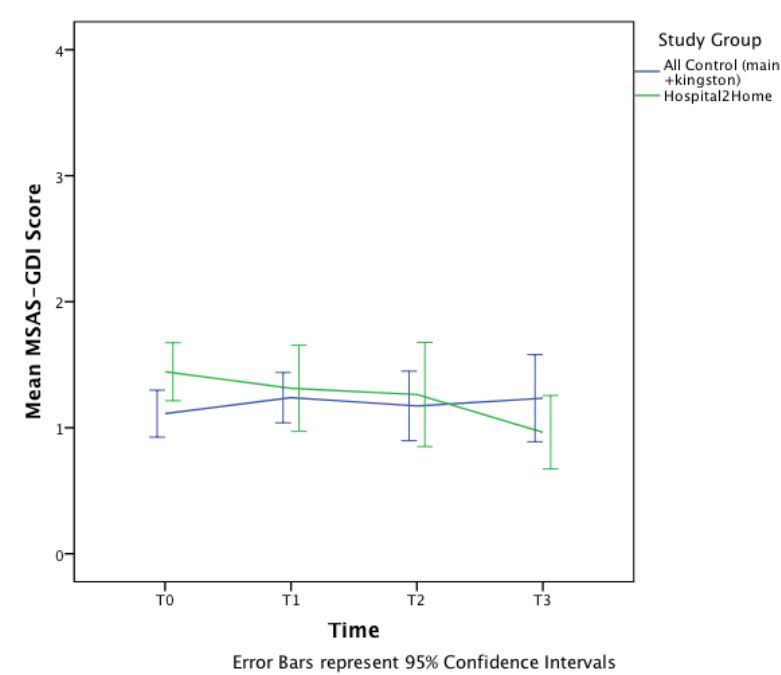


Table 5.35 Comparison of Mean MSAS-GDI Scores over time for H2H study group and AC Group

Time from recruitment		T0	T1	T2	T3
Mean MSAS-GDI Score	Total Population	1.24	1.27	1.20	1.18
	H2H	1.44	1.31	1.26	0.96
	AC	1.11	1.24	1.17	1.23
SD	Total Population	0.66	0.68	0.74	0.67
	H2H	0.63	0.79	0.65	0.24
	AC	0.65	0.62	0.78	0.73
Minimum	Total Population	0.0	0.08	0.0	0.0
	H2H	0.20	0.08	0.10	0.64
	AC	0.00	0.24	0.00	0.00
Maximum	Total Population	3.34	3.20	3.56	2.60
	H2H	3.34	3.20	2.36	1.28
	AC	3.22	3.02	3.56	2.60

N	Total Population	80	62	45	25
	H2H	31	23	12	5
	AC	49	39	33	20
Withdrew	Total Population	2	2	2	2
	H2H	0	0	0	0
	AC	2	2	2	2
Died (ADD)	Total Population	0	5	17	46
	H2H	0	3	11	23
	AC	0	2	6	23
ADI	Total Population	0	11	17	8
	H2H	0	5	8	4
	AC	0	6	9	4
Missing value- individual items missing so score not calculated	Total population	1	3	2	2
	H2H	1	1	1	0
	AC	0	2	1	2
Total	Total Population	83	83	83	83
	H2H	32	32	32	32
	AC	51	51	51	51

5.4.3.7.2 MSAS-SF GDI Individual profiles

These data are available for participants who had two or more completed time points with no missing data for items of the MSAS-GDI score (n = 57 (with 26 missing data)). In Figure 5.10 H2H participant vitagrams are shown in orange and AC participants in blue.

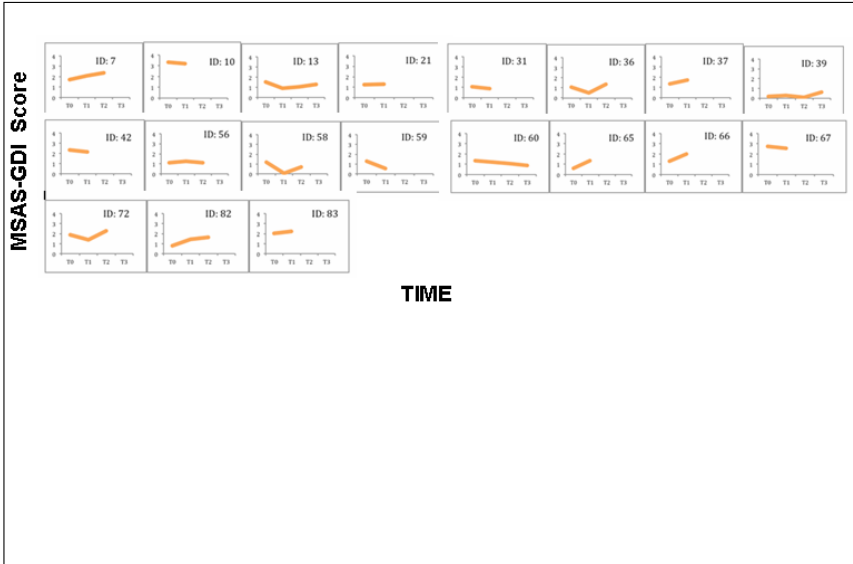
Descriptive analysis of these vitagrams highlights that symptom distress, measured by MSAS-GDI, showed five different trajectories: decreasing, troughed, undulating or stable, peaked, and increasing. Table 5.36 gives detail of these 5 categories and the study ID of participants who experienced each trajectory. These individual trajectories show that a large proportion of AC participants have either stable symptom distress (31.6%) or experience increase symptom distress (28.9%) over time with a comparatively small proportion (10.5%) experiencing less symptom distress over time. This is in contrast to the H2H group, where the proportions of participants experiencing increasing or decreasing symptom distress over time were equal (26.3%). On this descriptive analysis, a higher proportion of H2H participants show some improvement in symptom distress scores across time points (Trajectory=Decreasing + Troughed) from T0 compared to AC participants (H2H 52.6%, AC 28.9%).

Table 5.36 Descriptive analysis of Individual participant vitagrams for MSAS-GDI

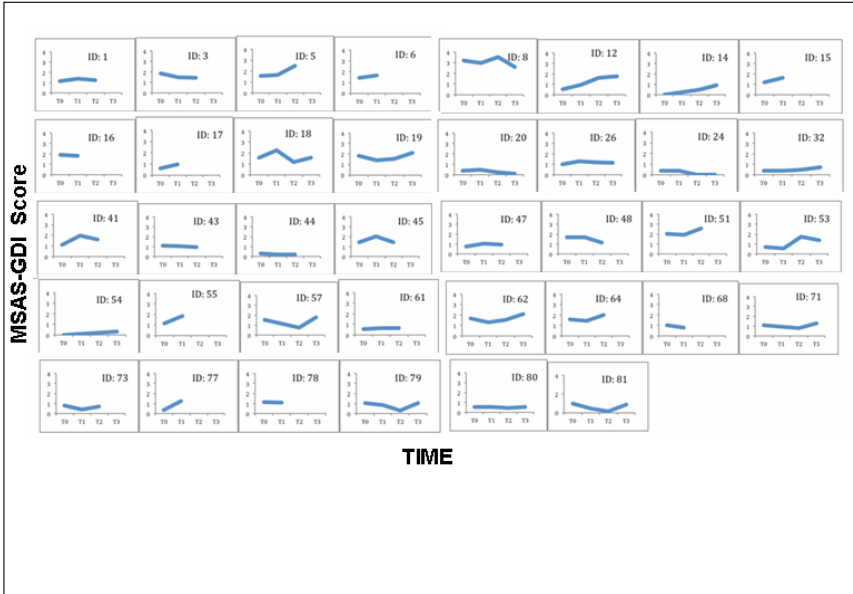
Category	Study Group	n	%	ID numbers
Decreasing	H2H	5	26.3	42, 31, 59, 60, 67
	AC	4	10.5	3, 48, 68, 18
Troughed	H2H	5	26.3	13, 30, 36, 58, 72
	AC	7	18.4	57, 62, 64, 71, 73, 79, 81
Stable	H2H	3	15.8	10, 28, 56
	AC	12	31.6	1, 16, 32, 38, 39, 43, 44, 54, 61, 78, 80, 83
Peaked	H2H	0	0	
	AC	6	15.8	8, 33, 41, 45, 47, 77
Increasing	H2H	5	26.3	7, 37, 40, 65, 66
	AC	11	28.9	5, 6, 14, 15, 17, 34, 12, 51, 53, 55, 82

Figure 5.10 Individual Vitagrams for MSAS-GDI split by study group

a) H2H participant individual longitudinal MSAS-GDI scores (n=19)



b) AC individual longitudinal MSAS-GDI scores (n=38)



5.4.3.7.3 Total MSAS Scores Population Profiles

Figure 5.11 Total Population Mean Total MSAS Score over time

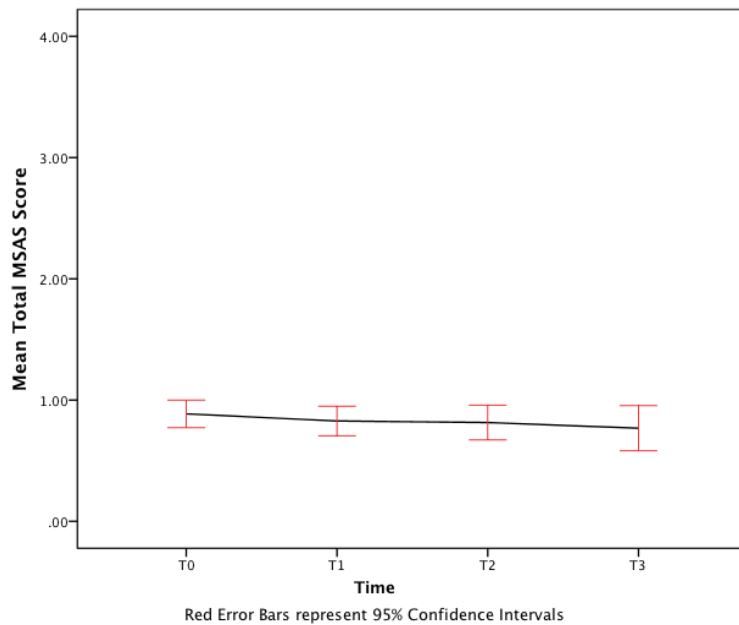


Figure 5.12 Mean Total MSAS Scores over time for H2H study group and AC Group

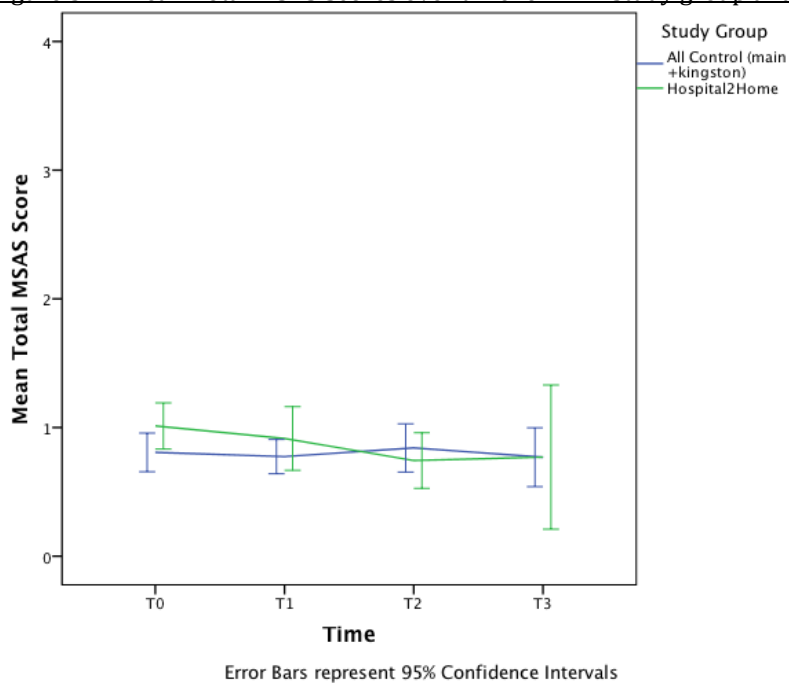


Table 5.37 Mean Total MSAS Scores over time for H2H study group and AC Group

Time from recruitment		T0	T1	T2	T3
Mean Total MSAS Score	Total Population	0.89	0.83	0.81	0.77
	H2H	1.01	0.91	0.74	0.77
	AC	0.81	0.77	0.84	0.77
SD	Total Population	0.50	0.46	0.47	0.45
	H2H	0.49	0.56	0.32	0.36
	AC	0.50	0.39	0.51	0.48
Minimum	Total Population	0.05	0.10	0.11	0.10
	H2H	0.16	0.10	0.11	0.48
	AC	0.05	0.19	0.18	0.10
Maximum	Total Population	2.48	2.03	2.56	1.89
	H2H	2.41	2.03	1.24	1.22
	AC	2.48	1.84	2.56	1.89

N	Total Population	77	57	42	23
	H2H	31	22	11	4
	AC	45	35	31	19
Withdrew	Total Population	2	2	2	2
	H2H	0	0	0	0
	AC	2	2	2	2
Died (ADD)	Total Population	0	5	17	46
	H2H	0	3	11	23
	AC	0	2	6	23
ADI	Total Population	0	11	17	8
	H2H	0	5	8	4
	AC	0	6	9	4
Missing value- individual items missing so score not calculated	Total population	5	8	5	4
	H2H	1	2	2	1
	AC	4	6	3	3
Total	Total Population	83	83	83	83
	H2H	32	32	32	32
	AC	51	51	51	51

The total population mean Total MSAS scores over the study period are detailed in Figure 5.11. The overall scores are low (less than 1) throughout the study and show minimal change over time.

Figure 5.12 and Table 5.37 detail the mean Total MSAS over the 12-week study period for each group. The H2H mean Total MSAS score reduced over time, whereas the AC score remained approximately the same. The mean AC group score was higher than for H2H participants at the end of the study, and the figure demonstrates the scores cross over between week 4 and week 12.

5.4.3.7.4 Total MSAS Scores Individual Profiles

Individual profiles are presented for participants who had two or more completed time points with no missing data items for Total MSAS (n = 57 (with 26 missing data)). In Figure 5.13 H2H participant vitagrams are shown in orange and AC participants in blue. Table 5.38 gives detail of the 5 trajectories and the study ID of participants who experienced each trajectory. The distribution was comparable to the MSAS-GDI scores. A large proportion of AC participants experienced either stable total symptom distress (30.6%) or increasing symptom distress (30.6%) over time. A comparatively small proportion (16.7%) experienced less symptom distress over time. This is in contrast to the H2H group, where a larger proportion of participants experienced decreasing symptom distress over time (19%) compared to increased distress (9.5%). Overall, a higher proportion of H2H participants showed improvement in symptom distress scores across time points. (Trajectory=Decreasing + Troughed) from T0 compared to AC participants (H2H 52%, AC 30.6%).

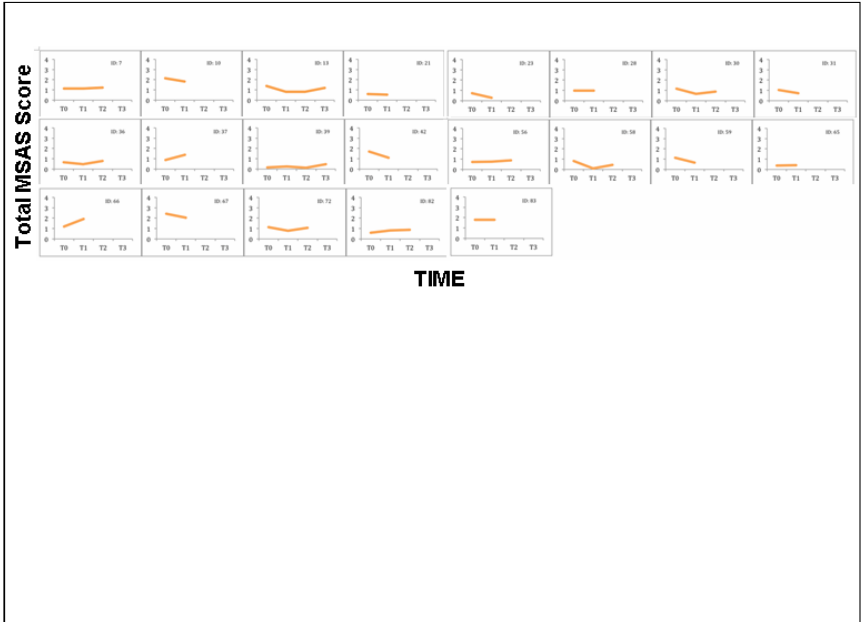
Table 5.38 Descriptive analysis of Individual participant vitagrams for Total MSAS Scores* in the H2H and AC study groups

Category	Study Group	n	%	ID numbers
Decreasing	H2H	4	19.0	10,23,42,67
	AC	6	16.7	20,24,44,48,68,73
Troughed	H2H	7	33.3	13,30,31,36,58,59,72
	AC	5	13.9	3,19,43,51,62
Stable	H2H	8	38.1	7,21,28,39,56,65,82,83
	AC	11	30.6	1,16,18,32,33,38,53,55,61,64,80
Peaked	H2H	0	0	
	AC	3	8.3	8,26,41
Increasing	H2H	2	9.5	37,66
	AC	11	30.6	5,6,12,14,15,17,34,40,45,71,77

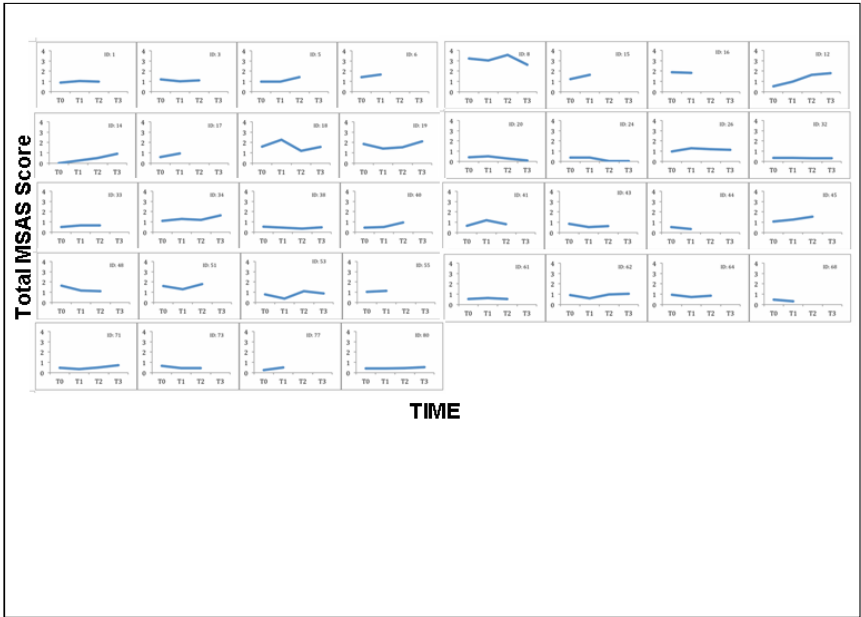
*- increasing trajectories indicate increase in symptom distress

Figure 5.13 Individual Vitagram plots for Total MSAS scores over time by study group *

H2H individual longitudinal Total MSAS scores (n=21)



AC individual longitudinal Total MSAS scores (n=36)



*H2H:orange plots, AC: blue plots

5.4.3.8 Longitudinal QoL scores (Total MQOL) over time

5.4.3.8.1 Total MQOL Population Profiles

The mean Total MQOL scores at each time point for the total population are shown in Figure 5.14. These show that participants scored their QoL high (over 7/10) at all time points throughout the duration of the study. The mean Total MQOL score for the total population showed minimal variation over time.

Figure 5.15 and Table 5.39 illustrate the Total MQOL scores over the study period for H2H participants and AC participants. These show that in the H2H study group the Total MQOL score increases over time, indicating an improvement in QoL, from baseline (T0: 7.2) to week 12 (T3 :8.18). The increase was 0.96 on the 0-10 scale. This must be interpreted with caution as again the cohorts are not identical at each time point and, by week 12 (T3), only five H2H participants' data are available in this feasibility study. The AC group Total MQOL scores showed minimal variation and no overall change across the study period (T0 7.72, T3 7.73). The increase in QoL in the H2H study group over time is consistent with the decrease in symptom distress scores seen in section 5.4.3.7 above.

Figure 5.14 Total Population Mean Total MQOL Score over time (baseline to 12 weeks)

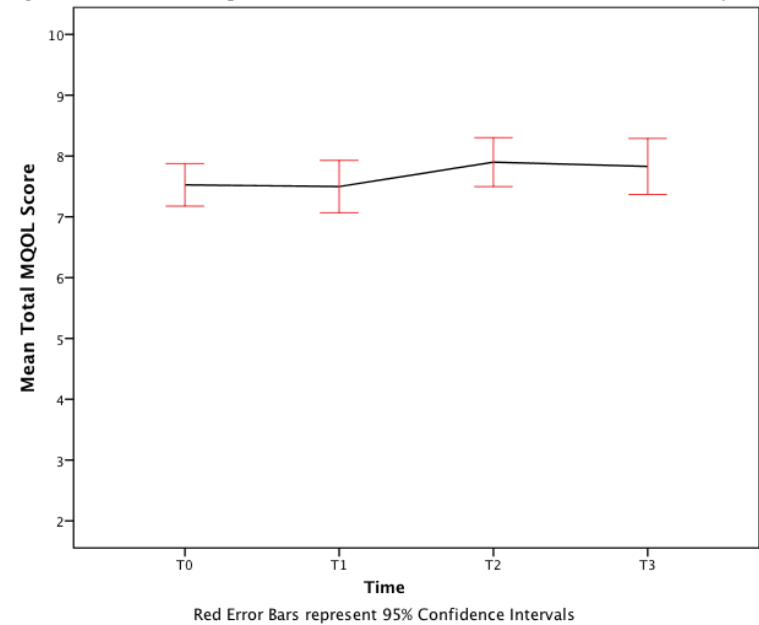


Figure 5.15 Mean Total MQOL Scores over time for H2H study group and AC Group

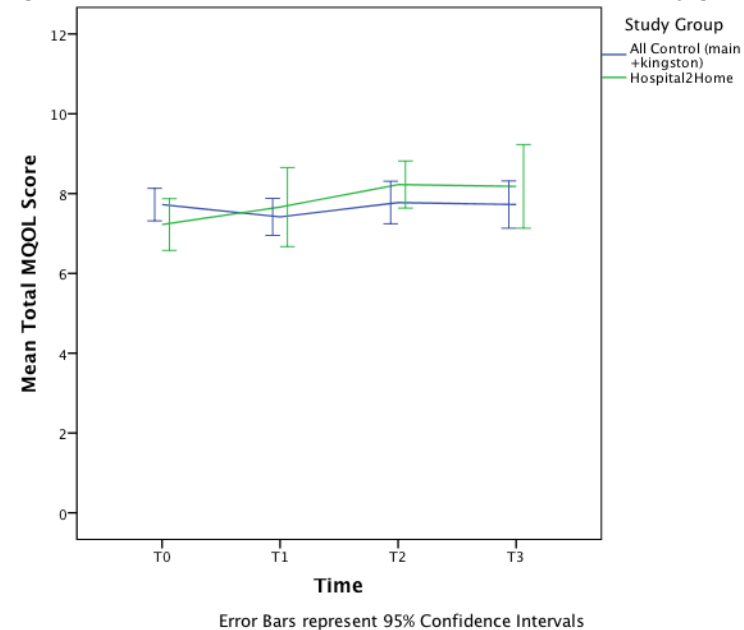


Table 5.39 Comparison of mean Total MQOL Scores over time for H2H study group and AC Group

Time from recruitment		T0	T1	T2	T3
Mean Total MQOL Score	Total Population	7.53	7.50	7.90	7.83
	H2H	7.22	7.66	8.23	8.18
	AC	7.72	7.42	7.78	7.73
SD	Total Population	1.51	1.59	1.28	1.09
	H2H	1.70	1.99	0.88	0.85
	AC	1.34	1.37	1.40	1.15
Minimum	Total Population	2.00	1.67	4.97	6.03
	H2H	2.00	1.67	6.90	6.72
	AC	4.97	4.40	4.97	6.03
Maximum	Total Population	10.00	10.00	9.90	9.87
	H2H	9.28	10.00	9.43	8.73
	AC	10.00	10.00	9.90	9.87

N	Total Population	73	54	40	22
	H2H	29	18	11	5
	AC	44	36	29	17
Withdrew	Total Population	2	2	2	2
	H2H	0	0	0	0
	AC	2	2	2	2
Died (ADD)	Total Population	0	5	17	46
	H2H	0	3	11	23
	AC	0	2	6	23
ADI	Total Population	0	11	17	4
	H2H	0	5	8	4
	AC	0	6	9	4
Missing value- individual items missing so score not calculated	Total population	8	11	7	5
	H2H	3	6	2	0
	AC	5	5	5	5
Total	Total Population	83	83	83	83
	H2H	32	32	32	32
	AC	51	51	51	51

5.4.3.8.2 Total MQOL Individual Profiles

Individual profiles are presented for participants who completed two or more time points with no missing data items for Total MQOL (n = 56, with 27 missing data). In Figure 5.16 H2H participant vitagrams are shown in orange and AC participants in blue.

Table 5.40 gives detail of the 5 trajectories and the study ID of participants in each trajectory. The MQOL scale is from zero to ten, with ten indicating an excellent QoL. Increasing trajectories over time correspond with improvements in QoL. A high proportion of AC participant trajectories show a decrease in QoL over time (38.5%) with a comparatively small proportion (5.1%) experiencing improvement of QoL over time. This is in contrast to the H2H group, where equal proportions of individual trajectories show increasing and decreasing QoL over time (17.6% in each category). On this exploratory descriptive analysis, a higher proportion of H2H participants show improvement in QoL scores across time points (Trajectory=Increased + Peaked) from T0 compared to AC participants (H2H 41.1%, AC 30.7%).

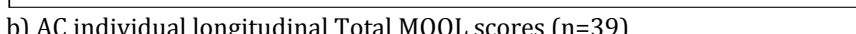
Table 5.40 Descriptive analysis of Individual participant vitagrams for Total MQOL*

Category	Study Group	n	%	ID numbers
Decreasing	H2H	3	17.6	7,27,42
	AC	15	38.5	1,3,12,14,15,43,55,57,61,68,71,73,77,80,81
Troughed	H2H	1	5.9	56
	AC	3	7.7	41,44,51
Stable	H2H	6	35.3	13,21,37,58,59,82
	AC	9	23.1	2,8,17,20,24,33,34,64,78
Peaked	H2H	4	23.5	23,30,36,39
	AC	10	25.6	5,18,19,32,38,40,45,47,53,79
Increasing	H2H	3	17.6	28,60,66
	AC	2	5.1	16,48

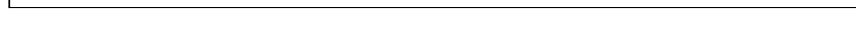
*increasing trajectories indicate improvement in QoL

a) H2H individual longitudinal Total MQOL scores (n=17)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466	467	468	469	470	471	472	473	474	475	476	477	478	479	480	481	482	483	484	485	486	487	488	489	490	491	492	493	494	495	496	497	498	499	500	501	502	503	504	505	506	507	508	509	510	511	512	513	514	515	516	517	518	519	520	521	522	523	52



Year	2000	2001	2002	2003	2004
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5.4.3.9 Symptom burden (MSAS-SF) and QoL (MQOL) Formal Summary Measure Analysis – Area Under the Curve

The formal summary measure of time-adjusted area under the curve was used to compare longitudinal changes in symptom scores (TMSAS, MSAS-GDI) and QoL scores (TMQOL). The calculated time-adjusted Area Under the Curve are detailed in Table 5.41a with statistical comparison given in Table 5.41b. Overall, these analyses of longitudinal changes to MSAS-GDI (z -0.45, p=0.66), Total MSAS (t test -0.93, p=0.36) and Total QOL (z -0.29, p= 0.77) show no difference between H2H participants and AC comparators. However, the descriptive trends seen in individual longitudinal data warrant future study in a larger evaluation trial.

Table 5.41 Summary measure statistical analysis comparing longitudinal data for symptom burden and QoL between the H2H and AC study groups

a)

	H2H Study Group						AC (AC) Study Group					
	N	Mean	SD	Median	Range	M	N	Mean	SD	Median	Range	M
MSAS-GDI	23	1.40	0.71	1.21	0.32-3.27	9	39	1.24	0.62	1.34	0.1-3.14	12
Total MSAS	22	0.94	0.57	0.88	0.04-2.22	10	35	0.81	0.46	0.79	0.1-2.21	16
Total MQOL	18	7.44	1.80	7.54	1.83-9.61	14	36	7.55	1.19	7.55	5.0-9.8	15

b)

Time Adjusted AUC Summary Measure	H2H Study Group (A)	AC Study Group (B)	Statistical Analysis comparing A) & B)				
	Mean (SD) Median (Range)	Mean (SD) Median (Range)	T Test	P value	Mann Whitney U Test	Z	P value
MSAS-GDI	1.21 (0.32-3.27)	1.34 (0.1-3.14)	X	X	407.00	-0.446	0.66
Total MSAS	0.94 (0.573)	0.81 (0.459)	0.932	0.36	X	X	X
Total MQOL	7.54 (1.83-9.61)	7.55 (5.0-9.8)	X	X	250.00	-0.291	0.77

*Time adjusted AUC summary measure requires a minimum of 2 time points for calculation.

**Missing value = Withdrew+Attrition due to illness (ADI)+Attrition due to death (ADD)+Missing score

5.4.4 Section Summary

The secondary outcome data collected in this feasibility study and presented in this section were longitudinal symptom control, patient and carer QoL and satisfaction data. The purpose of which was to make recommendations on the acceptability of repeated holistic outcome measurement at the EoL and provide early exploratory data on whether H2H has any potential benefit over standard care.

The data in this section shows a low withdrawal rate from the study. Two participants withdrew due to choice reflecting that the validated tools and study schedule, including repeated measurements close to death, were acceptable to patients and carers. Despite this willingness to participate the longitudinal data was limited by high ADI and ADD. ADI and ADD at week 1 was 22% and by 12 weeks was 80%. Therefore in this feasibility study only descriptive analyses were possible. The fact that ADI and ADD are informative drop outs in EoLC research alongside the finding here that only 65% of participants completed sufficient data collection for the calculation of the summary outcome measurement AUC, these results make the use of summary statistics such as AUC questionable in EoLC research. The questionnaire had 50 individual items for patients and 85 items for carers. The overall proportion of individual missing items for questionnaires completed was low (0.9%) suggesting telephone questionnaire was an appropriate data collection method to use and the questionnaire length was not too burdensome. However, at Week 1 the addition of the FAMCARE tool and H2H acceptability questionnaire increased the total items to answer at this assessment to 74 for patients and 113 for carers. This led to a higher rate of individual missing items (1.7%) for patient participants indicating the increased questionnaire length at Week 1 was too burdensome. These findings lead me to recommend that telephone follow up is feasible and the optimum questionnaire length for the larger definitive trial should be a maximum of 50 items for patients.

The results show small improvements in MSAS-GDI, Total MSAS, Total MQOL and Total CQOLC scores with H2H. This finding is encouraging because symptom burden is known to increase and QoL decrease at the EoL. Although not powered to detect a difference, this feasibility study shows H2H group at least maintain their symptom control and QoL from baseline to week 1, whereas the AC group shows small increases in symptom burden and decreases in QoL. The

limited longitudinal data supports these findings. It is also important to highlight that carer burden and QoL showed small improvements with H2H suggesting that the intervention is not having a negative impact on the carer experience. These preliminary results also show that patients and carers are more satisfied with care with H2H. One potentially important finding is that the baseline MSAS data presented here shows more participants 'worry' in the intervention group than in the standard care group, although by week 1 this is no longer the case. This feasibility work is underpowered and all the results presented here may have occurred by chance but merit further evaluation in the definitive study. This should include closer scrutiny and understanding of the possibility that the intervention may cause potential harm in the form of worry, through qualitative interviews.

Table 5.42 Summary of secondary outcome data for patients and carers in H2H and AC study groups

Outcome	H2H	AC	H2H versus AC			
			MD (95% CI) <i>MWU test</i>	p value	Clin Sign	H2H Trend
	<i>n=23</i>	<i>n=39</i>				
MSAS-GDI change _{T1-T0}	-0.15 (0.55)	0.10 (0.36)	0.25 (0.02-0.48)	0.03	Yes	Improve
	<i>n=22</i>	<i>n=33</i>				
Total MSAS change _{T1-T0}	-0.16 (0.36)	-0.04 (0.26)	0.12 (-0.05-0.29)	0.16	? Yes	Improve
	<i>n=17</i>	<i>n=34</i>				
Total MQOL change _{T1-T0}	0.14 (0.99)	-0.17 (0.92)	0.31 (-0.25-0.87)	0.27	No	Improve
	<i>n= 6</i>	<i>n= 10</i>				
Total CQOLC change _{T1-T0}	4.67 (7.42)	1.18 (6.48)	3.48 (-4.08-11.04)	0.34	No	Improve
	<i>n=23</i>	<i>n=23</i>				
MSAS-GDI change _{L0-T0}	0.00 (0.37)*	0.00 (0.44)*	<i>221.0, z=-0.95</i>	0.34	No	No diff
	<i>n=22</i>	<i>n=22</i>				
Total MSAS change _{L0-T0}	0.00 (0.33)*	0.00 (0.26)*	<i>205.5, z=-0.86</i>	0.39	No	No diff
	<i>n=20</i>	<i>n=22</i>				
Total MQOL change _{L0-T0}	0.00 (0.31)*	-0.17 (0.83)*	<i>164.5, z=-1.40</i>	0.16	No	No diff
	<i>n=23</i>	<i>n=38</i>				
MSAS-GDI AUC _T	1.21 (0.83)*	1.34 (0.92)*	<i>407.0, z=-0.45</i>	0.66	No	Improve
	<i>n=22</i>	<i>n=33</i>				
Total MSAS AUC _T	0.94 (0.573)	0.81 (0.459)	0.13 (-0.41-1.45)	0.36	No	Decline
	<i>n=17</i>	<i>n=31</i>				
Total MQOL AUC _T	7.54 (2.14)*	7.55 (1.36)*	<i>250.0, z=-0.29</i>	0.77	No	No diff
	<i>n=22</i>	<i>n=40</i>				
FAMCARE-P Score	87.50 (13)*	78.13 (15)*	<i>291.50, z=2.19</i>	0.03	Yes	Improve
	<i>n=11</i>	<i>n=22</i>				
FAMCARE Score	81.9 (7.27)	72.1 (20.80)	-9.77 (-19.89-0.35)	0.06	Yes	Improve

MSAS-SF scores: increase in score indicates increase in symptom distress, MQOL increase in score indicates improved QoL, CQOLC higher score indicates better/enhanced carer QoL and FAMCARE/FAMCARE-P higher score indicates greater satisfaction with care. MD mean difference, AC group. Normal data is presented as mean or mean change (standard deviation) otherwise median or median change (interquartile range) (indicated by *) is shown. The mean difference between the study groups has been calculated for normal distributed data and presented with confidence intervals (CIs), otherwise the Mann Whitney U test has been used (indicated by italics)

This section has contributed to the *feasibility and piloting phase* of the MRC framework for evaluating CIs by scrutinising the feasibility of collecting longitudinal symptom control and QoL data and evaluating potential preliminary effects of H2H. It has highlighted the following considerations for a definitive trial that are reflected on further in the discussion chapter of this thesis;

- Low withdrawal rate due to choice (1.7%)
- Missing data: High ADI and ADD ranging from 22% at week 1 to 80% by week 12
- Questionnaire content and length: Minimum individual missing items (0.9%) suggest questionnaires were acceptable and an appropriate length (50 items for patients)
- Limitations of fixed follow up period – unable to perform analysis backwards from death due to the fixed 3 month follow up and participant survival beyond 3 months, suggesting continued data collection monthly from Week 4 until death would be more informative
- Early exploratory analysis suggests H2H may have a positive effect on patient global symptom distress, carer quality of life and both patient and carer satisfaction at week 1.
- Increased worry in the intervention group at baseline, although not sustained at week 1, requires further exploration and consideration

5.5: Service Use and Exploratory Cost analysis

This section presents the service use data collection and exploratory cost analysis comparing the H2H study group with the AC group in this feasibility study and addresses study objectives 5, 17, 18 and 19.

Objective 17: *To describe and compare service use after discharge from oncology services in H2H intervention group compared to standard care.*

Objective 18: *To describe and compare the number of patient days spent in their PPC in H2H intervention group compared to standard care.*

Objective 19: *To describe and compare the number of admissions and days spent in hospital/hospice after discharge from oncology services in H2H intervention group compared to standard care.*

The data are presented in the following subsections:

- 5.5.1 Feasibility of patient reported service use data collection
- 5.5.2 Service use of all participants over the 12 week study period
- 5.5.3 Service use of participants who died during the 12 week study period (n=46)
- 5.5.4 Time Spent in PPC and Inpatient Facility
- 5.5.5 Cost of Care Analysis

5.5.1 Feasibility of patient reported service use data

The number of missing service use data questionnaires was low throughout the study. This reflects the appropriate data collection techniques used for this two weekly contact with participants. Service use data were collected from either the patient or carer and also collected retrospectively after death from the carer when contact was made at the next routine study time point. Table 5.43 gives detail of the number of participants in the study at each service use data collection time point and the number of missing questionnaires. The time point with the most missing data due to illness (ADI) or missing at random (ARR) was week 2. At Week Two, 6% (5/83) of participants had missing service use data, all of these participants were from the H2H group. Across the entire 12 week follow up for the study the number of possible service use data points to be collected, excluding attrition due to death (ADD) was 409. Of these 6.4% (26/409) were missing ADI and one (0.2%) questionnaire was missing ARR. Scrutiny of the missing data per study group highlights more missing data from ADI in the H2H study group compared to the AC group (H2H 8.5%, AC 5.7%).

Figure 5.17 gives detail of the number of participants alive at each service use data collection time point across the twelve weeks study period. This shows steady loss to follow up of service use data over the 12 weeks, and this is more marked in the H2H group. Overall 40% (22% in H2H group and 53% in AC group) of participants completed all 7 data collection points over the 12 week follow up period. The attrition in the service use data over time is less than the individual symptom and QoL questionnaires. There are two reasons for this:

- The patient **or** carer could provide the health service use information and therefore when the patient was too unwell to complete symptom and QoL assessments (ADI) the carer could still provide the health service use data.
- The collection of service use data was less onerous and time consuming than the symptom and QoL questionnaires. Therefore when the patient became more unwell some participants felt able to complete the service use data but not the symptom and QoL assessment tools.

Figure 5.17 Number of study participants and data collected at each service use time point from study entry

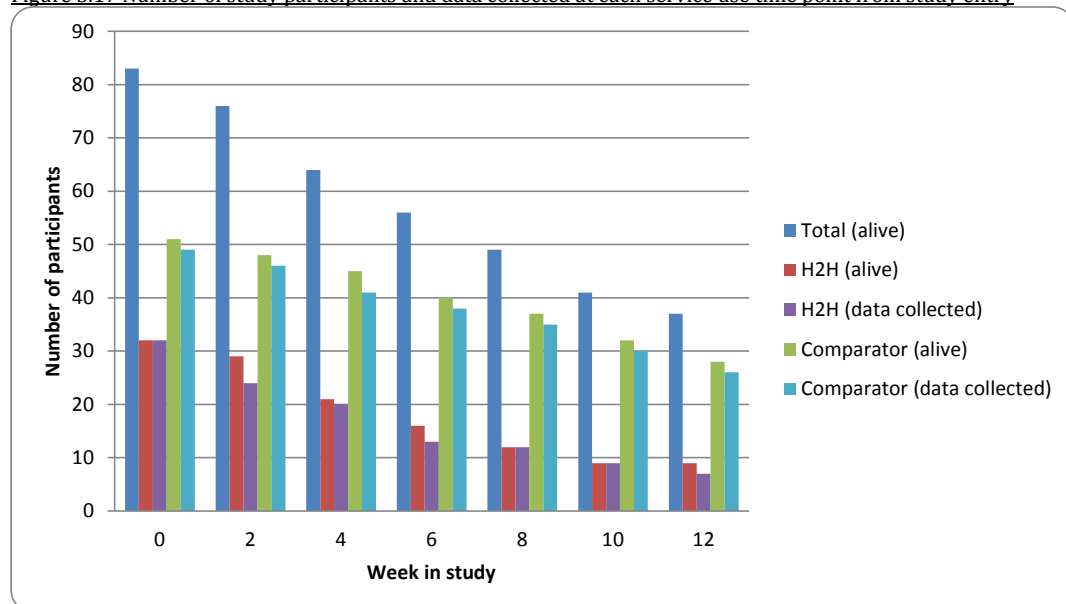


Table 5.43 Attrition from service use data collection over the 12-week study period

	Data collection week						
	Baseline	2	4	6	8	10	12
H2H							
Complete	32	24	20	13	12	9	7
Withdrew	0	0	0	0	0	0	0
ADD	0	3	11	16	20	23	23
ADI	0	4	1	3	0	0	2
ARR	0	1	0	0	0	0	0
Total missing	0	8	12	19	20	23	27
Comparator							
Complete	49	46	41	38	35	30	26
Withdrew	2	2	2	2	2	2	2
ADD	0	3	6	11	14	19	23
ADI	0	0	2	0	0	0	0
ARR	0	0	0	0	0	0	0
Total missing	2	5	10	13	16	21	25

Figure 5.18 & 5.19 give further detail of the missing service use questionnaires at each time point for individual participants in the H2H group and AC group respectively. In the same patterns seen for symptom and QOL data, the majority of service use missing data were terminal missing data and only one participant had intermittent missing data (Participant 72 in whom Week 2 service use data were missing but Week 4 data were complete).

Figure 5.18: Hospital2Home: Follow up and attrition for secondary outcome data – Service Use

H2H Participant ID	Service Use Data Collection Time point (weeks from study entry)						
	0	2	4	6	8	10	12
2				ADI	ADD		
4		ADI-A	ADD				
7							ADD
9			ADD				
10					ADD		
13							
21				ADI-A	ADD		
22							
23							
25		ADD					
27							
28						ADD	
30				ADD			
31			ADD				
35		ADD					
36				ADI	ADD		
37		ADI-A	ADD				
39							
42				ADD			
52				ADD			
56						ADD	
58							ADD
59			ADD				
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65							
66			ADD				
67			ADI-A	ADD			
69		ADI-A	ADD				
72				ADD			
74		ADD					
82						ADD	
83		ADI		ADD			

ADI: Attrition due to illness, ADI-A: Attrition due to illness (admitted) ADD: Attrition due to death

Figure 5.19: Comparator group: Follow up and attrition for secondary outcome data – Service Use

Comparator group	Service Use Data Collection Time point (weeks from study entry)						
Participant ID	0	2	4	6	8	10	12
1							
3					ADD		
5							
6						ADD	
8							
11	WITHDREW						
12							
14							
15		ADD					
16			ADD				
17			ADD				
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29					ADD		
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62							
63					ADD		
64					ADD		
68	ADD						
70	ADD						
71							
73							ADD
75	WITHDREW						
76		ADI	ADD				
77		ADI-A	ADD				
78		ADD					
79							
80							
81							

ADI: Attrition due to illness, ADI-A:Attrition due to illness (admitted) ADD: Attrition due to death

The missing service use data due to ADI (overall H2H 8.5%, AC 5.7%) is important to consider when interpreting the service use and cost analysis results presented here. Values reported are likely to be an underestimate of the true EOLC costs. In this feasibility study no imputation methods for missing data were used. However, service use is known to increase as death approaches[226] and therefore it can be assumed that the values of terminal missing data (i.e. ADI prior to death) are likely to be at least equal to the previous collected time point. With this in mind, one strategy to handle missing service use data that could be adopted in a larger study would be the 'Last observation carried forward' method. This alongside carer recruitment would enable a more accurate costing of EoLC. However, the use of patient/carers reported service use data collection as a single source will always underestimate true service input and costs for two important reasons; the patient is often unaware of all HCP to HCP interactions related to their care and therefore unable to report this data, and secondly patient reported service use will underestimate home death service use/costs more so than it will institutional deaths. Once a participant was admitted to a hospital or hospice for EoLC until death the cost of their care could be calculated even when they were unable to complete the data collection (ADI). However, relying solely on patient reported service use at home meant that the last few days/week of life service use data was often missing due to ADI, hence more accurate costs could be calculated for those participants who died in institutions.

5.5.2 Service use of all participants over the 12 week study period (n=81)

Table 5.44 below details the proportion of participants who had at least one contact, excluding H2H, with CHCPS during the study period. This shows that the proportion that had seen a GP at least once was similar across the study groups (87.5% H2H, and 83.7% AC group). However, the proportion of participants accessing district nursing was higher with H2H compared to the AC group (H2H 68.8%, AC 55.1%). A higher proportion of the AC group had at least one contact with CPCT (H2H 87.5%, AC 91.8%) and community allied health professionals (H2H 18.8%, AC 30.6%).

Table 5.44 Face -to -Face Contact with HCPS during the 12-week study period (all participants)

Contact with HCPS	Number with at least one contact over the 12-week study period n (%)			
	Total population (n=81)	H2H group (A) (n=32)	AC group (B) (n=49)	Statistical comparison (A) & (B)
GP	69 (85.2)	28 (87.5)	41 (83.7)	0.02, p=0.9
District Nurse	49 (60.5)	22 (68.8)*	27 (55.1)	1.0, p=0.3
CPCT	73 (90.1)	28 (87.5)	45 (91.8)	0.07, p=0.8
AHP	21 (25.9)	6 (18.8)	15 (30.6)	0.87, p=0.4

*2 H2H participants and 1 AC participant were nursing home residents- at the time of the study district nursing services did not routinely visit nursing home residents

Table 5.45 details the average number of community contacts over the 12-week period for each HCP group in each study group. To standardise for attrition due to death, the contacts are presented as number of contacts per week in the study. The H2H study participants had a higher number of contacts per week in the study from all community professionals. The average total number of all community contacts per week in the H2H group was also higher (mean 4.12 (SD 3.87), median 2.92) than the AC group (mean 1.82 (1.35), median 1.46, $p<0.01$). There are two possible explanations for the H2H group having a higher number of contacts: firstly, the participants were nearer death and service use increases as death approaches. Secondly, it may be the result of a more proactive approach to care as a result of H2H.

Table 5.45 Comparison of Community Service Use per week over the 12-week study period for A) Total population, B) H2H study group and C) AC group

Community Service Contacts per week	A) Total population	B) H2H study group	C) AC study group	Statistical comparison of B) & C)
GP <i>Mean (SD)</i> <i>Median (Range)</i>	0.64 (0.93) 0.33 (0-6)	0.99 (1.32) 0.5 (0-6)	0.41 (0.44) 0.31 (0-2)	Z=-2.16 p=0.03
District Nurse <i>Mean (SD)</i> <i>Median (Range)</i>	1.03 (2.09) 0.4 (0-14)	1.93 (3.04) 1.0 (0-14)	0.44 (0.63) 0.15 (0-2)	Z=-2.82 p<0.01
CPCT <i>Mean (SD)</i> <i>Median (Range)</i>	0.76 (0.61) 0.6 (0-3)	0.85 (0.73) 0.68 (0-3)	0.71 (0.52) 0.60 (0-2)	Z=-0.44 p=0.66
Allied HCP <i>Mean (SD)</i> <i>Median (Range)</i>	0.13 (0.34) 0 (0-2)	0.17 (0.43) 0 (0-2)	0.10 (0.34) 0 (0-2)	Z=-0.76 p=0.45
Total Community contacts <i>Mean (SD)</i> <i>Median (Range)</i>	2.73 (2.86) 2.0 (0-16)	4.12 (3.87) 2.92 (0-16)	1.82 (1.35) 1.46 (0-6)	Z=-2.73 p<0.01

5.5.3 Service use of participants who died during the 12 week study period (n=46)

In order to explore service use at the EoL, this subsection presents data for participants in each group who died during the 12-week service use data collection period. The contacts were averaged over all those who died (not just those who received care). The total number of participants who died during the 12-week data collection period was 46: 23 in the H2H study group (72%) and 23 in the AC group (47%). Hence all the analysis that follows considers only these 46 participants.

Table 5.46 shows that a higher proportion of H2H participants had at least one GP contact compared to AC participants. All other contacts were similar across the two study groups. HCP contacts in the last days of life may have missing data for some participants due to ADD and ADI.

Table 5.47 below details the average number of contacts during the 12-week follow up for those who died. It demonstrates that the H2H study group had less total GP face-to-face contacts than the AC group (H2H median 1, range 0-18, AC median 2, range 0-6). The average length (in minutes) of the GP contacts was also less in the H2H study group (H2H median 20 minutes, range 0-125, AC median 30 minutes, range 0-150). This trend remains when analysing all GP contacts (face-to-face and telephone)(H2H median 2 (0-18), AC median 3 (0-13)).

The median face-to-face district nursing contacts in this feasibility study were 2 in each study group, with a median average visit length of 30 minutes in both groups (H2H range 0-145 minutes, AC range 0-200 minutes). This gives an estimated average district nursing face-to-face contact time in each group of 60 minutes.

The average number of CPCT visits were higher for the AC group (mean 3.22 (SD 2.63), median 3 (0-10)) compared to the H2H group (mean 1.74 (SD 1.36), median 1 (0-5)). In addition to the higher number of visits, the average face-to-face visit length (shown in minutes) was longer and more variable in the AC group (mean 102.7 (SD 91), median 90 (0-330)) compared to the H2H group (mean 60.43 (SD 36.43), median 60 (0-120)).

The number of paid carer days was variable. Most participants did not have regular paid carers at home. Therefore, the median for both study groups was 0, but the range was wide (H2H range 0-90 days, AC range 0-60 days). The use of Marie Curie night sits was also minimal in these study participants. The majority of participants received no Marie Curie night sit.

Overall, the average number of total community contacts were similar in the AC group (mean 12.65 (SD 11.20, median 10 (0-37)) compared to the H2H group (mean 14.17 (SD 16.9), median 8 (0-18)). However, the survival of the AC group was longer (median survival AC group 47 days (3-85) compared to 32 days (3-89) in the H2H study group).

Contacts standardised by the number of weeks in the study for those who died (n=46) are shown in Appendix 7.4.4. The median total community contacts per week were similar across the study groups (H2H median 2.19 (range 0-14), AC median 1.97 (range 0-4.2) p0.23) although there was a wider variation in the H2H group.

Table 5.46 Face-to-Face Contact with HCPS during the 12-week study period (those who died n=46)

	Number with at least one contact over the 12 week study period			
	n(%)			
Contact with HCPS	Total population (n=46)	H2H group** (A) (n=23)	AC group (B) (n=23)	Statistical comparison (A) & (B)
GP	33 (71.7)	17 (73.9)	16 (69.6)	0.12, p=0.7
District Nurse	29 (63.0)	14 (60.9)*	15 (65.2)	0.09, p=0.8
CPCT	41 (89.1)	20 (87)	20 (87.0)	0.00, p=1.0
All community contact	43 (93.5)	22 (95.7)	21 (91.3)	0.36, p=0.6

*2 H2H participants and 1 AC participant were nursing home residents- at the time of the study district nursing services did not routinely visit nursing home residents ** excludes participation in H2H

Table 5.47 Comparison of Community Service Use for A) Total population, B) H2H study group and C) AC group for those who died during 12 week follow up

Health Service Contacts	A) Total population	B) H2H study group	C) All control study group	Statistical comparison of B) & C)
Total number of contacts				
GP contacts (Face to Face):				
Mean (SD)	2.39 (3.19)	2.65 (4.10)	2.13 (1.96)	Z=-0.37
Median (Range)	1.5 (0-18)	1.00 (0-18)	2.00 (0-6)	p=0.71
GP contacts (Face to Face): Total number of contact minutes				
Mean (SD)	35.22 (37.58)	31.09 (32.72)	39.35 (42.2)	Z=-0.46
Median (Range)	22.50 (0-150)	20 (0-125)	30 (0-150)	p=0.65
All GP contacts:				
Mean (SD)	3.63 (3.96)	3.9 (4.53)	3.35 (3.38)	Z=-0.19
Median (Range)	2 (0-18)	2.0 (0-18)	3.0 (0-13)	p=0.85
All GP contacts: Total number of contact minutes				
Mean (SD)	41.61 (40.45)	37.52 (35.46)	45.69 (45.33)	Z=-0.32
Median (Range)	30 (0-155)	30 (0-140)	30 (0-155)	p=0.75
District Nurse contacts (Face to Face)				
Mean (SD)	5.17 (11.50)	6.87 (15.4)	3.48 (5.24)	z=-0.02
Median (Range)	2 (0-71)	2.0 (0-71)	2.0 (0-21)	p=0.98
District Nurse contacts (Face to Face) Total number of contact minutes				
Mean (SD)	41.04 (48.12)	37.83 (44.23)	44.26 (52.53)	Z=-0.28
Median (Range)	30 (0-195)	30 (0-145)	30 (0-195)	p=0.78
All District Nurse contacts				
Mean (SD)	5.74 (11.55)	7.39 (15.29)	4.09 (5.78)	Z=-0.4
Median (Range)	2 (0-71)	2.0 (0-71)	3.0 (0-22)	p=0.69
All District Nurse contacts Total number of contact minutes				
Mean (SD)	43.76 (49.09)	40.43 (45.25)	47.09 (53.46)	Z=-0.03
Median (Range)	32.50 (0-200)	30 (0-145)	35 (0-200)	p=0.97
CPCT contact (Face to Face) Total number of contacts				
Mean (SD)	2.48 (2.20)	1.74 (1.36)	3.22 (2.63)	Z=-2.01
Median (Range)	2 (0-10)	1.0 (0-5)	3.0 (0-10)	p=0.05
CPCT contact (Face to Face) Total number of contact minutes				
Mean (SD)	81.57 (71.76)	60.43 (36.15)	102.70 (91.07)	Z=-1.64
Median (Range)	60 (0-330)	60 (0-120)	90 (0-330)	p=0.1
All CPCT contact Total number of contacts				
Mean (SD)	4.04 (3.71)	2.87 (2.34)	5.23 (4.45)	Z=-1.78
Median (Range)	3 (0-16)	2.0 (0-8)	4 (0-16)	p=0.08
Health Service Contacts	A) Total population	B) H2H study group	C) All control study group	Statistical comparison of B) & C)
All CPCT contact : Total number of contact minutes				
Mean (SD)	92.22 (81.57)	67.65 (39.79)	116.78 (103.75)	Z=-1.53
Median (Range)	80 (0-380)	65 (0-140)	109 (0-380)	p=0.1
Total Community contacts				
Mean (SD)	13.41 (14.22)	14.17 (16.94)	12.65 (11.20)	Z=-.03
Median (Range)	9.5 (0-78)	8.0 (0-78)	10 (0-37)	p=0.9
Proportion with Inpatient Admission n (%)				
No admissions	23 (50)	14 (60.9)	9 (39.2)	X ² =2.24
Hospice	11 (23.9)	4 (17.4)	7 (30.4)	p=0.33
Hospital	12 (26.1)	5 (21.7)	7 (30.4)	
Total Inpatient Admissions (Hospital +Hospice)				
Mean (SD)	0.65 (0.77)	0.52 (0.73)	0.78 (0.80)	Z= -1.25
Median (Range)	0 (0-3)	0 (0-2)	1 (0-3)	p=0.2
Total Inpatient Days (Hospital +Hospice)				

	<i>Mean (SD)</i> <i>Median (Range)</i>	5.54 (8.5) 0 (0-42)	4.57 (6.7) 0 (0-21)	6.52 (10.12) 4 (0-42)	Z=-0.88 p=0.3
Total Days in PPC	<i>Mean (SD)</i> <i>Median (Range)</i>	35.83 (24.27) 32.5 (3-82)	30.39 (20.49) 25.0 (3-79)	41.26 (26.90) 46.0 (3-82)	Z=-1.29 p=0.2
% of time spent in PPC	<i>Mean (SD)</i> <i>Median (Range)</i>	86.19 (21.82) 99.09 (10-100)	86.43 (21.79) 100 (19-100)	85.96 (22.35) 94.37 (10-100)	Z=-0.69 p=0.5

Mann Whitney U test was used for statistical analysis, *CPCT = CPCT

A second analysis to account for survival is shown in table 5.48. The table gives services use split into survival groups from study entry. Overall across all survival groups, GP and community nursing costs were higher with H2H with the exception of participants surviving more than 60 days after recruitment. CPCT contacts were lower with H2H across all survival groups. One explanation for this result is that H2H is fulfilling the goal of educating generalist community professionals in the palliative care needs of each patient, resulting in less specialist contact required from CPCT.

Table 5.48 Service use grouped by study group and survival times

		Days in study (time from recruitment to death)									
		0-2 days		3-14 days		15-30 days		31-60 days		> 60 days	
Service Type		H2H	AC	H2H	AC	H2H	AC	H2H	AC	H2H	AC
	No in group	0	0	3	3	7	3	10	9	3	8
All GP contacts	No (%) > = 1 contact	0	0	1 (33.3)	1 (33.3)	5 (71.4)	2 (66.7)	9 (90)	7 (77.8)	2 (66.7)	6 (75)
	Median, range	0	0	1, 1	0, 1	1, 12	1, 2	4.5, 17	3, 9	2, 2	6, 13
All Community nursing contacts	No (%) > = 1 contact	0	0	1 (33.3)	1 (33.3)	5 (71.4)	2 (66.7)	7 (70)	5 (55.6)	1 (33.3)	7 (87.5)
	Median, range	0	0	1, 2	0, 1	2, 7	3, 4	3, 26	1, 16	3, 71	5, 22
All CPCT contacts	No (%) > = 1 contact	0	0	3 (100)	2 (66.7)	6 (85.7)	2 (66.7)	9 (90)	9 (100)	2 (66.7)	7 (87.5)
	Median, range	0	0	1, 2	1, 0	1, 4	4, 5	4, 8	3, 11	3, 6	6.5, 16
Inpatient contacts	No (%) > = 1 contact	0	0	0 (0)	0 (0)	4 (57.1)	1 (33.3)	3 (30.0)	8 (88.9)	2 (66.7)	5 (62.5)
	Median, range	0	0	0, 0	0, 0	1, 2	0, 1	0, 2	1, 3	1, 1	1, 2
Admission Days	Median, range	0	0	0, 0	0, 0	4, 21	0, 6	0, 16	6, 42	10, 17	4, 23
All Marie Curie visits	No (%) > = 1 contact										
	Median, range	0	0	0, 0	0, 0	0, 0	0, 1	0, 5	0, 2	0, 1	0, 1

5.5.4 Time Spent in PPC and Inpatient Facility

Time spent in PPC was calculated as a time in PPC (days) as a proportion of the participant's total time in the study i.e. from discharge to death or 12 week follow up (92 days).

Table 5.47 details the comparison of time spent in PPC and time spent in hospital and/or hospice for the total population and each study group. The median percentage of time spent in PPC was marginally higher with H2H (median H2H 100% (19-100), AC 94% (10-100)). There was no statistical difference in the proportion of time spent in PPC between the study groups ($p=0.46$). A higher proportion of patients had no admissions to either hospice or hospital with H2H (H2H 60.9%, AC 39.2%), alongside a lower proportion of patients with at least 1 hospital admission with H2H (H2H 21.7%, AC 30.4%). The median number of admissions was lower with H2H (median 0, range 0-2) compared to the AC group (median 1, range 0-3). The average number of inpatient days was also lower with H2H. [H2H (mean 4.57 (SD 6.7), median 0 (0-21)), AC group (mean 6.52 (SD 10.12), median 4 (0-42))]. AC participants spent on average 2-3 days longer in hospital/hospice than H2H participants.

5.5.5 Cost of Care analysis

The table below (Table 5.49) gives a comparison of the average service use costs across the two study groups. Community costs, including participation in H2H, were calculated using the patient reported service use data collected and the average costs of community services from PSSRU 2010 data [227]. Hospital and hospice admission costs were calculated assuming a cost of £425/night, based on previous work[94].

In order for this cost analysis to reflect the cost of EoLC, these data are presented for participants in each group who died during the 12-week service use data collection period. The costs are averaged over all those who died (not just those who received care).

The average cost of the CHCP input at the H2H face-to-face CC was £97.07 (SD 110.84, median £99.05, range £0-£360). Overall, the total median community care costs were lower in the H2H group (median £329.33) compared to the AC group (median £507.50). The average total inpatient costs were also lower in the H2H group (mean £1940.22 (SD 2850.49), median £0) compared to the AC group (mean £2771.74 (SD 4301.59), median £1700). Collating all costs (inpatient cost, community cost and H2H cost) into the 'Total EoLC cost' shows that the average Total EoLC costs were higher in the AC group (mean £3380.75 (SD 4268.11), median £2631.67) compared to the H2H group (mean £2682.01, (SD 2729.91), median £1603.40). To standardise for the difference in survival between the 2 groups, costs per day were also calculated. These are detailed in Appendix 7.4.4 which shows, on average, costs per day were higher in the H2H group.

Table 5.49 Comparison of Total Community Service Cost over 12 week study period for A) Total population, B) H2H study group and C) AC group

Community Service Costs (£)	A) Total population	B) H2H study group	C) All control study group	Statistical comparison of B) & C)
H2H Cost				
Mean (SD)		97.07 (110.84)		
Median (Range)		99.05 (0-360)		
Total Cost over study period				
Total GP Costs				
Mean (SD)	321.58 (441.53)	364.73 (555.59)	278.43 (293.58)	Z=-0.06
Median (Range)	147.00 (0-2248)	133 (0-2248)	163.40 (0-901)	p=0.96
Total District Nurse Costs				
Mean (SD)	124.58 (192.09)	143.45 (218.17)	105.70 (164.72)	Z=-0.55
Median (Range)	68.50 (0-828.32)	75.83 (0-828.32)	64.17 (0-757.33)	p=0.58
Total CPCT Costs				
Mean (SD)	180.71 (177.23)	136.54 (110.73)	224.88 (218.89)	Z=-1.06
Median (Range)	122.17 (0-850.33)	119 (0-398.66)	173.67 (0-850.33)	p=0.29
IQR		120.50	296.64	
Total Community contact cost				
Mean (SD)	626.87 (600.44)	644.73 (679.62)	609.01 (524.31)	Z=-0.22
Median (Range)	377.03 (0-2490)	329.33 (0-2490.84)	506.50 (0-1671.33)	p=0.98
Total Inpatient Costs (Hospice)				
Mean (SD)	2355.98 (3632.5)	1940.22 (2850.49)	2771.74 (4301.59)	Z=-0.88
Median (Range)	212.50 (0-17850)	0 (0-8925)	1700.00 (0-17850)	p=0.34
Total Inpatient Costs (Hospital)				
Total EOLC Cost (Inpatient+Community+H2H)				
Mean (SD)	3031.38 (3560.08)	2682.02 (2729.91)	3380.75 (4268.11)	Z=-0.08
Median (Range)	(0-17,914)	1603.40 (79-9114)	2631.67 (0-17,914)	p=0.94
Median Total EOLC cost (£)		1603.40	2631.67	Z=-0.08, p=0.94
Median Daily EOLC cost (£)		58.38	40.61	Z=-0.67, p=0.50
Median Survival (days from recruitment)		32 (3-89)	47 (3-85)	
Number of deaths over 3 month period (% of total participants in study group)		23 (72%)	23 (45%)	
Number of deaths in PPD		15 (65.2%)	14 (60.9%)	X ² =1.11, p=0.57
Number of deaths outside hospital		18 (78.3%)	21 (91.3%)	X ² =0.67, p=0.41
Number of deaths at home		12 (52.2%)	12 (52.2%)	X ² =0.00, p=1.0
Calculated Unit Costs per location				
Unit Total EOLC cost per death in PPD (£)		2458.55	4323.46	
Unit Total EOLC cost per out of hospital death (£)		2048.79	2882.31	
Unit Total EOLC cost per death at home (£)		3073.18	5044.03	
Unit Daily EOLC cost per death on PPD (£)		89.52	66.72	
Unit Daily EOLC cost per out of hospital death (£)		74.60	44.48	
Unit Daily EOLC cost per death at home (£)		111.90	77.84	

The calculated overall costs of care per location by study group are compared in Table 5.49. The proportion of deaths occurring in the participants PPD for the 46 who died during the 12 week follow up were higher in the H2H group (H2H 65.2%, AC 60.9%). However, the proportion of deaths outside hospital was greater in the AC group (AC 91.3%, H2H 78.3%). This reflects the high number of AC participants dying in a hospice inpatient unit (n=9, 39%). The calculated unit cost of care per death in PPD for each group was estimated using the following equation:

$$\text{The Total or Daily EOLC cost per patient} = \text{Median Daily EOLC cost} * 23 / \text{Number of participants dying in their PPD}$$

The calculated unit cost of care per out of hospital death for each group was also estimated in a similar way using the following equation:

$$\text{The Total or Daily EOLC cost per patient} = \text{Median Daily EOLC cost} * 23 / \text{Number of participants dying outside hospital}$$

The calculated unit cost of care per home death was estimated by the same method and substituting the 'number of participants dying outside hospital' for the 'number of participants dying at home'.

The estimated total EoLC costs for a PPD death were lower in the H2H group (H2H £2458.55, AC £4323.46). In parallel with this, the Total EoLC cost per home death were also lower in the H2H group (H2H £3073.18, AC group £5044.03). When standardised to estimates of cost per day, the median unit daily EoLC cost of dying in PPD was marginally greater for the H2H study group (£89.52) compared to the AC group (£66.72). The unit daily out of hospital EoLC cost was also greater in the H2H study group (H2H £74.60, AC £44.15) as was the home death daily cost (H2H £111.90, AC £77.84).

Table 5.50 gives costs of services split into survival groups from study entry. The results show higher GP and community nursing costs with H2H for survival groups up until day 60. Participants surviving more than 60 days had lower GP and community nursing costs with H2H. The reverse trend was seen for CPCT contacts with lower average costs of CPCT contacts in H2H group for those surviving greater than 15 days after study recruitment. The table shows higher total service costs with H2H in all survival groups except survival of 31-60 days where costs were approximately £1000 less with H2H. The numbers are small in each group and should be interpreted with caution.

Table 5.50: Total Service Use Cost (£) H2H (n=23) and AC (n=23), by survival times (number of days in study) (adapted from Gage et al)

Median (Range)		Days in study (time from recruitment to death)									
		0-2 days		3-14 days		15-30 days		31-60 days		> 60 days	
Service Type		H2H	AC	H2H	AC	H2H	AC	H2H	AC	H2H	AC
	No in group	0	0	3	3	7	3	10	9	3	8
All GP contacts	Median, range	0	0	19, 49	0, 98	73.5, 1396	38, 147	272, 2172	261, 789	133, 78.6	461.25, 901
All Community nursing contacts	Median, range	0	0	4.83, 105	0, 35	70, 315	64.17, 84.5	133.2, 705.8	58.33, 219.7	24.2, 828.3	114.7, 757.3
All CPCT contacts	Median, range	0	0	90, 89	45, 61	90, 180	131.83, 384	139.8, 398.7	155.2, 446	122.2, 294.7	296.8, 850
Inpatient contacts*	Median, range	0	0	0, 0	0, 0	1700, 8925	0, 2550	0, 6800	2550, 17850	4250, 7225	1700, 9775
All Marie Curie visits	Median, range	0	0	0, 0	0, 0	0, 0	0, 64	0, 320	0, 128	0, 64	0, 64
Total Community costs	Median, range	0	0	94.8, 164	90, 79	220.5, 1802	343, 506.5	630.1, 2230	543.5, 1003	190.6, 1113	1161.3, 1671
Total EOLC costs	Median, range	0	0	94.8, 328.9	90, 79	1865, 9114	343, 3056	1609.6, 6870	2767, 17261	4440.6, 5989	2861, 10178

*Hospice + Hospital inpatient contacts

5.5.7 Section Summary

The secondary outcome service use and cost data presented in this section allow recommendations to be made regarding the feasibility of collecting patient reported service use at the EoL, and also to begin to consider any potential effects of H2H on service use and costs.

The service use data was subject to missing data from ADI and ADD. Overall only 40% of participants completed all 7 data collection time points over the 12 week follow up period. The main reason for drop out was ADD (88% 46/52). However, a further 6.4% of data for those still alive in the study was missing ADI. Given the data collection method chosen (2 weekly intervals, single source patient/carer report) the ADD category 'hides' a potentially large amount of missing service use data (maximum 13 days) between the last contact where service use data was collected and death. This is more problematic for deaths at home as service use cannot be easily extrapolated from previous time points. Participants whose deaths occurred in institutions (hospice/hospital) did not have any hidden missing data from ADD because the number of days in those locations and associated costs could be easily calculated without relying on patient/carer reports. This imbalance in hidden missing data from ADD across different death locations will have led to an underestimation of home care costs and needs careful consideration to determine the optimal data collection method in the larger definitive trial.

The outcome data presented in this feasibility study reveals the average total number of community contacts for all participants in the study (H2H n=32, AC n=49) were higher with H2H. Analysis of those who died during the first 12 week follow up (H2H n=23, AC n= 23) showed median total community contacts per week were similar across the two groups. GP and community nursing contacts were higher with H2H whilst specialist contact from CPCT was lower with H2H. The proportion of time spent in PPC was marginally greater with H2H, with fewer patients admitted to hospice or hospital in the H2H group.

The overall total community costs and inpatients costs were lower with H2H, although the issue of missing data close to death may have had an impact on this provisional finding.

This section has contributed to the *feasibility and piloting phase* of the MRC framework for evaluating CIs. It has highlighted the following considerations for a definitive trial that are reflected on further in the discussion chapter of this thesis;

- Patient/carer reports are not reliable as the single only source of service use data collection at the EoL. Underestimation of service use, particularly for home deaths, will result from this method alone.
- A larger definitive trial will need to consider employing bereavement collection of service use data from carers shortly after death and/or multiple data sources for service use data collection.
- The preliminary data, although not powered to make definitive conclusions, suggest H2H has an effect on the type of community service use accessed by participants with less specialist (CPCT) input in this group. This warrants further investigation in the larger definitive trial.

5.6 Feasibility of proxy outcome data

This section presents the results addressing the feasibility of using proxy outcome data in EoL research and in the evaluation of H2H. It addresses study objectives 7 & 8.

The data are presented in the following subsections:

- 5.6.1 Achievement of PPD as a proxy measure of QoL and satisfaction
- 5.6.2 Carer reported outcome measures as a proxy measure for patient symptoms and QoL

5.6.1 Achievement of PPD as a proxy measure of QoL and satisfaction

This sub section addresses the study objective 7:

Objective 7: *To determine if, in this population, the outcome measure of achieving PPD correlates with the patient reported outcome measure of QoL, and is therefore a feasible surrogate primary outcome measure.*

The outcome measure for QoL used in this analysis was the summary measure (time adjusted AUC) for patient overall QoL (MQOL Total Score) as outlined in Section 5.4.3.9. The null hypothesis was 'There is no difference in QoL for participants who achieve their PPD and those who do not'. Therefore the objective was to determine if, in this cohort of patients, those participants achieving their PPD had higher QoL scores overtime. Figure 5.19 gives the results, and Table 5.51 and 5.52 detail the statistical analysis. The median score was marginally higher in those who achieved their PPD. Time adjusted AUC Total MQOL median score was 7.56 (1.83-9.45) for those who achieved their PPD compared to a median 7.33 (4.9-9.8) for those who did not achieve their PPD. The results show no statistical significant difference between the groups ($p=0.80$). In this small

cohort achievement of PPD cannot be considered a proxy for QoL as death approaches.

Table 5.51 Comparison of summary measure (Time adjusted AUC) Total MQOL Score for PPD achieved and not achieved (n=45)

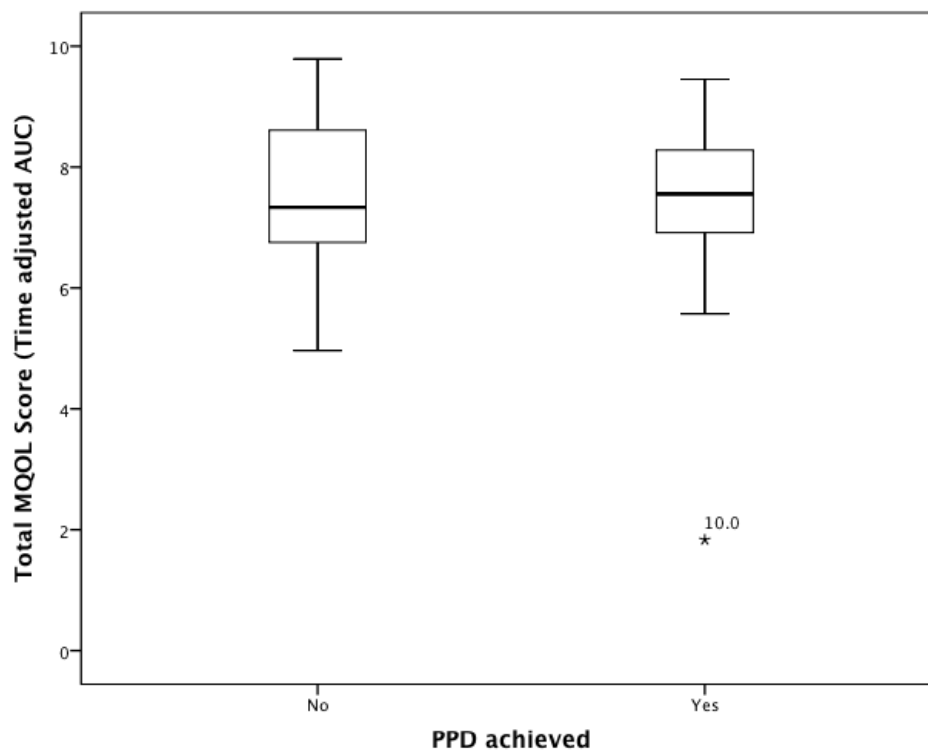
PPD (PPD) Achieved						PPD (PPD) Not Achieved					
N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
24	7.41	1.57	7.56	1.83-9.45	22	21	7.51	1.31	7.33	4.9-9.8	11

Table 5.52 Statistical analysis of summary measure (Time adjusted AUC) Total MQOL Score for PPD achieved and not achieved

AUC	PPD Achieved Group (A)	PPD Not Achieved Group (B)	Mann Whitney U Test	
	Median (IQR)	Median (IQR)		P value
TotalMQOL	7.56 (1.44)	7.33 (1.95)	241.0 ($z=-0.25$)	0.80

Test for normality violated therefore median (interquartile range) and the Mann Whitney U test has been used.

Figure 5.19 Summary measure (Time adjusted AUC) Total MQOL Score for PPD achieved and not achieved



5.6.2 Carer reported outcome measures as a proxy measure for patient symptoms and QoL

This subsection addresses study objective 8:

Objective 8: *To determine if proxy (carer) responses to patient symptoms and QoL tools match patient reports and therefore may be a feasible mechanism of minimising attrition due to illness by allowing continued data collection of patient symptom and QoL data as EoL approaches.*

This objective aims to inform the design of a larger trial with respect to the feasibility and value of collecting proxy carer responses to assess a patients symptoms and QoL. This is an important component of this feasibility study. Longitudinal data collection in EoL research is hampered by high rates of missing data due to attrition. This is evident in this feasibility study with a high ADI of symptom control and QoL data. It is important to understand how accurate a carer is at assessing the patient's symptoms and QoL. This is important for two reasons; firstly if there is sufficient agreement between patient and carer assessment then the carer responses could be used instead of marking a value missing when the patient can no longer answer questionnaires due to illness. Secondly, if there is good agreement it may be preferred, in order to minimise burden to the patient, not to ask the patient at all and use carer responses alone from the start of the study.

It is also important however, to minimise burden of study assessment for the informal carer, therefore an assessment of whether collecting patient data from the carer is useful and valid will provide evidence for the length of the carer assessment (85 items, 50 assessing the patient's symptoms and QOL) in this feasibility study.

The feasibility of using proxy carer responses for symptom and QoL to limit missing data from ADI depends on two factors; the agreement between patient-carer responses and the attrition of the carer across study time points.

In this subsection the data on patient and carer reporting of symptoms and QoL is presented as follows:

- Whole population descriptive analysis of patient and carer responses MSAS-SF and MQOL at baseline (T0) n=43
- Individual patient-carer dyads descriptive analysis of longitudinal data for MSAS and MQOL
- Bland-Altman assessment of agreement between patient and carer symptom and QoL scores for baseline scores
- Patient and Carer attrition over time

5.6.2.1 Whole population descriptive analysis of patient and carer responses MSAS-SF and MQOL at baseline (T0) n=43

The table below details the prevalence of individual physical and psychological symptoms reported by patients and carers at T0. These results are given for patients with a carer also completing the assessments. The total number of patient and carer responses was 43 in each group. Physical symptoms were reported less frequently by carers than by the patient at baseline. It is also noteworthy that the majority of physical symptoms were reported with a lower severity score by carers when compared to patients (e.g.) Difficulty concentrating Patient Severe 11.6%, Carer Severe 2.3%. However certain symptoms do seem to be reported more by carers. These symptoms centre around social interaction; difficulty concentrating, loss of appetite, changes in the way food tastes, difficulty sleeping and 'I don't look like myself'.

With regards to psychological symptom prevalence the results show the opposite. Overall, carer participants report more psychological symptoms than the patient. This is true across all four psychological symptoms assessed. The psychological symptom with the greatest difference in prevalence between carer and patient was '*Feeling Sad*'. Seventy two percent (n=31) of carers reported the patient experiencing this symptom, with 14% (n=6) identifying it as severe compared to 37.2% of patient participants (with 7% severe).

Table 5.53 Total population baseline patient and carer MSAS-SF individual item scores

Symptom	Patient Response (n=43)			Carer Response (n=43)		
	Overall prevalence	Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')	Missing data	Overall prevalence	Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')	Missing data
	Number (%)	Number (%)		Number (%)	Number (%)	
Difficulty concentrating	19 (44.2)	5 (11.6)	0	21 (48.8)	1 (2.3)	1
Pain	29 (67.4)	8 (18.6)	0	26 (60.5)	9 (21.0)	0
Lack of energy	41 (95.3)	22 (51.1)	0	41 (95.3)	21 (48.8)	0
Cough	20 (46.5)	5 (11.7)	1	24 (55.8)	7 (16.3)	0
Changes in skin	15 (34.9)	4 (9.3)	0	12 (27.9)	2 (4.6)	0
Dry mouth	24 (55.8)	7 (16.3)	0	14 (32.6)	8 (18.6)	1
Nausea	11 (25.6)	3 (7.0)	0	13 (30.2)	5 (11.6)	1
Feeling drowsy	34 (79.1)	13 (30.2)	0	31 (72.1)	18 (41.8)	0
Numbness/tingling in hand and feet	17 (39.5)	6 (14.0)	0	11 (25.6)	6 (14.0)	0
Difficulty sleeping	19 (44.2)	5 (11.7)	0	22 (51.2)	6 (14.0)	0
Feeling bloated	16 (37.2)	5 (11.7)	0	14 (32.6)	6 (14.0)	0
Problems with urination	8 (18.6)	4 (9.3)	0	7 (16.3)	3 (6.9)	1
Vomiting	3 (7.0)	0 (0.0)	0	7 (16.3)	2 (4.7)	0
Shortness of breath	29 (67.3)	9 (21.0)	0	28 (65.1)	10 (23.2)	0
Diarrhoea	13 (30.2)	6 (14.0)	0	12 (27.9)	10 (23.2)	2
Sweats	11 (25.6)	5 (11.7)	0	12 (27.9)	0 (0.0)	0
Mouth sores	4 (9.3)	0 (0.0)	0	4 (9.3)	0 (0.0)	0
Problems with sexual interest and activity	8 (18.6)	4 (9.3)	0	7 (16.3)	4 (9.3)	0
Itching	7 (16.3)	2 (4.6)	0	10 (23.3)	2 (4.6)	0
Lack of appetite	26 (60.5)	13 (30.2)	0	30 (69.8)	13 (30.2)	0
Dizziness	10 (23.3)	4 (9.3)	0	10 (23.3)	2 (4.6)	0
Difficulty swallowing	12 (27.9)	4 (9.3)	0	14 (32.6)	5 (11.6)	0
Changes in the way food tastes	18 (41.9)	10 (23.3)		21 (48.8)	10 (23.3)	0
Weight loss	24 (55.8)	8 (18.6)	0	24 (55.8)	13 (30.3)	1
Hair loss	9 (20.9)	2 (4.7)	0	4 (9.3)	1 (2.3)	0
Constipation	17 (39.5)	7 (16.3)	1	18 (41.9)	6 (14.0)	1
Swelling of arms or legs	10 (23.3)	1 (2.3)	0	13 (30.2)	3 (7.0)	0
'I don't look like myself'	15 (34.9)	7 (16.3)	0	20 (46.5)	7 (16.3)	0

Total population baseline patient and carer MSAS-SF psychological symptom individual item scores

Symptom	Patient Response			Carer Response		
	Overall prevalence	Frequency of Symptoms ('almost constantly' or 'frequently')	Missing data	Overall prevalence	Frequency of Symptoms ('almost constantly' or 'frequently')	Missing data
	Number (%)	Number (%)		Number (%)	Number (%)	
Feeling Sad	16 (37.2)	3 (7.0)	0	31 (72.1)	6 (14.0)	2
Worrying	17 (39.5)	8 (18.6)	0	24 (55.8)	8 (18.7)	2
Feeling irritable	17 (39.5)	4 (9.3)	0	21 (48.8)	8 (18.7)	0
Feeling nervous	9 (20.9)	1 (2.3)	0	11 (25.6)	3 (7.0)	4

Table 5.54: Total population baseline patient and carer MQOL individual item scores

MQOL Item		N	Mean	SD	Median	Range	Missing
Considering all parts of my life-physical, emotional, social, spiritual and financial- the quality of my life has been (0= very bad, 10 = excellent)	Patient	43	6.65	2.256	7.0	0-10	0
	Carer	43	6.16	2.319	6.0	0-10	0
(1) Over the past two days, one troublesome symptom has been..... (10= no problem, 0=tremendous problem)	Patient	43	4.77	3.408	4.0	0-10	0
	Carer	42	4.64	3.505	4.0	0-10	1
(2)Over the past two days, one troublesome symptom has been..... (10= no problem, 0=tremendous problem)	Patient	42	7.81	3.054	10.0	0-10	1
	Carer	39	6.56	3.851	10.0	0-10	4
(3)Over the past two days, one troublesome symptom has been..... (10= no problem, 0=tremendous problem)	Patient	43	8.49	2.923	10.0	0-10	0
	Carer	39	7.90	3.604	10.0	0-10	4
(4) Over the past two days, I have felt: (0= physically terrible, 10= physically well)	Patient	43	6.35	2.319	6.0	0-10	0
	Carer	42	6.14	2.581	6.0	0-10	1
(5) Over the past two days, I have been depressed: (10=not at all, 0= extremely)	Patient	43	8.63	2.391	10.0	0-10	0
	Carer	42	7.74	2.642	9.0	1-10	1
(6) Over the past two days, I have been nervous or worried: (10= not at all, 0=extremely)	Patient	43	8.40	2.647	10.0	0-10	0
	Carer	42	7.50	2.752	8.5	2-10	1
(7) Over the past two days, how much of the time did you feel sad? (10=never, 0=always)	Patient	43	8.21	2.522	9.0	0-10	0
	Carer	42	7.52	2.233	8.0	3-10	1
(8) Over the past two days, when I thought of the future, I was (10= not afraid, 0= terrified)	Patient	43	7.67	2.893	9.0	0-10	0
	Carer	37	6.16	3.296	7.0	1-10	6
(9) Over the past two days, my life has been: (0= utterly meaningless and without purpose, 1=very purposeful and meaningful)	Patient	41	7.12	2.685	8.0	0-10	2
	Carer	41	6.56	2.802	7.0	0-10	2
(10) Over the past two days, when I thought about my whole life, I felt that in achieving life goals I have: (0=made no progress whatsoever, 1=progressed to complete fulfilment)	Patient	42	7.93	1.905	8.0	4-10	1
	Carer	43	7.72	2.175	8.0	0-10	0
(11) Over the past two days, when I thought about my life, I felt that my life to this point has been: (0=completely worthless, 1=very worthwhile)	Patient	43	8.84	1.661	10.0	5-10	0
	Carer	43	8.51	2.004	9.0	0-10	0
(12) Over the past two days, I have felt that I have: (0=no control over my life, 10=complete control over my life)	Patient	42	6.31	2.789	7.0	0-10	1
	Carer	43	5.19	3.149	5.0	0-10	0
(13) Over the past two days, I felt good about myself as a person (0=completely disagree, 10=completely agree)	Patient	43	7.21	2.891	8.0	0-10	0
	Carer	41	6.83	3.154	8.0	0-10	2
(14) To me, the past two days were: (0= a burden, 10= a gift)	Patient	43	7.74	2.744	9.0	0-10	0
	Carer	42	6.88	3.542	8.0	0-10	1
(15) Over the past two days, the world has been: (0= an impersonal unfeeling place, 10=caring and responsive to my needs)	Patient	41	8.20	2.261	9.0	0-10	2
	Carer	41	7.93	2.534	9.0	0-10	2
(16) Over the past two days, I have felt supported: (0=not at all, 10= completely)	Patient	43	9.19	1.918	10.0	0-10	0
	Carer	43	9.0	1.746	10.0	0-10	0

Table 5.55 Comparison of baseline (T0) MSAS-SF and MQOL subscale scores for patients and carers

MSAS-SF Subscales*	Patient Response							Carer Response					
	N	Mean	SD	Median	Range	Missing		N	Mean	SD	Median	Range	Missing
Global Distress Index	42	1.27	0.71	1.20	0-3.3	1		38	1.37	0.621	1.45	0.1-2.6	5
Physical Symptom Subscale	42	1.19	0.632	1.20	0-2.87	1		40	1.23	0.624	1.20	0.1-2.8	3
Psychological Symptom Subscale	43	0.78	0.730	0.60	0-3.17	0		38	1.11	0.682	0.98	0.1-2.5	5
Total MSAS Score	41	0.89	0.499	0.86	0.1-2.4	2		33	0.92	0.430	0.86	0.1-2.0	10
MQOL Subscales**													
Physical Symptoms Score (Mean score of Items 1,2 &3)	42	7.02	2.464	7.33	1.33-10	1		38	6.46	3.142	7.167	0-10	5
Physical Well-being Score (Score of Item 4)	43	6.35	2.319	6.0	0-10	0		42	6.14	2.581	6.0	0-10	1
Psychological Score (Mean score of Item 5,6,7 &8)	43	8.23	2.276	9.0	0-10	0		37	7.18	2.336	7.25	1.8-10	6
Existential Score (Mean score of Item 9,10,11,12,13 &14)	40	7.55	1.766	7.83	3.3-10	3		39	7.08	2.050	7.5	0-9.7	4
Support Score (Mean score of Items 15 &16)	41	8.73	1.891	9.0	0-10	2		41	8.46	1.979	9.0	0-10	2
Total MQOL Score (Mean of all other 5 subscales above)	37	7.65	1.586	7.92	2-10	6		29	7.21	1.443	7.67	4-9.27	14

*MSAS subscale 0-4, 0= no distress, 4= severe distress

**MQOL subscales scores range from 0-10, 10 indicating the best/higher QoL

A comparison of baseline MSAS-SF and MQOL scores across patient and carer participants is shown in the table above. This shows that at the whole population level, the difference between patient and carer reports for global distress (MSAS-GDI), physical symptoms (MSAS-PHYS) and the Total symptom score (Total MSAS) equates to less than 0.1 on each zero (no distress) to four (severe distress) scale. At the whole population level proxy carer and patient symptom subscale scores appear to agree. However, a difference is noted in the psychological subscale (MSAS-PSYCH) score. This has the largest difference between patient and carers (patient mean 0.78, median 0.6, carer mean 1.11, median 0.95). Carers report more distress than patients with regards to psychological symptoms. The MQOL data show that in all 5 areas of QoL patient responses are higher than carer responses on a zero (poor QoL) to ten (excellent QoL) scale. At the population level patient and carer scores for the MQOL subscales, excluding the psychological scale, appear to agree with a differences of less than 0.5 between mean scores. The mean Total MQOL score for patients was 7.65 compared to 7.21 for carers. Similarly to MSAS, the domain with the greatest difference between patient and carer scores was the psychological scale (patient mean 8.23, median 9, carer mean 7.18, median 7.2).

5.6.2.2 Individual patient-carer dyads descriptive analysis of longitudinal data for MSAS and MQOL

The data presented above shows trends in the data at a population level however an assessment of agreement between individual patient and proxy carer dyads is required to inform us about the feasibility of using proxy responses in EoL research. This is addressed through examination of individual patient-carer dyads and formal agreement analysis.

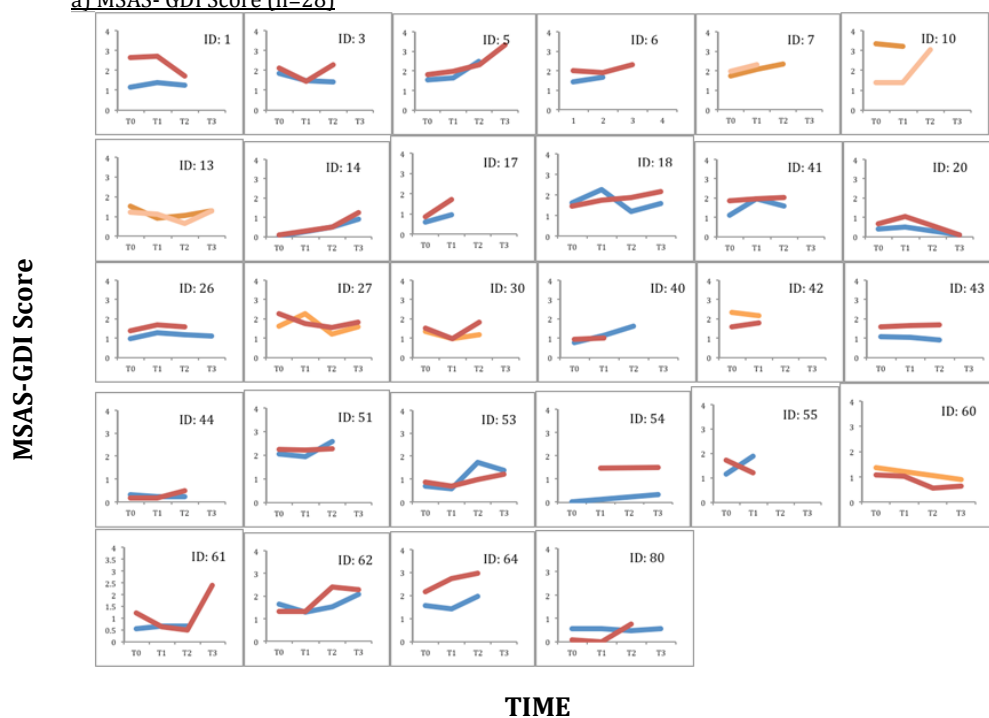
The figure below shows individual longitudinal plots for MSAS-GDI scores for matched patient and carer dyads. These are shown where there are more than two time points available for both the patient and the carer, $n=28$ (28/43, 65%). Plots in red (patient)/blue (carer) are AC participants and those shown in red (patient)/orange (carer) are from the H2H participant group. Descriptive analysis reveals that the dyads fall into three categories, Matched, Parallel and Crossed/Other. Table 5.56 details these categories along with the individual study ID for the patient carer dyads in each group. 'Matched' dyads are those where patient and carer responses are very similar, following a near identical trajectory over time e.g.) dyad ID 5. 'Parallel' refers to those dyads where the trajectory follows a similar trend but the baseline scores for patient and carer are different e.g.) dyad ID 1. In all 'Parallel' cases the patient score is higher indicating more global symptom distress than the carer recognised. The final category is 'Crossed/Other', in this group patient and carer trajectories bear no resemblance to each other and some cross each other indicating opposite trajectories e.g.) ID 55. The 'Matched' category has the largest number of dyads with 39.3% of dyads falling into this category. This lends cautious support to the use of proxy carer responses over time to assess the patient participants global distress.

Individual plots for Total MSAS scores for matched dyads are shown below. These Total MSAS dyads show similar trends to those described above for MSAS-GDI scores. Dyad trajectories follow the same 3 main descriptive categories detailed in the table below. The majority of dyads ($n=15, 60\%$) are 'Matched'

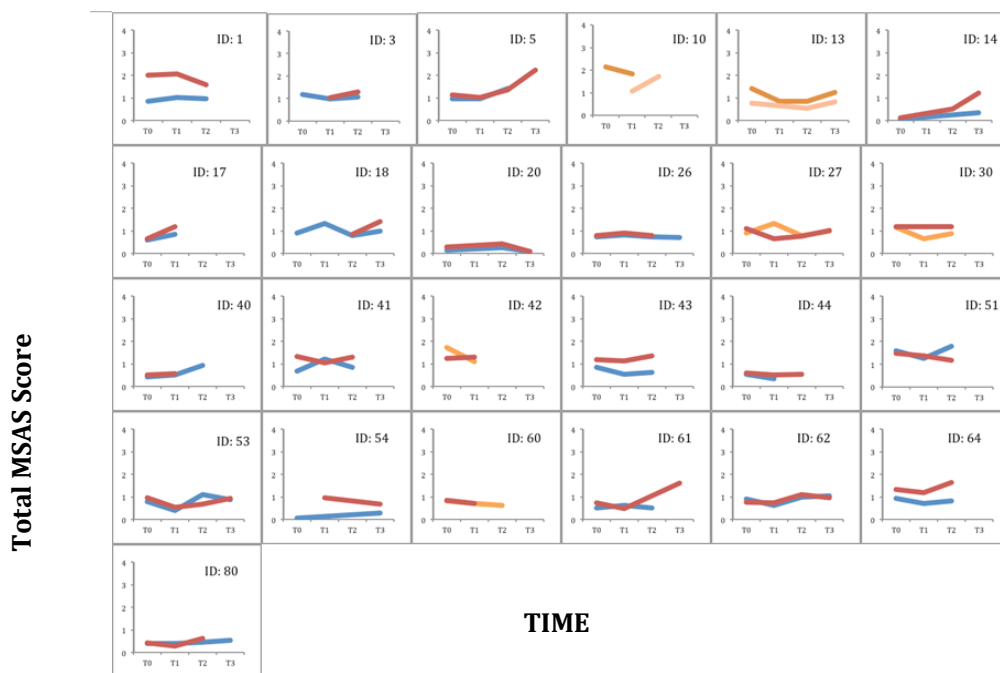
showing carers appear to understand the symptom burden of the patient overtime. A higher proportion of dyads match for Total MSAS compared to MSAS-GDI. This is likely due to the fact that MSAS-GDI weights heavily on psychological symptom scores, and from our population data carers appear less accurate at evaluating psychological distress. This data supports the use of Total MSAS scores as proxy responses in preference to MSAS-GDI scores.

Figure 5.20: Individual matched patient-carer dyad longitudinal vitagram plots*

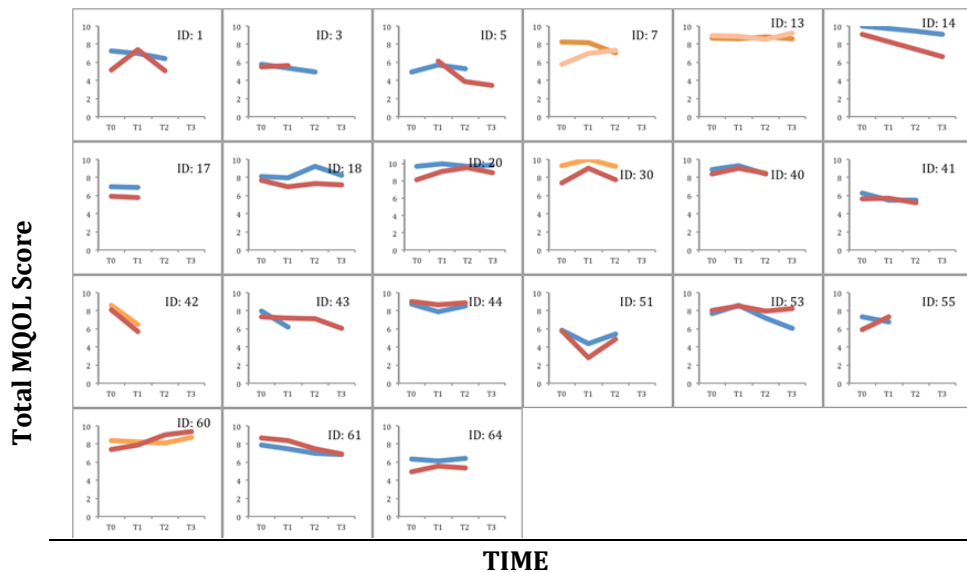
a) MSAS- GDI Score (n=28)



b) Total MSAS Score (n=25)



c) Total MQOL Score* (n=21)



*Red (patient)/blue (carer) plots are AC participants, Red (patient)/orange (carer) plots are H2H participants. These are shown for all dyads where both patient and carer had two or more time points with complete data.

Table 5.56: Descriptive analysis of visual agreement between patient and carer longitudinal dyads for symptom burden and QoL scores

Score	Category	ID numbers	n	%
MSAS-GDI (n=28)	Matched	5, 7, 13, 14, 20, 26, 30, 40, 44, 51, 60	11	39.3
	Parallel	1, 6, 10, 17, 42, 43, 54, 64, 80	9	32.2
	Crossed/Other	3, 18, 27, 41, 53, 55, 61, 62	8	28.6
Total MSAS (n=25)	Matched	3, 5, 13, 14, 17, 20, 26, 30, 40, 44, 53, 60, 61, 62, 80	15	60
	Parallel	1, 10, 43, 54, 64	5	20
	Crossed/Other	18, 27, 41, 42, 51	5	20
Total MQOL (n=21)	Matched	3, 13, 40, 41, 42, 44, 60, 61	8	38.1
	Parallel	7, 14, 17, 18, 30, 51, 64	7	33.3
	Crossed/Other	1, 5, 20, 43, 53, 55	6	28.6

The individual plots for Total MQOL matched dyads over time are shown in Figure 5.20c above. Similar descriptive trends are seen to those described for MSAS scores overtime. The three categories are again evident; matched, split and crossed/other and detailed in the table above. On this descriptive analysis less than 50% of MSAS-GDI and Total MQOL scores are ‘matched’, leading to the conclusion that proxy carer scores for these domains should be used with caution. The score with the most ‘matched’ dyads (60%) is Total MSAS. However, both ‘matched’ and ‘split’ dyads appear to correspond to the carer having an awareness of the trend of the patient’s symptom distress. Therefore descriptively less than a third of dyads in each symptom scale (Crossed/other category: MSAS-GDI 28.6%, Total MSAS 20%, Total MQOL 28.6%) show no relationship between patient and carer scores over time.

5.6.2.3 Bland-Altman assessment of agreement between patient and carer symptom and QoL scores

An assessment of the agreement between patient and carer scores for symptoms and QoL is essential to determine if proxy carer responses to patient symptom and QoL scale are a feasible alternative to collecting data directly from the patient. Previous studies [228, 229] have used either whole group mean differences or the correlation coefficient to report agreement between patient and carer proxy responses. However this approach is misleading [230]. To assess the agreement between patient and carer proxy responses the Bland-Altman method for assessing agreement was used. This allows comparisons at the individual dyad level to be plotted and compared. This method is more relevant than whole population comparisons. The results detailed here give this comparison for MSAS-GDI, Total MSAS and Total MQOL scores at baseline (T0). The table below gives the mean difference and SD of mean difference for each of these subscales. The MSAS subscales have a range from 0-4, whilst the MQOL subscale has a range from 0-10. It is important to determine for each subscale what range of limits of agreement is acceptable and what difference within the range would not be clinically important. For the purpose of this analysis MSAS subscale (scored from 0-4) limits within 1 and MQOL subscale (scored from 0-10) limits within 2 were acceptable and judged not to be clinically relevant. For each subscale two plots are shown, the first is a plot of patient scores against carer scores with the line of equality shown. This gives an idea of agreement before further analysis. The second plot is the Bland-Altman agreement plot- a plot of difference between patient and carer scores against the average of patient/carers scores for each dyad. This plot includes a central line to indicate the mean difference alongside two lines showing the upper and lower limits of agreement for the mean difference.

The mean difference in global distress (MSAS-GDI) between patient and carer dyads is -0.013 (SD 0.571). The mean difference of -0.013 is small suggesting good agreement in patient-carer dyads. Further inspection of the dyads using Bland-Altman agreement plots and calculating the 'limits of agreement' gives

limits of agreement for MSAS-GDI as -1.274 to +1.009. The Bland-Altman plot below shows that the majority of dyads lie within the limits of agreement (mean difference $\pm$ 2SD) (outliers Study ID 1,10,52). Although the plot suggests agreement the difference within the limits of agreement are likely to be clinically relevant as the MSAS-GDI subscale has a small range from 0-4. The same pattern is observed when assessing agreement between patient-carer dyad Total MSAS scores. The mean difference in Total MSAS between patient and carer dyads was -0.133 (SD 0.384). The negative difference for MSAS-GDI and Total MSAS implies the carer score patient's symptom distress lower than the patient at baseline. Again, the mean difference for Total MSAS was small suggesting good agreement between patient-carer dyads. The 'limits of agreement' for Total MSAS were -0.901 and +0.635 and the Bland-Altman plot (Figure 6.4.6.3) shows the majority of dyads lie between these limits, with two outliers (Study ID 1, 52). These limits are smaller than the MSAS-GDI limits and the difference of less than one from the patient score is not judged to be clinically relevant. Hence there is agreement between patient-carer Total MSAS scores at T0 thus carer proxy responses for symptom assessment are feasible and appropriate.

Figure 5.21: Assessment of agreement of patient and carer MSAS-GDI scores

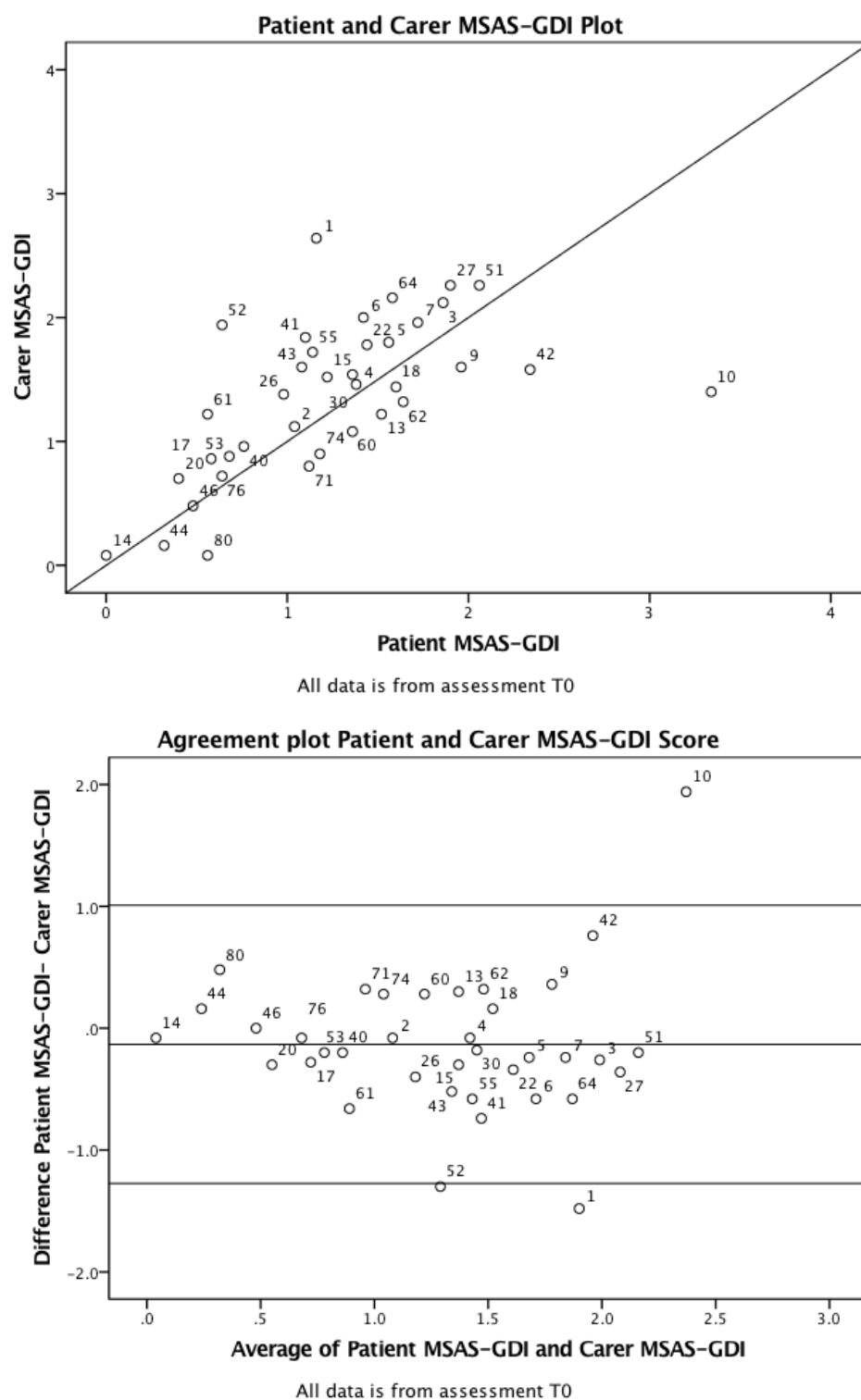
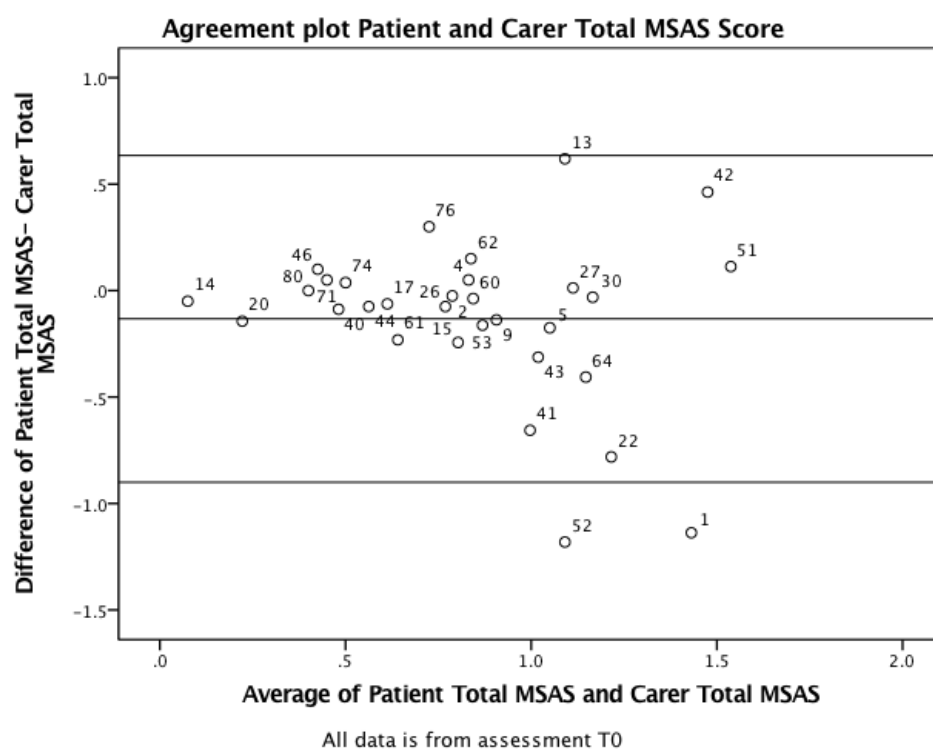
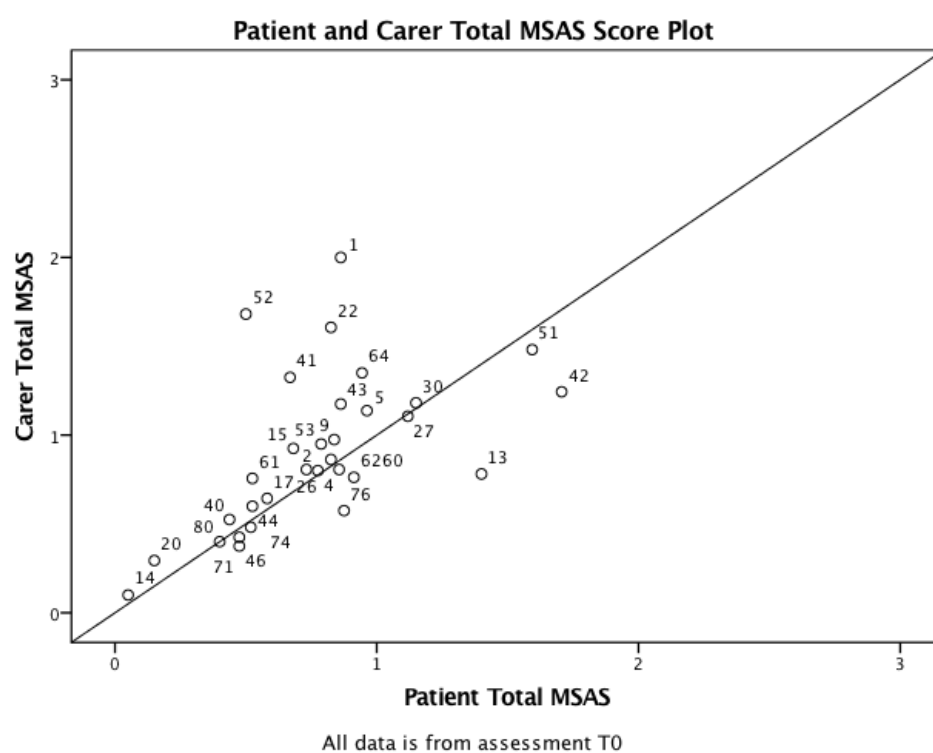


Figure 5.22 Assessment of agreement of patient and carer Total MSAS scores

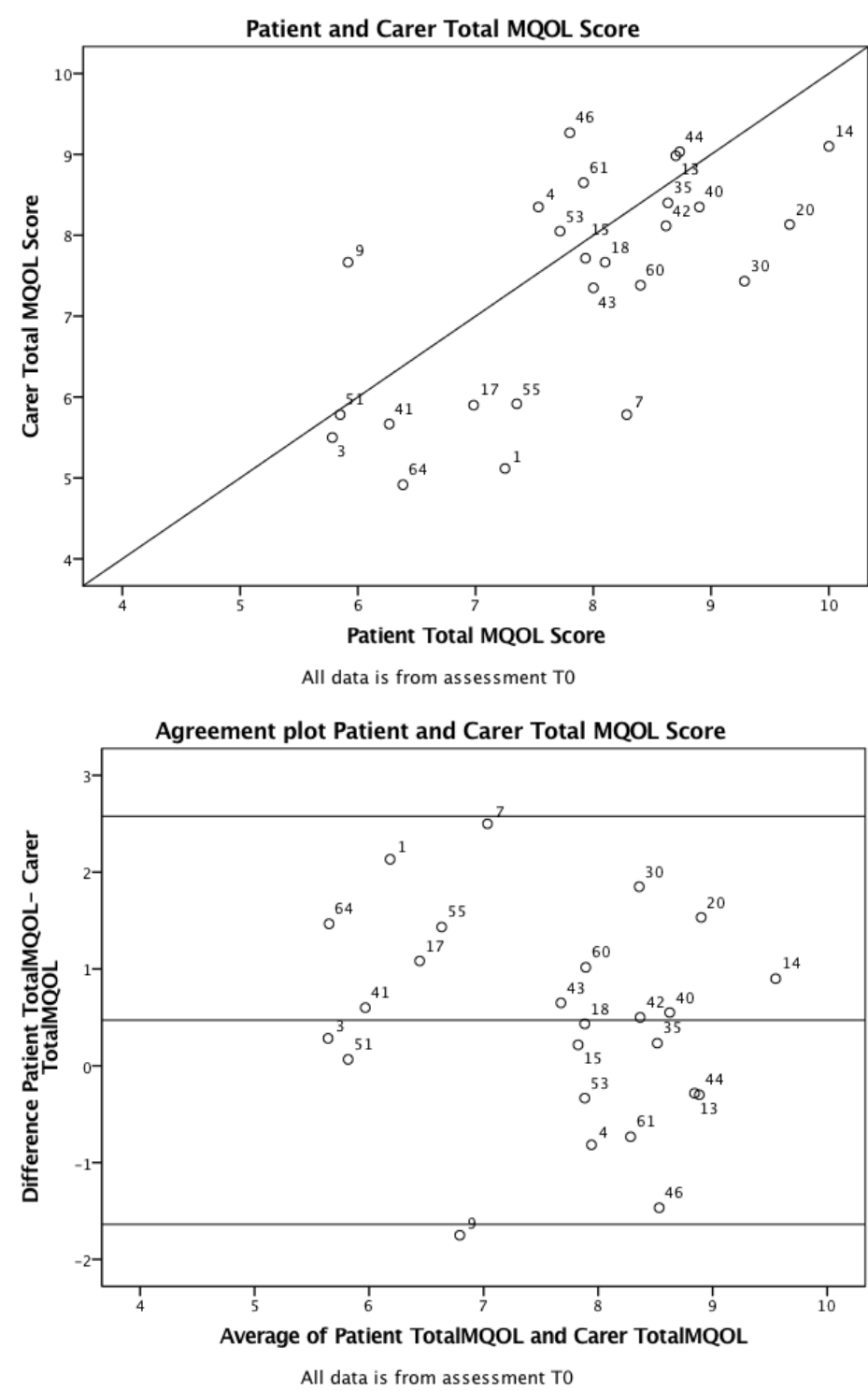


The Total MQOL score has a range from 0-10. The mean difference between patient-carer dyad responses is 0.471 (SD 1.054). The positive difference indicates that patients rate their QoL higher than their matched carer however the difference is small suggesting good agreement between patient and carer. Further inspection of the Bland-Altman agreement plot below shows 'limits of agreement' from -1.64 and +2.58, and all dyads lie within these limits except dyads study ID 9. This wide range of limits is clinically relevant and therefore carer assessment of patient QoL may not be a good proxy marker. However, the sample size for all the subscales was small and therefore the limits of agreement may be overestimated. Overall, the small mean differences across all subscales appears to support agreement between patient and carer responses although this should be retested on a larger sample of matched participants.

Table 5.57: Statistical analysis of agreement between Patient and Carer symptom and QOL scores (T0)

Symptom and QOL Score				Limits of agreement	
	n	mean difference (SD)	95% confidence interval	Lower	Upper
MSAS-GDI	37	-0.013 (0.571)	(-0.323, 0.058)	-1.274	1.009
Total MSAS	31	-0.133 (0.384)	(-0.274, 0.008)	-0.901	0.635
Total MQOL	25	0.471 (1.054)	(0.036, 0.906)	-1.638	2.579

Figure 5.23 Assessment of agreement of patient and carer Total MQOL scores



5.6.2.4 Patient and Carer attrition over time

The feasibility of using proxy carer responses for symptom and QoL to limit missing data depends on two factors; the agreement between patient-carer responses and the attrition of the carer across study time points.

The table below shows the number of complete subscales at each time point across the study for MSAS-GDI, Total MSAS and Total MQOL. The table shows that as patient data is missing from attrition due to illness or death (ADI and ADD) carer attrition also increases in a similar pattern. This implies that as the patient deteriorates the carer is reluctant to continue answering questionnaire assessments. This is relevant to future study design because given this pattern in this feasibility study carers do not appear to be a useful substitute for patient responses at the EoL because they appear unwilling to complete questionnaire assessments once the patient is approaching the EoL and unable to complete assessments themselves. The table shows that the use of carer responses for missing patient data would result in 2 extra TMQOL scores and 1 extra TMSAS score for analysis at week 1, and 2 additional TMSAS and 4 TMQOL scores at 4 weeks.

Table 5.58: Number of patient and carer complete scores at each symptom burden and QOL time point

	Time point			
	T0 (Baseline)	T1 (Week1)	T2 (1 Month)	T3 (3 Months)
MSAS-GDI				
Patient	42	31	25	12
Carer	38	32	23	12
Total MSAS				
Patient	41	28	23	11
Carer	33	29	21	11
Total MQOL				
Patient	37	25	22	11
Carer	29	27	18	11

The carer does appear to be a good proxy for patient symptom burden and QoL in this feasibility study however the use of these responses for imputing missing patient data is limited as the carer often dropped out of data collection at the same time point contact as the patient. This is an important finding for research involving participants in the last few months of life as it questions the usefulness of collecting carer proxy responses if patient data is already being collected. Substituting missing patient data with the matched carer response may not be possible in practice due to carer attrition.

5.7 Feasibility of the intervention - Fidelity and Acceptability of H2H

This section presents the data regarding the feasibility of H2H. The results consider the fidelity and delivery of H2H in this feasibility study alongside qualitative interviews exploring the acceptability of H2H. The purpose of this mixed methodology is to explore if the intervention in its current form is deliverable in the real world and to inform future modelling of H2H prior to further testing in a larger evaluation trial. This section addresses Objectives 9,10 &11.

The data in this section is presented in three subsections:

- 5.7.1 Fidelity and Delivery of H2H – Quantitative Analysis
- 5.7.2 Acceptability of H2H – Qualitative Analysis
- 5.7.3 Acceptability of H2H- Quantitative Analysis

5.7.1 Fidelity and Delivery -Quantitative Analysis

This feasibility study took a pragmatic approach to examine how the H2H was delivered in the 'real world'. Therefore participants receiving both face to face and telephone H2H models were included in recruitment. This section reports on the fidelity outcomes for H2H. These outcomes compare how the intervention was delivered during the study with how it was expected to be delivered.

Table 5.59 Fidelity outcomes for the delivery of H2H intervention

Fidelity measure	Criteria
Proportion delivered as face-to-face CC	> 75%
Time from discharge to CC	80% in < 3 working days
Length of CC	80% are between 30-60 minutes
Attendance at CC (%)	
Patient	90%
GP	100%
District nurses	75%
CPCT*	75%
If in agreement, patient received copy of care plan	100%

*CPCT – CPCT

Table 5.60 details the results. The service aims for the majority (>75%) of H2H to be delivered as face-to-face CCs. In this feasibility study the proportion of interventions delivered as face-to-face CCs was 72%. The CC component should be delivered within three working days, and last between 30-60 minutes. These criteria **were met**, over 91% of face-to-face CCs taking place within 3 working days of hospital discharge. The average length of the CC was 54 minutes, 70% lasting between 30-60 minutes. These data are comparable to the retrospective review of the service presented Chapter 3 (Time from discharge to CC median 3 days, Length of CC-52 minutes). This consistent delivery shows it is feasible to deliver the CC within the time frame of 3 working days and that patients and professionals are willing to engage for up to an hour in a detailed CC to enable a discussion of all the patients needs.

The aim of the intervention is to deliver a community multi-disciplinary handover CC. This requires the CHCPS to agree to attend the meeting. The patient involvement in the CC is the main reason for the CC being delivered in the patients own home. Therefore, >90% of CCs should have the patient or carer in attendance, if attendance in this feasibility study was lower than this it may indicate that the face-to-face CC is not acceptable to the patient/carers. The GP is the lead clinician in the community, and therefore the standard for the intervention is 100% attendance at CC by the GP, with at least 75% attendance by community nurses (DNs) and CPCTs. One hundred percent of CCs were attended by the patient. Nineteen (83%) CCs were attended by the GP, with twenty (87%) CCs attended by both the DNs and CPCT specialist nurses. These data reflect that community professionals are engaging with H2H although the criterion of 100% attendance by GPs was **not met**. These attendance figures are comparable to the retrospective review of the service presented in Section Chapter 3 (Patient or Carer 96.7%, GP 82.7%, DN 92.7%, CPCT 87.3%), and suggests continued sustained engagement of community professionals over time.

Table 5.60 Delivery of H2H intervention compared to fidelity outcome criteria

		n=32 (%)	Fidelity criteria
CC (CC) (n=32)	Face to Face	23 (71.9)	>75% NOT MET
	Telephone	9 (28.1)	
		n=23 (%)	
Percentage delivered within 3 working days		21 (91.3)	90% < 3 working days MET
Percentage of CC lasting 30-60 minutes		22 (95.7)	90% 30-60 minutes MET
Patient present	Yes	23 (100)	>90% MET
	No	0 (0)	
GP present	Yes	19 (82.6)	100% attendance NOT MET
	No	4 (17.4)	
Community/District Nurse present	Yes	20 (87)	75% attendance MET
	No	3 (13)	
CPC present	Yes	20 (87)	75% attendance MET
	No	3 (13)	
Carer present	Yes	20 (87)	
	No	3 (13)	
Other professionals present	Yes	11 (47.8)	
	No	12 (52.2)	
If in agreement, patient received a copy of the care plan	Yes	11 (57.9)	100% NOT MET
	No	6 (31.6)	
	No response	2 (10.5)	

5.7.2 Acceptability of H2H- Qualitative Interviews

Understanding the acceptability of H2H is an essential part of this feasibility study. The acceptability of H2H to patient and carer participants was assessed through two research approaches; a telephone questionnaire to all patient and carer participants at Week 1, and qualitative interviews with 8 patient participants who had received a face to face CC.

This section details the results of the in-depth qualitative interviews conducted with patients, oncologists and H2H SS. The qualitative results have been published in a shortened form in an article in the BMJ Supportive and Palliative Care[231]. The

characteristics of participants are presented and these are followed by each theme identified in the analysis. The results are presented in the following sections:

- 5.7.2.1 Participant characteristics and Delivered H2H
- 5.7.2.2 Loss at the end of cancer treatment
- 5.7.2.3 Transition Barriers
- 5.7.2.4 Transition Management
- 5.7.2.5 Community Care Concerns
- 5.7.2.6 Views on H2H/model

5.7.2.1 Participant characteristics and delivered H2H

Eight patient participants were interviewed in the qualitative study. Data saturation appeared to occur after 6 patients with no new themes emerging. However, to ensure this was the case a further 2 participants were interviewed. Thirteen oncologists were interviewed, with data saturation occurring after ten interviews. Table 5.61 gives individual participant characteristics to provide context to their views and perceptions. Characteristics of individual participants are used throughout the results to illuminate the findings from the interviews and the themes presented. Where quotes from participants are provided to illustrate findings, the name and age of a participant is routinely given. If relevant to the exploration of a specific theme, additional demographic descriptors may also be included. Patient and HCPS participant quotes are presented alongside each other for each theme discussed. This approach enabled me to gain a richer understanding of the important interactions, views and perceptions contributing to experiences of participants.

This section concentrates on the practical delivery of H2H for patient participants in these qualitative interviews. H2H is individualised to each patient and it is recognised that delivery may not be identical to each participant. The CC element of H2H is individualised to each patient participant. Table 6.63 details the delivery of the CC for the patient participants in the qualitative interviews. This information provides context to the feedback from the participants interviewed.

The majority (5/8) of CCs lasted between 30-60 minutes; two CCs were longer than one hour. Only John's CC lasted less than half an hour, and it was also John who had the lowest number of attendees (n=4) at his CC. There was good representation of community professionals at the CC. Five participants had three community professionals (GP, District Nurse and CPCT) in attendance. Tim had the highest number of attendees at his CC (n=7). All participants, except John, also had an informal carer present at the meeting. PPC and Death were discussed in all cases. The delivery of these CCs is comparable to the retrospective analysis of the service (Chapter 3) and those delivered in the quantitative arm of this study.

Table 5.61 Qualitative results: Demographics and characteristics of individual patient participant

Name*	Gender	Age	Ethnic Group	Marital Status	Living alone	Cancer Diagnosis	Extent of disease	Length of disease (days)	Length of disease (years)	Known to CPCT	PPS	Survival (days)	PPD	PoD
John	M	89	WB	Widow	Yes	Lung	LA	242	0.7	No	90	100	Home	Hospital
Geoff	M	91	WB	Widow	Yes	Prostate	M	982	2.7	No	60	36	Home	Hospice
Giles	M	68	WB	Single	Yes	GI	LA	271	0.7	No	60	82	NK	Hospital
Tim	M	64	WB	Married	No	GI	M	3590	9.8	Yes	50	93	Home	Hospice
Mark	M	62	WO	Married	No	Lung	M	334	0.9	Yes	50	11	Home	Home
Jean	F	71	WB	Widow	Yes	Ovarian	M	588	1.6	Yes	60	12	NK	Hospital
Diane	F	64	WB	Divorced	Yes	Ovarian	M	1577	4.3	Yes	50	31	Hospice	Hospice
Sarah	F	71	WB	Single	Yes	Ovarian	M	342	0.9	Yes	50	27	Hospice	Hospice

* To protect anonymity actual names have been changed to ethnicity and age specific alternatives
(WB-White British, WO-White Other, GI-Gastrointestinal, LA- Locally Advanced, M- Metastatic, NK-Not known)

Table 5.62 Qualitative results: Characteristics of HCPS

Study Identification	Name*	Gender	Ethnic Group	Field of Oncology	Number of years in Oncology	Regularly refer to H2H
HCPS 1	Dr Jones	F	White-Other	Medical Oncology	> 15 years	N
HCPS 2	Dr Jessop	M	White-British	Medical Oncology	> 15 years	Y
HCPS 3	Dr Hartup	M	White-British	Medical Oncology	> 15 years	Y
HCPS 4	Dr Peel	F	Asian Indian	Medical Oncology	< 5 years	Y
HCPS 5	Dr Elliot	M	White-British	Medical Oncology	10 -15 years	N
HCPS 6	Dr George	M	White-British	Clinical Oncology	10-15 years	N
HCPS 7	Dr Wallis	M	White-British	Medical Oncology	> 15 years	N
HCPS 8	Karen	F	White-British	H2H SS	-	-
HCPS 9	Dr Patel	M	Asian Indian	Medical Oncology	< 5 years	Y
HCPS 10	Dr Wood	F	White- British	Clinical Oncology	> 15 years	N
HCPS 11	Dr Ling	M	Asian –Other	Clinical Oncology	10-15 years	N
HCPS 12	Dr Fletcher	M	White-Other	Clinical Oncology	10-15 years	Y
HCPS 13	Dr O'Driscoll	F	White British	Medical Oncology	10-15 years	N
HCPS 14	Dr Jefferies	M	White – British	Clinical Oncology	< 5 years	N
HCPS 15	Susan	F	White-British	H2H SS	-	-
HCPS 16	Emma	F	White-British	H2H SS	-	-

- *To protect anonymity actual names have been changed to alternative

Table 5.63 Qualitative results: Details of H2H experienced by patient participants

Patient characteristics			H2H attendees*							Issues addressed at H2H						
Name**	Gender	Age	Length (mins)	GP	DN	CPCT	Patient	Carer	Other	Pain	Other symptoms	Mobility	Psycho-social	Social	Spiritual	PPD
John	M	89	<30	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	N	Y
Geoff	M	91	30-60	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Giles	M	68	60-90	N	Y	Y	Y	Y	Y*	Y	Y	Y	N	Y	N	Y
Tim	M	64	60-90	Y	Y	Y	Y	Y	Y*	Y	Y	Y	Y	Y	N	Y
Mark	M	62	30-60	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Jean	F	71	30-60	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Diane	F	64	30-60	Y	N	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
Sarah	F	71	30-60	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y

* The H2H SS attended all CCs Y* additional attendee was community matron

** To protect anonymity actual names have been changed to ethnicity and age specific alternatives

5.7.2.2 Theme 1: Loss at the end of treatment

This theme addresses the different perceptions of loss that participants associate with the last treatment consultation and end of oncology follow up. It is divided into four subthemes: Loss of Control, Loss of Hope and treatment, Loss of familiarity and trust and Experience of the last consultation – the ‘loss’ consultation. Loss is understood as the disappearance of something valued.

All patients interviewed made some reference to loss during their qualitative interviews. The narratives were striking because they describe multiple losses and how these seem to compound each other. Patients openly discussed these feelings and their impact. The final section in this theme focuses on the experience of the last treatment consultation and the breaking of bad news from oncologist to patient. The current referral criterion for H2H requires the oncology team to be honest and open with patients regarding future further treatment and to be explicit that this involves discharge from the RMFT. Hence the start of H2H begins with the breaking bad news consultation by the oncologist. Therefore, it is imperative to understand the perceptions and views of patients and HCPS surrounding loss and breaking bad news as these are likely to have a direct impact on the delivery and success of H2H.

5.7.2.2.1 Loss of Control

Patient participants spoke in depth about the loss of control their cancer diagnosis had brought to their lives. This meant that each day was filled with uncertainty, the significance of which could not be underestimated.

Mark, a 62-year-old man with metastatic lung cancer, described his experience of living with the physical uncertainties of a cancer diagnosis as 'crazy' saying:

"this disease is crazy and..... I don't know, for me, its so causes signs, you expect something, from there, and it comes from the other way"
(Mark, 62, PPS 50, Survival 11 days)

Diane, whose primary cancer was a gynaecological cancer, recounts a similar experience of the change and uncertainty a cancer diagnosis brings. She described how this uncertainty was a daily challenge.

"well of course it's a changing moving target all the time, so, when I saw the liver man, I didn't know I was going to have to see a chest man, and when I saw the chest man, I didn't know that it was going to turn into a chest operation, and as well as the gynae operation eventually and a liver resection"
(Diane, 64, PPS 50 Survival 31 days)

In the extract above, Diane was referring to her initial cancer diagnosis and treatment. However, this loss of control and its impact on her as a person was palpable during her interview. Here she talks about her situation at the time of the interview:

"because on Thursday I was feeling pretty grim, and by Friday I'm back in here (referring to hospital) so that that's you know quite frightening, how quickly things can all go pear shaped, I've had my blood transfusion and I still don't feel any different really.....but today's the day, and you know, I feel sort of in the hands of providence, so one doesn't really know what's going to happen, so I'm not thinking about it until decisions actually have to be made"
(Diane 64, PPS 50, Survival 31 days)

This loss of control and uncertainty was not limited to patients with a poor performance status.

John, who was physically independent with a PPS of 90 at the time of interview, also felt deep concern and anxiety about the uncertainty he was living with and the unknown of what the cancer was physically doing to his body:

"you can sit here and think well I don't feel anything, you know am I alright, am I getting worse, or suppose its spreading in fact...and sometimes you have a quiet moment um you think well what I wonder what's happening to me you know, which everybody would"
(John 89, PPS 90, Survival 100 days)

Giles, a 68-year-old man with gastric cancer, described the uncertainty of illness emphasising that HCPSs also have no control over the circumstances. He reconciled this to being a fact of life and that no one ever really has control of life itself.

"its just one of those things you know, it's um, whatever patient it is and whatever they've got wrong with them, you know, they've got no control over the situation....."
".....they've (referring to oncologists) got no control over the situation you know, life is life and its, you know, where its going, you know, nobody knows, you know, why are babies born with cancer"
(Giles 68, PPS 60, Survival 82 days)

5.7.2.2.2 Loss of treatment and hope- the last consultation

This subtheme refers to the consensus amongst participants that the act of ending treatment was inexorably associated with loss..

Seven patients recounted that the end of active treatment constituted a deprivation of hope and future. This event brought with it a range of complex negative emotions including shock, disappointment and a degree of resignation. Mark, a 62-year-old man with metastatic lung cancer, typifies these sentiments:

"I was very disappointed, I was hoping during the treatment for a year, (I was) looking (for a) green light as something to encourage me and (the oncologist) to do the rest of the treatment, with a little bit success, at least. It's terrible experience" (Mark, 62, survival 11 days)

Tim, a 64-year-old man who had been treated for his colorectal cancer for over 9 years found the stopping of treatment particularly distressing and upsetting. Although he understood there were no further oncology treatments for his cancer, he could not allow himself to fully believe it to be true:

"so, you know, again, I'm not criticising, because if there's

nothing there, there's nothing there, but I, I was a bit shocked to find that there's no more, er, no more treatment, and you know, obviously, one's concerned that disease will, er, develop and and eventually finish me off you"

"I mean I don't, I don't want to to er get stuck in thinking I wish I was having treatment if you're not going to get treatment, what's the point in getting stuck but I mean, there's always a hope that somebody might, I mean I'm sure, if something came up that they would get onto me and treat me"

(Tim 64, PPS 50, Survival 93 days)

Although most patients, like Tim, described discharge from oncology services as negative and disappointing, one, Diane, (treated for 4 years for metastatic ovarian cancer) paradoxically described her new reality as representing liberation from treatment. She said:

"I was on the merry go round if you like so when I had the opportunity to get off it, having had I suppose nearly 8 months without any treatment apart from um hormone pills, um, that was sort of like life back to sort of normal really"

(Diane 64, survival 31 days)

The H2H SS also discussed the significant link between treatment and hope, associating this with the oncologist being a 'hope' sign for patients and someone they have faith in. This made the end of treatment an even greater loss.

"because they have, they've known them all along (referring to the oncologist), but then also, they have got such faith in them, that actually its worse, because they've got such faith in them, that they thought that they would cure them and they would never be at this point and how could you have let me down"

(Susan, H2H SS)

The concept of further treatments being linked so closely to hope is important to recognize when modelling, implementing and evaluating H2H. Patients referred to H2H must be aware that there are no further oncological treatments available for their disease. The insights from these interviews show that when treatment is so intimately linked to hope, this news must be very carefully delivered to the patient. HCPS must not underestimate the impact this has on individuals and their families.

5.7.2.2.3 Loss of familiarity and trust

Both patient and oncologist allude to the notion of the cancer centre acting as a virtual community. The accounts revealed an overriding sense of loss of familiarity and security when the oncologist-patient relationship ceased. Patient participants told of the close relationship they had with the oncologist and the upset caused by not seeing their oncologist again.

Tim's narrative depicted a bond that extended to areas of life well beyond his illness:

"I mean he'd be perfectly happy to take the call (referring to the oncologist receiving a telephone call from Tim), he definitely would be quite pleased, because, we usually have a chat about golf or fencing or something like that"
(Tim, survival 93 days)

For Jean, a 71 year old lady with ovarian cancer who was already known to CPC services, the loss of hospital follow up was closely associated with a loss of support and loss of interest in her as a person and akin to people not caring

"getting the concern that nobodies interested in it" and when asked 'what makes you feel that? She replied: "cause I suppose because you're not under anybody any more"
(Jean 71, PPS 60, Survival 12 days)

Mark, 62, treated for less than one year at RMFT, spoke openly and frankly about the loss of his oncologist as a friend and a sign of hope. His feeling were so strong that he likened this loss to other significant life losses such as divorce

"it was the worst day of my whole treatment and my whole year, because I was so confident in the hands of (the oncologist) and that day it was like a divorce announcement with (the oncologist) it was not only for my health, I was really sorry, my treatment ends, and I was passing to the pain doctors"
..... I know him well. I was very happy with (the oncologist), I was only sad because I will not see him, I don't see him any more"
(Mark 62, PPS 50, Survival 11 days)

He went on to describe feelings of happiness and hope connected/associated to seeing his oncologist:

"it will be the happiness of my life to see him once more in my life" and continued "I was talking about as a person, with (the oncologist) every time I saw him, it was my hope, my my hope sign"
(Mark 62, PPS 50 Survival 11 days)

Oncologists too acknowledged this important bond. Dr Jones, an oncologist for over 15 years, reported this as a difficulty with regard to ending treatment and proposed that the more involved in a patient's life a doctor becomes, the more difficult it is to end treatment.

"if you know patients for 15-16 years, and then you've seen them for example, many many times during the year, and although you have the role in the relationship, patient and doctor, but it tends to be that they explain you know things of their life, you know my sister has 2 kids we celebrated that, and you get involved in the life and know better the whole family in fact, just not only the patient. Knowing this whole background is more difficult and you feel more close to the patient, and of course you feel bad" (Dr Jones)

Oncologists also acknowledged themselves as human. Parallels between their own lives and those of the patients made ending the therapeutic relationship much more difficult and upsetting. The more the doctor/ oncologist invests in the doctor-patient relationship, the more loss is felt by the oncologist at the end of treatment and end of follow up. Dr Peel describes this loss, relating its significance to both the length of the relationship and the parallels between the oncologist's and patient's lives:

"I find the ones that are most difficult are the ones probably are younger and I've often known for quite a while, and you just get to know them, probably more intimately, because you've got more in common with them and you get to know them more as human beings, not just as patients" (Dr Peel)

The loss of familiarity and trust in relation to the virtual community in a tertiary referral centre was felt by HCPSS as a 'double whammy' compounding the significant loss of treatment already being dealt with by patients. H2H SS had a concern that delivering both these losses in one consultation or outpatient appointment may be too much for patient and oncologist to accept emotionally.

'so I think it's difficult, um, for patients, because, once they have been coming here for many years, treatment, they find the transition, they find that stopping of treatment and not coming back here, very difficult to accept, as well as the fact that they're not having any further treatment, so that its like a double whammy really, they don't have any further treatment, and they're not coming back here, which has been their main source of support, so, for many years, and can mean that they haven't had links with their community team, even their GPs, because they would really rather phone here for information and and support, than go locally, so, it's a big change for them, it's a big culture shift" (Susan, H2H SS)

To refer to H2H the patient is discharged to the community service. With this in mind, the loss of hospital community and oncology friendship is an area of interest as it may well be a barrier to effective discharge and H2H. This is discussed further in the Theme 2: Barriers to transition, and has implications for future service development.

5.7.2.2.4 Experience of breaking bad news

The participants were asked to recall the last oncology appointment, specifically to remember how the oncologist delivered the significant news that their treatment and follow up at the hospital was to end. This is the first step in H2H and therefore insight into this experience may guide future adaptation of the intervention and provide guidance for teams aiming to set up similar services. Overall, the patients described their experience as a positive one, with few complaints or concerns about how the significant news was delivered or the oncologist's communication skills.

Sarah, a 71-year-old patient with ovarian cancer, remembered the oncologist breaking bad news as follows:

"Her manner was good because it's the ability to put across something that's not very nice in a decent manner and let, leave the person feeling ok (laughs)"
(Sarah 71, PPS 50 Survival 27 days)

Tim, 64, described a good experience at his last appointment, when an oncologist gave him and his wife significant news.

"I don't think anything else could have been done better, it was just stating the facts as they were seen and that was it, you know, it was carried out in a perfectly professional way"
(Tim 64, PPS 50 Survival 93 days)

However, despite patients being positive about the way in which bad news was broken, they were sceptical that the oncologist may not have been completely honest. Information was often not

openly offered and, if the patient wanted additional information, they needed to seek it. Concerns surrounding honesty were not alluded to by HCPSs. Patients desired maximal honesty where possible.

Sarah, 71, said:

"I know other people don't but I've always wanted honesty especially when it concerns your life, I think that is very important because you cannot prepare. I can't go blindly into the future, I am one of these awful people who need to be organized"
(Sarah 71, PPS 500 Survival 23 days)

Diane also talked about the importance of honesty and highlighted a concern about not always being given all the information, suggesting that it was often up to her to seek out the information herself. She said:

"when they give me important news, well they're very open when there's important news, but I feel if I want to have the full news, I have to have the right question..... they were open, but if I didn't have the right question, to follow up with myself um, there wouldn't be anything else added"
(Diane 64, PPS 50 Survival 31 days)

Tim also seemed to be somewhat sceptical about whether information was being withheld from him. He acknowledged that the information he was seeking may be unknown to his oncologist although, if it was, this was not clearly explained and honesty about the unknowns would have been helpful to his understanding. He spoke at length about the balance between honest information giving and unknowns:

"When I asked, for example, should I get my affairs in order to use the euphemism, um, it was said that, well you shouldn't be thinking in those terms, but, you know, obviously it's a good thing to have everything straight anyway, but I wouldn't be thinking along those lines, er, because you know you could go on for a long time, but it was not specified what a long time meant and as I say, I'm not making this as a criticism. I'm just stating that it may well be, that, the doctors present felt that they couldn't answer a question like that, that it was unanswerable, and I can well understand that"

He continued:

"If there was anything not clear at all it was what the life expectancy was. I mean I didn't feel that that was quite clear. I didn't go away sort of feeling that I'd really understood how long I had to live basically"

And then he went onto say:

"whether that was regarded as an unknown factor therefore they couldn't answer that question directly, I don't know"
(Tim 64, PPS 50, Survival 93 days)

However, when asked: 'Is that something that you would have liked to have known, given the choice?' He replied:

"Well, (long pause) I don't want to skirt around the answer but in some ways, I'd rather not know, I don't know, if you ask me one day I might think, I might think yes, and on another day I might think no, I'm afraid it's not easy to it depends what mood you're in"
(Tim 64, PPS 50 Survival 93 days)

Geoff, 91 widowed with advanced prostate cancer, was the exceptional case. He had concluded himself that he did not have any further treatment. He had no concerns for himself but was troubled by the impact of delivering this significant news on the junior doctor.

"A junior doctor was sent down to tell me the bad news, and it was a rotten job to do, as he had quite a lot of difficulty I felt with it, well it's not very nice to have to tell somebody, you can't help any further"
"I could sympathise with him"
(Geoff 91, PPS 60 Survival 36 days)

He went onto say:

"I thought he'd got a rotten job to do, if I have any criticism at all um out of the doctors of the three, um I would have appreciated if the others had time to come down altogether and relay the position together, rather than sending the junior doctor down, to break the bad news"
(Geoff 91, PPS 60 Survival 36 days)

There have been many published narratives relating to cancer diagnosis and loss[232, 233]. Loss is a crucial concept to consider in the development of any CI at the EoL particularly one, like H2H, that aims to navigate the transition from hospital-based care to community-based care. Sensitivity surrounding loss should be a key factor in how the service is designed and implemented. The H2H

model needs to cautiously circumnavigate this loss, ensuring the service does not cause undue harm through either insensitive delivery or initiating pathways of care that compound these losses and cause distress.

The feedback from interview participants about breaking bad news, asking for maximal honesty where possible and the opportunity to ask questions, also has important implications for the transition from hospital to community care and the possible barriers to H2H. It may be that more than one discussion with the oncologist is required for patients to have a full acceptance and understanding of their situation.

5.7.2.3 Theme 2: Transition Barriers

The second theme that emerged from the qualitative analysis related to barriers to transition. Transition is a period of change from one state to another. Here it specifically relates to the discharge process, a period of change from hospital-led to community-only care. This theme comprised three subthemes: Understanding and acceptance, attachment and follow up concerns.

5.7.2.3.1 Understanding and acceptance

The ability of patient participants to accept a change in their situation appeared to strongly influence their willingness to agree to discharge. However, this work identifies a spectrum of sentiments that portrayed participants' styles of acceptance. For example, Diane, a 64-year-old patient living with metastatic ovarian cancer, displayed willing acceptance of her situation. Therefore, the information that she has no further treatment options was not a surprise or shock to her:

"I've been a palliative care ever since I first arrived, which was 4 years ago because I knew that this (referring to her cancer) would go hand in hand with with, where we are now really" CS: what do you mean by 'where we are now'

"Where we are now, well we're um I'm not going to get any better, and the symptoms that are uncomfortable are being made as comfortable as possible, for the remainder of my life"
(Diane 64 PPS 50, Survival 31 days)

Although Diane shows a willing acceptance, the majority of participants reluctantly accepted their situation. Giles, age 82 with gastric cancer, who had never had oncological treatment, and Tim, 64 with metastatic colon cancer, who had undergone 9 years of treatment, both displayed a more ambivalent position of reluctant acceptance. Interestingly, neither died in their own home and this may relate to a continued active approach, seeking treatments and reversibility.

Giles recounts his surprise on being told there was no oncology treatment possible:

"I was quite, I was surprised, its one of those things you know you've got to accept other than that, its how I come to accept it now..... you know its not a very nice thing to accept, but the thing is you've got to accept it, I can't force them to give me the chemo"(Giles, survival 82 days)

Tim shared a similar ambivalent position alongside a hope of some reprieve. He explained:

"one's concerned that the disease will, er, develop and eventually finish me off you know, that's the bottom line. I think nobody is saying that it will, but you know, the obvious conclusion.... (but) there's always a hope that something might come up, that they would get onto me and treat me" (Tim, survival 93 days)

A H2H SS felt that culture played a role in acceptance and that this may influence the reach of H2H

"some cultures Japanese etc, um will not engage in this kind of approach, they are completely treatment focused completely, um will not talk about death and dying" (Karen, H2H SS)

Analysis of the oncologist and H2H SS interviews identified correspondence with these sentiments, while pointing out that difficulty in acceptance was often more pronounced among family members than the patient. Dr Hartup and Dr Bond illustrate this:

"some patients just aren't prepared to hear that, and actually, sometimes it's not the patient actually it's the relatives, that's the hardest bit. The patients in my experience are, they're the ones that cope with side effects of chemo, they're the ones that you know, know what it's all about, and my impression is that the patient's generally ok, it's the relatives who fear losing the patients, that find it difficult"(Dr Hartup)

“it’s much more frequently the carers rather than the patient, who need actually emotional and structural support feeling that they’ve tried and done everything they can” (Dr Bond)

HCPs participants expressed a concern that patients may not have had a clear understanding of the purpose of H2H and the discharge from oncology services. However, all patient participants did understand that their care was being transferred from the hospital to the community services, and that routine hospital oncology follow up had ended. Sarah’s articulate description of the service represents the generally good understanding by patients. When asked specifically about the role of the meeting, Sarah replied:

“I understood that she (referring to the H2H nurse) was there to help me get the best palliative care I could get, so that I wasn’t going to be in pain or in trouble when it comes to the end of my life”
(Sarah 71, PPS 50 Survival 27 days)

The interviews with HCPs illuminated the issue of the ability of the oncologist to accept the end of treatment and follow up. The interviews allude to the concern that some oncologists do not engage with EoLC due to professional or personal influences. Both oncology consultants and H2H SSs felt this was an important barrier to transition to community-led care:

“it was clear that the SHO and the registrar were struggling with the emotional aspects of handing this patient over, or, although he (the patient) did fully understand um, where he was in terms of treatment etc, um the he could articulate it, as a patient” (Karen, H2H SS)

“I think the reason a lot of people won’t do it is their own fears rather than I think they probably would say that its that worry that you’re rushing the patient or sort of pushing them but I also think part of it as well, is some oncologists find it harder than others to come to terms with giving that news” (Dr Peel)

5.7.2.3.2 Attachment

Attachment typically refers to an affection or fondness for someone or something. In our interviews, attachment was identified as being closely linked to the theme of loss of familiarity and security. Attachment was recognised as a barrier to discharge. Dr Wood portrayed this, when she

explained that the strength of attachment was often conditional on the length of the relationship with her patients:

"I don't say no you can't do that (referring to returning for a follow-up appointment) because, in a way looking after them holistically as a person, weaning them off the care, is part of the process because it isn't just looking after them physically, psychologically they just couldn't cope with that. I find it's more of a problem with patients you've looked after for a very long time. If you've looked after people for a much shorter time I think, maybe they have less time to sort of form a bond with the unit." (Dr Wood)

This sentiment was shared by many of the oncologists. The oncologists emphasised the psychological therapeutic benefits of the trusting relationship developed between themselves and the patient, so that once active oncology treatment has stopped the oncologist still has an important contribution to the patient's care through ongoing support. In these instances, the oncologist feels they have a duty to continue to support the patient holistically, and this cannot be achieved by community service to whom the patient is not known. Dr Jones explains:

"because if they know you for 20 years even if they know that you are not going to do anything actively medically you know, it (coming to follow up appointments), it it reassures them ok because they have been attached to you and I think this psychologically it has some effect some good effect" (Dr Jones)

The H2H SSs identify this patient attachment as a barrier to transition and Susan describes the bearing this has on community engagement with the patient:

"you do get attached to a certain place and patients that have been coming up here for many years, get attached, and they have a key worker here, and they know who to contact, but there aren't any beds all the time, so if they are linked in to here, it makes it difficult for the community teams equally to get involved, and that and that's been one of the criticisms" (Susan, H2H SS)

This belief resonates when considering some of the patient participants' interviews. Mark, a 62-year-old gentleman who underwent one year of palliative treatment for lung cancer, describes this attachment and the importance to him:

"it was the worst day of my whole treatment and my whole year, because I was so confident in the hands of (the oncologist) and that day it was like a divorce announcement with (the

oncologist) it was not only for my health, I was really sorry, my treatment ends” (Mark, survival 11 days)

The H2H SSs recognised that this was a two way attachment: the oncologist may be as attached to the patient as the patient is to them. This creates a reluctance to discharge patients to community services and is a clear barrier to transition. Emma explains:

“maybe because they just don’t want to let go of their patients, because they’ve built up a relationship with them, and maybe they don’t trust that we do as good a job, i.e. palliative care and H2H, as they’ve already do” (Emma, H2H SS)

5.7.2.4 Theme 3: Transition Management

This theme relates to the mechanisms that HCPSs use to ensure transition to community care occurs smoothly without undue distress to the patient.

Transition) was viewed as requiring three elements to be effective: preparation, a gradual phased approach and an open door policy. Each of these subthemes is now discussed.

5.7.2.4.1 Preparation

Preparation was identified as one of the key factors in acceptance. Dr Khan recognised the importance of sensitive preparation to ease his patients into a better state of acceptance:

“the key to me is preparation that this is a treatment and beyond that there won’t be any more, plus, understanding the risk/benefit ratio from a patient’s perspective...so it’s about letting them down gently.” (Dr Khan)

Patients acknowledged the oncologist consultants’ purposeful preparations. Sarah, a 71-year-old woman living with ovarian cancer, recalled her oncologist’s attempts to prepare her for the likelihood that her chances of surviving her illness were limited:

“Well last November (the oncologist) had told me that there was only a three in ten chance that I would recover and from the way my body was, I had a feeling that, I wasn’t going to be one of the lucky ones, but, that’s the way life goes” (Sarah 71, survival 27 days)

The H2H SSs recognised preparation as a fundamental contributor to a successful handover to community care. With this was the acknowledgement that, despite best intentions, it is not always possible to prepare patients for this transition, perhaps because of the speed of their illness or their willingness to accept the change. Emma describes this key issue:

"I think for the patients, what we want to do is to try to make sure that their transition from here to the community teams, is done as well as possible, um, and I think that some of the problems wouldn't arise if the communication was done better here in the hospital.....hmmm, yeah I think so, definitely prepare the patients and sometimes I admit you can't, because sometimes patients just don't hear, some of the prompts, and that is difficult, and sometimes they are given false hope as well." (Emma, H2H SS)

5.7.2.4.2 Phased gradual transition

Transition from care setting (hospital) to care setting (community-only care) was viewed as requiring a gradual phased approach to handover care effectively. The need for a gradual, phased approach balanced with honest communication was a concern for the H2H SSs. This was particularly true in the outpatient setting, where it was felt this approach might get overlooked due to time constraints. Karen voiced concern that, although over the time span of the service there have been improvements, in some instances where a gradual approach was not taken the last consultation with the oncologist could be 'brutal' for the patient.

"its more to do with, um, how the oncologists have handled taking them to the point where they understand there's no more treatment, you know, and they're getting so much better at giving the warning shots, and, thinking about the time span that they've got left and and so its not as brutal and I'm thinking more about clinics, its its different when they are in patients, because you've got palliative care involved, generally" (Karen, H2H SS)

The struggle between honesty and a gentle, gradual approach to the handover of care was met with unease by the HCPSs. From her observations of the impact of end of treatment on patients, Emma discussed this and considered a potential solution of returning to clinic for further discussion or an open door policy as something that should be offered to all patients referred to H2H.

'Its hard isn't it, because if there is no further treatment then, I guess they have to be honest with the patient, and tell them that actually, there is no further treatment, I don't know whether it would be helpful if they said, we'll bring you back in a couple of weeks to have this conversation again, or you know, just to go through things again with you, and we'll leave it open, so that, if you felt that you wanted to come back and discuss anything further we were here for you. Whether patients would actually have time to have come to terms with it, knowing that the appointment was there if they wanted it' (Emma, H2H SS)

Oncologists were unanimous in their view that, in order to temper the loss and grief reaction experienced by patients, transition into the community needed to be managed gradually and delicately. The importance of this gradual transition was allied to the length of their relationship with the patient, as Dr Wood describes:

"if you've got a good relationship with the patient, a long standing relationship with the patient, sometimes it can be difficult, because they don't want to let go, um and, in those patient you know, perhaps the easiest thing to do is to bring them back one or two times after that EoL discussion" (Dr Wood)

5.7.2.4.3 'Open door' approach

Oncologists and H2H SSs were undivided in their view that transition should include easy, open-door access for patients to contact them for advice or reassurance if necessary. Many of the oncologists felt that offering an open door to the patient was a duty and important to the patient's holistic care. There was a strong recognition that the interaction in a consultation between oncologist and patient had additional benefits outside the review of anti-cancer treatment. Dr James routinely offered patient choice regarding whether to return to clinic:

"So what I often say is look you know, you can come back at any time, there's no problems, but I won't make you another one (referring to appointment), I'll leave it up to you" (Dr James)

In agreement with the significance of this open door approach, Dr Fletcher suggested that psychological harm could be caused if the metaphorical open door was unequivocally shut to patients. She states:

"I don't say no you can't do that (referring to returning for a follow up appointment) because, in a way looking after them holistically as a person, weaning them off the care, is

part of the process because it isn't just looking after them physically, psychologically they just couldn't cope with that" (Dr Fletcher)

The concept of potential psychological harm being caused by the 'shut door' and a complete disconnect from the oncology centre was highlighted by the H2H SSs as an unintended negative outcome of the service's aim to transfer the patient's care to community-led care. Karen's unease with this scenario was palpable during her interview, where she likened complete handover to community services to abandonment by the oncology centre:

"you know, psychologically, you need to, you can't do that to the patient that was just awful, you know, um so its very important for them to understand that we hadn't gone away,.....you know, they weren't being abandoned, cause the whole point of H2H was that they shouldn't feel abandoned, so instead of a shut door, you know, we had a revolving door" (Karen)

Patient participants spoke indirectly of the significance of no further oncology follow up in terms of prognosis and the idea that, even though they had been discharged from oncology care, the door was still open and they had not been forgotten. Tim, who had been treated by the cancer centre for 9 years, spoke of his assumption that the door was always open:

"one's concerned that (the disease) will, er, develop and eventually finish me off you know that's, that's, that's the bottom line. I think nobody is saying that it will, but you know, the obvious conclusion...there's always a hope that somebody might, I mean I'm sure, if something came up that they would get onto me and treat me" (Tim, survival 93 days)

Dr Ling's explanation typified the oncologists' experience of the patients' need for reassurance regarding their treatment pathway:

"the advantage with the service (referring to H2H) is that we can, you know after we've had that discussion, we can immediately sort of, refer on and you can start taking over, but often we find that they often come back once more. They just need to make sure, that you've not forgotten about them, that it is safe, it is fine, and I find that often happens and we are happy for that.....they need that reinforcement one more time, that it is the right pathway."
(Dr Ling)

5.7.2.5 Theme 4: Community Care Concerns

This theme relates to the concerns of participants about community-led care.

A number of participants shared concerns about the ideal that care could be exclusively delivered in the community. These concerns divided into two subthemes: (1) lack of knowledge and trust in community care and (2) inadequate service provision. These will now be discussed.

5.7.2.5.1 Lack of Knowledge and Trust in Community Care

Patients, oncologists and H2H SSs all highlighted both the knowledge of community service and lack of trust brought on by prior bad experiences of community services as a worry about community-led care. These worries centred on a belief that, at times, the community teams lacked adequate knowledge to manage patients' specific cancer. Tim illustrated these concerns. Asked if his GP being in sole charge of his care would worry him, he replied:

"I wouldn't have said I'd be worried about it, but on the other hand, one cannot expect doctors, GPs, to be cancer experts, you know, with all due respect to my GP so an excellent GP I wouldn't necessarily expect them without looking up my case, to know as much as I do about it, you know, I mean they just wouldn't, I mean I know what drugs I've been on, I know for how long I've been on them, I know what, everything, all the dates the whole lot whereas...one of my dear friends at the Marsden, I just tell them my number, and they hear my number and they'd have my case right in front of them"
(Tim 64, Survival 93 days)

Dr Fletcher observed that lack of knowledge by community professionals was a concern for patients

"to have an opportunity to speak to a HCP who understands their disease prognosis, and generic treatment pathways to give them reassurance that this actually is ok, you know, it is the best for their particular situation, and that they're not missing out on some thing exotic, that would have made all the difference" (Dr Fletcher)

Jean, a 71 year old lady with advanced ovarian cancer, implied that a previous bad experience with her GP, delays in her initial cancer diagnosis and previous interactions with community nurses left her with a reluctance to trust community care:

"he really hasn't done anything wrong, but (sighs) he's always been a doctor you go to him for one thing unless he can cure that one thing or look at that one thing, he doesn't

think of an alternative. I'm sure he could have discovered this (referring to her cancer) a lot earlier than what he did if he wasn't concentrating on the first thing that I talked to him about"
(Jean 71, Survival 12 days)

She went onto say:

"the district nurses are no better well the first district nurse that came round for the meeting (referring to the CC) and that, she was fine, she was lovely, she was on board, she did everything. But the last one that come round, well, she needed more training or you know starting again, I thought to myself, well you go as soon as you like"

The H2H SSs recognised previous poor community care and lack of trust as another barrier to the delivery of H2H. Susan acknowledged that in this scenario, care couldn't be fully transferred to the community until these issues have been addressed by community services 'proving' themselves to the patient and family.

"if they've had a bad experience with community services in the past, if they don't trust their GP....if they've, yeah, had past experiences, which aren't good....the patient and their family, either or both....its not unusual, its not common but it's not unusual.....yeah, because then you, what you're trying to say is we offer a service that helps link you in with these people, that can pick up where we have left off, but if they don't want that, then its really really difficult, because they (referring to community services) have got to prove themselves before they (the patient) will accept that transition which makes it more difficult" (Susan, H2H SS).

Susan also recognised that the consultant oncologists may not trust community services. Referring to oncologists, Susan reflected on the issue of trust between HCPSs across care settings:

'maybe they (referring to oncologists) don't trust community services and therefore they just want to keep them (the patient) and come back here because they feel that it's the best place that they can receive the care that they need, maybe they just don't know about palliative care as much as they should' (Susan, H2H SS)

However, only one consultant, Dr Jessop, a consultant for over 15 years, expressed this as an issue. He did also acknowledge that community care could be excellent but that inequalities depending on geographical location are a contributing factor in his mistrust of community care:

"One of the reasons oncologists follow patients up is because palliative care services aren't quite as good as people think they are because they're not getting very good care in the community.... ..and of course it's very dependant on where you live. I mean my default

position is to bring patients back until I know that they're secure in the community. Most of those follow up problems are based on the fact that the community is not picking the patient up, because when it's done well in the community its spectacular" (Dr Jessop).

5.7.2.5.2 Inadequate Service Provision

This subtheme reflects the concern of participants that community services are limited and resources stretched. Participants felt this had a significant impact on how engaged community professionals were in leading the patient's care in the community. Karen, a H2H SS, discussed how these limited resources require informal carer support to enable patients to achieve their PPD. For Karen, these limited community resources meant that she felt a responsibility as part of H2H to offer accurate information about care at home so patients and family members can make informed choices:

'In my conversations with patients um I feel that their choices are informed choices I do think that's the important thing about it, if you choose to die at home, you know the family have to take on a big responsibility for that, um, do you understand what I mean? well, if you're a little old lady on her own, who doesn't have any family, who's got brain mets and needs 24 hour supervision, the likelihood of you being able to stay in your own home is very very slim indeed' (Karen, H2H SS)

This is a significant issue for H2H and the equality to all eligible patients with regards to achieving EoL preferences. The intervention relies on community services picking up the care of the patient, and inadequate service provision may hinder effective handover to community-led care.

Specifically relating to CPC input, published evidence suggests many patients have unmet needs and that referral to palliative care services is often too late[234, 235]. These studies advocate earlier referral to CPCTs; however, insights from the HCPSs participating in these qualitative interviews indicate that CPC services in certain areas do not have capacity to adequately support all their current referrals.

In the following statements, Dr Jones and Dr Jessop, both oncology consultants for over 15 years, describe their experience of this:

'not going to take all referrals and we do have patients that they frequently I send them, and they send back to me saying we've discharged for now cause they don't need the input

and you know I get lots of those letters but I understand that there's a limited resource'
(Dr Jones)

'One of the reasons oncologists follow patients up is because palliative care services aren't quite as good as people think they are because they're not getting very good care in the community, they're getting this on demand service rather than what they really want which is regularly touching base with somebody' (Dr Jessop)

The H2H SS also described inadequate service provision, combined with government ideals regarding community care, as stretching the already stretched community resources. Susan described her experience of the difficulties in community service provision:

'I think, with the patients that we are discharging now, I think the community teams are finding it difficult because there's not the amount of staff out there to pick up all these extra patients that they are getting referred. I think the community based thing has gone completely the other way, and the government are thinking that that's where everybody wants to be, at the end of their life um I'm not sure that that is right, but they don't seem to have thought that that is going to have an impact on the community staff that are struggling out there already' (Susan, H2H SS)

Mark, a patient with metastatic lung cancer, was the only patient participant to attribute gaps in his EoLC at home to lack of service provision. In his interview, Mark, who lived for 11 days after his interview and died at home, intensely described the community team's 'lack of time'. Later in his interview, he described that the impact on him was that he felt abandoned by community professionals. Here he is discussing the delivery of additional catheter bags:

"I been promised for their help, and also spare parts, because they do have a part that's over ride this problem but will never deliver, because they have no time...the community suffers from time" (Mark 62, Survival 11 days)

5.7.2.6 Theme 5: Views on H2H

Four subthemes about H2H emerged from the qualitative analysis: 1) Maximum information sharing 2) Visual integrated teamwork 3) Acceptability and Limitations to implementation and 4) Concerns and suggested changes.

The first two subthemes demonstrate the overwhelming positive experiences of H2H shared by participants. Patients and oncologists described the role of H2H as a reassurance to the

patient that care is considered and coordinated. All patient participants, except Jean, felt strongly that H2H was beneficial.

5.7.2.6.1 Maximum information giving/sharing

This theme relates to the clear sharing of knowledge from HCPS to patient, professional to professional, and also from patient to HCPS at the CC.

Patient participants appreciated the open forum of the CC as it enabled them to share their views and perceptions about their care. Sarah found this opportunity particularly valuable and shared this in her interview:

'I was given the time to think and put across what I felt, it wasn't rushed, nobody made me feel, got to get back, got to do this, which was very nice'
(Sarah 71, PPS 50 Survival 27 days)

The H2H SSs recognised the importance of the patients sharing their story with the community team who would be caring for them at the EoL.

"I think some people just find it a positive, cathartic thing, to talk things through, and have it all, have all of the professionals in the one place at the one time so they can physically see who's agreeing to what as opposed to it being on paper" (Emma, H2H SS)

As well as being able to share their story, views and wishes, patient participants identified the imparting of knowledge to the patient as a key benefit of H2H. Patients used the word 'enlightening' to describe the impact the CC had on their understanding or that of their families of both the illness and the likely future care. John described how the meeting was enlightening, allowing him to clarify areas of uncertainty:

"Well being enlightened, my position, I was happier than before the meeting as it were. Just the overall situation I'm in, had they not come on that day, I'd still been sitting here thinking about what I'd got (LAUGHS), how it was going to be treated and what not what not. But having that meeting here it cleared my mind on many of the er things, you know I was a little bit worried about probably" (John, 93)

The patients had an acute awareness that the course of their illness and change in goals of care focussed in the community were having a significant impact on their loved ones. Consequently, patients were particularly grateful that their family member or loved one had a chance for their questions and concerns to be listened to and addressed

'well the maximal information and everybody had a chance to ask their questions. My daughter was particularly anxious, to, understand the full implications, so it was a chance for her to ask all the questions and get professional answers, it was pretty good' (Geoff 91, survival 31 days)

The oncology consultants shared a similar view of how they perceived H2H was beneficial to the patient. One oncologist, Dr Peel, worked across hospital sites, including the comparator site for the study. She felt concerned about a possible gap in care and information sharing with standard handover arrangements to the community services. She felt troubled that for a period of time the patient may feel alone, frightened and without information about their future care. In her view, the main positive outcome of H2H was that it filled this gap and expedited community care.

'the best thing about it is its cutting out that whole interim process, its actually having a definitive plan, the patient understands what's happening, there's no, I sometimes feel with the service the way it is where you just make that referral, see them in clinic, and make that referral (referring to current handover to CPC), they don't really know, they don't really understand what's going to happen next, its frightening for them, they, they're anxious' (Dr Peel)

5.7.2.6.2 Visual integrated teamwork

This subtheme refers to the participant's experience that all teams involved in their care were over-archingly supportive of one another. Although the HCPSs attending the CC may never have met and were from both the acute and community services, the patients felt these HCPSs were working together as a team to provide a coordinated approach. There were no negative comments from patients about the HCPSs' interactions during the CC. Participants felt reassured by the CC and confident that the different services were working as a coordinated team, all 'Singing from the same hymn sheet'.

Diane, a 64-year-old lady with metastatic ovarian cancer, said exactly this:

"Everybody would be singing from the same hymn sheet, that what ever had been agreed, they'd all agreed together. I think that was the basis of us all knowing what was agreed. I think it was very important, um, and everything has worked like clock work"(Diane, 64, survival 31 days)

Geoff and Tim also spoke positively about the teamwork they witnessed between community services and H2H. The teamwork was considered exceptional by participants: members of the CC were supportive of each other, it was clear that care was coordinated and all HCPS were

given specific tasks. Geoff noted the support HCPSs gave one another:

“they are as a team of 4, they were always very supportive of each other and of me, very good, all singing from the same hymn sheet”
(Geoff 91,)

Tim’s views on the coordination of care show that he does not always expect HCPSs to agree on various aspects of care, and that to get this sort of agreement between professionals meant H2H had done something more than ordinary, ‘a great job’.

“My understanding was that she (referring to the H2H nurse) was there to help transition to being at home, to um, help the most smooth possible transition and bring the various agents and parties together so that it was coordinated”. He went onto say ‘..., I think, everybody went away, from the meeting as far as I can see, agreeing with how things were going to go. Well as she achieved that, everybody was in agreement, then she’d obviously done a good job”
(Tim 64, PPS 50 Survival 93 days)

The physicality of the CC and the patient witnessing these constructive interactions between HCPSs was significant in the positive impression the CC left with the patient. Sarah, a 71 year old with ovarian cancer, described her impression:

“I met the people I was going to be concerned with mostly, together. I saw their interaction as well, and that it was a good interaction”(Sarah, 71, survival 27 days)

Giles described himself as being ‘happy’ with the service and interactions between professionals he experienced at the CC:

“sort of like the community nurse saying what she’s gonna do, and the Macmillan nurse what she’s gonna do, and my Matron what’s she gonna do, and sort of what (the H2H nurse) is going to do, you know, it was sort of a general meeting and the teams getting together and saying well right we will do this side of the service, and you know sort of everybody was saying well we’ll do our side of the service, you know, and they agreed on everything so, you know, I’m quite happy with the treatment I’ve got” (Giles 68, survival 82 days)

The teamwork noted by the patients extended beyond the HCPSs to include their family members as part of the team. Patient participants found this inclusion of their loved ones invaluable. Sarah, a 77-year-old lady with ovarian cancer, recollects:

“my cousin was with me, and she (referring to the H2H nurse) included my cousin in the things, my cousin’s my next of kin and for me, that was also important that my cousin felt part of what was going on” (Sarah 71, PPS 50 Survival 27 days)

Tim made the point in his narrative that H2H ensured his wife was involved and that the CC also focussed on her needs. This was of great importance for him. He said:

"I think her (referring to the H2H nurse) job seemed to me to be a sort of coordinator really to bring the various parties and agents together including my wife, I mean she was very careful to bring my wife into it and she's since spoken to my wife, she was very concerned that my wife should not be over anxious, I mean if it all got too much for my wife, I wouldn't be at home, it would be impossible without her" (Tim 64, PPS 50 Survival 93 days)

The H2H SS report that during their experiences of delivering CCs, when the community teams work together, the meeting is powerful and patients feel well supported:

"just bringing people together, in the same room can be quite powerful really for the patient and I think it does ensure that the questions that the patient's want answering are answered, um, and and rubber stamped really um, and we try to identify key workers, and bring it all together"(Susan, H2H SS)

5.7.2.6.3 Acceptability of the CC and Limitations to implementation

This subtheme refers to how acceptable the service is in its current format. In order for the service to be feasible it must be acceptable to all: patients, oncologists and community health professionals. This information is essential in informing the future modelling and development of the service. The patient participants were all asked about any improvements they would make to the service. Interestingly, patients did not express any concerns about the CC model nor did they suggest any areas of improvement. However, HCPSs did have concerns about how acceptable the CC model was to patients. These concerns centre on the prospect that the number of professionals at the CC may be overwhelming, intimidating and stressful, and that repeating a discussion about EoL so soon after the last hospital consultation may be too psychologically distressing. Susan described this issue in particular reference to the patients with brain tumours:

"I think a big meeting would be distressing and I think that's something that has come up three times with the brain tumour patients recently, which I thought maybe we need to hear that and maybe just do it on the telephone, which is what I've been doing, so, um, because it can be, you know, people have said its quite intimidating, some people don't like it, um, some people find it quite worrying that people are going to come to their house, they think they have to tidy up, and they haven't got enough chairs, and they're worried about how their house is" (Susan, H2H SS)

“when they go home, erm, some people aren't ready to discuss, they just don't- they've just had enough of discussing things already in hospital, and they don't feel that that would be helpful” (Emma, H2H SS)

The HCPS were aware that the service had to be acceptable to both hospital and HCPSs, otherwise it was not possible to deliver it as intended.

One consultant oncologist, Dr Peel, described the referral criteria for the service requiring the oncologist to have an open and frank discussion with patient about the end of treatment as one significant potential reason for oncologists not accepting the service:

‘I think its just the fact that its so final, whereas its probably easier in some ways, to say we'll link you into the community team, they don't have to sort of have any more of the conversation, and then that's it. Whereas, H2H you have to have that conversation with them, because you have to explain what they're coming in to do, so you have to have quite a frank conversation, and I think some people will not want to have that conversation’ (Dr Peel)

The H2H SSs described experience of both extremes, from hospital and community reluctance to engage with the service to community professionals very appreciative of the service.

Emma's feelings typified those of the H2H team:

‘I think its more the support of everybody else that is instrumental in whether it works well or not from the professionals within the hospital, and other professionals out in the community.... whether they want to use it, and use it properly, whether they understand it, or if your getting a lot of resistance, then, even if you get a referral, and somebody's resisting you in the community, then its not going to work as well as it should’ (Emma, H2H SS)

Susan describes the varying response to the service when it first started:

‘What I find difficult is the huge um reluctance really, so you have to sort of entice people, so its about being a diplomat really so the hospital teams sometimes don't want us, initially the community CNSs didn't want it, and the district nurses were very grateful really cause they, I think they were a group that were being missed, so I think that's really good, that they're now being included in EoLC patients sooner than they normally would be’ (Susan, H2H SS)

The HCPS participants felt the main limitations to delivery of H2H in its current format were a possible capacity issue to deliver face-to-face CC to all eligible patients, late discharge from oncology and referral to H2H, and the quality of the community services involved in the patient's care.

Dr Jessop questioned whether the service in its current format was 'fit for purpose'.

He observed:

'number of patients that are dying from cancer I just wonder if it is fit for purpose in that it is able to deal with large numbers of patients (yeah) in other words the way it is designed to operate which is an ideal' (Dr Jessop)

The H2H SS, Emma, believed that late referrals to the service limited her ability to deliver the intervention as intended.

'I think sometimes they could do with being referred earlier because, actually if its too late, then its too far along to be doing those sort of things...they're too ill, to participate in things like CCs or advanced care planning, so you don't really know whether, what they want' (Emma, H2H SS)

Both H2H SSs and oncology consultants felt that poor quality community services limited the delivery of the CC and also the delivery of the advance care plan outcomes agreed at the CC.

'it relies on having really good GPs and really good community nurses you know, and really good palliative care doctors, who are out there in the community and a lot of these places don't have that and of course the poorer and more deprived you are, the more difficult it is to setup home in a way that's appropriate for a dying person' (Dr Hartup)

Referring to the CC itself, Emma describes that the meeting can expose poor community team work to patients, and these poor relationships limit the delivery of the intervention as intended:

'Things will generally go better if everybody is talking to each other in the community, and the GP gets on with the District Nurses, and they get on with the CNSs and they're meeting regularly, then generally it will be good....and they agree to come to our meetings, if there's resistance and discord between the teams with any of the professionals, then it can go bad, and the patient's know which ones they have, because they, they'll know if they've got a good team or a bad team' (Emma, H2H SS)

5.7.2.6.4 Concerns and Suggested changes

This subtheme relates to concerns about the current H2H and participants' views on changes that would improve the delivery and acceptability of the service. These two areas are closely linked. Suggested changes relate to the main concern highlighted about the current service: the

speed of transition from hospital to community care. HCPSs were concerned that transition to community care was too fast for the patient, and that the gradual phased approach towards transition advocated in the transition management theme was not always adopted.

The speed of transition was not a perceived concern for patient participants; however, both oncology consultants and H2H SSs felt unease about the speed and finality of referrals to H2H. When asked if there was anything negative about the service, Dr Peel, a regular referrer to the service, said:

'I suppose the only thing I can think is maybe they (referring to patients) think the whole thing is too quick, and that patients perhaps need some time to come to terms with everything and I can see that side of it, um, that you know, you tell a patient, you let them digest that information, you let them come to terms with it, you give them some time to think about it, and then you go in with the next step, because ultimately the next step is talking about where they want to die and how, you know, how they want to be, which is quite raw probably in some cases, because they've only just been told' (Dr Peel)

Susan, a H2H SS, described the handover as too quick and that if this is unexpected it can have a detrimental impact on the patient.

'I think its I think its genuinely too quick, sometimes, patients, especially if they haven't seen it coming, its, its they feel abandoned, that's the word that they have used, abandoned, kicked out, neglected' (Susan, H2H SS)

The two suggested changes to the service to mitigate against this main concern relate to the subtheme 'phased gradual transition' and 'open door policy' in the transition management theme discussed above. The suggested changes made by participants were a 'check in' appointment and feedback to the oncologist regarding the patient wellbeing.

Oncology consultants and H2H SS suggested an offer of a 'check in' appointment. This is currently not routinely offered as part of the service and relies on community professionals contacting the oncology teams should the need arise. A 'check in' appointment could be booked and planned by the oncology team or arranged by the patient at a later date. HCPSs felt this would provide patients with reassurance that their palliative treatment plan would be reviewed and that the patient would see a specialist again.

'maybe we just there needs to be a little bit of little bit of flexibility when it comes to being able to communicate back to us and say, 'hang on, you said that id be dead in 4 weeks, but 3 months later I'm feeling ok, were you right?' something, you know, 'did you get it wrong?'. Well I mean it wouldn't necessarily mean that they would have more treatment

but they might need reassurance, they might need another x ray or a scan or something'(Dr Hartup)

Dr Wallis had reservations about how abruptly the end of treatment decision is imparted to the patient:

'we don't give them much warning we make a decision, if I go on a ward round or in outpatients clinic this is as far as we can go.....maybe we could if there was an information brochure we, should we give that to patients and then bring them back a week later for the initial discussion with the H2H coordinator' (Dr Wallis)

He went on to discuss a suggested end of treatment approach with parallels to consent and treatment with anti-cancer therapies:

'a bit like informed consent I mean, you know, you give the patient the information sheet, and you give them a week to think about it, so that when you get the consent they know what questions to ask if they haven't understood it probably, and in a sense its such a major transition that I think it would be helpful to give them a bit of time' (Dr Wallis)

Talking about a check in appointment, Susan reflects that it would be a good additional component to H2H, although it should be optional. Susan felt that not all patients would find it necessary after the CC.

'if they wanted it, because I think actually, a lot of patients perhaps wouldn't have it because there might be the thing that once they've had time to go home and think about it, and they know that that appointment's there, that actually, perhaps, they wouldn't need it um, but lots of patients have said to me I think that that was done very very abruptly, I need to come back again and have a discussion' (Susan, H2H SS)

The oncology consultants explained that, as it currently is delivered, H2H does not included feedback to oncology teams about patient outcomes in the community. This would reassure oncologists that the patient was well cared for with no concerns highlighted that the oncologist needed to address. Dr Jones describes how feedback from H2H about individual patients would ensure the patient's care at home was working and also help the oncologist with his/her detachment from the patient.

'I would like certainly you to keep us informed on what they (the patient) are doing. I mean it was my patient and it's quite reasonable to know what happened... I think yeah, what happened and how is he or she, is quite reasonable if it had been your patient for

many years, suddenly you don't hear anything until you know he's dead, and you know it's a bit of a shock its reassuring that that patient is ok at home, that things are ok, that there is no major disaster that he is comfortable' (Dr Jones)

5.7.3 Acceptability of H2H – Quantitative results

Table 5.64 gives the results of the telephone questionnaire and the free comments from participants in the quantitative component of the study

There were 32 participants in the H2H study group, 23 received a face-to-face H2H and 9 a telephone CC. 8 of the 23 patient participants who received a face-to-face H2H had a carer recruited to the study.

Nineteen patient participants (82.6%) and 7 carer participants (87.5%) completed the Week 1 acceptability questionnaire. The majority of patient and carer participants thought the CC length was 'about right' (Patient 73.7%, Carer 85.7%). However, three (15.8%) patient participants considered the CC 'too short'. No patient or carer found the CC 'too long'. This suggests that the face-to-face CC format and length is acceptable to patients and not over burdensome for this group. Over 80% of patients felt all the important issues were addressed, and encouragingly 84.2% of patient participants and 100% of carers would recommend the service to other patients.

These results provide evidence that H2H in its current format is acceptable to patients and carers. There were no negative free comments about the service, and the positive comments are detailed in Table 5.64. The main themes from these comments were that it was important to the patient to know and meet everyone involved in their care, to see that all HCPS knew the same information about the patient and their roles were defined. These findings complement the main themes found in the qualitative interviews highlighting the importance of retaining the elements visual integrated team work and maximum information sharing in any remodelling of H2H.

Table 5.64 Acceptability of H2H

	Patient n=19 (%)	Carer n= 7 (%)
Length of CC		
Too short	3 (15.8)	1 (14.3)
About right	14 (73.7)	6 (85.7)
Too long	0 (0)	0 (0)
No response	2 (10.5)	0 (0)
Met new community professionals		
Yes	4 (21)	1 (14.3)
No	11 (58)	6 (85.7)
No response	4 (21)	
All important care issues were addressed		
No, a lot missing	1 (5.3)	0 (0)
No, some missing	0 (0)	0 (0)
Yes, mostly	0 (0)	2 (28.6)
Yes, completely	16 (84.2)	5 (71.4)
No response	2 (10.5)	0 (0)
Received a copy of the care plan		
Yes	11 (57.9)	2 (28.6)
No	6 (31.6)	5 (71.4)
No response	2 (10.5)	0 (0)
Understood the care plan (n=11)		
Yes	7 (63.6)	2 (100)
No	1 (9.1)	0 (0)
No response	3 (27.3)	0 (0)
Recommend a CC to others		
Yes	16 (84.2)	7 (100)
No	1 (5.3)	0 (0)
No response	2 (10.5)	0 (0)

Study ID	Patient participant free comments
2	Definitely, 'go and get in queue tomorrow', never thought resources of NHS went this far, cannot fault the care
31	Very Satisfied with it. Everybody around. Everybody knows exactly the same information which is good
36	Very helpful. Surprised not had call from DM Nurse since the meeting, although he is monitoring his BM, thought there would be follow-up
56	Very good for his wife because that was the first time she had met anyone
58	Not sure if beneficial in the future for me but in favour of it, should have been done years ago to get people home
59	It was probably better than expected. Expecting it to be a bit vague but all those things, symptoms were dealt with well.
67	Good to get to know everyone involved. Good for everyone to know each other and their roles.
72	It was brilliant
	Carer participant comments
31	Good all to be together
67	Reduces stress for the patient knowing that everyone is informed

5.7.4 Section Summary

This section has explored the fidelity and acceptability of H2H. The section informs both the *modelling phase* and the *feasibility and piloting phase* of the MRC framework.

H2H was delivered as expected during this feasibility study, with the exception of a lower GP attendance at the CC meetings than the 100% attendance standard. This requires further consideration as the GP is the lead clinician for the patient once care is transferred to the community and therefore H2H without their involvement is of questionable value. This finding suggests a need to explore the views of all community professionals involved in H2H.

H2H navigates the transition from specialist oncology care in the acute sector to best supportive care at the EoL in the community. Therefore, the understanding of perceptions surrounding this transition is essential in grasping the mechanisms by which H2H may be having an impact, and to inform further **modelling** and adaptation of the H2H for clinical use. The key themes regarding discharge to community care discussed by participants were loss, transition barriers, transition management and community concerns.

Loss-The patient participants spoke in depth about the losses they felt at the last consultation. Losses were multiple, including loss of treatment, loss of hope, loss of control, loss of familiarity and trust. The loss of familiarity and trust was particularly important to patients, and a concern to oncologists. Oncologists felt this was a loss that should be tempered where possible by gradual transition and review by the oncologist in the future where necessary.

Transition Barriers- This work identified a number of barriers that the H2H needed to overcome to ensure a smooth, streamline transition. The barriers elicited in these interviews were understanding and acceptance, attachment, and follow up concerns. The ability of patients and their families to accept the end of treatment was recognised by all participants as influencing the patient's willingness to agree to discharge into community services. Oncologists and H2H SS recognised that the oncologist's ability to accept that the patient was at the end of active treatment was an influencing factor in the use of the H2H. Attachment, referring to an affection or fondness for someone or something, was also a clear barrier to transition. Patients

and oncologists agreed that both could become attached to one another, with the patient also attached to the familiar environment of the specialist centre.

Transition Management - Participants described strategies to limit the potential distress caused by discharge to community-led care. Preparation, a phased gradual transition managed delicately, and an open door approach offering the patient future contact with the oncologist were all discussed as ways to improve transition to community services. A small number of HCPSs felt the current H2H rushed and truncated this process and this could possibly cause distress to patients and their carers. No patients reported this as a concern.

Community concerns- The results show both participant groups - patients and HCPs - had concerns about the standard of community care. These concerns fell into two categories: lack of service provision in the community, and lack of knowledge. This was linked to a lack of trust in community services.

Views on H2H- The views of patient participants regarding H2H were overwhelmingly positive. Patients and oncologists described the role of H2H as a reassurance and proof to the patient that the transition was being managed. The physicality of H2H reinforced to patients that the discharge to community care was considered and co-ordinated. The format of the CC allowed open shared knowledge between patient, carer and all professionals. Patients felt their views were actively listened to and expressed that the fact they had witnessed effective teamwork between professionals was of particular importance. One important aspect of the CC was that the patient was involved in sharing their story with the community teams.

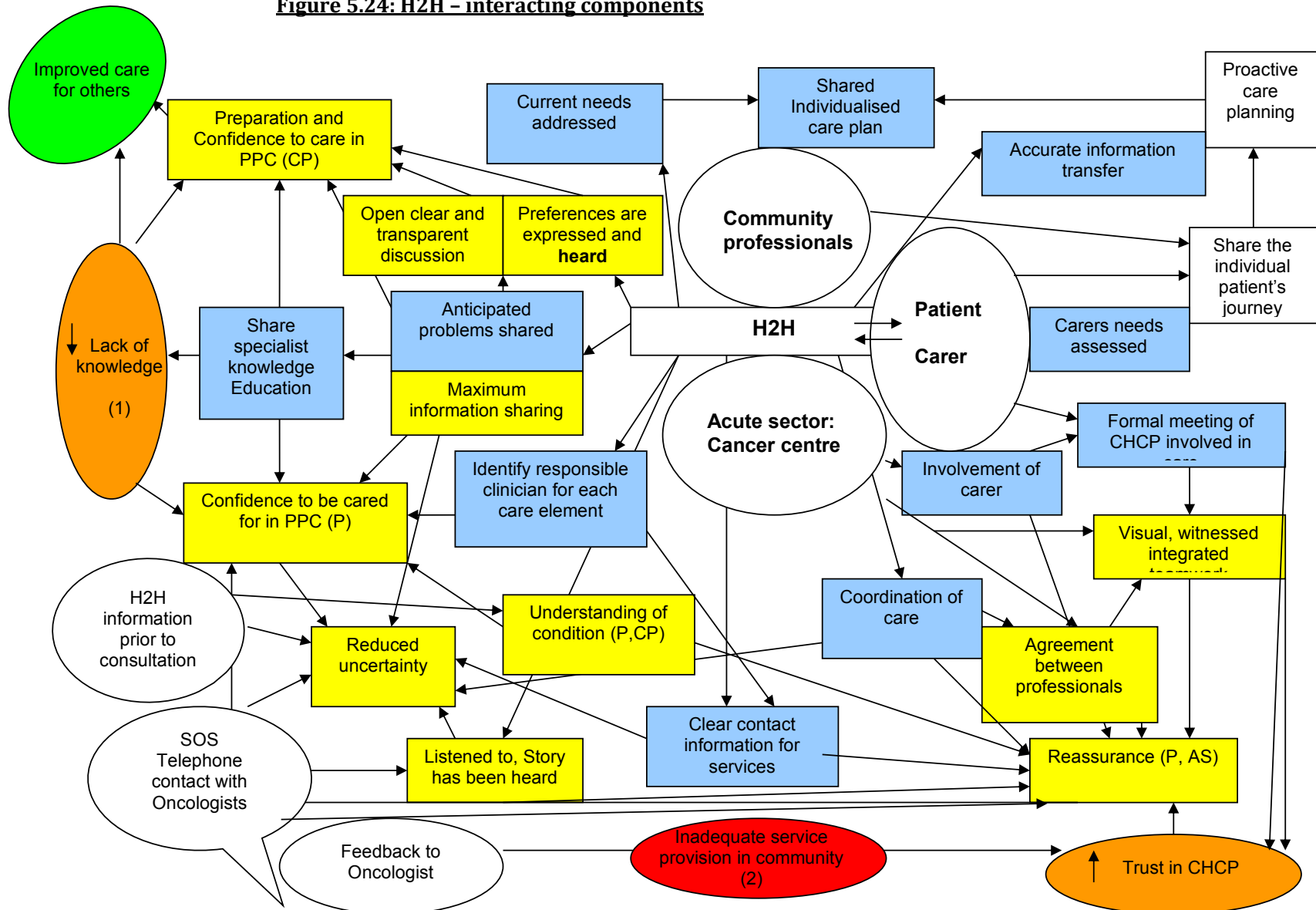
Barriers to the use of the service- The barriers to the service being implemented and run effectively were the oncologists' ability to break bad news along with reluctance to stop active treatment and follow-up at an appropriate time. HCPSs felt unease at the speed and the finality of referral to H2H. H2H SSs discussed how late referrals to H2H, leading to a fast transition to community services, were poor practice that regularly occurred. The concern was that this speedy transition might result in feelings of abandonment for the patient referred to the service. One patient participant described feelings of abandonment associated with the referral to H2H.

Overall, H2H was acceptable to both patients and HCPs.. The interviews provide insight into how H2H may increase death in PPD alongside sustaining symptom control and QoL over and above the outcomes of standard discharge and SPCT community follow up. Figure 5.24 is a conceptual model of H2H interacting components and the impact on patients and HCPs.

This section highlights the following considerations for a definitive trial that are reflected on further in the discussion chapter of this thesis;

- Prior to a larger definitive trial there is the need for qualitative work, through interviews and/or focus groups, with community HCPs and carers to explore their views
- Further modelling of H2H may be required to optimise community engagement and maximise the use of technology in the of delivery coordinated care
- The finding of the importance of a phased gradual transition to community led care should be carefully considered and incorporated into any H2H remodelling
- Visual integrated teamwork and maximum information sharing are strong active components of H2H and should remain key to any H2H remodelling

Figure 5.24: H2H – interacting components



5.8 Bereavement Analysis

5.8.1 Section Introduction

This section presents the quantitative results of bereaved family members satisfaction with care in the H2H study and the parallel population of participants who died in hospital. The results address objective 20 & 21 of the study.

Objective 20: *To describe and compare the bereaved family members satisfaction with care in the H2H study with those of family members of patients who died in the hospital*

Objective 21: *To determine if the degree of satisfaction with care is related to any patient clinical, demographic, or preferences factors*

The bereavement questionnaire used had 3 parts: a preference questionnaire, the FAMCARE satisfaction tool and a free comments section. In this section, the recruitment and results of the bereavement component of the longitudinal H2H study are presented. This is followed by the recruitment and demographic data for the inpatient participants. Data on preferences is presented alongside FAMCARE individual item scores and Total FAMCARE scores. These results from each group are then discussed in relation to one another. Finally, I detail the exploratory analysis of factors influencing satisfaction with care in the inpatient death study group. The qualitative analysis of the free text comments is presented in Appendix 7.4.7.

The data are presented in the following subsections:

- 5.8.2 Feasibility of bereavement component
- 5.8.3 The prospective H2H study participants: Preferences and Satisfaction in bereavement
- 5.8.4 Inpatient death study: Preferences and Satisfaction in bereavement
- 5.8.5 Comparison of H2H study participants and inpatient death satisfaction
- 5.8.6 Exploratory analysis of factors influencing satisfaction with care
- 5.8.7 Section summary

5.8.2 Feasibility of bereavement component

5.8.2.1 Recruitment to bereavement survey in the feasibility study (longitudinal study)

The feasibility study included an 'opt out' bereavement survey conducted over the phone with the bereaved carer at least 3 months after death. The informal carer consented to this contact at the beginning of the study and they were included if the patient participant died during the initial 12 week follow up of the study. The carers of participants who died after the 12-week follow up period ended were not approached to participate. The number of participants in this section was small and therefore no confident conclusions can be drawn from this analysis alone. Table 5.65 details recruitment for the bereavement component of the feasibility study. Overall 46 participants died during the first 12 week follow up period, and of these 28 had a carer recruited to the study. Of these 28 carers nineteen (68%) completed the telephone bereavement questionnaire (H2H group 9/12 (75%) and AC group 10/16 (63%)). A higher proportion of participants from the H2H study group agreed to participate compared to the AC group. Three participants across both study groups were not contactable. The questionnaire was completed over the telephone and thus there were no individual missing items.

Table 5.65 The feasibility study: Recruitment to bereavement FAMCARE survey

	Total Population	H2H group	AC group
Number of carers recruited	43	16	27
Number of patient participants who died in first 12 week follow up	46	23	23
Number of patient participants who died in first 12 week follow up with a recruited carer	28	12	16
Total number of eligible bereaved participants	28	12	16
Declined to participate	6 (21%)	2 (17%)	4 (25%)
Unable to contact	3 (11%)	1 (8%)	2 (12%)
Completed FAMCARE	19 (68%)	9 (75%)	10 (63%)

5.8.2.2 Recruitment to Inpatient bereavement survey: Recruitment, Participants, non-participant characteristics and missing data

A total of two hundred and forty six questionnaires were sent to bereaved relatives of patients who died in hospital between August 2010 and January 2012. Eighty-eight questionnaires were returned completed. This is a response rate of 35.8%.

To inform the validity of the findings of the completed questionnaires demographic and clinical characteristics of participants and non-participants are compared in Table 5.66

Participants and non-participants had similar demographic characteristics. This indicates that the results from the survey analysis are likely to be applicable in the wider context of the tertiary referral cancer centre. The carer gender split was similar between participants and non-participants (Male 38.6%, 40.8% respectively $p=0.85$). In both groups the majority of carer respondents were a spouse or partner (70.5% participants, 68.2% non- participants $p=0.87$).

With regards to patient factors, there was no significant difference between participants and non-participants across the majority of patient demographic and illness factors. The two groups had a similar mean age of 62.3 years and 60.3 years for the participants and non-participants respectively. In both groups half of the patients were male (51.1% participants, 50.6% non-participants). There was no statistical difference between participants and non-

participants in marital status and whether they lived alone. The comparison of patient illness factors showed no statistical difference across diagnosis, disease extent, time from diagnosis to death, time from last treatment to death and treatment type. The proportion known to either hospital or community SPC was similar between the two groups and median time from hospital admission to death was also comparable (9 days in participants and 11 days in non-participants). This indicates that the study population were largely comparable to the whole population. However, two noteworthy differences between the groups were that significantly more carer participants were White British (81.8%) compared to non-participants (65.8%, $p=0.01$) and more carers of patients on an adjuvant or curative treatment declined participation in the study (8.6% participants, 21.2% non-participants, $p=0.03$).

Table 5.66 Inpatient deaths bereavement questionnaire: Comparison of demographic and illness factors for the total population, participants (A) and non-participants (B) (continued onto next page)

PERSONAL AND SOCIAL FACTORS		Total Population n=246	(A) Participants n= 88	(B) Non-participants n= 158	Statistic comparing A &B)
RESPONDENT GENDER	Number (%)				
	Male	98 (40)	34 (38.6)	64 (40.8)	$\chi^2= 0.04$
	Female	148 (60)	54 (61.4)	94 (59.2)	$p=0.85$
RESPONDENT RELATIONSHIP TO	Number (%)				
	Spouse/Partner	169 (69)	62 (70.5)	107 (68.2)	$\chi^2= 0.27$
	Adult Child	30 (12.2)	11 (12.5)	19 (12.1)	$p=0.87$
	Other	46 (18.8)	15 (17.0)	31 (19.7)	
PATIENT DEMOGRAPHICS					
AGE IN YEARS	Mean (SD)	61 (14.1)	62.3 (12.8)	60.3 (14.8)	$Z=-0.75$
	Median	64	65	63	$p=0.45$
GENDER	Number (%)				
	Male	125 (50.8)	45 (51.1)	80 (50.6)	$\chi^2= 0.00^*$
	Female	121 (49.2)	43 (48.9)	78 (49.4)	$p=1.00$
ETHNICITY	Number (%)				
	White British	176 (74.9)	72 (81.8)	104 (65.8)	$\chi^2= 6.03^*$
	Other	59 (25.1)	16 (18.2)	46 (34.2)	$p=0.01$
MARITAL STATUS	Number (%)				
	Married/ Partner	174 (70.7)	62 (70.5)	112 (70.9)	$\chi^2= 0.76$
	Widowed/Single/Divorced	64 (26.0)	22 (25.0)	42 (26.6)	$p=0.68$
	Not disclosed	8 (3.3)	4 (4.5)	4 (2.5)	
LIVING ALONE	Number (%)				
	Yes	54 (22.0)	19 (21.6)	35 (22.2)	$\chi^2= 0.00^*$
	No	192 (78.0)	69 (78.4)	123 (77.8)	$p=1.00$

ILLNESS FACTORS	Total Population n=246	(A) Participants n= 88	(B) Non- participants n= 158	Statistic comparing A) & B)
CANCER DIAGNOSIS				
<i>Number (%)</i>				
Lung	22 (8.9)	9 (10.2)	13 (8.2)	$\chi^2= 8.12$ $p=0.42$
Gastrointestinal	74 (30.1)	19 (21.6)	55 (34.8)	
Urological	23 (9.3)	10 (11.4)	13 (8.2)	
Breast	31 (12.6)	14 (15.9)	17 (10.8)	
Haematological	40 (16.3)	13 (14.8)	27 (17.1)	
Sarcoma	11 (4.5)	5 (5.7)	6 (3.8)	
Head and Neck	9 (3.7)	5 (5.7)	4 (2.5)	
Gynaecological	19 (7.7)	8 (9.1)	11 (7.0)	
Other	17 (6.9)	5 (5.7)	12 (7.6)	
EXTENT OF DISEASE				
<i>Number (%)</i>				
Local disease	58 (23.6)	15 (17.0)	43 (27.2)	$\chi^2= 2.70$ $p=0.10$
Metastatic disease	188 (76.4)	73 (83.0)	115 (72.8)	
TIME FROM DIAGNOSIS TO DEATH (Days)				
<i>Mean (SD)</i>				
<i>Median</i>	1074 (1392)	1132 (1389)	1042 (1398)	$z=-0.56$ $p=0.58$
	554	577.5	493.5	
LAST TREATMENT TYPE				
<i>Number (%)</i>				
Chemotherapy	148 (60.2)	59 (67.0)	89 (56.3)	$\chi^2= 6.75$ $p=0.08$
Radiotherapy	47 (19.1)	17 (19.3)	30 (19.0)	
Other	32 (13.0)	5 (5.7)	27 (17.1)	
No Treatment	19 (7.7)	7 (8.0)	12 (7.6)	
TREATMENT INTENT (n=227)				
<i>Number (%)</i>				
Adjuvant/ Curative	38 (16.7)	7 (8.6)	31 (21.2)	$\chi^2= 5.06^*$ $p=0.03$
Palliative	189 (83.3)	74 (91.4)	115 (78.8)	
TIME FROM LAST TREATMENT TO DEATH (Days)				
<i>Mean (SD)</i>	75.8 (187.6)	59.2 (109)	85 (219)	$z=-1.51$ $p=0.13$
<i>Median</i>	27	24	28	
NUMBER OF ADMISSIONS IN LAST 6 MONTHS				
<i>Mean (SD)</i>				
<i>Median</i>	2.2 (1.4)	2.2 (1.7)	2.2 (1.2)	$z=-0.75$ $p=0.46$
	2	2	2	
KNOWN TO HOSPITAL PALLIATIVE CARE TEAM				
<i>Number (%)</i>				
Yes				$\chi^2= 0.45^*$ $p=0.49$
No	200 (81.3)	69 (78.4)	131 (82.9)	
	46 (18.7)	19 (21.6)	27 (17.1)	
TIME KNOWN TO HOSPITAL PALLIATIVE CARE PRIOR TO DEATH (Days)				
<i>Mean (SD)</i>				
<i>Median</i>	93.4 (259)	67.5 (149.6)	106.9 (300)	$z=-1.08$ $p=0.28$
	13	10	15	
KNOWN TO CPCT				
<i>Number (%)</i>				
Yes				$\chi^2= 0.00^*$ $p=1.00$
No	114 (46.3)	41 (46.6)	73 (46.2)	
	132 (53.7)	47 (53.4)	85 (53.8)	
NUMBER OF DAYS FROM ADMISSION TO DEATH (Days)				
<i>Mean (SD)</i>	14.2 (14.7)	11.83 (10.8)	15.5 (16.4)	$z=-1.57$ $p=0.12$
<i>Median</i>	10	9	11	

The number of missing individual items on the returned bereavement questionnaire was low. Ninety one percent of questionnaires had no missing items. 6 % of questionnaire had one missing item and these were missing at random. Two questionnaires had greater than 10 items missing.

Table: 5.67: Bereavement Study: Number of missing items on FAMCARE

Number of missing items per questionnaire	Frequency (%)
0	80 (91.0)
1	5 (5.7)
2-5	1 (1.1)
6-10	0 (0.0)
> than 10	2 (2.2)

5.8.3 The prospective H2H study participants results: Preferences and satisfaction in bereavement

5.8.3.1 H2H: PPD

Table 5.68 gives the results of the preference section of the survey.

47.4% of patients died at home and 42% in a hospice. The proportion of home deaths was greater in the H2H group (55.6%) compared to the AC group (40%). All bereaved relatives had discussed PPD with the patient participant. The majority (63%) of patient participants chose home as their PPD. This proportion was lower in the H2H group compared to the AC group (55% H2H, 70% AC group). Overall, a higher proportion of carers would have preferred a home death (total population 68.4%), and in the H2H study group more carers preferred a home death than the patient participants themselves (H2H carer 66.7%, H2H patient 55%). However in the AC group the proportion of patient and carer participants preferring a home death was equal (70%). There was a high level of congruence between patient and carer PPD (89.5%). More specifically, where patient PPD was home (n=12) this was the preferred location for 11 of the matched carers (91.7%) and for hospice (n=5) this was the preferred location for 4 of the matched carers (80%).

Table 5.68 Prospective longitudinal comparator study bereavement PPD responses

Number (%)	Total population (n=19)	H2H (n=9)	AC group (n=10)
POD			
Home	9 (47.4)	5 (55.6)	4 (40)
Hospice	8 (42.1)	3 (33.3)	5 (50)
Hospital	1 (5.3)	0 (0)	1 (10)
NH	1 (5.3)	1 (11.1)	0 (0)
DID THE PATIENT DISCUSS PPD?			10 (10)
Yes	19 (100)	9 (100)	0 (0)
No	0 (0)	0 (0)	
PATIENT PPD			
Home	12 (63.2)	5 (55.6)	7 (70)
Hospital	0 (0)	0 (0)	0 (0)
Hospice	5 (26.3)	2 (22.2)	3 (30)
Nursing Home	1 (5.3)	1 (11.1)	0 (0)
Other location	1 (5.3)	1 (11.1)	0 (0)
DID CARER HAVE A PPD			
Yes	18 (94.7)	8 (88.9)	10 (100)
No	1 (5.3)	1 (11.1)	0 (0)
CARER PPD			
Home	13 (68.4)	6 (66.7)	7 (70)
Hospital	0 (0)	0 (0)	0 (0)
Hospice	5 (26.3)	2 (22.2)	3 (30)
Other location	0 (0)	0 (0)	0 (0)
No preference	1 (5.3)	0 (0)	0 (0)
Not answered	0 (0)	1 (11.1)	0 (0)
DID THE PATIENT AND CARER PPD AGREE			
Yes	17(89.5)	7 (77.8)	10 (100)
No	2 (10.5)	2 (22.2)	0 (0)
PATIENT PPD ACHIEVED			
Yes	13 (68.4)	6 (66.7)	7 (70.0)
No	6 (31.6)	3 (33.3)	3 (30.0)

5.8.3.2 H2H: FAMCARE individual items and total scores

The individual FAMCARE items (Table 5.69) were scored highly by bereaved relatives across each study group. With the exception of 2 items median scores were 4 or 5. Five indicates bereaved relatives were highly satisfied with care. The two lowest scoring items were 'the availability of a bed' total population median score 3, H2H 4, AC 3. 'Time to diagnosis' total population median score 2, H2H 2, AC 2.

The highest scoring individual items were 'availability of a nurse to answer questions' total population median score 5 (H2H 5, AC 5) and 'pain relief' total population median score 5 (H2H 5, AC 4.5). The average total FAMCARE scores (Table 5.69) were equal across the study groups (H2H mean 76.9, median 78, AC mean 76.9, median 79). The H2H group scores had dropped when compared to Week 1 scores (H2H Week 1 mean 84, median 87.5) whereas the AC group scores have remained the same (AC week 1 mean 78.5, median 78). However, the conclusions to be drawn from this change over time are limited due to the small number of participants that completed the bereavement survey, and therefore the participant cohort in bereavement was different to Week 1.

Table 5.69 Comparison of individual bereavement FAMCARE item mean scores and % satisfied and dissatisfied in H2H and AC study groups

FAMCARE Individual Items	H2H Study Group (n=9)						AC Study Group (n=10)					
Item <i>How satisfied are you with.....*</i>	Mean	SD	% Dissatisfied		% Satisfied		Mean	SD	% Dissatisfied		% Satisfied	
			1+2	1	4+5	5			1+2	1	4+5	5
The patients pain relief	4.33	1.1	11.1	0	77.8	66.7	4.30	0.9	10.0	0	90.0	50.0
Information provided about the patients prognosis	4.13	1.1	12.5	0	75.0	50.0	3.90	1.1	10.0	0	60.0	40.0
Answers from HCPS	3.78	0.9	11.1	0	66.7	22.2	4.00	1.7	22.2	22.2	77.8	66.7
Information given about side effects	3.44	0.7	11.1	0	55.6	0	4.20	0.79	0	0	80.0	40.0
Referrals to specialists	3.75	1.0	12.5	0	62.5	25.0	3.20	1.7	30.0	30.0	50.0	30.0
Availability of hospital bed	4.0	0.9	0	0	66.7	33.3	3.20	1.0	10.0	10.0	30.0	10.0
Family conference held to discuss the patients illness	4.33	0.9	0	0	77.8	55.6	3.40	1.5	20.0	20.0	50.0	30.0
Speed at which symptoms are treated	3.67	1.2	22.2	0	55.6	33.3	4.20	0.9	10.0	0	90.0	40.0
Doctors attention to the description of symptoms	4.00	0.9	0	0	66.7	33.3	4.10	1.1	10.0	0	70.0	50.0
The way tests and treatments were performed	4.11	1.1	11.1	0	77.8	44.4	4.10	1.0	10.0	0	80.0	40.0
Availability of doctors to the family	4.33	0.7	0	0	77.8	44.4	3.40	1.1	10.0	0	70.0	20.0
Availability of nurses to the family	4.22	1.3	11.1	11.1	88.9	55.6	4.70	0.7	0	0	90.0	80.0
Coordination of care	3.56	1.5	33.3	11.1	66.7	33.3	4.00	0.9	10.0	0	80.0	30.0
Time required to make a diagnosis	2.44	1.1	55.6	22.2	22.2	0	2.44	1.6	55.6	44.4	33.3	11.1
The way the family is included in treatment and care decisions	4.22	0.8	0	0	77.8	44.4	4.00	1.3	10.0	10.0	70.0	50.0
Information about how to manage the patients pain	3.89	1.1	11.1	0	77.8	33.3	4.30	1.1	10.0	0	80.0	60.0
Information about the patients tests	4.00	1.0	11.1	0	77.8	33.3	4.10	1.3	10.0	10.0	80.0	50.0
How thoroughly the doctor assesses the patients symptoms	3.56	1.3	22.2	11.1	66.7	22.2	3.60	1.6	20.0	20.0	60.0	40.0
The way tests and treatments are followed up by the doctor	3.78	1.0	11.1	0	66.7	22.2	4.30	1.1	10.0	10.0	80.0	60.0
Availability of the doctor to the patient	4.22	0.8	0	0	77.8	44.4	4.10	1.1	10.0	0	70.0	50.0

Table 5.70 Bereavement Total FAMCARE scores: Total population, H2H and AC study groups

	FAMCARE Scores						Statistical Analysis comparing A&B
	Number	Mean	SD	Median	Range	Missing	Mann Whitney U
Total population	19	76.9	12.27	78	47-94	0	
Study groups							
H2H study group (A)	9	76.9	11.20	78	56-94	0	
AC study group (B)	10	76.9	13.77	79	47-91	0	
Preferences							
PPD achieved (A)	13	80.0	12.77	82	47-94	0	Z=-1.62 p=0.1
PPD Not achieved (B)	6	72.7	8.93	74	62-83	0	

An exploratory analysis comparing Total Carer FAMCARE scores for those patients who achieved their PPD and those who did not achieve PPD is shown in Table 5.70. The results show that the median bereavement FAMCARE score for carers of patients who achieved their PPD was 8 points higher on a 0-100 scale than those carers whose NOK did not achieve their PPD. A difference of this order may be clinically significant but requires further evaluation in a larger trial.

5.8.4 Bereaved family members satisfaction with care: Parallel inpatient deaths results

5.8.4.1 Inpatient: Preferences for PoD

The results of the preference section for inpatient deaths are given in Table 5.71. These are shown alongside the results already presented for all bereaved relatives in the longitudinal H2H study. The proportion of next of kin (NOK) who had discussed PPD with the patient was 56.8%. This was considerably lower than the bereaved relatives in the longitudinal study in which 100% had discussed PPD with the patient. For those who had discussed PPD, home was the preferred place in 56.8% of patients who died as an inpatient. This was also lower than the longitudinal study. A substantial proportion of patient who died in hospital (24.3%) had expressed hospital as their PPD, although the percentage of next of kin who chose hospital was even higher (42.9%). None of patients or carers in the H2H longitudinal expressed hospital as the PPD. The high proportion of NOK who expressed hospital as their PPD for inpatient deaths is likely to be clinically relevant, and may represent a barrier to discharge at the EoL. Also noteworthy is the discrepancy in congruence between patient and carer PPD in those who died in hospital. Congruence between patient and carer PPD was 65.8% in those who died in hospital. This compares to 94.4% congruence in the H2H longitudinal study where the majority of participants (18/19) died outside of hospital. This suggests there may be a link between patient and carer PPD congruence and the likelihood of achieving an out of hospital death.

Table 5.71: Inpatient death bereavement survey: Preferences for PoD

<i>Number (%)</i>		Inpatient Participants n=88	H2H Study Participants n=19
PoD	Home Hospice Hospital Nursing Home	0 (0) 0 (0) 88 (100) 0 (0)	9 (47.4) 8 (42.1) 1 (5.3) 1 (5.3)
DID THE PATIENT DISCUSS PPD?	Yes No Not answered	37 (42.1) 50 (56.8) 1 (1.1)	19 (100) 0 (0)
IF KNOWN, PATIENT PPD	Home Hospital Hospice Nursing home Other location	(n=37) 21 (56.8) 9 (24.3) 6 (16.2) 0 (0) 1 (2.7)	(n=19) 12 (63.2) 0 (0) 5 (26.3) 1 (5.3) 1 (5.3)
DID RESPONDENT HAVE A PPD FOR THE PATIENT	Yes No Not answered	56 (63.6) 31 (35.3) 1 (1.1)	18 (94.7) 1 (5.3) 0 (0)
IF KNOWN, RESPONDENT PPD (n=56)	Home Hospital Hospice Other location	(n=56) 22 (39.3) 24 (42.9) 10 (17.8) 0 (0)	(n=18) 13 (72.2) 0 (0) 5 (27.8) 0 (0)
DID THE PATIENT AND CARER PPD AGREE?	Yes No	(n=37) 25 (65.8) 13 (14.8)	(n=18) 17 (94.4) 1 (5.6)

5.8.4.2 Inpatient: FAMCARE Individual item and Total score

The average scores for FAMCARE individual items are shown in Table 5.72. This table also details the percentage of participants who were satisfied and dissatisfied with each area of care. The average total FAMCARE score was mean 81.68 (15.6) median 85 (range 25-100). The comparison of this with bereaved NOK scores in the longitudinal study is given in Table 5.73. This shows the NOK of patients who died in hospital scored satisfaction higher than those in the H2H longitudinal study where 18/19 (94%) died outside of hospital.

The highest scoring item was 'availability of nurses to the family' (mean 4.44 (0.8) 89.7% were satisfied with this element of care and 2.3% dissatisfied. The three lowest scoring individual items (highlighted in red) were 'time required to make a diagnosis' (mean 3.7 (1.3) 23.3% of participants were dissatisfied with this aspect of care, 'information provided about the patients prognosis' (mean 3.86 (1.2) 18.4% dissatisfied and 'information given about side effects' (mean 3.82 (1.2) 16.1% dissatisfied.

Table 5.72 Inpatient deaths bereavement survey: FAMCARE individual item scores compared to H2H study group

Item <i>How satisfied are you with.....*</i>	Inpatient respondents (n=88)						H2H study group respondent (n=9)					
	Mean	SD	% Dissatisfied		% Satisfied		Mean	SD	% Dissatisfied		% Satisfied	
			1+2	1	4+5	5			1+2	1	4+5	5
The patients pain relief	4.17	1.1	9.3	4.7	80.2	51.2	4.33	1.1	11.1	0	77.8	66.7
Information provided about the patients prognosis	3.86	1.2	18.4	3.4	67.8	40.2	4.13	1.1	12.5	0	75.0	50.0
Answers from HCPS	4.19	0.9	7.0	1.2	82.6	44.2	3.78	0.9	11.1	0	66.7	22.2
Information given about side effects	3.82	1.2	16.1	4.6	69.0	33.3	3.44	0.7	11.1	0	55.6	0
Referrals to specialists	4.18	1.0	8	2.3	81.6	47.1	3.75	1.0	12.5	0	62.5	25.0
Availability of hospital bed	4.38	0.9	7	1.2	89.5	57.0	4.0	0.9	0	0	66.7	33.3
Family conference held to discuss the patients illness	3.91	1.1	15.3	1.2	70.6	36.5	4.33	0.9	0	0	77.8	55.6
Speed at which symptoms are treated	3.85	1.3	18.6	9.3	70.9	41.9	3.67	1.2	22.2	0	55.6	33.3
Doctors attention to the description of symptoms	4.14	1.1	10.3	3.4	75.9	51.7	4.00	0.9	0	0	66.7	33.3
The way tests and treatments were performed	4.28	0.9	5.9	1.2	87.1	48.2	4.11	1.1	11.1	0	77.8	44.4
Availability of doctors to the family	4.09	1.0	9.3	3.5	82.6	39.5	4.33	0.7	0	0	77.8	44.4
Availability of nurses to the family	4.44	0.8	2.3	1.1	89.7	57.5	4.22	1.3	11.1	11.1	88.9	55.6
Coordination of care	4.19	1.1	9.3	4.7	84.9	47.7	3.56	1.5	33.3	11.1	66.7	33.3
Time required to make a diagnosis	3.71	1.3	23.3	9.3	68.6	34.9	2.44	1.1	55.6	22.2	22.2	0
The way the family is included in treatment and care decisions	4.21	1.0	9.3	1.2	84.9	46.5	4.22	0.8	0	0	77.8	44.4
Information about how to manage the patients pain	3.95	1.1	9.3	3.5	70.9	37.2	3.89	1.1	11.1	0	77.8	33.3
Information about the patients tests	4.07	0.9	8.1	2.3	83.7	33.7	4.00	1.0	11.1	0	77.8	33.3
How thoroughly the doctor assesses the patients symptoms	4.16	0.9	8.1	2.3	86.0	40.7	3.56	1.3	22.2	11.1	66.7	22.2
The way tests and treatments are followed up by the doctor	4.16	0.9	7.0	2.3	87.2	38.4	3.78	1.0	11.1	0	66.7	22.2
Availability of the doctor to the patient	4.26	0.9	7.0	7.0	87.2	45.3	4.22	0.8	0	0	77.8	44.4

* Scale 1-5, 1= very dissatisfied, 5 very satisfied

Table 5.73 Total FAMCARE scores: Inpatient death scores and prospective longitudinal study scores for total population, H2H and AC groups

Study Group	FAMCARE Scores					
	Number	Mean	SD	Median	Range	Missing
Total population (Longitudinal study)	19	76.9	12.27	78	47-94	0
H2H study group (A)	9	76.9	11.20	78	56-94	0
AC study group (B)	10	76.9	13.77	79	47-91	0
Inpatient group	88	81.7	15.62	85	25-100	1

5.8.4.3 Secondary outcome Part 2- Qualitative Comments

The results of the qualitative analysis of free text comments are detailed in Appendix 7.4.7.

5.8.5 Exploratory analysis of factors influencing satisfaction with care (for inpatient deaths)

This section presents the results of the exploratory analysis of factors influencing satisfaction with care of patients dying in hospital. Univariate analysis of the effect of patient demographic, illness and preference factors on total FAMCARE scores is presented followed by multivariate analysis using PCA followed by MRA.

The results of the univariate analysis are detailed in Table 5.74. Factors with a significance value of <0.2 on univariate analysis were retained and analysed in the multiple regression analysis. There were 6 factors relating to FAMCARE scores that had a significance value of <0.2 on univariate analysis:

- Living alone
 - The mean FAMCARE score was higher in patients not living alone (Living alone 73.1, not alone 84.1)
- Marital Status
 - The NOK of patients who were widowed/single or divorced were less satisfied with care than those who were married or had a partner (Widowed/single/divorced 75.2, Married/partner 83.7)
- Treatment Intent
 - The NOK of patient in whom anticancer treatment was adjuvant or curative were less satisfied (mean 74.5) than those in whom treatment was with palliative intent (mean 82.7)
- Number of admission days on last admission
 - The NOK of patients who had been an inpatient for over 2 weeks prior to their death were less satisfied (76.4) than those where the patient had a shorter admission prior to death (83.9)
- Patient PPD Achieved

- If the patient who died in hospital did not achieve their PPD the NOK was less satisfied (76.7) than if hospital was their PPD (89.9) or their preference was unknown (83.1)
- Carer PPD Achieved
 - Similarly to patient PPD, if the patient did not die where the NOK would have wanted they were less satisfied (77.4) than if hospital was the NOK's PPD (85.3) or they had no preference (83.6).

Table 5.74 Univariate analysis of demographic, illness and preference factors on Total FAMCARE scores (continued onto next page)

CARER PERSONAL AND SOCIAL FACTORS	Mean Score	SD	F Statistic	df1, df2	p
RESPONDENT GENDER					
Male	83.8	15.4	1.11	1, 67.5	0.29
Female	80.4	15.8			
RESPONDENT RELATIONSHIP TO PATIENT					
Spouse/Partner	82.9	16.02	1.04	2, 22	0.36
Adult Child	78.8	14.84			
Other	78.7	14.80			
PATIENT DEMOGRAPHICS					
AGE IN YEARS					
Less than 40	90.6	5.51	0.68	3, 9.96	0.57
40-59	79.2	15.52			
60-79	82.2	16.07			
80 and Older	79.0	18.89			
GENDER					
Male	81.2	17.34	0.01	1, 84.9	0.91
Female	82.2	13.74			
ETHNICITY					
White British	81.1	14.67	0.33	1, 14.78	0.57
Other	81.9	21.03			
MARITAL STATUS					
Married/ Partner	83.7	15.0	2.47	2, 9.14	0.09
Widowed/Single/Divorced	75.2	16.8			
Not disclosed	85.8	9.5			
LIVING ALONE					
Yes	73.1	13.0	10.44	1, 32.74	0.002
No	84.1	15.5			

PREFERENCES	Mean Score	SD	F Statistic	df1, df2	p
PATIENT PPD					
Home	76.4	19.18	1.33	3, 19.26	0.27
Hospital	89.9	6.55			
Hospice	77.3	22.45			
Not Known	83.1	13.30			
CARER PPD					
Home	77.1	18.70	1.26	3, 37.4	0.24
Hospital	85.3	14.60			
Hospice	77.9	12.56			
Not Known	83.6	14.54			
PATIENT PPD ACHIEVED					
Yes	89.9	6.55	2.01	2, 27.67	0.14
No	76.7	19.55			
No Preference stated	83.1	13.30			
CARER PPD ACHIEVED					
Yes	85.3	14.60	1.87	2, 54.8	0.16
No	77.4	16.70			
No Preference stated	83.6	14.54			

ILLNESS FACTORS	Mean Score	SD	F Statistic	df1, df2	p
CANCER DIAGNOSIS					
Lung	71.8	18.0	0.91	8, 24.32	0.51
Gastrointestinal	77.6	21.7			
Urological	85.3	14.3			
Breast	87.8	11.4			
Haematological	82.4	11.5			
Sarcoma	81.7	9.3			
Head and Neck	79.6	16.4			
Gynaecological	88.6	9.5			
Other	81.0	12.8			
EXTENT OF DISEASE					
Local disease	82.3	12.1	0.02	1, 23.69	0.90
Metastatic disease	81.5	16.3			
TIME FROM DIAGNOSIS TO DEATH					
Less than 3 months			1.24	4, 39.58	0.30
3-12 months	73.7	16.26			
1-2 years	82.2	13.29			
2-5 years	84.8	12.99			
Greater than 5 years	82.6	13.82			
	83.1	20.45			
LAST TREATMENT TYPE					
Chemotherapy	81.1	16.4	0.43	3, 12.37	0.74
Radiotherapy	84.0	14.6			
Other	85.6	14.5			
No Treatment	78.1	13.5			
TREATMENT INTENT (n=227)					
Adjuvant/ Curative	74.5	11.18	2.60	1, 9.07	0.11
Palliative	82.7	16.08			
TIME FROM LAST TREATMENT TO DEATH					
Less than 2 weeks	83.8	14.64	0.62	3, 35.18	0.61
2-4 weeks	82.8	19.24			
1-3 months	80.7	15.43			
Greater than 3 months	77.9	12.16			

ILLNESS FACTORS	Mean Score	SD	F Statistic	df1, df2	p
KNOWN TO HOSPITAL PALLIATIVE CARE TEAM					
Yes	81.6	15.47	0.16	1, 23.72	0.69
No	82.1	16.64			
TIME KNOWN TO HOSPITAL PALLIATIVE CARE PRIOR TO DEATH					
Less than 1 month	81.2	13.14	0.88	1, 29.50	0.35
Greater than 1 month	82.5	20.17			
KNOWN TO CPCT					
Yes			0.18	1, 84.04	0.67
No	81.0	15.88			
	82.4	15.48			
ADMISSIONS IN LAST 6 MONTHS					
2 or less	80.6	16.00	0.94	1, 54.26	0.34
3 or more	84.0	14.78			
NUMBER OF DAYS FROM ADMISSION TO DEATH					
Less than 14	83.9	13.98	3.86	1, 43.95	0.05
15 or Greater	76.4	18.14			

The 6 variables with a p value of <0.2 on univariate analysis were subjected to principal component analysis (PCA) using SPSS version 20. PCA was chosen in preference to multiple linear regression as the sample size ($n=88$) was smaller than the sample size recommended for multiple linear regression (minimum 90 participants for 6 variables). Prior to performing PCA, the suitability of data for factor analysis (PCA) was assessed. First, inspection of the correlation matrix revealed a number of coefficients of 0.3 and above. The Kaiser-Meyer-Olkin value was 0.51, this does not exceed the recommended value of 0.6 but it is acceptable. The Bartlett's Test of Sphericity reached statistical significance ($p=0.000$), supporting the factorability of the correlation matrix.

PCA revealed 3 components with Eigenvalues exceeding 1 explaining 30.29%, 22.21% and 18.75% of the variance respectively. In total these 3 components cumulatively explained 71.25% of the variance. An inspection of the screeplot revealed a clear break after the third component. This reinforced the decision to retain 3 components in the analysis based on the Eigenvalues exceeding 1. To aid in the interpretation of these three components oblimin rotation was performed. The rotated solution revealed the presence of a simple structure[225] with all three components showing strong loadings and all variables loading substantially on only one component.

Table 5.75 gives in detail the pattern and structure matrix for PCA with Oblimin Rotation of Three Factor Solution for these demographic and illness variables.

Table 5.75 Inpatient deaths bereavement survey: Pattern and Structure Matrix for PCA with Oblimin Rotation of Three Factor Solution for Demographic, Illness and preference factors

Item	Pattern Coefficients				Structure Coefficients			Communalities
	Component 1	Component 2	Component 3		Component 1	Component 2	Component 3	
Living Alone	0.91	-0.059	0.020		0.908	-0.052	-0.055	0.828
Marital Status	0.91	0.061	0.014		0.909	0.069	-0.068	0.830
PPD Achieved	-0.161	0.825	0.116		-0.163	0.816	0.077	0.708
Carer PPD Achieved	0.176	0.778	-0.130		0.195	0.788	-0.195	0.672
Treatment Intent	0.206	-0.009	0.775		0.139	-0.057	0.758	0.617
Admission Days*	0.192	-0.004	-0.748		0.256	0.045	-0.764	0.620

* Admission Days = Last admission total number of days from admission to death

Table 5.76 Inpatient deaths bereavement survey: Factors affecting FAMCARE scores (Reflect Square Root FAMCARE score). Standard Regression Coefficients (n=88).

Factor	Values	Standardised β Coefficient	Standard Error	t value	p
Social Factor	Continuous covariate	0.242	0.20	2.26	0.03
Preference Factor	Continuous covariate	0.004	0.196	0.038	0.98
Treatment Factor	Continuous covariate	-0.252	0.199	-2.35	0.02
R₂=0.134	Adjusted R₂=0.100				

These 3 components are distinct from each other and can be categorised clearly into 3 different discrete areas. In the multiple regression analysis these components were labelled to correspond with the variables they represent as follows:

- Component 1: **Social Factors** (Living alone and marital status)
- Component 2: **Preference Factors** (Patient and Carer PPD achieved)
- Component 3: **Treatment Factors** (Treatment intent, admission days)

The final step in the analysis was to determine if any of these three factors had a significant bearing on the mean satisfaction score reported by bereaved participants after adjustment for the other two factors. To determine this, these factors were subject to Standardised Multiple Regression Analysis. As with the univariate analysis this MRA used the transform FAMCARE dependent variable Reflect Square Root of FAMCARE score. This variable satisfies the assumptions of a normal distribution.

Preliminary analyses were conducted to ensure the data did not violate the assumptions of normality, linearity, multicollinearity and homoscedasticity. Inspection of the Normal Probability Plot (P-P) of the Regression Standardised Residual reveals that the individual participant points for Reflect Square Root FAMCARE score lie in a straight diagonal line. The Scatterplot shows the residual are distributed evenly around the 0 point in no clear pattern. These two plots confirm the dependent variable is normally distributed. The Scatterplot also confirms that these data have no outliers as no cases have a standardised residual of more than 3.3 or less than -3.3[236]. The collinearity statistics support the use of multiple regression showing minimal collinearity between factors. These statistics are as follows; Tolerance values for Social, Preference and Treatment factors are 0.991, 0.994, and 0.984 respectively, and VIF values are 1.009, 1.006 and 1.016 respectively.

Table 5.76 gives the multiple regression statistics for the three factors in determining satisfaction scores. This shows that both social factors (Living alone and marital status) and treatment factors (treatment intent and number of admission days) have a significant impact of NOK satisfaction with care ($p=0.03$ and $p=0.02$ respectively) for patients who die in hospital. Whether the patient or NOK preferences for PoD were met appeared to contribute to satisfaction, although after considering other factors this was not significant in this analysis.

5.8.6 Section summary

This section contributes to the *feasibility and piloting phase* of the MRC framework.

The recruitment data suggests carers are willing to participate in bereavement questionnaires as part of a longitudinal study and the postal questionnaire for inpatient bereaved relatives had a comparable response rate to other bereavement work.

The preliminary exploratory results show congruence was high between patient and carer PPD (94.4%) in the feasibility study. A lower proportion of carers in the inpatient cohort reported discussing PPD with the patient compared to the feasibility study. Where PPD was discussed congruence between patient and carer preferences was lower (65.8%) for patients who died in hospital compared to the feasibility study where the majority of participants died at home or in a hospice. Interestingly, a relatively high proportion (42.9%) of inpatient carers expressed hospital as their PPD for the patient. This suggests carer PPD may have an important impact on actual PoD.

The average total FAMCARE score was higher in the inpatient cohort (mean 81.65) than in either group in the bereavement component of the feasibility study (mean 76.9). Of importance is that the individual items concerned with information giving (information about prognosis, information about side effects) had lower satisfaction scores in the inpatient death cohort compared to H2H group. Exploratory analysis of factors influencing carer satisfaction for those who died in hospital showed social and treatment factors had an independent significant impact on bereaved carer satisfaction. Preference factors of patients and carer were not independently significant contributors to carer satisfaction. This finding correlates with the provisional finding in Section 5.6 1 that QoL were not linked to achieving PPD. This raises the question for any future larger definitive trial as to whether PPD should be used as a proxy measure for a good quality death, an area of research that requires further investigation

5.9 Factors influencing PoD

5.9.1. Section Introduction

This section presents the results of the retrospective analysis of the EPRs (EPR) to determine factors influencing PoD in this cancer population. This section addresses objective 22.

Objective 22: *To determine other factors influencing PoD in the wider cancer population treated at the RMFT.*

The demographics of the study population are presented followed by PoD data. I then detail the results of univariate analysis and finally the forward stepwise multivariate binary logistic regression. The analysis presented here compares firstly compares home death to deaths in other locations and then in a separate analysis compares hospital death to other locations to determine factors that influence the likelihood of dying at home or in hospital.

The results in this section are presented in the following subsections:

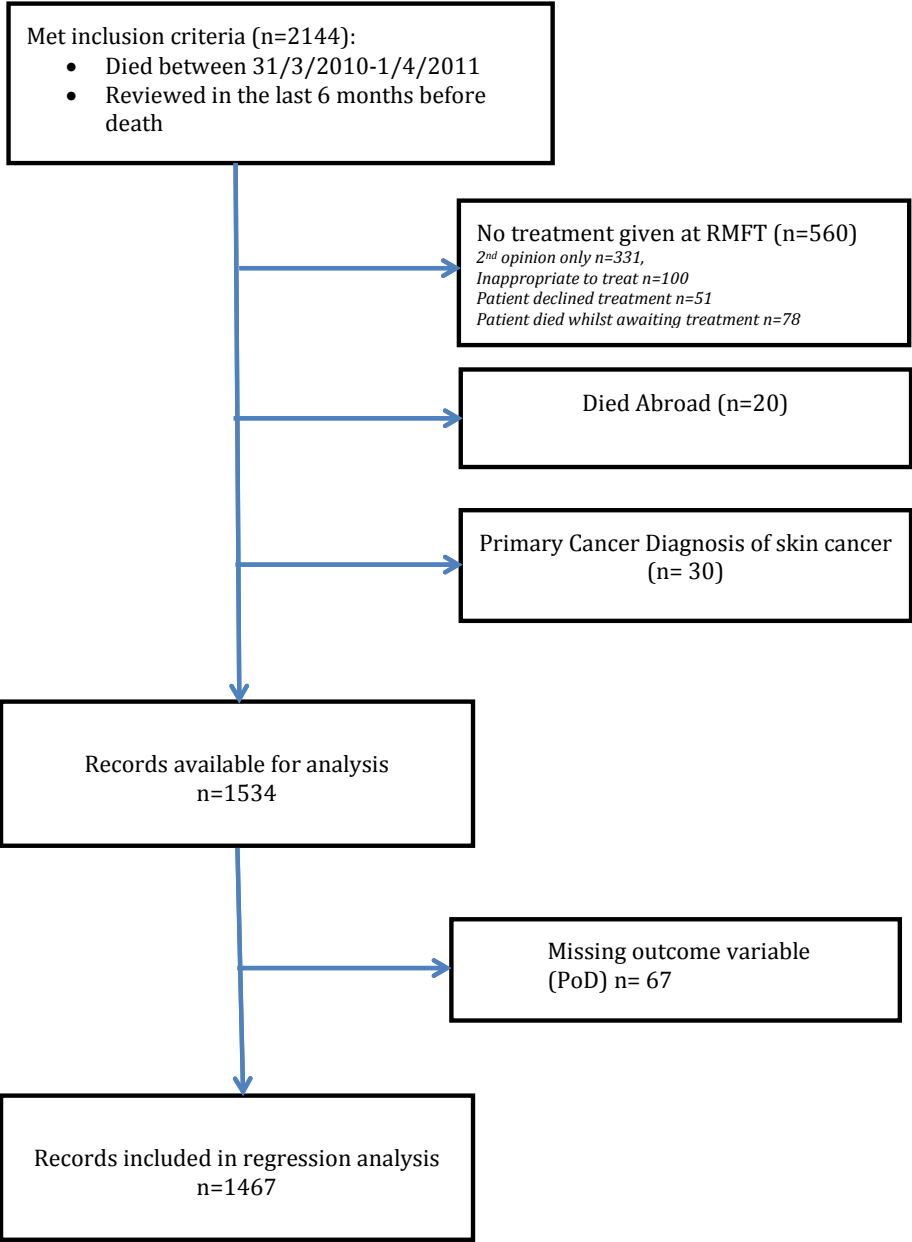
- 5.9.2 Study population and inclusion
- 5.9.3 Demographic and illness factors
- 5.9.4 PoD analysis
- 5.9.5 Univariate analysis of factors influencing PoD (Home V other location, Hospital V other location)
- 5.9.6 Multivariate analysis of factors influencing PoD
- 5.9.7 Summary Section

5.9.2 Study population

An initial search of the RMFT EPR identified 2,144 records of patients who had died between the study dates 1st April 2010-31st March 2011 and who met the inclusion criteria of being reviewed by the RMFT within the 6 months prior to death. Figure 5.25 gives detail of the records excluded from the analysis. Five hundred and sixty patients were excluded because

they did not receive any treatment from the RMFT and twenty were excluded because they died abroad. A further thirty were excluded as their primary cancer diagnosis was a superficial skin cancer requiring only localized treatment. The PoD was missing for 607 records on the EPR. Telephone contact with individual patient GP surgeries clarified PoD for 540 of these, and therefore in the final dataset PoD was missing in 67 (4.4%) records. A total of 1, 467 patient records were included in the final analysis.

Figure 5.25: Study inclusion and exclusion of records for factors influencing PoD analysis



5.9.3 Demographic and Illness factors

The Individual factors, factors related to illness and environmental factors of the patients in each location of death are detailed in Table 5.77. The table is split over three pages. The mean age of patients was 65 (SD 13.66). The youngest patient was 19 years old whilst the oldest was 104. The majority of patients were White British (83.5%), half were married (58.5%) and only a minority lived alone (20.7%). The two highest individual cancer diagnoses were GI cancer (22.1%) and Lung cancer (15.3%). The mean time in years from diagnosis to death was 3.5 (SD 4.4) suggesting there should have been sufficient time to involve palliative care in the management of patients and consider EoLC issues. However, the median time from last treatment to death was relatively short at 69 days, with the median time from last appointment to death only 32 days. There was evidence of CPCT involvement in over two thirds of patients (69.8%), and 9% had H2H.

Table 5.77 Factors influencing PoD: Personal, social demographics and illness factors for the total study population, death in hospital, hospice, at home and in a nursing home

PERSONAL AND SOCIAL FACTORS	Total population n= 1467	Hospital deaths n=518	Other location* n=949	Hospice n=494	Home n=399	Nursing home n= 53
AGE IN YEARS						
<i>Mean (SD)</i>	65 (13.66)	65(13.92)	65 (13.52)	64(13.56)	64(13.18)	75(10.90)
<i>Range</i>	19-104	20-95	19-97	24-97	19-96	50-96
<i>25th Percentile</i>	57	57		55	56	67
<i>Median</i>	66	67	65	64	65	77
<i>75th Percentile</i>	75	75		74	74	84
MALE						
<i>Number (%)</i>	720 (49.1)	266 (51.4)	454 (47.8)	221 (44.7)	210 (52.6)	21 (39.6)
ETHNICITY	n=1397	n=489	n=908	n=468	n=385	n=52
<i>Number (%)</i>						
White British	1167 (83.5)	396 (81.0)	771 (81.2)	396 (84.6)	326 (84.7)	46 (88.5)
White Other	108 (7.7)	36 (5.0)	72 (7.6)	44 (9.4)	24 (6.2)	4 (7.6)
Asian	63 (4.6)	26 (5.3)	37 (3.9)	17 (3.6)	17 (4.4)	2 (3.8)
Black	45 (3.2)	23 (4.7)	22 (2.3)	9 (2.0)	13 (3.4)	0 (0.0)
Chinese	4 (0.3)	3 (0.6)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Other	11 (0.7)	5 (1.0)	6 (0.6)	2 (0.4)	5 (1.3)	0 (0.0)
<i>(Missing)</i>	<i>(72)</i>	<i>(29)</i>	<i>(41)</i>	<i>(26)</i>	<i>(14)</i>	<i>(1)</i>
MARITAL STATUS						
<i>Number (%)</i>						
Married	858 (58.5)	295 (56.9)	563 (59.3)	287 (58.1)	251 (62.9)	24 (45.3)
Partner	13 (0.9)	7 (1.4)	6 (0.6)	3 (0.6)	2 (0.5)	1 (1.4)
Widowed	179 (12.2)	58 (11.2)	121 (12.8)	65 (13.2)	41 (10.3)	13 (24.5)
Single	188 (12.8)	71 (13.7)	117 (12.3)	64 (13.0)	46 (11.5)	7 (13.2)
Divorced	124 (8.5)	47 (9.1)	77 (8.1)	41 (8.3)	32 (8.0)	4 (7.5)
Not disclosed	105 (7.2)	40 (7.7)	65 (6.8)	34 (6.9)	27 (6.8)	4 (7.5)
LIVING ALONE						
<i>Number (%)</i>	304 (20.7)	117 (22.6)	187 (19.7)	120 (24.3)	57 (14.3)	8 (15.1)
DEPRIVATION QUINTILE						
<i>Number (%)</i>						
1 (most deprived)	153 (10.5)	62 (12.1)	91 (9.6)	52 (10.5)	32 (8.1)	7 (13.2)
2	243 (16.7)	103 (20.0)	140 (14.8)	65 (13.2)	67 (16.9)	7 (13.2)
3	278 (19.1)	89 (17.3)	189 (20.0)	93 (18.9)	89 (22.5)	7 (13.2)
4	333 (22.8)	116 (22.6)	217 (23.0)	126 (25.6)	7.8 (19.7)	12 (22.6)
5 (least deprived)	452 (31.0)	144 (28.0)	308 (32.6)	157 (31.8)	130 (32.8)	20 (37.7)
Missing	8	4	4	1	3	0
PCT spend/death (QUARTILES)						
<i>Number (%)</i>						
1 (least spending)	228 (16.2)	64 (12.9)	164 (17.9)	79 (33.3)	77 (20.0)	7 (13.2)
2	502 (35.6)	171 (34.5)	331 (36.2)	171 (36.1)	140 (36.4)	19 (35.8)
3	512 (36.3)	189 (38.1)	323 (35.3)	173 (36.5)	128 (33.2)	21 (39.6)
4 (most spending)	169 (12.0)	72 (14.5)	97 (10.6)	51 (10.8)	40 (10.8)	6 (11.3)

ILLNESS FACTORS	Total population n=1467	Hospital deaths n=518	Other locations n=949	Other locations		
				Hospice deaths n=494	Home deaths n=399	Nursing home deaths n= 53
TREATMENT SITE						
<i>Number (%)</i>						
Main site (Chelsea)	469 (32.0)	162 (31.3)	307 (32.3)	163 (33.0)	130 (32.6)	13 (24.5)
Main site (Sutton)	949 (64.7)	344 (66.4)	605 (63.8)	309 (62.6)	257 (64.4)	38 (71.7)
Kingston	49 (3.3)	12 (2.3)	37 (3.9)	22 (4.4)	12 (2.2)	2 (3.8)

CANCER DIAGNOSIS						
<i>Number (%)</i>						
Lung	224 (15.3)	72(13.9)	152 (16.0)	86(17.4)	59(14.8)	6(11.3)
Gastrointestinal	324 (22.1)	119 (23.0)	205 (21.6)	105 (21.3)	93 (23.3)	6 (11.3)
Urological	194 (13.2)	70(13.5)	124 (13.1)	62(12.6)	51(12.8)	10(18.9)
Breast	177 (12.1)	63 (12.2)	114 (12.0)	59 (11.9)	39 (9.8)	16(30.2)
Haematological	105 (7.2)	65 (12.5)	40 (4.2)	12 (2.4)	25 (6.3)	3(5.7)
Sarcoma	100 (6.8)	32(6.2)	68 (7.2)	44(8.9)	21(5.3)	3(5.7)
Gynaecological	94 (6.4)	21 (4.1)	73 (7.7)	46 (9.3)	26 (6.5)	1(1.9)
Other	249 (16.9)	76(14.7)	173 (18.2)	80(16.2)	85(21.3)	8(15.1)
TIME FROM DIAGNOSIS TO DEATH (Years)						
<i>Mean (SD)</i>	3.5 (4.4)	4 (4.0)		3.4(4.5)	3.4(4.1)	4.1(5.3)
<i>Range</i>	0-32.8	0-24		0.1-32.8	0.1-24.9	0.2-24.3
<i>25th Percentile</i>	0.8	1		0.8	0.8	0.7
<i>Median</i>	1.7	2		1.7	1.7	1.6
<i>75th Percentile</i>	4.2	5		4.1	4.0	5.1
LAST APPOINTMENT TYPE						
<i>Number (%)</i>						
Outpatient						
Inpatient	897 (61.1)	272 (52.5)	625 (65.9)	330(66.8)	250(62.7)	43(81.1)
Ward Attender/Day Services	453 (30.9)	199 (38.4)	254 (26.8)	128(25.9)	117(29.3)	9(17.0)
	117 (8.0)	47 (9.1)	70 (7.4)	36(7.3)	32(8.0)	1(1.9)
TIME FROM LAST APPOINTMENT TO DEATH (Days)						
<i>Mean (SD)</i>	46 (42.4)	31 (39)	53 (42)	55 (43)	47 (39)	74 (44)
<i>Range</i>	1-183	1-182	1-183	2-183	2-169	3-169
<i>25th Percentile</i>	14	1		23	16	38
<i>Median</i>	32	16	41	43	37	74
<i>75th Percentile</i>	67	39		76	67	109
LAST TREATMENT TYPE						
<i>Number (%)</i>						
Chemotherapy	810 (55.2)	285 (55.0)	525 (55.3)	258 (52.2)	250 (62.7)	16 (30.2)
Radiotherapy	476 (32.4)	176 (34.0)	300 (31.6)	166 (33.6)	110 (27.6)	23 (43.4)
Hormonal treatment	93 (6.3)	19 (3.7)	74 (7.8)	39 (7.9)	24 (6.0)	4 (7.5)
Surgery	76 (5.2)	28 (5.4)	48 (5.1)	30 (6.1)	14 (3.5)	10 (18.9)
Stem Cell Transplant	12 (0.8)	10 (1.9)	2 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)
TIME FROM LAST TREATMENT TO DEATH (Days)						
<i>Mean (SD)</i>	151 (415)	157 (477)	147 (377)	143 (342)	142 (419)	181(208)
<i>Range</i>	1-7376	1-6306	2-7376	2-5741	2-7376	15-1324
<i>25th Percentile</i>	32	18.3		42	38	86
<i>Median</i>	69	43	81	80	76	140
<i>75th Percentile</i>	138	113		145	132	202

ILLNESS FACTORS	Total population n=1467	Hospital deaths n=518	Other location n=949	Hospice n=494	Home n=399	Nursing home n=53
PERFORMANCE STATUS (WHO)						
<i>Number (%)</i>	n=279	n=116	n=163	n=75	n=81	n=5
0/1	50 (17.9)	28 (24.1)	22 (13.5)	9 (12.0)	13 (14.8)	0 (0)
2	69 (24.7)	35 (30.2)	34 (20.9)	16 (21.3)	17 (21.0)	1 (20.0)
3	116 (41.6)	41 (35.3)	75 (46.0)	35 (46.7)	37 (44.4)	3 (60.0)
4	44 (15.8)	12 (10.3)	32 (19.6)	15 (20.0)	16 (19.8)	1 (20.0)
(Missing from record)	(1247)	(402)	(786)	(419)	(316)	(48)
NUMBER OF ADMISSIONS						
<i>Mean (SD)</i>	1 (1.5)	1(1.6)	1 (1.5)	1 (2)	1 (1)	1 (1)
<i>Range</i>	0-13	0-9	0-13	0-13	0-10	0-4

KNOWN TO HOSPITAL PALLIATIVE CARE TEAM <i>Number (%)</i>	509(34.7)	180(34.7)	329 (34.7)	186(37.7)	132 (33.1)	11 (20.8)
KNOWN TO CPCT <i>Number (%)</i>	1024(69.8)	237 (45.8)	787 (82.9)	419(84.8)	334(83.7)	33(62.3)
H2H INVOLVED IN CARE <i>Number (%)</i>	130 (8.9)	20(3.9)	110 (11.6)	45 (9.1)	62 (15.5)	3 (5.7)

*Other location n=949 includes 3 participants who died in a location other than home, hospice or nursing home

4.8.4 PoD Analysis

PoD was the outcome variable for this retrospective analysis. Figure 5.26 and Table 5.78 detail the results. The proportion of home deaths (27%) was equivalent to national figures but the proportion dying in a nursing home was considerably lower in the RMFT populations (RMFT 4%, ONS 12.6%). Thirty-four percent of cancer patients known to the RMFT died in hospital compared to 40.3% nationally[13]. A higher proportion of RMFT patients died in a hospice inpatient unit than the proportion of cancer patients nationally (34% compared to 16.9%). The higher number of hospice deaths parallels with the results seen in the H2H prospective feasibility study in which 42.3% of the total population (n=78) died in a hospice.

Figure 5.26 Factors influencing PoD: PoD for Study Population 2010-2011 by location (%) compared to ONS (ONS) data 2011

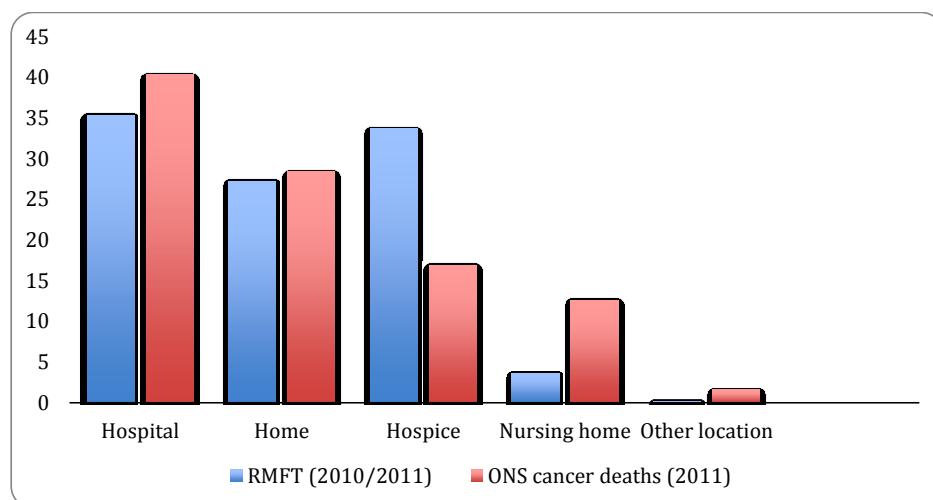


Table 5.78 Factors influencing PoD: PoD for Study Population 2010-2011 by location compared to H2H study data and ONS (ONS) data 2011.

PoD	RMFT (2010/2011) (n=1467)		H2H study (n=78)		ONS Cancer deaths 2011 (n=142948)	
	Number	%	Number	%	Number	%
Hospital	518	35	16	21	57592	40.3
Other location	949	65	62	79	85,356	59.7
Other location, detail:						
Home	399	27	29	37	40558	28.4
Hospice	494	34	33	42	24159	16.9
Nursing Home	53	4	0	0	17979	12.6
Other location	3	0	0	0	2285	1.6

5.9.5 Univariate analysis of factors influencing PoD

Table 5.79 summarises the results of the univariate (UVA). Variables with a p value < 0.2 were entered into the multivariate analysis of factors influencing home deaths. The individual variables with a p value < 0.2 were: age, ethnicity, marital status, and living alone. The illness related variables were: time from diagnosis to death, last treatment type, time from last treatment to death, time from last appointment contact to death and intent of last treatment. The environmental variables were: deprivation quintile, Primary Care Trust (PCT) spends per death, known to the CPCT and had a H2H. The trend in the data showed that as functional status declined a higher proportion of patients died at home. Performance status 0/1 24% died at home compared to performance status 4 (bedbound), 36.4% died at home. However, this was not significant at the p<0.2 level (p=0.5) and therefore not included in the multivariate analysis. No variables showed high collinearity between them, and therefore the 13 variables were subject to forward step multiple logistic regression.

Table 5.79: Factors influencing PoD: Univariate analysis of variables influencing home deaths (continues over page)

Page 1

<i>Number (%)</i>	Home death(A) (n=399)	Other location death (B) (=1068)	Chi-squared*
INDIVIDUAL FACTORS			
AGE IN YEARS			Overall p=0.16
16-44	31 (25.6)	90 (74.4)	
45-64	165 (29.5)	394 (70.5)	
65-74	116 (28.3)	294 (71.7)	
75+	87 (23.1)	290 (76.9)	
GENDER			p=0.2
Male	210 (29.2)	510 (70.8)	
Female	189 (25.3)	558 (74.7)	
ETHNICITY			p=0.11
White British	326 (27.9)	841 (72.1)	
Other	59 (25.7)	171 (74.3)	
MARITAL STATUS			p=0.04
Married	251 (29.3)	607 (70.7)	
Other	148 (24.3)	461 (75.7)	
LIVING ALONE			p<0.01
Yes	57 (18.8)	247 (80.2)	
No	341 (29.3)	821 (70.7)	
ENVIRONMENTAL FACTORS			
IMD DEPRIVATION QUNITILE			Overall p= 0.05
1 (most deprived)	32 (20.9)	121 (79.1)	
2	67 (27.6)	176 (72.4)	
3	89 (32.0)	189 (68.0)	
4	116 (34.8)	255 (76.6)	
5 (least deprived)	130 (28.8)	322 (71.2)	
PCT SPEND/DEATH QUARTILE			Overall p=0.06
1 (least spending)	77 (33.8)	151 (66.2)	
2	140 (27.9)	362 (72.1)	
3	128 (25.0)	384 (75.0)	
4 (most spending)	40 (23.7)	129 (76.3)	
KNOWN TO CPC			p<0.01
Yes	334 (32.6)	690 (67.4)	
No	65 (14.7)	378 (85.3)	
H2H			p<0.01
Yes	62 (47.7)	68 (52.3)	
No	337 (25.2)	1000 (74.8)	
ILLNESS FACTORS			
PERFORMANCE STATUS (WHO) (n=279)			Overall p=0.5
0/1	12 (24.0)	38 (76.0)	
2	17 (24.6)	52 (75.4)	
3	36 (31.0)	80 (69.0)	
4	16 (36.4)	28 (63.6)	
TREATMENT SITE			Overall p=0.8
Chelsea	130 (27.7)	339 (72.3)	
Sutton	257 (27.1)	692 (72.9)	
Kingston	12 (24.5)	37 (75.5)	

CANCER DIAGNOSIS				Overall p=0.25
Lung		59 (26.3)	165 (73.7)	
Gastrointestinal		93 (28.7)	231 (71.3)	
Urological		51 (26.3)	143 (73.7)	
Breast		39 (22.0)	138 (78.0)	
Haematological		25 (23.8)	80 (76.2)	
Sarcoma		21 (21.0)	79 (79.0)	
Gynaecological		26 (27.7)	68 (72.3)	
Head and Neck		23 (35.4)	42 (64.6)	
Neurooncology		17 (38.6)	27 (73.7)	
Skin		21 (34.4)	40 (65.6)	
Phase 1 Clinical Trial patient		2 (30.4)	55 (69.6)	
TIME FROM DIAGNOSIS TO DEATH				Overall p=0.03
1-3 months		12 (14.3)	72 (85.7)	
3-6 months		38 (29.2)	92 (70.8)	
6-12 months		78 (29.9)	183 (70.1)	
1-2 years		84 (25.3)	248 (74.7)	
2-5 years		107 (31.3)	235 (74.8)	
>5 years		80 (25.2)	238 (74.8)	
LAST APPOINTMENT TYPE				Overall p=0.73
Outpatient		250 (27.9)	647 (72.1)	
Inpatient		117 (25.8)	85 (72.6)	
Ward Attender/Day Services		32 (27.4)	336 (74.2)	
TIME FROM LAST APPOINTMENT TO DEATH				Overall p=0.03
< 1 month		185 (24.5)	571 (75.5)	
1-3 months		158 (31.2)	349 (68.8)	
3-6 months		56 (27.5)	148 (72.5)	
LAST TREATMENT TYPE				Overall p<0.01
Chemotherapy		250 (30.9)	560 (69.1)	
Radiotherapy		110 (23.1)	366 (76.9)	
Hormonal treatment		24 (25.8)	69 (74.2)	
Surgery		14 (18.4)	62 (81.6)	
Stem Cell Transplant		1 (8.3)	11 (91.7)	
LAST TREATMENT INTENT				p=0.03
Adjuvant/Curative		36 (20.5)	140 (79.5)	
Palliative		363 (28.1)	928 (71.9)	
TIME FROM LAST TREATMENT TO DEATH				Overall p<0.01
< 1month		80 (21.4)	294 (78.6)	
1-3 months		154 (28.9)	378 (71.1)	
3-6 months		107 (32.8)	219 (67.2)	
6-12 months		39 (27.1)	105 (72.9)	
1-2 years		7(14.9)	40 (85.1)	
>2 years		12 (27.3)	32 (72.7)	
NUMBER OF ADMISSIONS				p=0.96
Mean (SD)		1.16 (1.45)	1.17 (1.56)	
Range		(0-10)	(0-13)	
KNOWN TO HOSPITAL PALLIATIVE CARE				
Yes		132 (25.9)	377 (74.1)	
No		267 (27.9)	691 (72.1)	p=0.43

*p values in bold indicate factors was taken forward into multivariate analysis

5.9.6 Multivariate analysis of factors influencing PoD

The forward multi-variant binary logistic regression analysis identified seven variables as independent factors associated with the likelihood of dying at home, and eight variables significantly associated with dying in hospital. The multivariate analysis of home is given in Table 5.80, hospital is available in Appendix 7.4.7, and the comparison of analysis for home and hospital is shown in Table 5.81 below. Of interest is that these variables are not identical, some variables influence home deaths but seem to have no association with hospital deaths and visa versa. The five variable independently associated with both locations are: time from last contact to death, type of last treatment, PCT spend per death, known to CPCT and H2H. The variables with the strongest independent association for home death and out of hospital deaths are being known to CPCT and having a H2H.

Individual variables

- Deprivation was associated with independently associated with home deaths, the more deprived being less likely to die at home. The reference category here was most deprived (quintile 1), and in comparison those living in an quintile 3 area were over 1.5 times more likely to die at home than quintile 1 (OR 1.65, 1-2.7)

Factors related to illness

- Last contact type- Outpatients were a third less likely to die in hospital compared to the reference category of last contact –inpatient admission (OR 0.62, 0.45-0.85).
- Time from last contact to death- In comparison to the reference category of last contact less than a month prior to death, those last seen between 1-3 months (OR 0.32, 0.22-0.45) or 3-6 months prior to death (OR 0.30, 0.18-0.51) were two thirds less likely to die in hospital.
- Last treatment type- The reference category was chemotherapy, and compared to chemotherapy patients whose last treatment was radiotherapy were significantly less likely to die at home (OR 0.73, 0.54-0.99). Those whose last treatment was a stem cell transplant were nearly 6 times more likely to die in hospital than chemotherapy patients, although the confidence intervals were wide due to the low number of patients in the stem cell transplant group (OR 5.67, 0.95-33.87). Chemotherapy and

radiotherapy patients were twice as likely to die in hospital than those patients on hormone treatment alone (OR 0.53, 0.28-0.98).

- Time from last treatment to death- the reference category here was treatment less than one month before death. Interestingly, as time from treatment increases the likelihood of dying in hospital decreases up to the 1-year point. Those whose last treatment was between 6-12 months were a third less likely to die in hospital than those treated within the month prior to death (OR 0.63, 0.36-1.12). After one year from treatment the likelihood of dying in hospital increases and those patients whose last recorded treatment was over 2 years ago were as likely to die in hospital as those treated within the month prior to death (OR 1.09, 0.5-2.35). The confidence intervals for all categories cross 1 therefore these trends should be interpreted with caution.

Environmental factors

- Living alone – In comparison to the reference category of living with someone, those living alone were third less likely to die at home (OR 0.66, 0.45-0.97).
- PCT spending per death – The higher the PCT spend on palliative care/per death the less likely the patient was to die at home. Patients living in the PCTs spending the most on palliative care (Quartile 4) were over twice as likely to die in hospital than those living in the PCT with the least spend (OR 2.35, 1.42-3.88).
- Known to CPC- Those known to CPCTs were over twice as likely to die at home (OR 2.36, 1.68-3.31), and those not known to CPC were nearly 6 times more likely to die in hospital (OR 5.6, 4.2-7.7).
- H2H- those who had a H2H were with nearly twice as likely to die at home (OR 1.97, 1.31-2.96), with those with no input from the H2H team twice as likely to die in hospital compared to those patients who received a H2H (face-to-face or telephone) (OR 2.1, 1.2-3.7).

Table 5.80 Factors influencing PoD: Multi-variant forward binary logistic regression analysis of factors influencing home death

VARIABLE	Home n=399 N (%)	Other location n=1068 N (%)	Odds Ratio	95% CI	p value
INDIVIDUAL					
IMD DEPRIVATION QUNITILE					
1 (most deprived) (ref)	32 (20.9)	121 (79.1)	1		
2	67 (27.6)	176 (72.4)	1.49	(0.89-2.50)	p=0.13
3	89 (32.0)	189 (68.0)	1.65	(1.00-2.70)	p=0.05
4	116 (34.8)	255 (76.6)	1.03	(0.62-1.71)	p=0.91
5 (least deprived)	130 (28.8)	322 (71.2)	1.26	(0.77-2.05)	p=0.35
ILLNESS/TREATMENT FACTORS					
TIME FROM LAST CONTACT					
< 1 month (ref)	185 (24.5)	571 (75.5)	1		
1-3 months	158 (31.2)	349 (68.8)	1.38	(1.00-1.90)	p= 0.05
3-6 months	56 (27.5)	148 (72.5)	1.26	(0.79-2.02)	p=0.34
LAST TREATMENT					
Chemotherapy (ref)	250 (30.9)	560 (69.1)	1		
Surgery	110 (23.1)	366 (76.9)	0.50	(0.24-1.04)	p=0.06
Radiotherapy	24 (25.8)	69 (74.2)	0.73	(0.54-0.99)	p=0.04
Hormone Treatment	14 (18.4)	62 (81.6)	0.67	(0.38-1.16)	p=0.15
Stem Cell Transplant	1 (8.3)	11 (91.7)	0.22	(0.03-1.88)	p=0.17
ENVIRONMENTAL FACTORS					
LIVES ALONE					
Yes	57 (18.8)	247 (80.2)	1*		
No	341 (29.3)	821 (70.7)	1.52	(1.03-2.2)	p=0.04
PCT SPENDING QUARTILE					
Quartile 1 (least spending) (ref)	77 (33.8)	151 (66.2)	1		
Quartile 2	140 (27.9)	362 (72.1)	0.83	(0.57-1.2)	p=0.32
Quartile 3	128 (25.0)	384 (75.0)	0.66	(0.45-0.96)	p=0.03
Quartile 4 (most spending)	40 (23.7)	129 (76.3)	0.65	(0.40-1.07)	p=0.09
KNOWN TO CPC					
No			1		
Yes	65 (14.7) 334 (32.6)	378 (85.3) 690 (67.4)	2.36	(1.68-3.31)	p<0.001
H2H					
No	337 (25.2)	1000 (74.8)	1		
Yes	62 (47.7)	68 (52.3)	1.97	(1.31-2.96)	P<0.01

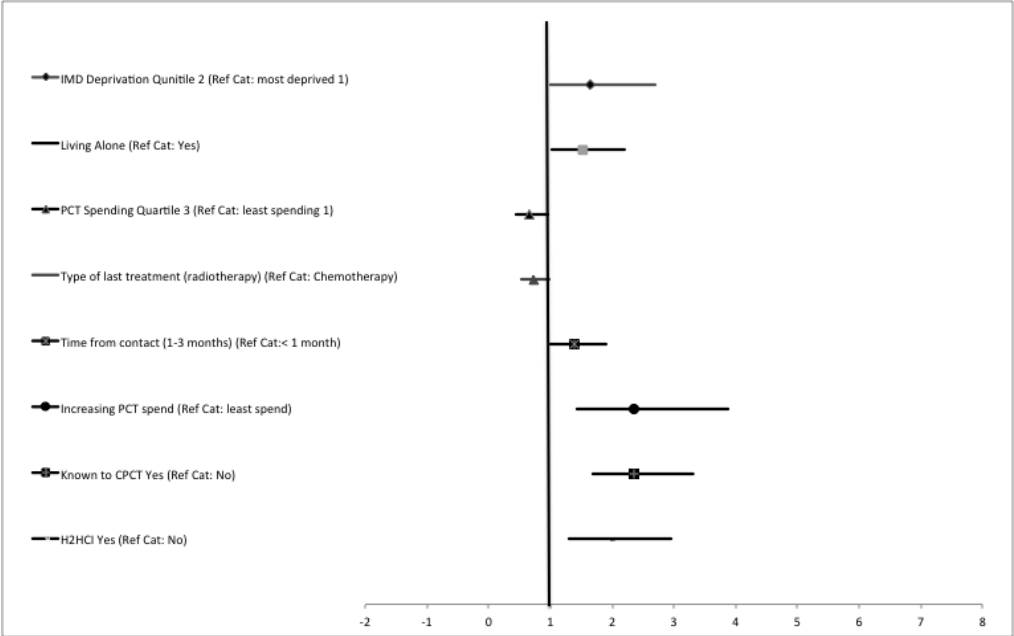
Table 5.81 Factors influencing PoD: Multivariate analysis forward binary logistic regression analysis of factors influencing home and hospital deaths (continued on next page)

	Home n=399 n (%)	OR	95% CI	p value	Hospital n=518 n (%)	OR	95% CI	p value
INDIVIDUAL VARIABLES								
AGE IN YEARS								p=0.02
16-44 (ref)					48 (40)	1		
45-64					176 (32)	0.80	(0.48-1.32)	0.39
65-74					156 (38)	1.32	(0.79-2.22)	0.29
75+					138 (37)	1.28	(0.74-2.20)	0.38
IMD DEPRIVATION QUNITILE								
1 (most deprived) (ref)	32 (20.9)	1						
2	67 (27.6)	1.49	(0.89-2.50)	p=0.13				
3	89 (32.0)	1.65	(1.00-2.70)	p=0.05				
4	116 (34.8)	1.03	(0.62-1.71)	p=0.91				
5 (least deprived)	130 (28.8)	1.26	(0.77-2.05)	p=0.35				
TREATMENT FACTORS								
LAST CONTACT								p<0.01
Inpatient (ref)					272 (30.3)	1		
Ward Attender					199 (43.9)	1.06	(0.63-1.78)	p=0.84
Outpatient					47 (40.2)	0.62	(0.45-0.85)	p=0.03
TIME FROM LAST CONTACT								p<0.01
< 1 month (ref)	185 (24.5)	1			365 (48.3)	1		
1-3 months	158 (31.2)	1.38	(1.00-1.90)	p= 0.05	104 (20.5)	0.32	(0.22-0.45)	p<0.01
3-6 months	56 (27.5)	1.26	(0.79-2.02)	p=0.34	49 (24.0)	0.30	(0.18-0.51)	p<0.01
LAST TREATMENT								p=0.03
Chemotherapy (ref)	250 (30.9)	1			285 (35.2)	1		
Surgery	110 (23.1)	0.50	(0.24-1.04)	p=0.06	176 (37.0)	0.68	(0.36-1.29)	p=0.24
Radiotherapy	24 (25.8)	0.73	(0.54-0.99)	p=0.04	19 (20.4)	1.14	(0.84-1.55)	p=0.41
Hormone Treatment	14 (18.4)	0.67	(0.38-1.16)	p=0.15	28 (36.8)	0.53	(0.28-0.98)	p=0.04
Stem Cell Transplant	1 (8.3)	0.22	(0.03-1.88)	p=0.17	10 (83.3)	5.67	(0.95-33.87)	p=0.06
TIME FROM LAST TREATMENT								p=0.01
< 1 month (ref)					210 (56.1)	1		
< 3 months					164 (30.8)	0.60	(0.43-0.85)	p<0.01
3-6 months					65 (19.9)	0.53	(0.34-0.84)	p<0.01
6-12 months					39 (27.1)	0.63	(0.36-1.12)	p=0.12
1-2 years					19 (40.4)	1.01	(0.46-2.23)	p=0.97
> 2years					21 (47.7)	1.09	(0.50-2.35)	p=0.83

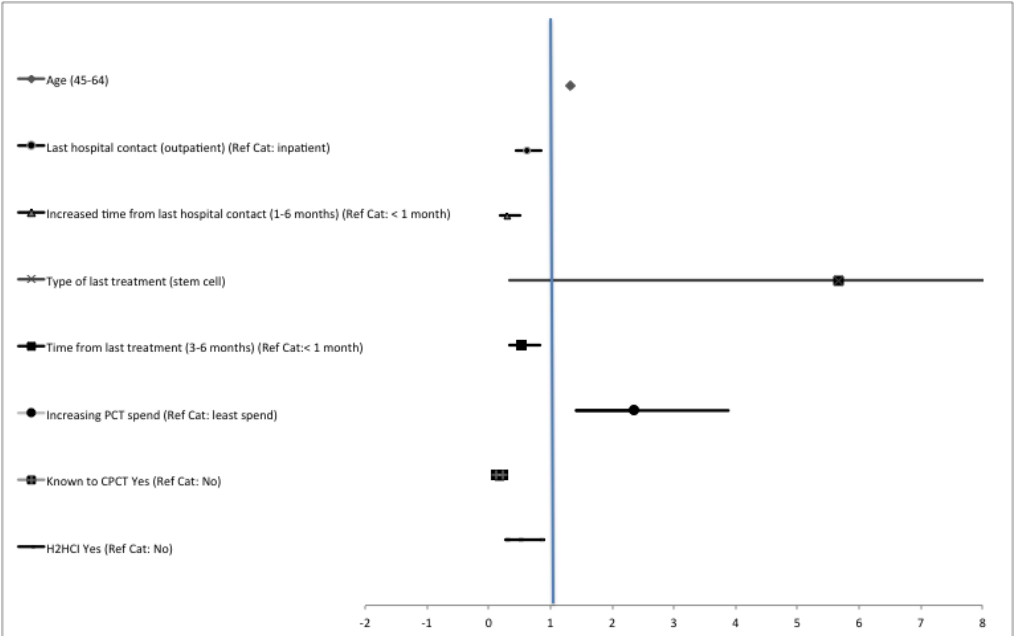
ENVIRONMENTAL FACTORS								
LIVES ALONE	Yes	57 (18.8)	1*					
	No	341 (29.3)	1.52	(1.03-2.2)	p=0.04			
PCT SPENDING QUARTILE								P<0.01
Quartile 1 (least spending) (ref)		77 (33.8)	1			64 (28.1)	1	
Quartile 2		140 (27.9)	0.83	(0.57-1.2)	p=0.32	171 (34.1)	1.55	(1.01-2.37) p=0.04
Quartile 3		128 (25.0)	0.66	(0.45-0.96)	p=0.03	189 (36.9)	1.85	(1.22-2.82) p<0.01
Quartile 4 (most spending)		40 (23.7)	0.65	(0.40-1.07)	p=0.09	72 (42.6)	2.35	(1.42-3.88) p<0.01
KNOWN TO CPC								
No								p<0.01
	Yes	65 (14.7)	1			237 (23.1)	5.6	(4.2-7.7)
		334 (32.6)	2.36	(1.68-3.31)	p<0.001	281 (63.4)	1	p<0.01
H2H								
	No	337 (25.2)	1			20(15.4)	2.1	(1.2-3.7)
	Yes	62 (47.7)	1.97	(1.31-2.96)	P<0.01	498 (37.2)	1	p<0.01

Figure 5.27 Forest Plot: Results of analysis of Factors influencing place of death at a tertiary referral cancer centre

a) Odds of dying at Home (values > 1 increased odds of dying at home)



b)Odds of dying in hospital (values >1 increased odds of dying in hospital)



5.9.7 Section summary

The results of this analysis highlight some important considerations regarding PoD in this cancer population. Age was the only demographic factor with an independent influence on hospital death, and with confidence intervals that include 1 this influence is questionable. It is therefore illness factors (and more specifically treatment factors) and environmental factors that influence PoD. Those patients under regular follow up and treatments are more likely to die in hospital compared to those patients whose last treatment and follow up were stopped at least a month prior to death. Those patients not known to CPCT were 6 times more likely to die in hospital, whilst **those who had a H2H were half as likely to die in hospital and twice as likely to die at home.**

Stopping treatment and tertiary referral follow up alongside early referral to CPC and H2H are important factors in reducing hospital death rates in these cancer patients. This analysis supports the early results from the feasibility study (Section 5.2) that showed more home deaths in H2H study group compared to standard care. However, it is important to note that only 9% of patients known to RMFT who died had the H2H intervention. This shows the reach of H2H is low and suggests modelling of the intervention to enable delivery to more patients is required. The finding that those not known to CPCTs are 6 times more likely to die in hospital suggests that one way of stratifying the H2H input may be by previous input from CPCT.

6. Discussion

6.1 Introduction

This chapter begins with a summary of the thesis and the main feasibility findings. The main findings are then discussed in the context of the study aims and current research. I will then discuss the limitations of the study, implications for clinical practice and recommended remodelling of H2H. Finally, I will discuss the implications this work has for research involving patients in the last few months of life and thus the recommendations for the design and conduct of a larger definitive evaluation trial of H2H.

6.2 Discussion: Main findings

The aim of this thesis was to evaluate the feasibility of a CI, H2H, in cancer patients at the EoL. I adopted the MRC CI guidance as a framework for this evaluation. The process evaluation presented in Chapter 3 and the qualitative interviews from the mixed methods feasibility study contribute to the *Development and Modelling phase* of the MRC framework. The quasi-experimental longitudinal mixed method comparator feasibility study tested the H2H against standard care as part of the *Feasibility/Piloting phase* providing data on the fidelity and acceptability of H2H and recommendations for the proposed design of a larger definitive evaluation trial. Finally, the bereavement study and retrospective analysis of factors influencing PoD provide context to H2H through data on overall EoLC in the tertiary referral cancer centre.

Fidelity and Acceptability of H2H: The data here shows that H2H is both feasible and acceptable. H2H was delivered as intended with the exception of the patient copy of care plan, only 58% of patient's recalled receiving this documentation. No patient or carer felt the CC was too long or distressing and there were no negative outcomes reported from participants. Eight- four percent of patients would recommend H2H to

others. The qualitative interviews complement these quantitative findings with patients reporting a positive experience from H2H that hinged around their view that H2H provided the opportunity for maximum information sharing between professionals and the patient and their carer, as well as enabling the patient to visualise integrated coordinated team work. This was paramount given the significant losses described as a result of discharge from the cancer centre. HCPs raised concerns about a risk of H2H leading to patient distress but no patient reported this. Qualitative interviews provided deeper and wider understanding into perceptions surrounding the end of cancer treatment and the importance of navigating the transition from active treatment to best supportive care in a sensitive and timely manner to temper loss. The recommendations arising from these interviews - preparation, gradual transitions and an open door approach - reach past H2H and apply to how all specialisms can encourage community-led care.

Feasibility of studying H2H: It was feasible and acceptable for patients and carers to participate in a longitudinal study in the last few months of life. Although the total study sample size was not met, feasible recruitment rates of patient and carer participants were met. Overall, the quasi-experimental study design was acceptable for this feasibility study to test study schedule and outcome measures for a larger trial. However, the quasi-experimental design resulted in considerable differences in baseline demographic and clinical variables suggesting selection bias across groups, meaning a similar quasi-experimental design would not be appropriate for a larger definitive trial. The longitudinal study design with multiple research contacts over a 12 week period was feasible with minimal withdrawal (2.5%) from the study due to choice, over 50% of participants completing two or more time point assessments, and carers willing to participate past the patients death and into bereavement. The results show that the use of PPD as a outcome measure has limitations due to missing data, and that substituting missing values of PPD for a value of 'home' is not a valid approach to missing data. ADI was high in this study leading in limitations of symptom control and QoL outcomes and patient reported service use. Carer proxy scores for patient symptom control agreed with patient scores on the validated tool used (MSAS-SF) but may not be an answer to ADI missing data from patients close to death due to similar carer attrition rates longitudinally.

Potential benefits of H2H were seen in this feasibility study. Improvements in the documentation and achievement of PPD, along with improvements in patient satisfaction and small improvements in symptom burden, QoL and informal carer QoL, were found with H2H although these early findings need to be tested in a larger definitive trial.

The bereavement work showed that overall bereaved relatives were satisfied with the care of the patients dying in the cancer centre. Social factors (patients living alone and marital status) and treatment factors (treatment intent and length of admission) both had a significant independent impact on satisfaction with care. The achievement of preferences for PoD was linked with satisfaction (increased satisfaction if PPD achieved); although, this was not an independent predictor of satisfaction when considering all other factors. This suggests that PPD should not 'trump' all other considerations when evaluating what constitutes a 'good death' or high quality EoLC.

The retrospective factor analysis of variables influencing PoD found that earlier discharge from the specialist centre increased the probability of dying outside of hospital in the first year after discharge. The results also support the preliminary findings of the feasibility study: that H2H increases home deaths (OR 1.97, 1.31-2.96). H2H also independently increased the likelihood of dying outside of hospital two fold. The strongest factor on PoD was CPCT involvement. Those known to CPCTs were nearly 6 times more likely to die outside of hospital than those not known to these services. These results lead me to recommend early referral to CPCTs for all cancer patients embarking on palliative treatments or deemed to be in the last year of life, and future modelling of H2H to engage earlier in the patient's cancer journey.

6.3 Discussion of research with respect to AIM1: To perform early process evaluation and modelling of H2H

Process evaluation is a vital part of evaluating any CI in order to be able to inform future studies and policy makers about how the CI may be having an effect, the fidelity and context of the CI, implementation issues and the reach of the CI. Multiple methods can be used to assess these aspects for a single CI. The main process evaluation findings from the *development phase* of evaluating H2H have been presented in Chapter 3. The *development phase* found engagement with H2H from CHCP was good suggesting that H2H was acceptable to these CHCP. It gave an understanding of contextual adaptations that had occurred to H2H since the pilot service began, namely the development of telephone CC and enabled fidelity outcomes to be set for the feasibility study. The MRC guidance recognises that process evaluation needs to be repeated as an integral part of each phase of evaluation. Thus the *feasibility and piloting phase* (the feasibility study) tested H2H acceptability and fidelity whilst the FIPD and bereavement work provided context to H2H and knowledge about the reach of the service. These process evaluation outcomes are discussed in Section 6.4 and 6.5 below.

6.4 Discussion of research with respect AIM 2: To determine the feasibility of evaluating H2H in a cancer population

This section presents and discusses the study findings in relation to the feasibility of the intervention and scrutinises the fidelity and acceptability of H2H.

6.4.1 Feasibility of the intervention:Fidelity and Acceptability

This feasibility study aimed to evaluate H2H in real terms: to observe and understand how H2H was working and being delivered in daily clinical practice. Therefore, a mixture of face-to-face CCs and telephone CCs were included in the study. The fidelity of the intervention was assessed by recording data on the timing of the intervention, length of CC and attendees at the CC, whilst acceptability was assessed through a short quantitative questionnaire and the indepth qualitative interviews with patients and

oncology consultants. These data and emerging themes inform both the *modelling phase* and the *feasibility and piloting phase* of the MRC framework.

The quantitative results testing H2H fidelity show that H2H was delivered as intended, with 72% delivered as a face-to-face CC and over 90% of these organised and delivered within 3 working days from discharge. In the study by Abernethy [237], the CC took considerably longer to organise than reported here (mean 69 days). The author concluded that part of the delay was because the responsibility for delivering the CC fell to the hospital palliative care CNS, and that urgent clinical patient workload took priority over organising a routine CC. The short time between discharge and H2H in this feasibility study may have been the result of a dedicated H2H team of specialist nurses employed solely to organise and deliver the CC. All CCs in the Abernethy study[237] included the GP, patient and/or family member and a palliative care representative, indicating that these CHCPs were willing to engage with the intervention. Overall, in this feasibility study the CC was acceptable to staff, patients and carers, with high attendance rates. However, although over 80% of face-to-face CCs were attended by GPs this was lower than the fidelity standard set of 100% attendance. This high standard for GP attendance was set because the GP is the senior responsible clinician for the patient once care is community led, and therefore the success and overall value of H2H is questionable without their engagement. The qualitative interviews with H2H SS also highlighted concerns around the willingness of the community teams to engage, and therefore CHCP views about the format of H2H should be sought prior to a larger definitive trial.

The median length of the CC in the Australian trial was 36 minutes with a range of 20 minutes to 58 minutes. The majority of CC in this study lasted 30-60 minutes. The majority of patients and carers felt the CC length was 'about right' and that the CC addressed all or most of their issues. No participant felt the CC was too long. Over 80% of patients and carers would recommend the CC intervention to others, and only one patient would not recommend the intervention. H2H includes the distribution of a care plan based on the discussions at the CC. This is sent to all attendees including the patient and copied to out of hours services. The results of this feasibility study show that the patient is not always aware that this part of the intervention has been

completed. 58% of patients reported receiving the paper copy of the care plan. This suggests another method of handing over the documented care plan should be considered to disseminate the care plan to all involved. Since the start of this research an electronic record has now become widely available with the routine use of CoordinateMyCare[95] which has also piloted a platform for patients to view their record through a smart phone application. The use of technology such as this should be integrated further into the modelling of H2H.

H2H navigates the transition to community-led care. Therefore in order to explore the acceptability of H2H and understand in more detail how the intervention may have been working it was crucial to appreciate the views and perceptions of patients and oncologists surrounding this transition and discharge to community care. The purpose of which was to guide the ***modelling and development phase*** of the MRC framework. Participants discussed four key themes: loss, transition barriers, transition management and community concerns.

The losses described by patients were multiple and included loss of treatment, loss of hope, loss of control, loss of familiarity and trust. The published literature [238] describes multiple losses and concerns at hearing the diagnosis of cancer, including the fear of certain death. These losses seem to come to the fore again when cancer treatment stops. The most important loss to recognise for transition to community led care and future modelling of H2H is the loss of familiarity and trust the patients felt at not needing to attend the cancer centre. The familiarity of trustworthy HCPs was particularly important to patients, and a concern for oncologists. Oncologists described three main transition management strategies to temper this loss and improve transition to community services; preparation, a phased delicately managed gradual transition and an 'open door' approach with the patient aware that review by the oncologist in the future was available if necessary.

Overall, the views of patient participants regarding H2H were overwhelmingly positive. Patients and oncologists described the role of H2H as a reassurance and proof to the patient that the transition was being managed. The visual aspect of H2H reinforced to patients that the discharge to community care was considered and co-ordinated.

Patients expressed the fact they had witnessed teamwork between professionals first hand was of particular importance. All patient participants, with the exception of one, found the CC format beneficial. The findings from the qualitative interviews correspond with the results from the quantitative acceptability questionnaire whereby the majority of patients (84.2%) and carers (100%) would recommend H2H to others. Importantly, no patient participant reported harm or distress as a result of H2H. The benefits of H2H centred on visual teamwork, shared knowledge between professionals, patients and families, shared decision making and also the open forum of the CC where patient participants felt their views, priorities and concerns were actively listened to and addressed. Hanratty et al used mixed methods to understand experiences of transitions between settings for older adults at the EoL. They found families recognised that good relationships and communication between professionals in different settings had an important influence on transitions [239]. Our results support this finding; in particular, our patient participants emphasized the importance and reassurance of witnessing teamwork between acute and CHCPs.

One other important aspect of the CC was that the patient was involved in sharing their story with the community teams. The patients also appreciated the opportunity for their loved ones to be involved and be listened to. Patients described the positive impact the CC had on them, as they met the people who would be looking after them in the future, shared their story, and witnessed the coordination of care and responsibility amongst HCPs. This was an important reassurance to participants. The free comments of participants in the quantitative study corroborate the qualitative findings indicating that it was important to the patient to know and meet everyone involved in their care, to see that all HCPS knew the same information about the patient and that their roles were defined.

The interviews explored barriers to H2H and transition to community led care. These barriers hinged around how patients, families and oncologists processed and adapted to the multiple losses described. The barriers described were understanding and acceptance, attachment, and follow up concerns. All these transition barriers, if not managed appropriately, were barriers to the delivery and success of H2H. The ability of patients and their families to accept the end of treatment was recognised by all

participants as influencing the patient's willingness to agree to discharge into community services, thus presenting an obstacle for complete integration of H2H into a standardised discharge process for all patients. However, the majority of patient participants reluctantly accepted the change in their situation. Oncologists and H2H SS recognised that the oncologist's ability to recognise and accept that the patient was at the end of active treatment was an influencing factor in the use of H2H. Attachment, referring to an affection or fondness for someone or something, was intimately linked to the loss of familiarity and trust described by patients and was a barrier to transition and H2H. Patients and oncologists agreed that both could become attached to one another, and the patient could also become attached to the familiar, safe environment of the cancer centre.

The main barrier specific to H2H being delivered in its current format was HCPs concerns about the speed and the finality of H2H.. Participants felt H2H and how it was delivered needed to be receptive to their ideals for managing transition gradually. The impression from the HCPs was that the current H2H format may at times rush or truncate the process of transition, eliminating the open door attitude to patients approaching the EoL. There was a concern that this may cause distress to patients and their carers. Late referrals to H2H, leading to a fast transition to community services, were discussed as poor practice that regularly occurred. The concern was that this speedy transition might result in potential harm to the patient through evoking feelings of abandonment. However, even though this issue was raised by HCPs, only one patient participant described feelings of abandonment associated with the referral to the H2H. Earlier involvement of H2H and the transition management strategy of an open door approach would minimise this potential adverse effect as a result of the handover to community-led services. HCPs also discussed the issue that the face-to-face CC may be overwhelming and intimidating to some patients. H2H SS discussed this as a barrier to patients accepting H2H; no patient participants raised this as a concern. A third barrier to H2H in its current format was that it does not include any feedback to the referrer (the oncologist) about the outcomes for the patient. This made oncologists reluctant to refer and it was suggested that, if feedback was included, (for example, a copy of the care plan was sent to the oncologist), they may be more likely to refer again. A fourth barrier to H2H discussed by HCPs was that of community services, firstly community

professionals' reluctance to engage with H2H and secondly concerns about the standard of community care available. However, from the patient's perspective, H2H showed all HCPSs working as one team. This implies that any difficulties encountered by the H2H team engaging the CHCPSs when organising the meetings were not visible to the patient during the meeting. No patient participant commented on witnessing any difficulties with CHCP engagement. The quantitative and qualitative results are divergent on this matter. As already discussed, the quantitative work shows the CCs were well attended with over 80% attended by all three main community professionals (GP, DN and CPCT). This data corresponds with the Abernethy et al[237] study, where CC attendance by HCPs was high (99% attended by the GP, 90% by palliative care specialists). The quantitative results and absence of patient concerns around community engagement suggest the concerns of the hospital HCPs may be unfounded although exploration of this before the larger definitive trial is recommended. All participants had concerns about the standard of community care. These concerns were split into two categories: lack of service provision in the community, and lack of knowledge. Both concerns meant patients and oncologists had serious reservations about the community teams' abilities to continue to offer the style of care that was expected. This could lead to a lack of trust in community services. This mirrors findings from research into oncology community follow-up of cancer survivors[240]. It highlights the importance of both the educational component of the CC and the visual exchange of knowledge between HCPs at the CC to reassure the patient and family. The oncologists' lack of trust in community services results in a reluctance to discharge the patient and, in this scenario, the clinician will not use H2H. Effective feedback to oncologists after a CC about each patient's management in the community may gradually allay these fears.

This is the first study to explore the views of patients and oncologists surrounding this specific transition to community-led, best supportive care in cancer patients. However, the themes are evident in other transition research in health. Research into the transition of adolescents into adult services highlights similar concerns to the qualitative interviews in this feasibility study. In particular, loss of close relationships, attachment, and concerns about future trust with new service providers [241-243] were all of importance. The views of patients and oncologists presented here correspond with those in transitional care in adolescence. A particular concern centred around the loss of

trusted relationships with HCPs that had developed over a considerable period of time [242]. This highlights that the length of the relationship between the patient and doctor is a factor to consider. These concerns around transition are a potential barrier to H2H and effective BSC in the community, and need to be managed sensitively. Basconi et al [244] observed high levels of family satisfaction when oncologists were part of the patient's care until death. They concluded that when a long and trusting relationship has been established, the connection between patient and oncologist should not be lost [25]. This finding should be considered carefully in relation to the current H2H model. It may be beneficial to routinely offer a post CC oncology contact perhaps via telephone or via other means such as email or skype.

This is also the first study of a CC model in cancer patients at EoL in the UK. In this study the fidelity outcomes set for H2H were largely met, however previous work by Abernethy[237] found difficulty organising CC within a time frame, reporting that only 23% (38/167) were conducted within the planned 28 day after randomisation. The average time from randomisation to CC was 69 days (SD 55). A similar study[150] in patients with ILD in the UK also reported delays in the CC after randomisation with difficulty engaging CHCPs. The fidelity findings in this study do not agree with this published literature. H2H was conducted within 3 working days for the majority of participants (> 90%). This may be the result of the H2H team being a separate service to the main SPCT at the hospital. This enabled the H2H SS to prioritise the organisation of new CCs and avoid delays. A contributing factor may also have been that patients in this feasibility study had a shorter estimated prognosis from their oncologists than participants in the Abernethy study. The H2H SS practice is to inform the CHCPs of this short prognosis when organising the meeting. This may have made the meeting a priority for the CHCPs, as at times they were able to combine their own necessary assessments and reviews with the CC. The patient experience of H2H was positive, with patients sharing that the CC was a demonstration that the areas of care important to them were addressed. Particular reference was made to their story being heard, needs addressed, coordination of care, awareness of who is responsible for care and involvement of the patient and carer in their care plan. These themes mirror the 7 themes identified in 2015 by the National Choice in EoL Care programme[25]. Figure 4.25 is adapted from the 2015 'What's important to me' with reference to H2H.

However, although the potential benefits of H2H have been elucidated by this qualitative work it has also highlighted an area of potential harm that requires considered attention prior to a larger definitive trial. The view of HCPs that H2H may at times be at risk of causing harm through the process being too rushed and truncated for patients and families and the finality of complete discharge from the cancer centre. This concern may be important as currently H2H involvement only occurs at the end of active treatment, with one hospital assessment from the H2H SS. The current model does not allow for a phased gradual transition and with a median prognosis after discharge of just over one month this leaves little time for the transfer of patient trust to community services through the H2H SS to become fully established. One recommendation would be to remodel the intervention to be involved earlier in the patient's oncology journey, proactively eliciting the holistic needs of the patient and family, supporting and managing other episodes of care transitions along the active treatment pathway. In this way EoLC, including advance care planning, would phase in as active oncology phased out. The modelling should retain the strong components of H2H; the visual integrated teamwork and maximum information sharing with community teams. This would require development and testing of new triggers for referral to H2H. Earlier involvement and collaboration would allow the important delicately managed phased transition to occur, minimising any harm associated with a more speedy process and may yield better outcomes for patients.

Figure 6.1: 'What's important to me' Choices adapted with reference to H2H model and qualitative results[25]



6.4.2 Feasibility of study design, limitations and lessons for the future

In this section the results of the feasibility study are discussed with reference to the feasibility of the study design. This contributes to the *feasibility and piloting phase* of the MRC framework, the purpose of which is to inform the design of a larger definitive trial. It has key learning implications for any study involving patients in the last month of life. Feasibility objectives were set at the start of the study. These are revisited at the end of this section, alongside the success of the study against these objectives.

Defining the intervention and standard care

H2H is a CI with many different components. In this study, H2H was offered in addition to standard care. A limitation of this study was the ability to define and standardise H2H, alongside difficulties defining standard care. This limitation has been recognised by the MRC[245] and other researchers. However, it is also acknowledged that to over-standardise the delivery of a CI for the purposes of research is to make it unreal. This risks the intervention becoming unacceptable in clinical practice[246].

The minimum standard care delivered was definable. Standard care for oncology patients on discharge from the cancer centre was a discharge summary to the GP and referral to CPCT, or a copy of the discharge summary sent to the CPCT if the patient was already known. However, beyond this, what was offered to patients as part of standard care varied depending on where the patient lived, clinician routine practice, GP engagement in palliative care and the needs of the patient. This variability was an issue for both study groups. A second issue was that other stakeholders, such as community services or CPCTs, may have introduced their own interventions around the same time as H2H was being studied. One such intervention known to the researcher was an electronic palliative coordination system, Coordinate My Care[95]. The use of this electronic record was available to both the H2H group and standard care and complemented the care received. Therefore it should not have had more impact for one study group more than the other on the outcomes seen.

I attempted to clarify the baseline standard for H2H as much as possible prior to the start of the study. This was done through the workshop with H2H SSs presented in Chapter 3. Usual practice and delivery of the H2H was discussed and a consensus agreed. We agreed minimum standards and documentation alongside criteria for telephone case conferencing. These appeared to be adhered to by the H2H SSs, evidenced by the fidelity outcomes presented in Section 5.7.1. However, further work could be done to understand the intervention and also to define standard care. Tape recordings of face -to -face CCs could be thematically analysed to further define and develop the intervention. Qualitative analysis of H2H care plans and oncology discharge letters would determine which elements of care; symptoms, anticipated symptoms, preferences and advanced decisions, are routinely documented in oncology discharge letters as part of standard care and as part of the H2H care plan.

Study design and schedule

A mixed methods study design was chosen for this feasibility study. This approach is endorsed by the MRC guidance[245] and MORE care best practice statement[139]. However, a number of weaknesses have been cited regarding mixed methods studies. Limitations of mixed methods studies include practical issues, such as time constraints, and the ability of the researcher to confidently conduct each research methodology. These issues were relevant to this study as I was the sole researcher with limited experience of conducting research. The use of both methods may possibly have reduced my ability to recruit to the quantitative component of the study; however, it was crucial to employ both methods to gain a full insight into the feasibility of H2H. Higher numbers of recruited patients to the quantitative component of the study were desirable but hampered more by the poor performance status of the patients being studied, rather than researcher time constraints. The inclusion of the qualitative interviews was essential to determine how acceptable H2H was to clinicians and patients. The H2H questionnaire alone gave some insight into this but a much fuller explanation was derived from the combination of the quantitative and qualitative results. The qualitative work provided valuable insight into the views and perceptions of patients and oncologists regarding transition to BSC in the community, alongside an understanding of the reasons why H2H had potential benefits for patients and carers in this feasibility study. However, the findings are based on a small number of interviews with participants within the UK NHS system.

Recruitment of patients to the qualitative interviews was slow and problematic: 5/13 (38%) of patients approached declined to participate. HCP recruitment was good: only 2/15 (13%) declined participation. Although the inclusion criteria was open to English-speaking patients with any cancer diagnosis who had had H2H, it was expected that the majority of patients in the qualitative interviews would be recruited from the quantitative study cohort of Lung and GI cancer patients. However, only 2 of the participants in the qualitative interviews were also participants in the quantitative study. In these cases, the qualitative interviews were conducted at Week 1 of the quantitative study. This time point was chosen to limit the burden of the initial visit however attrition due to illness or death was high at week 1 (25%) limiting the number of potential participants for the qualitative interviews and, for some potential interviewees, completion of both quantitative assessments and a qualitative interview at Week 1 was deemed too burdensome. These findings suggest that an embedded mixed method design with patient qualitative interviews will not be feasible in a larger definitive trial due to patient burden. Therefore, the recommendation is that embedded interviews with carers and community HCPs are conducted in the definitive trial. In this feasibility study, recruiting to the qualitative interviews from outside the quantitative study recruits was a reasonable strategy to understand the broader experience of H2H. However, I was reliant on the H2H SS to approach all other potential participants by giving the PIS after a CC. During the weekly meetings with the H2H team, we would discuss patients who might be appropriate for the qualitative interviews; however, the discussion was often met with 'reasons' why approaching the patient would not be a good idea. These 'reasons' were outside the exclusion criteria and were often the H2H SSs' paternalistic judgement of whether a patient would want to be involved in research, which I always questioned. The H2H SSs became more open to the research as the study progressed and this became less of an issue. Within the scope of this feasibility study it was not possible for me to conduct face-to-face interviews with all the stakeholders involved in H2H. Informal carers, GPs, community nurses and CPCTs were not interviewed. Patients gave their insights into how H2H may benefit their informal carers, suggesting it provides a firm support base and clear management plan. Evidence suggests that family members often occupy a unique position: not only do they provide practical and emotional care but they also potentially need support in order to continue in their role. Given the small number of

patient participants recruited to the qualitative interviews, it may have been possible to recruit either the patient or informal carer to the face-to-face interviews. However, this may have led to fewer patients participating overall. Future studies should focus the qualitative component on interviews with the informal carers and interviews or focus groups with CHCPs. The concerns raised in the qualitative interviews regarding community HCP engagement with H2H leads me to recommend further qualitative work with CHCPs is a necessity to inform further modelling of H2H prior to conducting a larger definitive trial.

The MRC guidance recommends, where possible, the use of RCTs for the quantitative component when evaluating CIs. Randomisation accounts for known and unknown confounding factors across the study groups. Quasi-experimental studies designed to determine the effectiveness of the intervention, but without the designation of a randomised group [173], have a number of cited limitations[176]. These limitations and their relevant impact on the internal validity of this feasibility study are detailed in Table 6.1 below.

Table 6.1: Threats to internal validity from Quasi-experimental design in the feasibility study

Limitation	Explanation	Relevance to the feasibility study
Ambiguous temporal precedence	Lack of clarity about whether intervention occurred before outcome	Not relevant: Intervention occurs before the outcome.
Selection	Systematic differences over conditions in respondent characteristics that could cause the observed effect	Relevant: The H2H group was significantly different in home ownership, ethnic origin and survival. All these factors are associated with a decreased likelihood of home death. Therefore observed effect size likely an underestimation of the true effect of the H2H
History	Events occurring concurrently with intervention could cause the observed effect	Relevant: Standard care may include other CIs that could influence outcome but this could have occurred across both study groups
Maturation	Naturally occurring changes over time could be confused with a treatment effect	Not relevant: Home death rates have increased over study period but again this trend effected both study groups equally
Regression	When outcome is investigated due to extreme patterns being noticed they often have less extreme subsequent scores and this can be confused with an intervention effect	Not relevant
Attrition	Loss of respondents can produce artifactual effects if this loss correlates with intervention	Not relevant to primary outcome PPD. Relevant to secondary outcomes but accounted for in analysis
Testing	Exposure to a test can affect scores on subsequent exposure to the test	Not relevant to primary outcome
Instrumentation	The nature of a measurement may change over time or conditions	Not relevant to primary outcome
Interactive effects	The impact of an intervention may depend on the level of another intervention	Relevant: The impact of H2H depends on the Community teams willingness to engage and continue to execute the agreed care plan after CC.

Overall, the study design was an appropriate pragmatic approach that has yielded valuable results in an area not previously studied in the NHS health system. The results provide key learning to inform future larger studies conducted in patients at the EoL including a larger study to determine H2H effectiveness based on these preliminary findings. The most relevant limitation of the quasi-experimental study design for the feasibility study was **selection bias**. The AC group in this quasi-experimental study design included participants from two different comparator groups with the aim of reducing selection bias. The main comparator group was recruited from the satellite site at Kingston Hospital where the H2H was not in use. In this group, clinical factors or oncologist preference factors could not influence the uptake of H2H. The majority of AC

participants were recruited from the Kingston site. Alongside this, participants were recruited from the RMFT main site where selection to receive H2H was through oncologist or patient choice. The study design allowed for participants who had been assigned to the comparator group by the oncology team at the main site to request H2H, and therefore self-refer to the intervention group. This was clearly explained in the patient information sheet. None of the main site comparator participants requested this, suggesting that the trial design in this feasibility study was acceptable to participants.

The success criterion for the quasi-experimental design to be considered feasible was that less than 10% of demographic variables were statistically significantly different across the study groups. Twenty-one different baseline demographic and disease variables were compared across the study groups. The groups were broadly comparable with 17 of the variables showing no difference across study groups. 4 (19%) variables were statistically different across the groups therefore the feasibility success criterion was **not met**. Participants in the H2H group were less likely to own their own home, more likely to have an ethnicity other than White British, had a shorter survival and higher symptom distress scores at baseline. The differences in these factors are likely to have influenced the size of any potential benefit seen from H2H in both the primary and secondary outcomes tested. Studies have shown that these factors independently decrease the likelihood of a home death [28]. As most participants chose home as their PPD, any benefit of H2H on this outcome is likely to have been underestimated in this feasibility study. It is also known that symptom burden and service use increase [112] whilst QoL decreases [247] as death approaches. Therefore, the discrepancy in survival across the study groups may have influenced the secondary outcome results in this study. This was accounted for in the analysis by comparing changes in symptom and QoL scores from baseline to week 1 for participants with data at both time points rather than comparing absolute values at each given time point. The service use data were presented by study group and survival group. This allowed more meaningful comparisons across the groups to be made, and is an effective strategy in analysis that should be used in the larger trial.

A further limitation of this feasibility study is that only patients who could speak and understand English and who had a Lung or GI cancer diagnosis were included in the study. Therefore, assumptions regarding the potential feasibility of H2H in other cancer

diagnoses and non-English speaking patients cannot be made. Complexity was also not quantified for participants in each study group. The qualitative interviews with oncologists revealed that they were more likely to use H2H if they judged the patient or family to have increased physical or psychosocial complexity. It is possible that this variable may have contributed to unknown selection bias across the groups.

A quasi-experimental comparator study design was acceptable for this feasibility study but I would not recommend such an approach in a larger definitive trial. The appropriate study design to limit selection bias would be an RCT in a different cancer centre where H2H has not been used. An alternative to a standard RCT that would have the additional benefit of minimising contamination would be a Cluster RCT.

Recruitment rates and retention in study

One hundred and eighty four patients were invited to participate in the study; 83 were successfully recruited (45%). The success criteria of >20% recruitment rate in each study group **was met**. Fifty-five percent declined to participate, this refusal rate was similar to a previous study of a CC intervention in palliative care patients in Australia[237], in which 53% of the patients approached declined to participate. In this feasibility study, recruitment rates overall were considerably higher than Mitchell et al's study of CCs in palliative care (26.8%)[127]. In comparison with the wider research in patients with advanced cancer recruitment rates in this feasibility study are similar [248]. A recent RCT evaluating H2H in patients with interstitial lung disease (ILD) reported recruitment rates of 65%. This is higher than reported here; however, two factors may have contributed to this difference. Firstly, the majority of patients in the H2H ILD study were not known to CPCT services, and it was not standard clinical practice to refer to CPCT; this was arranged once participants agreed to enrolment in the study. In the feasibility study, standard practice was to refer cancer patients to their local CPCTs. The majority were already known to these services at the time of discharge from oncology. All remaining patients were referred at discharge by the clinical team irrespective of enrolment in the feasibility study. Therefore, the added benefit of referral to CPCT in the H2H ILD study may have encouraged comparatively higher recruitment rates. Secondly, participants in the H2H ILD study had a longer survival than this study group, with only 11% dying during the follow up period. This suggests the ILD group may have been in better health when approached to participate in the

study. Indeed, a high proportion of patients who declined to participate in this feasibility study reported they were 'too unwell', with a number of them requesting I call them back at a later date. However, these participants subsequently deteriorated and either felt more unwell, had been admitted to hospital/hospice or had died on my second contact. Interestingly, recruitment rates were higher at the satellite site (SS) (59.7%) than at the main site (35.7%), suggesting that SS patients were more willing to participate. Two issues may have influenced their decision to participate. Firstly, the SS comparator group had a longer survival and therefore may have been more physically willing and able. Secondly, it has been shown that patients with advanced cancer, once active treatment has ended, find research contact over time a positive experience[188]. The H2H group had follow-up planned through the intervention; the comparator group did not. Thus the comparator group may have been more willing to agree to the research study as a way of maintaining a form of contact with the cancer centre. Indeed it must be mentioned here that the importance of familiarity and trust, alongside the strong theme of 'attachment' to the cancer centre described in the qualitative interviews may have had a positive influence on recruitment rates in both study groups because agreeing to participate in this research study meant that although the patient had been discharged from clinical care and oncology follow up, the link with the cancer centre was still maintained. Fifty-five of the 83 study patients (66%) identified a carer to approach regarding recruitment to the study. Of those approached, 78% were successfully recruited and thus the success criteria for carer recruitment **was met**.

The overall recruitment target of 180 patients over the two-year study period was not reached and therefore the study was extended by one year whilst I was on maternity leave. However, possibly due to the lack of medical palliative care presence in oncology clinics during this extra time, the study still did not reach its recruitment target. In hindsight, recruitment of 180 patients over two years was optimistic at a single study site with one main researcher. This feasibility study had a recruitment rate of 45%, suggesting a screen to recruit ratio of approximately 2:1 should be expected in a larger definitive trial. The data here also suggests a monthly recruitment rate of 2-3 patient participants per month across two study sites. The calculated sample size calculation for a larger definitive RCT using PPD as the primary outcome and assuming 5% significance, 80% power with effect size of 20.1% (PPD achieved H2H 68.8%-AC 47.8%) is 95 participants per group. To account for missing data (PPD not known 13/83

(15.7%)) and drop-outs (withdrawal from study 2/83 (2.4%), and still alive at end of follow up 3/83 (3.6%)) the recruitment target per group would need to be increased to 121 participants per group. The 2:1 (45%) screen to recruitment ratio found in this feasibility study suggests at least 538 potential patient participants would need to be approached to successfully recruit 242 overall. The monthly recruitment rates 3/month suggest a single site RCT would take over 6 years to recruit, and therefore the study would need to be multi-centred.

PPD as an outcome measure

The primary outcome of effect tested in this feasibility study was achievement of PPD (PPD). This outcome measure necessitates two pieces of data to be complete: documented PPD and PoD. The success criterion for using this outcome measure was that 70% of study participants would have a PPD documented by the end of the study period. Numerous studies [95, 97, 237, 249] have found PPD is not always known by SPCTs or GPs, either because it was not asked or the patients do not always want to discuss PPD. Therefore, at the planning stage of this feasibility study, the project advisory group had concerns that the frequency of documenting PPD in clinical practice in the comparator group may be low. However, it was decided not to ask about PPD in the research assessments in case this action affected the outcomes of the study. There was a possibility that if PPD was asked in the research assessment, this would encourage the patient participant to discuss these preferences with their community teams which may have diluted any potential benefit of H2H. It also felt unethical to be aware of a patient's PPD as part of a research study and not inform the clinical team caring for the patient. Although over the total study population 83% had a documented PPD, and thus the success criterion for using this outcome measure was **met**, the concern that PPD documentation would be low in the comparator group was found to be true with PPD missing for 26%. The concern about missing PPD has also been highlighted in the literature. The use of PPD as an outcome is supported by De Roo et al[75]. They considered both home death rates and PPD achievement as quality indicators in EoLC and concluded that PPD offers a broader view of care than examining home death rates alone. However, it was acknowledged that GPs were frequently not aware of patient preferences (39% were not known). Thus it is a more difficult measure to collect in comparison to actual place of death, which was almost always known. De

Roo et al conclude that PPD should still be used but the information is also sought from bereaved relatives to minimize missing data. This feasibility study supports this with the results showing that an additional 11.5% of documented PPD was ascertained after death from bereaved relatives. The strategy of consulting multiple sources for PPD was a pragmatic one in this study however if PPD is to be used an outcome measure in a definitive trial overall levels of missing of 17% are too high and therefore the multiple data source method used here is not sufficient. In the statistical analysis missing PPD was dealt with by substituting missing values for a PPD of home. However, this feasibility study has highlighted the emphasis on home as first choice PPD was different across the study groups (H2H PPD home 74.2%, AC PPD home 56.8%). A substantial proportion of patients choose hospice as their PPD. The proportion of which was higher in the comparator group with 32% choosing hospice as their PPD. This makes the validity of substituting missing values of PPD for a value of home a questionable approach, and one that would have preferentially bias H2H. A definitive trial therefore cannot rely on multiple data sources for PPD or substituting missing values of PPD for 'home'. The study must be designed to incorporate a standardised question on PPD in the repeated research assessment tools, and this question should include a preference for 'no preferred location' as some patients even on direct questioning will not have a preferred option. This research has highlighted the difference between preference and informed choice in EoLC. The two are not the same. I suggest that preference for PoD enquires about *'in a ideal world, if all resources were available, where would you like to die?'* whereas informed choice of PoD enquires about *'given your current circumstances, and the likelihood of deterioration in the future, where would you like to die?'* A patient may give different answers to these questions. PPD and informed choice PoD are different outcome measures. A larger definitive trial should seek to explore the importance of this distinction to patients and carers and collect data on both of these outcome measures. This feasibility study also revealed a relatively high proportion of hospital deaths in the H2H group (28%) however whether this was an acceptable location for participants is not known. A definitive trial should include a question on unacceptable place of death to determine the proportion of patients dying in an inappropriate location. The combined outcomes of PPD, informed choice PoD and unacceptable PoD would be more informative regarding the success of any CI at the EoL including H2H, than either outcome measure alone or solely collecting data on actual PoD.

Achievement of PPD has been cited as a quality marker of EoLC[3]. Objective 7 aimed to evaluate if this is a feasible assumption. To do this, summary statistics of QoL over time were compared for participants who achieved their PPD and those who did not. The summary statistic used was Time-adjusted Area Under the Curve TMQOL. The results showed that QoL over time in patients who achieved their PPD was only marginally better than those who did not achieve their PPD (Median TMQOL PPD achieved 7.56, not achieved 7.33). This small feasibility study was not powered to detect a difference in QoL between participants who achieve their PPD and those who do not. However, this exploratory analysis does not suggest that achievement of PPD is necessarily an appropriate proxy for QoL in patients approaching the EoL. However, in the feasibility study and inpatient bereavement work, the satisfaction scores of bereaved relatives of patients who achieved their PPD were higher than those in whom the patient did not achieve their PPD. For example, the feasibility study (FAMCARE median (range): PPD achieved 82 (47-94), PPD not achieved 74 (62-83)). This potential association warrants further study.

Data collection, Follow up and missing data

Attrition is defined as the loss of patients from the study. The MORE care statement[139] recommends classifying attrition into three groups: Attrition due to death (ADD), Attrition due to illness (ADI) and Attrition at random (ARR). Common cited causes of attrition in EoL and palliative care research are attrition due to death (ADD) and attrition due to illness (ADI). The primary outcome of effect for this feasibility study was achievement of PPD. Therefore ADD and ADI did not affect data collection for this outcome. However, these causes of attrition did affect the longitudinal secondary outcome data collected. The data collection method applied in this study was an initial face-to-face assessment in the location of the participant's choice, which was always home or nursing home. This was followed by further assessments over the telephone. This regular contact, as opposed to receiving the questionnaire by post, allowed me to develop a rapport with the patients and carers. This may be the reason for the low withdrawal rate from this study 2.4% (2/83). Two participants withdrew between the baseline and week 1 assessment. The reason for withdrawal in both cases was time constraints. This withdrawal rate is considerably lower than other EoLC studies[127]. The low withdrawal rate reflects the detailed explanation of the study at

the consent stage. It also suggests the study schedule and data collection method chosen were not too burdensome or distressing for participants, and that continuity with the same researcher at each contact appears to be an effective method to minimise study withdrawal. Another contributing factor to the low withdrawal rate may have been that this study was conducted at a tertiary referral cancer centre with an active research ethos. Patients were likely to have participated in oncology trials before being approached for this study and this familiarity with research may have made them less likely to withdraw from the study. After the first visit and completion of assessment tools, I asked all participants how they had found answering the validated questionnaires and also if they would be willing to answer them again in a week's time as per the study schedule. Some participants acknowledged that answering the MQOL assessment tool had 'made them think about life' but none reported finding the assessment distressing and all agreed for me to contact them the following week to complete the same assessment as per the study schedule.

The success criterion for conducting longitudinal data collection was that over 50% of participants would complete at least two time point assessments. 56% of the study population completed 2 or more time point assessments and therefore this criterion **was met**. The most common cause of attrition from the longitudinal data collection in this feasibility study was ADD. At Week 1, ADD for the total study population was 5 participants (6%): 3 participants from the H2H group and 2 from the AC group. By 4 weeks, ADD was 30%. At 12 weeks, ADD was 55% (46 participants): 23 (74%) from the H2H group and 23 (45%) in the AC group. Only one participant chose, on telephone contact, not to complete questionnaires. However, when asked if he wanted to withdraw from the study, he was clear that he still wanted to participate with regular telephone contact. Despite not answering the symptom and QoL assessments, he continued to provide service use data every two weeks. ADI after baseline was high across all time points with 16% ADI at week 1, 30% at 4 weeks and 25% at 12 weeks. Therefore, the criterion of 80% questionnaire completion for participants still alive at each time point was **not met** after week 1. H2H participants dropped out due to illness or death at earlier time points than the AC group. These high ADI and ADD rates ranging from 22% at week 1 to 80% by week 12 are comparable to previous palliative care studies with dropout rates of up to 59% in longitudinal studies conducted over 2 or more months[237]. ADI was significant in this study and was exacerbated by the

decision not to collect data from participants who were no longer at home (i.e. admitted to hospice or hospital). This decision was taken to limit burden and distress from research involvement; however, it may have been that some participants were willing to continue completing telephone assessments as inpatients. The practicalities of this should be considered in a future study, and the patient offered a choice of whether to discontinue assessments if admitted to a hospital or hospice.

Although after the initial visit each subsequent assessment was completed over the telephone the symptom control and QoL tools used were designed and validated for self-completion; however, previous published work had used nurses to complete the tools with the patient[145]. It is difficult to know whether this method of data collection had any impact on the item responses but the benefits of this approach were clear.

Firstly, the number of missing individual items for each questionnaire was very low (1%), as the researcher could ensure all questions were answered. Secondly, the same researcher completed all contacts with an individual patient and carer, allowing a rapport to be established between patient and researcher. The PPS was difficult to accurately assess over the telephone. In a future study, if resources allow, it may be beneficial for the researcher to visit the patient's home and complete all follow up assessments face-to-face. This was not possible in this study as I was the sole person collecting assessment data (with the exception of during my maternity leave, when a single research nurse continued the study). All follow up assessments stopped at 12 weeks. It would have been more valuable to include monthly or two-monthly assessments thereafter up until death or end of study. This would have allowed an assessment of symptoms and QoL backwards from death. Similarly, the small bereavement component of this work was limited to contacting participating carers of patients who died during the 12 week follow up period. The retention rate for the bereavement assessment was encouraging at 68%. This shows carer participants are willing to continue longitudinal research into bereavement once a regular contact and a rapport has been established. If data collection had continued monthly after 12 weeks until death it would have been appropriate to contact all carer participants in bereavement as there would not have been a long time period without contact.

Moreover, when carers were contacted close after death at a routine service use data collection point, as described below, a number were willing to provide the researcher with data for the study therefore waiting 3 months after death before completion of the bereavement component may not be necessary. The bereavement contact could be

sooner and this would enable the collection of symptom control and QoL data as well as the carer satisfaction data collected in this feasibility study.

When the whole questionnaire was not missing due to attrition, the assessment was completed over the telephone with participants. This strategy had been used in previous palliative care research and had been found to be effective at reducing missing items[145]. In this study individual missing data items were low (less than 1 %). Missing data is the absence of part of the participants' data[250]. It can be classified into three subtypes: missing at random (MAR), missing completely at random (MCAR) and missing not at random (MNAR)[251]. In this feasibility study, across all assessments, data were missing not at random. I observed patterns of common questions not answered on each of the assessment tools. The questions in the MSAS-SF and the CQOLC most likely to be unanswered related to sexual activity and interest. This question was missing from three patient and fifteen carer baseline assessments. The patients and carers did not seem distressed by the question but did often comment that this was 'not relevant' anymore. However, neither tool allowed the answer 'not applicable' and therefore it appeared as a missing item. The patient questionnaire had 50 individual items and the carer questionnaire had 85 items. The telephone contacts to complete these assessments lasted between 20-30 minutes. Participants did not appear to find this burdensome and it was not uncommon for them to continue informal discussions with me after the assessment had been completed. This indicates that the assessment had not been too tiring or distressing for the participant. Only one carer at one contact asked to prematurely end the assessment; on one other occasion I stopped a patient initial assessment as I felt the patient was too fatigued to continue. At Week 1, the number of items answered by the patient participant increased to 74, and for the carer increased to 113 items. This was due to the addition of the FAMCARE satisfaction questionnaire and an 8-item questionnaire about the CC intervention. The missing data suggests that this may have made the assessment at Week 1 too long for some patient participants. The FAMCARE tool had the most missing data of all the assessment tools. These data were MNAR with either the whole questionnaire missing when other questionnaires at that time point had been completed (n=3), or the end of the questionnaire was missing (n=5). In those where the whole FAMCARE questionnaire was missing, I ended the assessment early due to patient fatigue. The collection of satisfaction data as an outcome measure is important. Therefore, careful consideration

is needed in the design, length and order of questions in patient and carer questionnaires in any future study. It may be that changing the order of the questionnaires in the assessment would have been sufficient in minimising this missing data from fatigue because participants would have been answering a familiar questionnaire (completed at initial assessment) last and this may have been more acceptable. However, this feasibility work suggests acceptable maximum questionnaire length is approximately 50 items for patients, 85 for carers. Therefore, it may be that a future study uses a combined symptom and QoL outcome measure, such as the Palliative Care Outcome Scale[252], with a smaller number of items assessing similar domains as the MSAS-SF and the MQOL. POS was not used in this study because the outcome measures were chosen to allow comparisons with the previous CC studies. However, it has since been used in the feasibility study of H2H in ILD patients[150], proving to be feasible and acceptable.

The service use data were collected through a telephone contact to the patient or carer participant every 2 weeks. This was normally a short telephone consultation. ADI and ADD were the most common causes of attrition from the service use data collection leading to important limitations to the data collected. Firstly, service use was only collected from the patient or carer; no attempt was made to collect data from HCPs directly or the information systems holding this data. Participants were contacted frequently (every two weeks) to record service use, in an attempt to minimise recall bias and limit the number of 'forgotten' visits. The approach of collecting data directly from the patient or carer has been extensively used in other areas of health care such as psychiatry[253]. However, in the study of EoLC patients, this method has more difficulties associated with it. There may be more missing data from 'behind the scenes' work of HCPs, recall bias, and from ADI /ADD preventing the collection of service use in the final days of life. Collation of data from HCP records and information systems is likely to be more accurate and thus yield higher costs. H2Hspanned many PCTs and service providers across London and South East England; therefore, with no central recording of such data, data collection from health information systems was not possible in this small feasibility study. Another limitation is that the data presented here omits an important area of care: the informal carer costs. The collection of this data would have given a more accurate picture of overall total care costs at the EoL.

All these issues with the service use data highlight that the results in this study are most likely an underestimation of true service use and costs. However, data on service use and cost at the EoL is sparse, therefore, this part of the study, including the lessons learnt, is of great value. Interestingly both patient and carer participants were willing to continue the 2 weekly contacts to collect service use data despite ADI from the symptom and QoL questionnaires. As the study recruited it appeared to me that this two weekly contact was particularly important to the carer. Therefore, I decided to contact carer participants as arranged on the previous telephone contact, even if I knew the patient had died between the two contacts. I felt this was the most ethical and respectful approach, as the carer may have been expecting my call. This contact also gave me an opportunity to collect final service use data, PoD and importantly to thank the carer and their deceased loved one for their participation in the research study. Although this telephone contact was sometimes difficult and took time, it seemed to give the carer and myself some closure and I would advocate this approach in a future study. A larger definitive trial should consider employing bereavement collection of service use data from carers shortly after death to minimise missing data.

The use of Proxy assessments

Proxy assessments are reports by someone other than the patient[128]. There are benefits involved in proxy reports; however, the research evidence regarding the accuracy of the proxy rating is conflicting. The longitudinal secondary outcome data from patients in this feasibility study had high attrition rates due to death (ADD) and illness (ADI). Previous research has recruited proxy carers to provide assessments of the patient symptom burden and QoL [254]at the EoL. However, in most of the published studies, survival from recruitment was longer than the population studied here. Given the short survival of H2H recipients in the retrospective service evaluation (Chapter 3), a high ADI of secondary outcome data was anticipated in this feasibility study. Consequently, to mitigate for missing data due to ADI in a future trial, an aim of the feasibility study was to evaluate the informal carer's accuracy at estimating the patient's symptom burden and QoL. If this feasibility study showed agreement between patient and informal carer responses, the informal carer responses could be used as a substitute for missing patient scores at the time of ADI. This would minimise missing data due to illness. The results from both the individual matched longitudinal vitagrams and the Bland-Altman agreement plots support the use of carer responses as a proxy for

patient symptom burden and QoL. The Total MSAS Score showed the highest agreement between patient and carer responses. Sixty percent of individual plots were in the 'matched' category and there was a small mean difference (0.13) and narrow limits of agreement on agreement plots (-0.9-+0.64).

Previous work has shown that carers are more accurate at estimating physical symptom burden than psychological symptom burden[255], and this may be the reason the Total MSAS score has a smaller range of limits of agreement than MSAS-GDI or TMQOL. The MSAS-GDI and Total MQOL have a number of psychological questions contributing to the overall score. Previous studies have shown that, compared to self-reports, spouses or partners overestimate the severity of some symptoms [256]. This was seen for some individual symptoms on the MSAS-SF tool; however, the Total MSAS scores from patients and informal carers were almost identical (-0.13). Carers in this study did score patient QoL lower than the patient participant. Carer participants had more individual missing items on MSAS-SF and MQOL than patient participants, often commenting that certain questions were very difficult to answer. This resulted in more missing total scores in the carer group. Overall in the literature, patients and carers agree about more overt symptoms, such as mobility and appetite, but there is less agreement around more subjective symptoms including feelings and thoughts[257]. This study has examined the validity of carer proxy responses very close to death and draws the same conclusions, with carer proxy reports in this study less accurate for the psychological domains of the MSAS-SF tool. However, across all three scores, carer responses in this study provide reasonable agreement with patient responses.

The EAPC [128] suggests that, ideally, measures that have evidence to show the comparability between patient and proxy reports are best. This is because it then enables the research team to collect the outcome measurements with patient and families throughout the whole course of the illness up until death[128]. This study shows that MSAS-SF has comparability between patient and carer responses. However, the recommendation to use carer proxy responses in a larger evaluation trial requires the attrition of the carer during the study to be minimal. The results from this feasibility study show that, with the exception of the Week 1 time point, carer attrition matches patient attrition at the EoL. At the time the patient was too unwell to participate in the telephone questionnaire, the carer was also not willing to continue. Therefore, although this feasibility study shows agreement between patient and carer responses, the

parallel between patient and carer attrition makes the benefits of collecting proxy responses as a substitute for missing data minimal and questionable.

6.4.4 Overall Feasibility outcomes

For the purpose of this work, feasibility was judged using Shanyide et al's criteria check list[181]. The table below summarises these issues in relation to the feasibility study.

Table 6.2 Shanyide feasibility study checklist and the feasibility study

Criteria	Addressed by the H2H study	Quan/Qual	Comments
Sample size	Yes	Quan	RCT 121 participants per group
Eligibility	Yes	Quan	Eligibility criteria was appropriate although suggests it may be useful to include an upper prognosis limit or a prognosis range (2 weeks -6months)
Recruitment	Yes	Quan	Recruitment rates of 2-3/month
Consent	Yes	Quan	Consent rates of 45% show study schedule was acceptable.
Randomisation procedures	No		Not assessed
Blinding procedures	No		Not assessed
Compliance/adherence to intervention	Yes	Quan/Qual	Participants, H2H SS and CHCP were compliant with H2H and for the majority it was delivered as intended
Acceptability of intervention	Yes	QUAL/Quan	Qualitative work showed the H2H was acceptable to patients
Cost and duration of intervention	Yes	Quan	Preliminary cost data on the cost of the CC and EoLC after CC has been presented
Outcomes	Yes	Quan	PPD assessed as a feasible outcome only alongside other measures. Although there are concerns about missing data. PPD should not be collected in isolation
Selection of most appropriate outcomes	Yes	Quan	
Retention	Yes	Quan	Low withdrawal rates through choice show retention of patients in a longitudinal study evaluating a CI up until death was possible
Logistics of a multicentre trial	No		Not assessed
How all components work together	Yes	Quan/Qual	Qualitative interviews have shown benefits of each element of H2H

More specific feasibility outcomes and whether these were met for the H2H study are given in the table below.

Table 6.3 Specific feasibility outcomes for the feasibility study

Feasibility Objectives	Success Criteria	Criterion met/not met
Recruitment	> 20% of recruited pool - Each study site recruits >20% of eligible patients/carers - The target of 180 patient participants met in time available >70% of eligible informal carers recruited	MET MET NOT MET MET
Eligibility criteria	To study EoL, >60/70% die during the 3 month assessment period	NOT MET
Study design- choice of control group	<10% of demographic variables are statistically significant across study groups	NOT MET
Retention of participants	<10 % withdrawal from the study by choice	MET
Intervention acceptability	- Positive response from patients and HCPs in qualitative interview - Delivery: >80% of CC last 30-60 minutes > 70/80% of CC delivered within 3 working days of discharge if inpatient, 5 working days if outpatient > 80% of invited HCPs attend the CC	MET MET MET MET
Feasibility and acceptability of the primary outcome piloted	> 70% of PPD documented (rather than substituted in analysis)	MET
Feasibility and acceptability of the secondary outcomes piloted	> 80% of data complete at each time point. Unknown values (blank or participant refusal) are considered missing.	T0 & T1 MET T2 & T3 NOT MET
Feasibility and acceptability of collecting longitudinal data in this study setting	> 50% of participants complete 2 or more assessments (ref 2)	MET
Feasibility of using the informal carer as a proxy response for patient data	Agreement of patient and carer MSAS and MQOL scores on Bland-Altman plots	MET
Feasibility of assuming/using PPD as a proxy for QOL at the EoL	Statistically significant difference in QOL score between participants who achieve their PPD and those who do not.	NOT MET

Overall, the results show the intervention and study schedule to be largely feasible and acceptable. This feasibility study has not assessed the acceptability of randomisation in this patient group.

6.5 Discussion of research with respect AIM 3: To explore potential benefits of H2H compared to standard care in a cancer population

In this section the exploratory analysis for the primary and secondary outcomes of effect tested in this feasibility study are presented. The feasibility study was not statistically powered to provide definitive results, thus the purpose of this section is to present possible emerging trends and potential benefits of H2H to inform the development of a larger evaluation trial.

The primary outcome of effect tested in this feasibility study was the proportion of participants dying in their PPD. The hypothesis was that, through shared care planning across health care sectors, H2H would increase the likelihood of cancer patients dying in their preferred place compared to standard discharge care. The results show a higher proportion of H2H participants (97%) had a documented PPD compared to the AC

group (73.9%, $p=0.02$). The k statistic for agreement for PPD and actual PoD was higher in the H2H study group compared to ACs (H2H k 0.53 (0.28-0.77), AC k 0.39 (0.16-0.63)). On unadjusted analysis H2H appears to have a positive effect on PPD with 68.8% of H2H achieving their 1st or 2nd choice PPD compared to 45.7% of the AC group. This positive effect was sustained when substituting all unknown PPDs in each study group for a PPD of home. On multivariate analysis the H2H odds ratio for a home death was 1.12 (reference category: No H2H).

H2H includes an initial holistic assessment prior to discharge. This incorporates explicit questions surrounding preferences for place of care and death. At the CC, this information is shared with the community teams and an individualised care plan agreed. Given evidence that having an expressed preference increases the likelihood of dying in a preferred place [28, 49, 146], it is difficult to know whether any effect on achievement of PPD was the result of all the interacting active components in the H2H or due only to the attention paid to eliciting PPD and expressing these wishes in the CC. There is also a possibility that H2H may 'activate' community services, including CPCTs, in a more proactive way than standard discharge and this could influence outcomes. These promising preliminary findings warrant further investigation in a definitive trial.

The two RCTs that studied CCs in cancer patients [6, 145, 146] did not use achievement of PPD as the primary outcome, although PPD was a secondary outcome. Agar [6] reported secondary analysis showing congruence of 59.4%, k 0.45 for the total population. The feasibility study had comparatively higher results for total population overall congruence of 67.7% with similar kappa values (k 0.46) (Table 6.1). However, results for the CC group alone in the Australian study have not been published, and after contact with the author Abernethy these data are not available, and therefore direct comparisons for the intervention are not possible.

Other studies reporting congruence between PPD and Actual PoD can be broadly split into those evaluating a specific palliative care CI, and retrospective analyses of palliative care services or population data. Table 6.4 summarises the outcomes of the feasibility study compared to the work of Agar et al [6], Gage et al [112] and De Graaf [89]. Gage reported on a quasi-experimental controlled study evaluating a hospice rapid response service in South East England. The population was not exclusively cancer patients, and

the results showed no significant difference between controls and the intervention in proportions achieving PPD. Overall PPD congruence (all locations) in the intervention group was lower than seen in this study (Gage 61.9%, This study 71%). Home PPD congruence was higher in the intervention group in the Gage study compared to the feasibility study (Gage 74.2%, this study 63.2%); however, Hospice PPD congruence was considerably lower (Gage 53.8%, this study 80%). De Graaf[89] reported a retrospective evaluation of a 'hospice assist' service in the Netherlands. No comparator group was included in the analysis; however, participants enrolled in the 'hospice assist' service had high congruence between PPD and actual PoD (86%). They concluded that shared responsibility for proactive care in primary care collaboration enabled patients to express preferences and achieve these preferences. This may be one of the dominant components of effect in H2H. Table 6.5 summarises recent studies in which PPD congruence were reported, most of which were retrospective studies. Overall, PPD congruence was higher in this early feasibility work compared to the majority of recent studies.

Table 6.4 Comparison of results for achievement of PPD with published studies.

PPD (down)	Actual PoD											
	Intervention						Comparator group					
	Home	Hospice	Hospital	Care Home	Total	OC (Kappa) OR (CI)	Home	Hospice	Hospital	Care Home	Total	OC (Kappa)
This Study (n=65) ⁺												
Home	12 (63.2)	1	6	0	19	71% K 0.53 1.19 (0.39-3.6)	11 (52.4)	7	3	0	21	64.7% K 0.39
Hospice	2	8 (80)	0	0	10		1	11 (91.7)	0	0	12	
Hospital	0	0	2 (100)	0	2		0	1	0 (0)	1	1	
Care Home*	0	0	0	0	0		0	0	0	0	0	
Total	14	9	8	0	31		12	19	3	0	34	
Agar et al ^[6] (n=69)												
Home							9 (37.5)	5	10	0	24	59.4% K 0.45
Hospice							2	20 (76.9)	4	0	26	
Hospital							1	2	5 (62.5)	0	8	
Care Home							0	1	3	7 (63.6)	11	
Total							12	28	22	7	69	
Gage et al ^[112] (n=681)												
Home	141 (74.2)	33 (17.3)	14 (7.3)	2 (1.1)	190	61.9% 0.95 (0.79-1.14)	96 (43.0)	79 (35.4)	39 (17.5)	9 (4.0)	223	62.2%
Hospice	14 (26.9)	28 (53.8)	5 (9.6)	5 (9.6)	52		15 (9.7)	117 (75.5)	11 (7.1)	12 (7.7)	155	
Hospital	0	0	0	0	0		1 (25)	2 (50)	1 (25)	0 (0)	4	
Care Home	0	0	0	2 (100)	2		1 (2.1)	1 (2.1)	2 (4.3)	43 (91.5)	47	
Total	155	61	19	9	244		113	199	53	64		
De Graaf et al ^[89] (n=107)												
Home	70 (91)	4 (5)	3 (4)	-	77	86%						
Hospice	2 (9)	21 (91)	0	-	23							
Home/hospice	0	1 (100)	0	-	1							
Unknown	3 (50)	0	3 (50)	-	6							
Total	75	26	6		107							

OC – overall congruence, number of participants dying in met preference location / number of participants with a preference. + intervention was H2H. ^ intervention was a rapid response community PCT. *Care home counted as a home death – as it was participants usual residence.

Table 6.2 The feasibility study congruence between PPD and Actual PoD compared to published literature

Study	Design, n	% PPD Home	Congruence (method A*, n (%))				Kappa statistic (95% CI)
			Overall	Home	Hospice	Hospital	
This study Quasi-experimental longitudinal comparator study 100% cancer	Total population n=65	40/65 (61.5)	44/65 (67.7)	23/40 (57.5)	19/22 (86.4)	2/3 (66.7)	0.46 (0.29-0.63)
	H2H group, n= 31	19/31 (61.3)	22/31 (70.9)	12/19 (63.2)	8/10 (80)	2/2 (100)	0.53 (0.28-0.77)
De Graaf et al (2016) ^[89]	Retrospective cross-sectional study, n=107, 89% cancer patients	77/107 (72)	92/107 (86)	70/77 (91)	21/23 (91)	0	0.76 (0.62-0.91)
Burge et al (2015) ^[111]	Retrospective population based mortality follow back study, n=1316	-	315/606 (52)				0.29
Ko et al (2014) ^[92]	GP mortality follow back study n=2026	695/873 (79.6)	570/780 (73.1)	528/695 (75.9)	42/85 (52.9)	-	0.16 (0.08-0.23)
Brogaard et al (2013) ^[93]	Prospective longitudinal study n=73	33/48 (68.8)	21/48 (43.8)	16/33 (48.5)	5/12 (41.7)	0/2 (0)	0.25 (0.13-0.37)
Ishikawa et al (2013) ^{[33]*}	Retrospective survey of HCP, n=258	123/250 (49.2)	-	93/123 (75.6)	-	-	
Hunt et al (2013) ^{[27]*}	Bereaved relatives survey Cancer component n=407	66.7	57.2	-	-	-	
Oxenham et al (2013) ^[16]	Retrospective audit n=196	83/159 (52)	113/159 (71)	53/83 (63.9)	60/68 (88)	-	0.51 (0.38-0.64)
Jeukar et al (2012)	EPR* retrospective cohort study, n=7391	3153/3561 (88.5)	-	1735/3153 (55)	-	-	
Scholes et al (2012)	3 month audit of patient known to SPT n=708	184/426 (43.2)	349/426 (81.9)	-	-	-	
Smith C et al (2012)	Retrospective EPR review n=1087 records, 207 deaths 53% cancer	82/149 (55)	94/149 (63.1)	56/82 (68)	11/32 (34)	7/10 (70)	0.2 (0.02-0.37)
Meeussen et al (2011)[96]	Retrospective follow-back study, n=422	-	167/219 (76.3)	-	-	-	
Holdsworth et al (2010) ^[97]	Retrospective case note audit n=298	80/131 (61.1)	71/131 (54.2)	42/80 (52.5)	25/29 (86.2)	2/2 (100)	0.35 (0.22-0.47)
Walker et al (2010)	Prospective observation study, n=41	53.7	47.2	-	-	-	

The study population as a whole had a higher proportion of participants dying at home (37.5%) and in a hospice (42.3%) alongside a lower hospital death rate (20.5%) when compared to national cancer figures (ONS)[13]. The results showed H2H had a higher proportion of home deaths (H2H 43.8% compared to 32.6% in AC group). These results are supported by the retrospective analysis showing H2H was independently associated with an increased likelihood of dying at home (OR 1.97 (1.31-2.96), $p < 0.01$). Interestingly, over half (52.2%) of AC participants died in a hospice. This is a considerably larger proportion than H2H (28.1%) and also markedly higher than national statistics for cancer patients in the same year (2011) (16.9%)[13]. This result was not anticipated. Most AC participants were recruited from the Kingston site. Kingston hospital has one main local hospice unit caring for the palliative care patients in that area. Interaction and engagement with palliative care is a complex issue. The hospice supporting Kingston patients had a well-developed community team with access to 28 inpatient beds for the surrounding community of approximately 1 million people[258]. This is less inpatient bed provision than recommended, and therefore access to hospice inpatient beds alone is unlikely to be the explanation for this result. It may be that this hospice unit had a more proactive approach to achieving hospice PPD than other units.

The proportion of patients dying in hospital was lower with H2H (28.1%) than national cancer figures (48%), although there were more hospital deaths with H2H than the comparator (H2H $n=9$, 28.1% AC $n=7$, 15.2%). This finding contradicts the larger retrospective analysis ($n=1467$) that showed H2H was independently associated with a decreased likelihood of a dying in hospital. The reason for these contradictory findings may be the relatively small sample size in the feasibility study and the different cancer populations studied in the two analyses. The feasibility study enrolled only Lung and GI patients. It may be that other factors unaccounted for, such as the complexity (physical and/or psychosocial) of the patient, influenced the result in the feasibility study.

In this study, after adjustment for all other variables, marital status and accommodation type were both independent variables significantly linked to achieving a home death. Participants living in a house were nearly 7 times more likely to die at home than those living in other types of accommodation (OR 6.77, (CI 1.29-35.61). Participants married

or with a partner were eleven times more likely to die at home (OR 11.03, (CI 1.05-115.8), $p=0.05$) than other participants. This association between marital status and home death is consistent with published work [28]. However, this study shows a stronger association than most published studies. Interestingly, in the feasibility study disease stage, extended family support and accommodation type did not have an independent effect on dying at home, although disease factors were linked to dying in a preferred location. This discrepancy in the effect of disease factors on PPD and PoD highlights that there is a difference between achieving a home death and PPD: the two are not the same. In this study, PPD was somewhere other than home for 30% of the H2H group and just over 50% of the AC study group.

The outcomes of H2H were likely to be multiple and therefore the secondary outcomes of effectiveness tested in this study were also multiple in an attempt to capture feasibility data on the outcome measures chosen (See Section 6.4.3 below), capture early data on all possible potential benefits from H2H and to inform the research team about the safety of H2H and the priorities for outcome measures in a future larger trial. The secondary outcome measures tested were patient symptom control, QoL, carer QoL, satisfaction and service use. Previous research studies into a CC intervention in palliative care in Australia used a variety of symptom control, QoL, Carer QoL and service utilisation outcomes[127, 145]. This was the first time the CC intervention was studied in the UK NHS health system and therefore similar outcomes measures were used.

The symptom and QoL secondary outcome measure was the change in scores from baseline to week 1. To mitigate for the effects of ADD and ADI, this analysis was performed at the individual patient level. The difference in each score from baseline to week 1 was calculated for each patient and the averages of these differences compared for each group ($n=65$). The results show a reduction in all but one MSAS score from baseline to week 1 with H2H. This indicates a potential improvement in physical symptom distress with H2H. The mean difference was -0.25 (95% CI -0.02--0.48, $p=0.03$) for MSAS-GDI and -0.12 (95% CI -0.29-0.05) for Total MSAS scores. These differences are arguably of limited clinical relevance, with previous work citing a change in MSAS score of 0.59 for MSAS-GDI and 0.45 for TMSAS as clinically

meaningful[259]. However, the patterns show maintenance of symptom control and possible small improvements in symptom burden with H2H that again merit further consideration in a definitive trial.

Change in QoL scores from baseline to Week 1 show the mean difference in the change in Total MQOL score was +0.31 (95% CI -0.25-+0.87). This preliminary result suggests H2H may have a possible beneficial effect on QoL. Previous studies in palliative care have considered an effect size of one standard deviation from the mean of the control group to be clinically important [127, 260]. In this study, this equates to a change in Total MQOL of +/-1.37; other studies have suggested a change in score of +/- 1 is clinically relevant. Therefore, the clinical relevance of the change seen in this feasibility study is questionable. However, the fact that no reduction in QoL scores was seen in the H2H group is encouraging, and should be explored further.

Studies of cancer patients that include the last month of life are limited [261]. However, the available evidence has shown that QoL diminishes as death approaches [262]. This pattern was seen in the AC group but was absent in the H2H group. In the AC group, all MSAS subscale scores, except the physical symptom subscale, increased from baseline to Week 1. This indicated more symptom distress, and all MQOL subscales (except the physical symptom subscale) decreased indicating deteriorating QoL from baseline to Week 1. In the H2H group, some subscales improved whilst others remained the same. It appears that H2H may enable QoL and symptom burden to be maintained from baseline to Week 1 with these preliminary findings also showing small improvements. In EoLC, an intervention that maintains symptom control and QoL is clinically meaningful and importantly these preliminary results show no evidence of patient harm resulting from H2H in this feasibility study. Thus, these results are encouraging and warrant further study in a larger evaluation trial.

The small positive changes in MSAS and MQOL scores in the H2H group in this cross-sectional analysis were supported by the results of the longitudinal analysis of MSAS and MQOL scores from baseline to week 12. The descriptive results from the longitudinal plots show H2H mean MSAS scores (Total and GDI) decrease over time whilst the AC group scores increase from baseline to week 12. The H2H mean Total MQOL scores increase from baseline (7.22) to week 12 (8.18), whereas the AC group

scores show no change over time (AC baseline 7.72, Week 12 7.73). The descriptive analysis of the individual vitagrams supports these overall trends on an individual patient level. A lower proportion (9.5%) of the H2H group MSAS-GDI scores showed increasing symptom scores over the 12 weeks compared to the AC group (30.6%). A higher proportion of the H2H group Total MQOL scores showed an increasing QoL trajectory over the 12 weeks compared to the AC group (H2H 17.6%, AC 5.1%). In parallel, a higher proportion (38.5%) of AC participants Total MQOL trajectories show a decreasing QoL trajectory over time compared to the H2H group (17.6%). The results of both the MSAS and MQOL assessments show positive, albeit small, effect changes on physical symptom burden and QoL longitudinally with H2H that need to be retested in a fully powered study.

The results of this study differ from Abernethy et al[237], who reported the CC intervention had no impact on average total daily symptom distress (using a summation of individual item MSAS-SF scores) compared to standard care. The two Australian studies found conflicting results for the impact of CCs on patient QoL. Abernethy[237] reported no measurable increase in patient QoL, with average daily Total MQOL scores of 5.87 in the CC group and 5.81 in the control group. These total MQOL scores are lower than our study findings. Mitchell et al[148] found no change in global QoL scores, but QoL scores at fixed time points prior to death (14 days and 35 days) were significantly better in the domains of physical and mental wellbeing in the CC intervention group. The author concluded that as patients become more ill, the impact of CCs increases through effective care plans that are enacted when rapid deterioration inevitably occurs in the last days of life. This was the hypothesis in this feasibility study and may explain the small positive changes in QoL seen in the H2H study group compared to the comparator group. Indeed, the population studied in this feasibility study were closer to death than the participants in the Australian studies. The study inclusion criterion was a prognosis of greater than one month for Mitchell's study, and Abernethy restricted data analysis to participants surviving greater than 60 days. The small improvements seen in this feasibility study therefore support Mitchell's theory that more dependent patients derive greater benefit from the CC[237].

The CQOL-C tool was used to assess carer QoL in this study, with higher scores representing better QoL. Improvements were seen across all CQOL-C domains, except

positive adaptation, from baseline to week 1 with H2H. The AC group showed a mixed picture across the domains with a reduction in scores (indicating worsening QoL) for carer burden and disruption, but improvements in positive adaptation and the total CQOL-C mean scores. The Total CQOL-C score increased by +5.86 from baseline to week 1 with H2H. The results show the CQOL-C burden subscale displayed the greatest difference in scores across study groups. The mean difference in the change in burden scores from baseline to week 1 across the study groups was +6.06 (95% CI -4.15-+16.28, $p=0.23$). A positive change was in favour of the intervention. Therefore, these exploratory results suggest H2H may lead to decreased carer burden over time compared to standard care. The finding that no additional caregiver burden resulted from H2H is important because a change in focus of care to the community setting may result in more responsibility and burden for the carer in the day to day care of the patient. There is a concern that this may place undue stress on informal carers causing harm. H2H includes a discussion in the presence of the patient and the carer regarding who will be responsible for different elements of the patient's care moving forward. This includes giving the patient and carer the correct telephone numbers for the different services and guidance on which ones to use and when. The qualitative interviews with patients voiced that this process was 'enlightening' and empowering. Patient participants expressed reassurance for themselves and family members of observing and being part of a positive, coordinated and collaborative interaction where 'everyone was singing from the same hymn sheet'. This reassurance corroborates and may explain the small positive impact on carer burden seen in this feasibility study. These complementary findings support carer QoL as a recommended important outcome for a larger definitive trial where any benefit of H2H can be fully evaluated. Alongside this, qualitative interviews with carers should explore the likely mechanism of any effect seen.

These findings agree with published work. Mitchell et al[148] evaluated a telephone CC between HCPs and reported a positive impact on carers with significant reduction in burden in two domains (impact on schedule and lack of family support). However, a more recent feasibility study of an adapted H2H in Interstitial Lung disease patients[150] using the same assessment tool as this study (CQOL-C) found no difference in carer burden 4 weeks post CC. H2H has many components, one of which is

a shared approach to advanced care planning across health sectors with the patient and family. Other published work evaluating the impact of ACP[263] found similar positive effects on carer QoL compared to standard care.

H2H also appears to have a potential positive effect on patient and carer satisfaction at week 1 (FAMCARE Score Patient H2H median 87.5 (51-100), AC 78.3 (51-100), $p=0.03$, Carer H2H 83 (67-90), AC 77.0 (13-100), $p=0.06$). Individual question responses showed the H2H group had higher satisfaction scores for both patients and carer for 'coordination of care' and 'family conferences held to discuss the patient's illness'. The results show that overall both study groups have high levels of satisfaction with care, with patients reporting higher satisfaction than carers. Zimmermann et al[247] evaluated early palliative interventions in cancer patients and found similar levels of high satisfaction with care compared to the control group. The control group was no palliative care input. The comparator group in this study (AC group) were all referred to CPCT as part of standard discharge processes. This feasibility study suggests that H2H may have a potential benefit of improved patient and carer satisfaction above standard community SPC involvement. The published studies of CC interventions did not evaluate patient or carer satisfaction so results cannot be compared.

In the context of limited resources, the evaluation of any new CI should include service use and cost analysis. This study collected patient level service use data to describe service use in each study group and begin exploratory EoLC cost analysis for H2H compared to standard care. Over the 12-week data collection period, the H2H group had a higher average number of community contacts for all CHCPs except CPCT contacts, which were approximately equal across the study groups. In order to exclusively evaluate EoL service use, a sub analysis including only patients who died in the 12 week follow up period ($n=46$) was conducted. The results show the average number of GP and CPCT visits were less with H2H. In addition, the average CPCT face-to-face visit time was less with H2H (median H2H 60 minutes (0-120), AC 90 minutes (0-330)).

The percentage of time spent in PPC was marginally higher with H2H (median H2H 100% (19-100), AC 94% (10-100)). In this feasibility study, a higher proportion of H2H

participants had no admissions to either hospice or hospital (H2H 60.9%, AC 39.2%), with a lower proportion of hospital admissions in the H2H group (H2H 21.7%, AC 30.4%). The average numbers of inpatient admissions were less and the mean length of admission was 2 days shorter with H2H (number of admissions H2H mean 0.52 (0.73), median 0, AC mean 0.78 (0.80), median 1. Length in days H2H mean 4.57 (6.7), median 0 (0-21), AC mean 6.52 (10.12), median 4 (0-42)). Abernethy[237] found similar results, with the addition of a single CC to usual SPC significantly reducing hospitalisation by approximately 0.5 hospitalisations per patient.

Overall, total EoLC costs were approximately £1000 lower with H2H (median H2H £1603 (79-9114), AC £2631 (0-17914)). The estimated total EoLC cost per death in PPD was also approximately £2000 lower with the H2H (H2H £2458.55, AC £4323.46). The shorter survival of the H2H group and higher proportion of AC participants choosing hospice as their PPD may have had a bearing on these results. These results cannot account for the impact of patient complexity on the cost of care. A recent quasi-experimental study by Gage et al[112] reported on service use and cost for a hospice rapid response service. The method of service use data collection was different: Gage[112] collated service use from the service provider records (rather than directly from the patient). However, costs were calculated in a similar way and, therefore, some cautious comparisons are still possible. The costs of services received per survival group (in days) in this feasibility study show similar trends to Gage et al[112]. Analysis of cost per survival group mitigates for differences in survival between the two study groups. Overall across all survival groups, GP and community nursing costs were higher with the H2H, with the exception of participants surviving more than 60 days after recruitment. CPCT costs were lower with the H2H across all survival groups. Gage found an identical pattern of increased GP and community contact costs and lower hospice contact costs in the intervention group until survival of 60 days or more, where costs in the intervention group increased. One role of the CC is to educate the community professionals about the individual patient's needs in order to enable them to manage these more effectively. The CC also makes plans for current and future palliative care needs. A combination of these two elements of the CC may have enabled the community professionals (GPs and DNs) to confidently manage their patients with less community SPC input.

Gage et al[112] reported higher total service costs in the intervention group in all survival groups except those surviving 15-30 days from study entry, where total costs were on average £1500 less in the intervention group compared to standard care. This feasibility study finds similar preliminary data with higher total service costs with H2H in all survival groups except survival of 31-60 days, where costs were approximately £1000 less with H2H. EoLC is known to account for a large proportion of health care resource [7]. However, there is still limited information available about community service use at the EoL and the associated costs [8]. This feasibility study adds to the limited information available in this area and provides valuable learning about the pitfalls of collecting service use data to inform a larger definitive trial. These are discussed in the next section.

6.6 Discussion of research with respect to AIM 4: To understand the wider EoLC experience

This section considers Aim 4 to understand the wider EoLC experience in this tertiary referral cancer centre. This had led to recommendations for H2H and more general clinical recommendations to improve patient experience at the EoL. The wider EoLC experience was evaluated through a bereavement survey and a retrospective analysis of factors influencing place of death addressing Objectives 20-22

The bereaved relatives' survey included 2 groups of relatives; bereaved relatives from the feasibility study and a parallel cohort of bereaved relatives of patients who died in hospital at RMFT. Congruence was high between patient and carer PPD (94.4%) in the feasibility study. A lower proportion of carers in the inpatient cohort reported discussing PPD with the patient compared to the feasibility study. Where PPD was discussed, congruence between patient and carer preferences was lower (65.8%) for patients who died in hospital compared to the feasibility study (where the majority of participants died at home or in a hospice). Interestingly, a relatively high proportion (42.9%) of inpatient carers expressed hospital as their PPD for the patient. The UK ONS national survey of bereaved relatives conducted in 2015 reported a similar finding[264]. The majority of respondents in the ONS survey reported the patient PPD

as home (81%), with 3% stating hospital. However, 74% of respondents for whom the deceased died in hospital believed it was the right place. This indicates that, although of great importance, PPD may not trump all other considerations for high quality EoLC. It also highlights the importance of not using patient PPD as an isolated outcome measure and suggests carer PPD should be collected in parallel in a larger trial.

The average total FAMCARE score was higher in the inpatient cohort (mean 81.65) than in either group in the bereavement component of the feasibility study (mean 76.9). Of importance is that the individual items concerned with information giving (information about prognosis, information about side effects) had lower satisfaction scores in the inpatient death cohort compared to H2H group.

The Association of Palliative Medicine has conducted yearly service evaluations of hospital, hospice and CPCTs using the FAMCARE satisfaction tool[265]. The FAMCARE tool in the APM service evaluation had been modified to obtain views on the SPCT only rather than satisfaction with overall care. Therefore, the questions were not identical and only cautious comparison between our study and these data are made here. In the APM evaluation, the aspect of care with the highest level of dissatisfaction for hospital deaths was 'the speed in which symptoms were treated'. Our study found 'time required to make a diagnosis', 'information given about prognosis' and 'information about side effects' were the aspects of care where bereaved carers were most dissatisfied. Johnsen et al[266] also found highest levels of dissatisfaction with 'time taken to make a diagnosis' and 'speed at which symptoms were treated'. Hannon[267] studied patients and carers in oncology outpatients and found both groups were least satisfied with information regarding prognosis and pain management; in addition, carers were less satisfied with coordination of care and family inclusion in treatment and care decisions. This suggests information needs are a particular concern throughout the disease trajectory. Total FAMCARE scores were not published for the APM service evaluation and therefore comparisons in scores cannot be made.

Although the numbers in the H2Hf bereavement study were small (n=19), it is important to reflect on why the satisfaction scores were lower than inpatient scores. The qualitative analysis of NOKs perceptions surrounding hospital deaths (Appendix 7.4.6.2) revealed that proactive complex symptom management and access to immediate on-hand nursing care were important influences on NOK satisfaction. The

qualitative interviews with patients and HCPs in the feasibility study highlighted a concern regarding inadequate service provision in the community. If this is the case, this may be linked to decreased satisfaction with community EoLC for bereaved relatives. This association cannot be confirmed by the work in this thesis; however, qualitative interviews with carers during EoLC and in bereavement in the community and hospital setting would be invaluable.

Exploratory analysis of factors influencing carer satisfaction for those who died in hospital showed social and treatment factors had an independent significant impact on bereaved carer satisfaction. Patient and carer preferences were also linked to satisfaction but neither was an independently significant contributor. When the next of kin (NOK) completing the questionnaire was the spouse or partner, they were more satisfied with care than other bereaved relatives. The next of kin of patients who had been living alone were less satisfied with the care received. The treatment factors with a significant impact on satisfaction were treatment intent and number of admission days prior to death. Firstly, not surprisingly, those NOK of patients in whom anticancer treatment was adjuvant or curative at the time of death were less satisfied (mean 74.5) than those in whom treatment was with palliative intent (mean 82.7). This is to be expected because the cancer diagnosis itself was not a life limiting one in the adjuvant group; deaths were most likely related to treatment side effects. However, this result may indicate either late recognition of dying in this group or that the patient and family had unmet needs during the last admission leading up to death. It is likely that all active treatment was rightly pursued for these patients and that during the course of this, other patient and carer needs, such as information needs and psychological support, were not addressed. Secondly, the NOK of patients who had been an inpatient for over 2 weeks prior to their death were also less satisfied (76.4) than those where the patient had a shorter admission prior to death (83.9). This is an important observation. A number of themes from the qualitative analysis of free text comments (Appendix 7.4.6.2) may have had an impact on satisfaction with care after a prolonged admission, including late recognition of dying, confusion over goals of care, over investigation and medicalization at EoL, and possible 'missed' opportunity for discharge to PPD. Blinderman and Billings[268] give guidance on EoL discussion in hospital. These highlight the importance of early conversations, assessing patient and carer information

sharing preferences and enquiring about patient and family concerns. Attention to these areas of care by all hospital physicians may improve satisfaction with care. That said, in a similar study Sadler et al did not find a significant relationship between length of hospital stay and satisfaction[269].

The NOK of patients who died in hospital when it was not the patient's PPD were less satisfied (76.7) than if the patient achieved their preference (89.9) or their preference was unknown (83.1). Similarly, if the patient did not die where the NOK would have wanted, the NOK were less satisfied (77.4) than if hospital was the NOK's PPD for the patient (85.3) or they had no preference at all (83.6). Interestingly, a relatively high proportion (42.9%) of inpatient NOK expressed hospital as their PPD for the patient. Contrary to this, the majority of known preferences for patients were outside of hospital (Home 56.8%, Hospice 24.3%). This suggests there may be some discord between patient and carer preference for those whose final place of care is hospital. Patient and carer PPD were not significant independent determinants of satisfaction; however, a difference of +13.2 when the patient's PPD was hospital, and +7.9 when the carer's PPD was hospital, are clinically relevant. Sadler et al[269] found a significant association between patient PPD achievement and satisfaction with hospital EoLC. The bereaved NOK were 1.7 times more likely to be satisfied if hospital was the patient's PPD.

Improving the experience of patients dying in hospital is imperative. Blinderman and Billings[268] highlight that discussions about goal-setting at the EoL for hospital inpatients are associated with greater congruence with patient wishes. Our data supports this recommendation with individual items relating to information-giving having lower satisfaction scores. Gallagher et al concluded that the ability to provide high quality EoLC depends on many factors, including system issues, lack of focusing on goals of the patient and family, with the complexity of personal, environmental, and relational factors adding to these difficulties [270]. This study also points to the particular attention needed to revisit patient and family understanding of goals of care, especially during a prolonged length of stay, and the importance of eliciting place of care preferences where possible.

The retrospective analysis of factors influencing place of death provides context to the patient population offered the intervention. This objective was met by conducting a retrospective analysis of factors influencing PoD in the tertiary referral cancer population. This enabled factors known from the literature as affecting PoD to be examined in this setting. It also enabled local factors influencing PoD that may impact on the H2H to be explored, as well as determining whether the H2H contributed to PoD independent of any other factors in the wider population.

The results of this analysis highlight some important considerations regarding PoD in this cancer population. Age was the only demographic factor with an independent influence on hospital death; with confidence intervals that include 1, this influence is questionable. It is therefore illness factors (and more specifically treatment factors) and environmental factors that influence PoD. Those patients under regular follow-up and treatments are more likely to die in hospital compared to those patients whose last treatment and follow up were stopped at least a month prior to death. Patients living with someone were 1.5 times more likely to die at home than those living alone.

Interestingly, as PCT spend per death on palliative care increases, the likelihood of a hospital death increases and of a home death decreases. Those patients not known to CPCT were nearly 6 times more likely to die in hospital, whilst those known to CPCT were over 2 times (2.34) more likely to die at home. In addition to CPCT involvement, **those who had H2H were half as likely to die in hospital and twice as likely to die at home.**

These results show that H2H has an independent link to increasing home deaths over and above the contribution from CPCTs. Stopping treatment and tertiary referral follow-up alongside early referral to CPCTs and H2H are important factors in reducing hospital death rates in these cancer patients. Figure 6.1 shows the Gomes et al variation in PoD model[28] adapted for this cancer population. The findings concerning demographic factors influencing PoD reported here parallel with previous research[28, 45]. The finding that CPCT involvement increases the likelihood of a home death also corresponds with the literature evidence[45, 47]. One finding that is contrary to expected is that, as PCT spend per death increases, the likelihood of a home death decreases. This may warrant further consideration and study on a more national level. The finding that the H2H is associated with increased home deaths is encouraging and

provides evidence for the efficacy of the intervention. The findings that those under regular follow up at the cancer centre are more likely to die in hospital suggests more work is needed in recognition of the EoL phase in these cancer patients, and points to a role for H2H and SPCT engagement early in diagnosis and treatment in the outpatient setting. However, although the findings for H2H are positive, in this analysis only 9% of patients known to RMFT who died had H2H involvement. Further modelling of H2H is required to improve the reach of the intervention.

The studies presented here to explore the wider EoLC experience at the cancer centre have several limitations;

The **inpatient bereavement study** was a relatively small study (n=88) in a tertiary referral cancer centre. Therefore results may not be generalisable to the wider cancer population. The response rate was 35.8%. This response rate is comparable to other bereavement work, with the majority of studies reporting response rates of between 21% and 45%[124, 271]. In order to minimise potential harm and distress to potential participants, an 'opt in' approach was adopted for this study. This involved participants returning an 'opt in' reply slip before being sent the postal questionnaire to complete and return. This two-step approach may have reduced the number of successful participants recruited to the study. Since this research was conducted, Hunt et al[124] have compared 'opt in' and 'opt out' methodology for bereavement postal research and found response rates significantly higher in the 'opt out' group, without causing additional harm or distress. The 'opt in' group were significantly more likely to decline to participate ($\chi^2=28.60$, $p\text{-value}<.01$). A national survey in the UK conducted yearly since 2012 has adopted an 'opt out' approach and median response rates vary between 45-54%[265]. Therefore, future work should adopt a similar 'opt out' approach. The study was also limited to next of kin who could read and write English and may not be generalisable to non-English-speaking families. I was only able to contact the families of patients who died as inpatients if the next of kin details, including a full address, were listed on the EPR system at RMFT. This may have implications for the results, as the listed next of kin may not always have been the family member or friend most involved in the patient's care at the EoL.

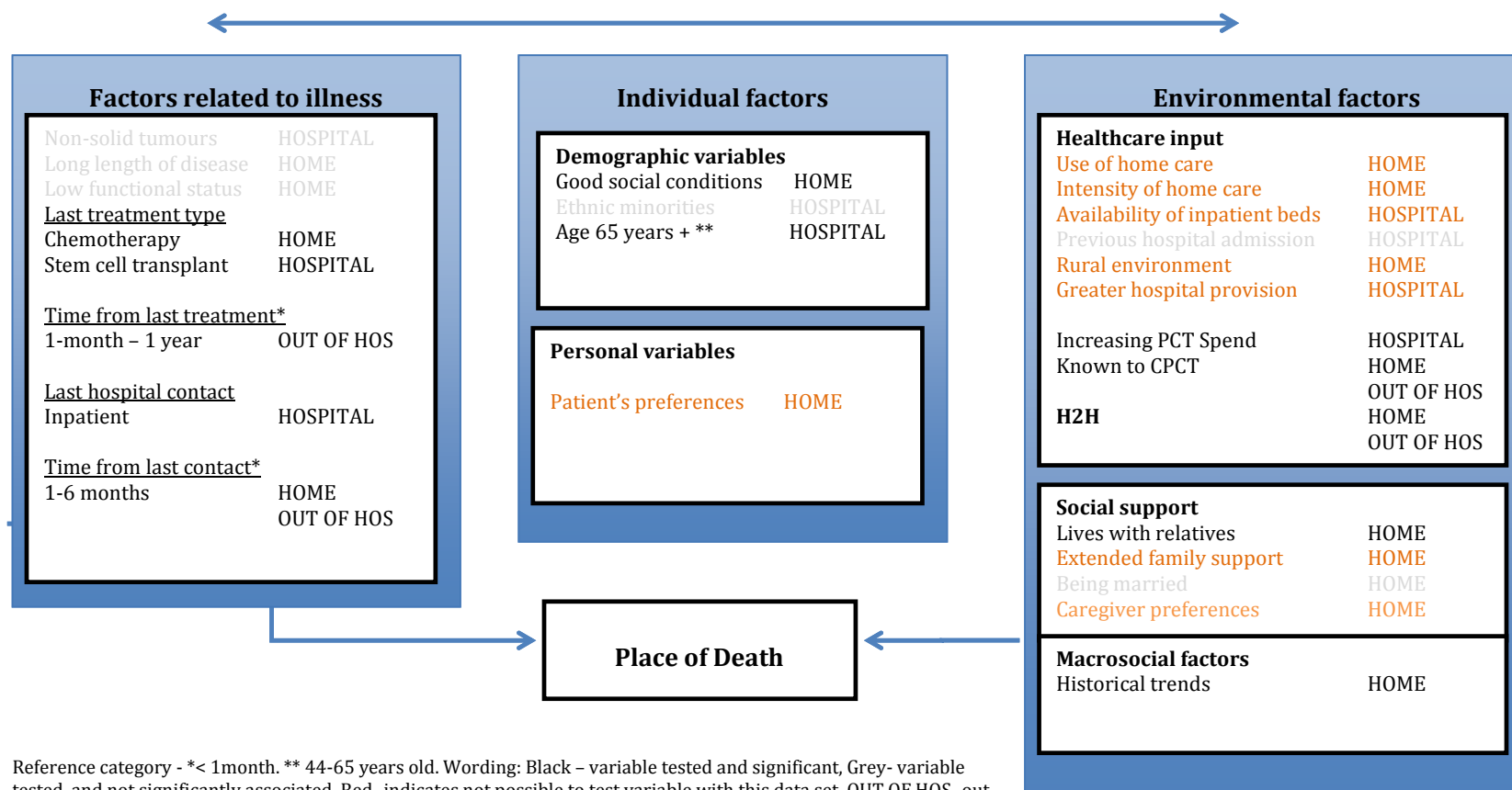
The delay between death and postal questionnaire is a debated topic in bereavement research: contact too early may be distressing for potential participants and too much

time delay between the patient's death and study contact may result in recall bias. These issues were minimised by attempting to send invitations to participate in the study as close to 6 months after the death as possible, in order that the majority of questionnaires were completed and returned by 9 months. However, some questionnaires were returned considerably later than this. Six months between death and bereavement invitation is in line with other research[124].

The dataset used in this **retrospective analysis** was derived directly from the RMFT EPR. The large dataset (n=1,534) and low number of records with an unknown place of death (67/1534, 4.4%) were strengths of this work, although there were some limitations that need to be discussed. Firstly, the original death certification records for each patient were not reviewed. This was therefore a study of factors influencing place of death for patients known to a cancer centre rather than a study of patients who died of cancer. This is a subtle but important difference. Secondly, some important data fields had no standard recording method on the EPR system and therefore could not be extracted directly. This required me to review the complete EPR record and extract these individual data items for each patient. This was time-consuming and labour-intensive as we used two researchers to data check. The data items that required this approach were number of metastases, known to CPCT, known to have a H2H and performance status. CPCT involvement has been shown to increase the likelihood of dying at home[58, 272]. Evidence of involvement with CPCTs was taken from clinic letters. It was either written in the main text of the letter, or the CPCT was copied into the letter. If no such evidence was present in letters up to 6 months prior to the patient's death, it was assumed they were not known to CPCT services. This method may have underestimated the number of participant known to CPCT. Performance status was missing from 85% of patient records (1247/1467) and therefore was excluded from the final factor analysis. Previous studies[28, 45] have shown a link between functional status and home death rates and therefore this is relevant to the validity of the findings. The number of metastases was determined by my review of the most recent imaging report. Number of metastases gives an idea of disease burden for most cancers but not for all. For example, haematological cancers, head and neck cancers and sarcomas do not have to be metastatic to have a high burden of disease. Finally, multiple comorbidities have been linked to an increased likelihood of a hospital death[273]. There was no standard field with which to extract patient comorbidities

from the EPR and therefore this potentially significant factor was not included in this analysis.

Figure 6.2 Adapted Gomes et al[28] model of variations in PoD: Results of analysis at a tertiary referral cancer centre



Reference category - * < 1 month. ** 44-65 years old. Wording: Black – variable tested and significant, Grey- variable tested, and not significantly associated, Red- indicates not possible to test variable with this data set. OUT OF HOS- out of hospital

6.7 Clinical implications and recommendations for modelling of H2H

The retrospective analysis of factors influencing PoD and the inpatient bereavement study enables general recommendations to be made regarding EoLC. The qualitative work enables practical suggestions to changes in the discharge from oncology to best supportive care in order to improve the patient experience at the EoL.

The *retrospective analysis of factors influencing place of death* showed that patients known to CPCTs and who had the H2H were more likely to die out of hospital and at home compared to other patients. Another significant finding was that those patients whose last contact was closer to death were more likely to die in hospital. Two-thirds of patients in this analysis were known to CPCTs. This suggests that, for a one third of patients, the recognition of EoL is late in the illness trajectory. In order to plan for patient preferences, HCPs need time. Therefore, these findings lead me to advocate for early referral and engagement with PCTs in patients receiving palliative chemotherapy. This study is not the first to recommend earlier referral to palliative care. It is a recurring theme in the literature. Zimmermann found early palliative care in lung cancer patients improves outcomes[247]. The integration of early palliative care in lung cancer has been shown to improve patient outcomes, including survival[274], and the Enhanced Supportive Care[275] model is currently being piloted in the UK. Alongside improved symptom and survival outcomes early integration may enable the patient to develop confidence in palliative care services and this may ease the transition to best support care when this time arrives. If referral to palliative care becomes more routine at the start of palliative oncology treatments all patients should then be known to palliative care at the time of their death and this is highly likely to enable more patients to die outside of hospital.

The *inpatient bereavement study* has shown that patients and carers do choose hospital as a preferred location of death and therefore clinicians should strive to improve this experience alongside models aimed at increasing out of hospital deaths. A proportion of patients and families chose the cancer centre as their PPD with corresponding high satisfaction with care. However, bereaved relatives of patients who had been in hospital more than 2 weeks were less satisfied than those with a shorter admission. Preferences about place of care should be elicited, however difficult the conversation: where preferences were known to carers and not achieved, satisfaction with

EoLC was lower than where patients achieved their PPD. Particular attention should also be paid to revisiting patient and family understanding during a prolonged length of stay. The individual item scores of the bereavement study also show carers need more detailed information on prognosis, likely symptoms and side effects of treatment. It is imperative, therefore, that the health care system includes clinicians who have the skills to provide compassionate, high quality care at the EoL regardless of location[269]. The aim to achieve this in hospital should have the same importance as other locations of care requiring investment in hospital palliative care teams and generalist training in communication and EoLC. Qualitative interviews with bereaved relatives would add valuable insight into the preference for hospital death and, for those whose hospital admission leading to death is prolonged, would provide insight into factors impacting on satisfaction with care. This would also allow for clinical guidelines to be created to optimise the quality of EoLC in hospital, based on bereaved relatives' views on the care they encountered.

The ***qualitative results*** presented here support the following recommendations for the transition of care from one setting to another within the UK NHS health system:

1. **Early referral to community services**: Early referral to community services would enable relationships to develop between patient, family and team prior to discharge from the acute sector follow up.
2. **Shared responsibility during active treatment**: Early engagement with GPs sharing responsibility for monitoring and follow up of patients whilst on active treatment. This would ensure patients, families and acute sector health professionals build trust in community services.
3. **Preparation meeting**: A preparation meeting plus information sheet for patient and family members prior to the discharge consultation. This would allow time for reflection prior to the end of regular acute sector follow up. This may enable patient and family concerns to be addressed prior to discharge.
4. **Support line**: A contact within the hospital who supports CHCPS with on-going management issues immediately and for a period of 4 weeks after discharge.
5. **Check in phone call**: Planned check in phone call is booked with the patient. The hospital team makes contact 2-4 weeks after discharge to ensure transition has been successful and there is no unmet need requiring hospital review.
6. **SOS period/appointment**: The patient is not fully discharged from the acute sector follow up but held on a 'wait to hear' caseload, whereby if necessary they can be reviewed again in clinic without re-referral.

7. Split post roles. Some specialities may work better with split roles in both the acute sector and community to provide continuity and support to patients, families and other CHCPSs. However, this recommendation is unlikely to work in a specialist cancer centre due to the large catchment area for the centre.

Synthesis of the quantitative and qualitative data regarding the feasibility of H2H has led me to the following recommendations for the further modelling and development of H2H:

1. Stratification of H2H based on patient need and Increased use of the Telephone CC: The FIPD analysis shows H2H is independently associated with increased home deaths and decreased hospital deaths. However, it also shows only 9% of patients known to RMFT who died had a H2H intervention. Stratification of patients referred to H2H based on need and complexity, and then increased use of the telephone CC in patients with less complex care needs could improve the reach of the service. One way to do this would be with the use of the OACC suite of outcome measures[276].
2. Preparation information: Information about the H2H could routinely be given to all patients at their first visit attending the specialist centre for palliative treatment. This would enable the service to be reintroduced at an appropriate time in the patient's disease journey and more information to be offered as appropriate.
3. Earlier involvement of the H2H team in preparation meeting: Involvement of the H2H team prior to the last consultation at the specialist centre. This would enable the patient and family to gain trust in the team and the service provided.
4. Involvement of cancer specific CNSs: Delivery of the H2H through cancer specific CNSs who have previously met the patient, rather than a 'new face'.
5. Support line/SOS contact: The current H2H includes contact details for the CHCPSs to contact the H2H team if hospital intervention is required for the patient's symptom control. This could be supported by a routine check in phone call from the H2H team to the patient and family at 2-4 weeks, with the option for an oncology contact or outpatient visit if unanswered questions were identified.
6. Feedback to referrers: The feedback from H2H to the referring teams is currently informal. However, lack of feedback to consultant oncologist was a strong criticism of the current service identified in this work. Thus, the consultant oncologist could receive a copy of the H2H care plan and follow up letter summarising the patient outcomes 3 months after discharge.

7. Electronic handover of care: At the time of this feasibility study an Electronic Palliative Care Coordination System (EaPCCS) was being piloted in London. This meant where available H2H care plans were documented electronically. This EaPCCS has become Coordinate My Care[95], a web-based IT system that allows healthcare professionals to electronically record patient's wishes and ensures their personalised urgent care plan is available 24/7 to all those who care for them across London. Routine use of this system would complement the aims of H2H and extend the impact of a H2H care plan. It may also be the case that if patients are stratified according to need using OACCS H2H could be modelled to deliver different levels of intervention accordingly. For example: Level 1: low level of need- care plan entered on EaPCCS, Level 2: moderate level of need – Telephone case conference and EaPCCS entry, Level 3: high level of need – Face-to-face case conference and EaPCCS entry.
8. Virtual consultation via Skype: One method that should be considered to improve the reach and impact of H2H is the use of Skype or similar technology. H2H virtual clinics led by either H2H SS or the site specific CNS may enable the important components of H2H, visual integrated teamwork, maximum information sharing and coordination, to be delivered in a more cost effective manner.

6.6 Key learning and suggested future study

This feasibility work was designed to provide recommendations for a larger definitive trial of H2H. It has highlighted key learning points for the conduct of EoLC research, and in particular research involving patients in the last 3 months of life.

Key learning for EoL research

The key learning points for research in patients very close to death, in the last 3 months of life are as follows:

- Patients very close to the end of life with a poor performance status at study entry are considerable vulnerable however this study shows these patients are still willing to participate in research and should have the opportunity to do so.
- Screen to Recruitment rates in this study were approximately 50%. This was limited because of the deteriorating patient at EoL not having capacity to consent to the study. Since this work was completed other study protocols for EoL research have included enrolling patients without capacity to consent. This should be advocated where ethically appropriate to ensure research is truly capturing EoL and to improve recruitment rates.

- Multiple longitudinal research contacts, as frequently as every 2 weeks, are acceptable to patients near end of life and their carers. Contact from the same researcher at these assessment time points is advocated as a method of ensuring low withdrawal rates in longitudinal research.
- PPD as a single primary outcome in EoL research is questionable. It is recommended that PPD is used alongside other PoD outcomes such as informed choice PoD and unacceptable PoD.
- Carer proxy responses for patient symptom burden agree with patient self- scores. However, the use of carer responses as a substitute for missing values from patients to minimise patient ADI is limited by carer drop out close to death.
- Longitudinal studies involving carers that collect follow up data past death into bereavement are acceptable at the EoL and offer the opportunity to collect valuable outcomes that would otherwise be missed.
- Service use is an important outcome measurement that should be routinely included in the evaluation of a CI. However, patient/carers reported service use data at the EoL has limitations due to ADI and missed service use data after this point. The use of patient/carers reported service use alone will underestimate service use and therefore costs, particularly community contacts. Multiple data sources should be used to collect accurate service use at EoL.

Next steps for the evaluation of H2H

The original aim of this feasibility work was to inform a larger definitive trial, however I recommend a step-wise approach to the further evaluation of H2H that involves revisiting the **modelling phase** of the MRC framework with additional **feasibility** testing of H2H and the chosen outcome measures prior to a definitive trial.

Step 1: **Modelling phase:** Further work on the design of H2H

The conduct and fidelity of the H2H was evaluated through quantitative measures. It may be that, as suggested in other research[237], tape recording the CC and qualitative analysis of these recordings may provide valuable insights into the mechanism and interacting components of the H2H alongside more detail on the fidelity of the intervention. This should be considered prior to a larger study, as it will direct any further necessary modelling of H2H and allow the intervention to be replicated more uniformly across multiple study sites in a larger trial.

The qualitative interviews in this feasibility study were cross-sectional, and limited to patients and hospital HCPs. The interviews gave valuable insight into the how the intervention may have been having an effect; however, the views of community professionals and carers have not been explored. Further study should include qualitative interviews with carers, GPs, community nurses and CPCTs. The qualitative interviews with patients were only conducted at one time point, shortly after the CC. Views and perceptions may have changed over time under the community-led care. Although Shipman et al[188] reported palliative care patients found serial interviews acceptable, the short survival in this patient group means longitudinal interviews with patients are not likely to be feasible. However, longitudinal qualitative interviews with carers, including a bereavement interview, would be valuable and allow further insight into care provision in the community alongside knowledge about any sustainable positive outcomes or indeed negative outcomes from H2H as well as exploring the safety of H2H. These may provide suggestions for further modelling of the intervention.

Step 2: **Feasibility phase:** Further assessment of outcomes measures

There is a need for more research into appropriate outcome measures at the EoL. I suggest qualitative interviews to explore the importance and differences between PPD, informed choice PoD and unacceptable PoD and to develop and validate clear questions which distinguish between PPD, informed choice PPD and unacceptable PoD.

Step 3: **Evaluation phase:** Design of a definitive trial

In view of the baseline differences in demographics and survival that resulted from the quasi-experimental design, a larger definitive study should be randomised. This would not be possible in this cancer centre; therefore, H2H would need to be studied in other specialist centres or acute hospitals. This could be in the form of a multi-centre RCT or to avoid contamination between H2H and the control group a Cluster Randomised Controlled Trial. A multicentre RCT would be required to recruit 242 participants (121 per group).

This study only considered lung and GI cancer patients. Although it would introduce heterogeneity, a larger study should include wider cancer diagnoses. Also, in this feasibility study, telephone and face-to-face CCs were evaluated as one. Telephone CCs are less time consuming, likely to be more cost effective and therefore could extend the reach of the service. It is therefore important to evaluate whether a telephone CC model is as effective as a face-to-face model of care. A larger study should analyse these CC interventions separately, randomising clusters to face-to-face, telephone or standard care. Follow up questionnaires should be extended past the 12-week follow up used in this study, with monthly questionnaires thereafter. This would enable more accurate assessment of symptom burden and QoL up until death for those participants who survive longer than 3 months. Ideally, the service use data should be collected from the patient and also from the community services, hospital and CCG databases to allow more accurate costs to be calculated.

6.7 Personal reflection

The work involved in this PhD thesis has afforded me many opportunities to reflect on the care of patients with advanced cancer and also on my own abilities, strengths and weaknesses. I reflect on these to show how this work has shaped my opinions on the needs of cancer patients at the EoL and to demonstrate the impact this work has had on me. A PhD of this kind may be finished and complete but is never forgotten. The participants I have worked with, as well as the life lessons they have taught me, will remain with me forever. This thesis has changed the way I practise as a palliative care doctor. I have been struck by the willingness of patients to engage with my research and that it was as important to them as it was to me. I have been amazed, time and time again, by the character of the human race and been privileged to gain in-depth insight into how the end of cancer treatment was really affecting these patients. The qualitative work had a particular impact on me: the sentiments of how important active listening is to the patient and family struck a chord. In my clinical work, this has led me to never underestimate the patient in front of me. I endeavour to ensure all the patients I meet have the opportunity to tell me what preferences and wishes are

important to them, and would like to think the patients I now care for feel important to me, perhaps more so than before I embarked on this work. I have reflected on the experiences of the cancer patients in this study: some good, some bad and some challenging. For EoL care there is a lot more to do. This study was in cancer patients, a population where the health service has been improving palliative care access and EoL care for many years. However, gaps and misconceptions about palliative care still exist among patients, carers and doctors. If cancer is still struggling with these issues, the challenge for all other life-limiting illness is great. We all must strive for excellence in clinical practice and research every day.

6.8 Conclusion

This study is the first feasibility study of a CC model of care (H2H) at the transition from specialist led cancer care to community led care in the UK. H2H is an innovative CI designed to ensure a seamless transfer of care that includes important opportunity for holistic palliative care assessment, a CC attended by the patient, informal carer, hospital and community professionals, and lastly the agreement of an individualised care plan for each patient. Understanding in what ways this service may achieve important patient and family centre outcomes is vital. This feasibility study contributes to important methodological knowledge concerning future prospective longitudinal research involving patients very near EoL. First, the MRC guidance on evaluating CIs recommends that quasi-experimental studies can be appropriate where randomisation is not ethically or practically possible. However, this study shows CIs at EoL are at high risk of selection bias threatening the validity of findings in quasi-experimental design where participants in comparator groups are determined by clinical decision-making, HCP choice or patient complexity. PPD has been a important clinical outcome in EoL for the last 2 decades however its use as an outcome measure in research is problematic and has limitations including a standardised definition and missing data. Comparison of multiple PoD outcomes; PPD, informed choice PoD, unacceptable PoD and carer PPD would provide a fuller evaluation of CIs at EoL. There was high ADI with over 50% of patient participants dead in the first three months follow up, however there was minimal withdrawal rate due to patient or carer choice. This implies longitudinal research in the last few months of life is acceptable to patient and carer participants. All eligible patients should be given the opportunity to participate at the earliest possibility to ensure follow-up is maximised and important patient and family centred outcomes can be observed.

The findings from the quantitative component of the quasi-experimental mixed methods study and the retrospective study of factors influencing place of death suggest that H2H increases the likelihood of a patient dying at home and achieving their PPD. The findings also suggest that H2H may have a potential positive effect on patient and carer symptom control, QoL and satisfaction. The qualitative interviews find correspondence with the findings from the quantitative component of this study; patients considered the CC model to be a positive, enlightening experience that reassured them of multidisciplinary team work at an important juncture in their lives. However, this feasibility study suggests the intervention requires further optimisation to further benefit patients and their families. Specifically, it would benefit from further modelling to clarify the role of the telephone CC. The qualitative work provides the first evidence of patient and oncologist experience of discharging patient at the EoL. This work illustrates the multiple losses of: hope, treatment, familiarity and trust. Oncologists also recognised their own experience of loss associated with discharge when a patient had been well known to them. These losses compound to make the transition to community care complex. A larger definitive trial is needed to further evaluate the potential positive effects of H2H, as well as seeking the views of community professionals and informal carers.

7 Appendix

Appendix 7.1: INTRODUCTION

Appendix 7.1.1: ONS definitions of place of death

ONS Definitions of Place of Death[13]

Home	Deaths at home are those at the usual residence of the deceased (according to the informant), where this is not a communal establishment
Hospital	Hospitals include NHS general hospitals and multi-function sites, maternity hospitals, private hospitals and military hospitals
Care Home	Care homes include homes for the chronic sick, nursing homes, homes for people with mental problems and non-NHS multi-function sites
Hospice	Hospice include Sue Ryder Homes, Marie Curie Centres, Oncology centres, voluntary hospice units and palliative care centres
Other communal establishments	Other communal establishments include holiday homes and hotels, common lodging houses, aged persons accommodation, assessment centres, schools, convents and monasteries, nurses' homes, university and college halls of residence, young offenders institutions, secure training centres, detention centres, prisons and remand homes
Elsewhere	All places not covered above

Appendix 7.1.2: More Care Best practice statements and relevance to H2H

Fstudy

	Recommendations	The H2H feasibility study
Introduction Background	1. Present theoretical framework for the intervention and levels of need established	Theoretical framework: Australian work on CCs Local need: Audit of inpatient stays showed reason for admission was symptom control. Outlined in Chapter 1
	2. Present objectives appropriate to the level of intervention development	Appropriate objectives were set – Chapter 2
Study design	3. Indicate and justify stage in MRC guidance for development and evaluation of CI	The feasibility study was a feasibility study in the feasibility and piloting stage. Justification: necessary to evaluate study schedule, outcome measures alongside feasibility and acceptability of the CI
	4. Feasibility stages should test both feasibility of the intervention and of the methods of evaluation, including outcome measurement	The feasibility study includes qualitative interviews to determine feasibility of the CI and quantitative work to explore the feasibility of multiple outcome measures
	5. Justify methods, considering appropriate use of existing data sets and secondary analysis as these may produce rapid information	Retrospective analysis included to provide evidence from existing data sets
	6. Justify methods of empirical studies considering mixed methods, observational and randomised trials	Use of mixed-methods to establish views and perceptions of both patients and HCP essential to inform a wider

		roll out
Study team	7.Ensure involvement from: (i) consumers, patients and caregivers, (ii) relevant clinicians, (iii) relevant methodologists to develop study questions, questionnaires and procedures; and (iv) researchers familiar with challenges in EoLC studies	
	8. Ideally, involvement should be well established and continuing, beyond a specific study, with joint meetings or rotations between clinical and research staff	Weekly H2H meetings involved research and clinical staff Monthly research meetings involving research and clinical staff were in place
Ethics	9. Note in ethics committee application that it is ethically desirable for patients and families in EoLC to be offered involvement in research and evidence of patient willingness to be approached	Ethics application for The feasibility study included reference to Shipman et al (REF). Evidence of palliative care patients views on research
	10. Work within legal frameworks on mental capacity, consent and so on, to ensure that those who may benefit from interventions are offered an opportunity to participate if they wish	The feasibility study only enrolled patient participants with capacity
	11. Collaborate with patients and caregivers in the design of the study, vocabulary used, consent procedures and any ethical aspects	Patient representative reviewed protocol, patient information sheet and qualitative topic guide
	12. Attend the committee meeting with a caregiver or patient, as a means to help the committee better understand the patient perspective	This was not done for the feasibility study
	13. Ensure proportionality in patient and caregiver information sheets, appropriate to the study design and level of risk, as excessive information in itself can be tiring/distressing for very ill individuals	Patient information sheet and carer information sheet both reviewed by patient representative – not tiring/distressing
Participants	14. Adjust eligibility criteria to recruit those patients who may benefit most from the intervention, ensuring equipoise	Eligibility criteria for The feasibility study was clear and matched the referral criteria for the service therefore included all patients likely to benefit
Procedures	15.Minimise burden for existing clinical staff for participation in the study	Minimal burden on clinical staff. In the feasibility study – clinical staff were only involved in identification of potential participants. Delivering the CI was already part of clinical care
	16. Clearly distinguish between service received and research activity interviews in the study arms when multiple interviews with patients are undertaken in trials	Clear distinction between H2H and research schedule
Outcome measures	17. Choose outcome measures that meet the following criteria: - Established validity and reliability in relevant population - Responsive to change over time - Capture clinically important data - Easy to administer and interpret - Applicable across care settings to capture change in outcomes by location - Able to integrate into clinical care - Minimise problems with response shift	Primary outcome of achievement of PPD met all criteria except 'responsive to change over time'
	18. Consider including patient experience of care, as this is central to many interventions	The feasibility study included quantitative questionnaire about experience of H2H and qualitative interviews
	19. Select time points of outcome measurement to balance the value of early recording, to reduce attrition, but to allow enough time for the intervention to have had an effect	Difficult issue. In the feasibility study the time points for secondary outcomes were chosen based on pre audit survival of H2H participants
	20. Consider the potential effect of response shift	
Missing data and attrition	21. Estimate in advance levels of, and reasons for, attrition and missing data, integrating these into sample size estimates and planned collection of data from proxies	Minimal missing data for primary outcome measure Attrition and missing data likely to be

		high for secondary outcome data therefore carers recruited as proxy
	22. Monitor during the study and report all levels of, and reasons for, attrition and other missing data	The feasibility study closely monitored attrition and this is presented in Section 4.4
	23. Assume missing quantitative data NOT to be at random unless proven otherwise	This was assumed and missing data descriptively reported
	24. Test results from different methods of imputation- noting that 'using only complete cases' is a form of imputation	Primary outcome data: home imputed as PPD if unknown 'Using only complete cases' was the method of imputation for secondary outcome data.
	25. Use the MORECARE classification of attrition that is, • ADD – attrition due to death • ADI- attrition due to illness • AaR- attrition at random	Section 4.4 uses the MORECARE classification of attrition
	26. Consider reasons for missing data which are not due to attrition. Consider these in analysis and the potential imputations	Section 4.4 discusses common individual missing items that participants refused to answer and questionnaire length as reasons for missing data not due to attrition
Mixed method studies	27. Mixed methods can be appropriate in all phases of development and evaluation	The feasibility study was a mixed method study
	28. Ensure appropriate multi-disciplinary skills mix or training of team	
	29. Define the theoretical paradigm and method of integrating results and safeguards to ensure rigour at the outset	The framework analysis was chosen with results integrated at analysis stage
	30. Plan investigation to avoid undue burden of qualitative and quantitative questionnaires – perhaps dividing data collection or selecting questions and/or sampling appropriately	Qualitative interviews planned for after Week 1 and open to potential participants from a wider diagnosis to minimise burden on participants
	31. Take into account any potential therapeutic effect of qualitative interviews where participants can express their feelings, if these are similar to components of the intervention	All qualitative interviews were conducted after week 1 therefore should not have affected primary and secondary outcomes collected
	32. Ensure that those collecting data are appropriately trained in qualitative data collection	I attended a monthly qualitative workshop, performed practice interviews with supervisors, and reflected on interviews as conducted
Implementation	33. Consider implementation implications, including workforce and training needs, in all phases of the study	Only hospital staff and patients included – larger resource would have included CHCP and carers
Cost-effectiveness	34. Integrate into preliminary evaluations and test feasibility of methods	The feasibility study included patient/carer reported service use data collection. The feasibility of which is discussed in Section 4.4 and Chapter 5
	35. Collect data on use of service including health, voluntary, social and informal care, to take societal approach to care costs	Informal care cost not estimated.
	36. Justify appropriate outcome measures to generate cost effectiveness	Not included in the feasibility study. Preliminary exploratory analysis included 'cost per achieved PPD'

Appendix 7.1.3 H2H Referral form

Patient information			
Date of referral			
Date of birth	Age	Gender	Marital status
Address and telephone number			
Name and contact details of carer/NOK			
Name and designation of referrer			
Name of Primary Care Trust			
GP name and surgery address		Telephone no.	Fax no.
District Nurse name/team and address		Telephone no.	Fax no.
CPCT name and address		Telephone no.	Fax no.
Any other relevant professionals and their contact details		Telephone no.	Fax no.
Patient information			
Ethnic origin	Main language spoken	Interpreter required	
Diagnosis		Date of diagnosis	
Type of most recent anti-cancer therapy (Chemotherapy/surgery/radiotherapy/hormone)		Previous intent of treatment (adjuvant/neo-adjuvant/palliative)	

Accommodation type and living arrangements	
DSS benefit information/Macmillan grants etc.	
If No benefits, action taken (please circle)	Patient refused / HCP informed
Details of continuing care funding and Marie Curie Nursing service	
If there is a carer available – who is this and what is their relationship to the patient	Does the carer live with the patient? (Y/N)
Hospitals the patient has recently received care at or has been admitted to	

Triage information	
Reason for referral	
Triggers/events leading up to referral	
Patient's understanding of prognosis and future care	
Carer/relatives understanding of prognosis and future care	
Clinical prognostic indicator (A, B, C or D)	
Who is coordinating the patient's discharge?	

Hospital2Home initial assessment					
Palliative Performance Scale (Circle %)					
Palliative Performance Scale					
%	Ambulation	Activity and evidence of disease	Self-care	Intake	Level of consciousness
100	Full	Normal activity No evidence of disease	Full	Normal	Full
90	Full	Normal activity Some evidence of disease	Full	Normal	Full
80	Full	Normal activity with effort Some evidence of disease	Full	Normal or reduced	Full
70	Reduced	Unable to do normal job/work Some evidence of disease	Full	Normal or reduced	Full
60	Reduced	Unable to do hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full or confusion
50	Mainly sit/lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or confusion
40	Mainly in bed	As above	Mainly assistance	Normal or reduced	Full or drowsy or confusion
30	Totally bed bound	As above	Total care	Reduced	Full or drowsy or confusion
20	As above	As above	Total care	Minimal sips	Full or drowsy or confusion
10	As above	As above	Total care	Mouth care only	Drowsy or coma
0	Death	-	-	-	-
Is pain currently problematic? (Y/N) Describe key factors					
Are any other symptoms currently problematic? (Name all) Describe key factors					
Where is the patient's PPC?			1. 2.		
Where is the patient's PPD?			1. 2.		

Outcome of referral	
Patient discharged (Y/N) if not give outcome	
Date of discharge from hospital	
Decision on H2H CC or H2H telephone discharge/handover	
State reasons for this decision	
Date of H2H CC/telephone discharge handover	

Appendix 7.1.4: H2H CC Record

H2H No.

CC form for Hospital2Home patient

Date of CC __/__/__

Start time : End time :

Home Address:

Patient consent obtained and documented	Yes ☐	No ☐	N/A ☐
Carer consent obtained and documented	Yes ☐	No ☐	N/A ☐
GP has agreed to attend CC	Yes ☐	No ☐	
Copy of RMH community nursing referral form	Yes ☐	No ☐	N/A ☐
Copy of RMH medical discharge summary	Yes ☐	No ☐	N/A ☐
Copy of SPC referral	Yes ☐	No ☐	N/A ☐
Copy of Continuing Care form	Yes ☐	No ☐	N/A ☐

Persons attending the CC

Name	Participation Code	Discipline	Organisation	Phone	Fax	Copy sent

Participation codes: P: present at meeting T: telephone NP: not present

Current medication(s) including name, dose and frequency:

Drug	Dose	Route	Frequency	Drug	Dose	Route	Frequency
RMH Pharmacist Signature			Name			Date and Time	
Has the pharmacist completed and given the patient 'A guide to your medicines sheet'? (Delete as appropriate)						Yes / No	

Palliative Care Plan

Optional, include if appropriate

Has the patient expressed any wishes/instructions concerning matters related to their future care or death?

Yes ☐ No ☐

Comments:

If yes, have the appropriate organisations been notified for e.g. hospice, emergency services.

Yes ☐ No ☐

Comments:

Palliative Performance Scale at time of CC

Palliative Performance Scale					
%	Ambulation	Activity and evidence of disease	Self-care	Intake	Level of consciousness
100	Full	Normal activity No evidence of disease	Full	Normal	Full
90	Full	Normal activity Some evidence of disease	Full	Normal	Full
80	Full	Normal activity with effort Some evidence of disease	Full	Normal or reduced	Full
70	Reduced	Unable to do normal job/work Some evidence of disease	Full	Normal or reduced	Full
60	Reduced	Unable to do hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full or confusion
50	Mainly sit/lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or confusion
40	Mainly in bed	As above	Mainly assistance	Normal or reduced	Full or drowsy or confusion
30	Totally bed bound	As above	Total care	Reduced	Full or drowsy or confusion
20	As above	As above	Total care	Minimal sips	Full or drowsy or confusion
10	As above	As above	Total care	Mouth care only	Drowsy or coma
0	Death	-	-	-	-

Plan for Documentation

Care plan prepared Yes ☐ No ☐

H2H team to distribute care plan Yes ☐ No ☐

Signature of Hospital2Home team member completing form.....

Name and designation.....

Date and time.....

Care plan to faxed to all professionals attending the CC. The original document form to be filed the in patient's medical notes at The Royal Marsden NHS Foundation Trust.

Appendix 7.1.5: H2H Care Plan

Issue/problem	Problem Codes	Patient goals of care and Management goals	Actions required	Person/People responsible	Review date

Care Plan for Royal Marsden Hospital2Home Patient

Problem Codes

1. Pain control
2. Other symptom control (e.g. breathlessness, nausea and vomiting, oedema)
3. Functional issue (e.g. difficulty walking, assistance with showering, assistance with taking medications)
4. Psychological distress (e.g. depression, anger, guilt)
5. Social issue (e.g. carer coping, carer availability, increasing dependence, change in relationships)
6. Spiritual concern (e.g. religious issues, existential issues)

Name of nurse completing.....

Designation.....

Signature.....

Date and time.....

Appendix 7.3: METHODS

Appendix 7.3.1: Patient information sheet: Quantitative

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

'We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this'

What is the purpose of the study?

This study is trying to find out how doctors and nurses from the hospital can best help GPs and community nurses to care for people with cancer in their place of choice, which is most commonly home, and how we can stop people being admitted to hospital unnecessarily. This study examining how doctors and nurses from the hospital communicate with patients and their families at crucial time points in their illness.

We are studying patients like you who are cared for by the Royal Marsden Hospital. Currently if you are a patient at the Royal Marsden Hospital your hospital team will keep your GP informed about your care through letters from clinic and discharge summaries with or without a CC meeting held in your home.

This study will compare patients who have a CC meeting and those who do not, with the aim of finding the best way hospital teams can keep yourself, your GP and your community nurses informed.

It will also look at your symptoms and experiences in the community, as well as looking at the experiences of your close family and carers. This will allow us to work out the best way to improve the services in the community to support GP's, community nurses, patients and their carers.

This study will also explore your views and feelings at this important time in your illness. The aim of this is to learn from the experiences of patient's like yourself in order to improve care in the future

Why have I been chosen?

You have been invited to take part because you are a patient with cancer attending hospital. We are inviting 180 patients like you, along with their close family and carers, to take part in the study.

Do I have to take part?

It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep along with a record of when we will contact you, and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be visited at home (or elsewhere if more convenient to you) by the researcher and be asked some basic questions about you, including diagnosis and medications, along with a questionnaire about your symptoms and feelings. You will also be asked about visits you have had from community nurses, carers or your GP, as well as any hospital visits. Your close family member or carer will also be asked some similar questions. You will then be contacted after one week, 1 month, and finally at 3 months by telephone from the same researcher to complete the same questionnaire. The first visit will take about 45 minutes, and each telephone call after this will take about 30 minutes.

You or your close family member will be contacted two weekly by telephone for approximately 5 minutes to check if you have needed any extra health services or equipment over that week.

A questionnaire will also be sent to the community doctors and nurses you know best to find out their views on the information from the hospital

If at any point during the study the researcher feels you are too unwell to complete the questionnaires you will not be asked to do so, but your close family member can continue to complete their questionnaires if they so wish.

After the last contact to complete the questionnaires, with your permission the researcher will keep in contact with your general practitioner and community teams about your health.

If you have participated in a CC meeting you may also be asked to participate in a one to one interview with a researcher specifically to discuss your feelings and views about this service. This interview is likely to last between 45 minutes to one hour. If this is the case, after discussing the study with the researcher you may decide that you wish to participate in both parts of this study or that only one part (the questionnaires or the interview) particularly interests you. This is completely acceptable, and participating in one part does not mean you have to participate in both parts of the study.

What are the possible disadvantages of taking part?

Taking part in the study will not adversely affect any aspect of your treatment at home or in hospital. Sometimes being asked about your feelings may be difficult to answer. If so, you do not have to continue or answer anything you do not feel comfortable with. If you feel after answering our questions you need more support to deal with any emotions you have we will arrange this for you.

What are the possible benefits of taking part?

You will be offered a referral for additional support and assessment if necessary. The study will help people in the future by making health professionals more aware of the problems or experiences of patients who have cancer, and their carers, who are looked after in the community. This will lead to deciding how support can be organised between the hospital and the community to improve current practice

Will my taking part in this study be kept confidential?

If you consent to take part in the research, any of your medical records may be looked at by a member of the research team or regulatory authority. Your name, however, will not be disclosed. You will not be identified in any report or publication that arises as a result of the study.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in various medical journals. If you would like a summary of the results when available please inform your doctor or research nurse.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital.

The study is funded by the Royal Marsden Palliative Care Research Fund. The researchers will not be paid for including you in the study.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study, and given their approval

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

**Dr Julia Riley and Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust, Chelsea, London
0207 808 2761**

Appendix 7.3.2: Carer information sheet

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

'We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this'

What is the purpose of the study?

This study is trying to find out how doctors and nurses from the hospital can best help GPs and community nurses to care for people with cancer in their place of choice, which is most commonly home, and how we can stop people being admitted to hospital unnecessarily.

We are studying patients who are cared for by the Royal Marsden Hospital. Currently if you are a patient at the Royal Marsden Hospital your hospital team will keep your GP informed about your care through letters from clinic and discharge summaries with or without a CC meeting held in your home.

This study will compare patients who have a CC meeting and those who do not, with the aim of finding the best way hospital teams can keep yourself, your GP and your community nurses informed.

It will also look at the patients symptoms and experiences in the community, as well as looking at the experiences of their close family and carers. This will allow us to work out the best way to improve the services in the community to support GP's, community nurses, patients and their carers.

Why have I been chosen?

You have been invited to take part because you are the close family member/carer of a patient with cancer attending hospital. We are inviting 180 patients along with their carers like you, to take part in the study.

Do I have to take part?

It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your loved one receives.

What will happen to me if I take part?

You will be visited at home (or elsewhere if more convenient to you) by the researcher and be asked some basic questions about you, including age, medical problems and occupation, along with a questionnaire about your loved ones symptoms and your experiences and feelings about caring for them. You will also be asked about visits from community nurses, carers or the GP, as well as any hospital visits your loved one has had. Your loved one will be asked similar questions.

You will both then be contacted after one week, 1 month, and at 3 months by telephone from the same researcher to complete the same questionnaire. The first visit will take about 45 minutes, and each telephone call after this will take about 30 minutes. The patient or yourself will also be contacted 2 weekly by telephone for approximately 5 minutes to check if your loved one has needed any extra health services or equipment over that week.

Your loved one/family member may also be asked to participate in a one-to-one interview with the researcher regarding their feelings and views about being discharged from the oncologists care.

A questionnaire will also be sent to the community doctors and nurses that you and your loved one know best to find out their views on the information from the hospital. If at any point during the study the researcher feels your loved one is too unwell to complete the questionnaires they will not be asked to do so, but you can continue to complete your questionnaires if you so wish.

After the last contact to complete the questionnaires, with your loved ones permission the researcher will keep in contact with their general practitioner and community teams about their health.

If your loved one dies during the study period we would also like to contact you after 3 months to participate in a questionnaire about your feelings on your loved ones care, and anything you think might improve the care of others in a similar situation.

What are the possible disadvantages of taking part?

Taking part in the study will not adversely affect any aspect of your loved ones treatment at home or in hospital. Sometimes being asked about your feelings may be difficult to answer. If so, you do not have to continue or answer anything you do not feel comfortable with. If you feel after answering our questions you need more support to deal with any emotions you have we will arrange this for you.

What are the possible benefits of taking part?

You will be offered a referral for additional support and assessment if necessary. The study will help people in the future by making health professionals more aware of the problems or experiences of patients who have cancer, and their carers, and how they are looked after in the community. This will lead to deciding how support can be organised between the hospital and the community to improve current practice.

Will my taking part in this study be kept confidential?

If you consent to take part in the research, any of your research records may be looked at by a member of the research team or regulatory authority. Your name, however, will not be disclosed. You will not be identified in any report or publication that arises as a result of the study.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in various medical journals. If you would like a summary of the results when available please inform your doctor or research nurse.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital. The study is funded by the Royal Marsden Palliative Care Research Fund. The researchers will not be paid for including you in the study.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study and have given their approval

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

**Dr Julia Riley and Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London
0207 808 2761**

Appendix 7.3.3: HCP information sheet

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

Your patient (*insert name and dob*) has agreed to take part in the above research study.

Provided below is a brief description of the study and its purpose.

What is the purpose of the study?

Around 500,000 people die in the UK each year, a common cause of death is cancer. Most people say they would prefer to die at home if given the choice, but 58% die in hospital. This study is trying to find out how doctors and nurses from the hospital can best help GPs and community nurses to care for people with cancer in their place of choice and achieve their PPD, and how we can stop people being admitted to hospital unnecessarily. This study will look at people's symptoms and experiences in the community, as well as looking at the experiences of their close family and carers. It will compare a Royal Marsden Hospital pilot CC based discharge scheme (known as Hospital2Home) with standard care for patients at the Royal Marsden Hospital who do not have a CC. This will allow us to work out the best way to improve communication between hospital and CHCPs in order to improve the services in the community to support GP's, community nurses, patients and their carers.

Why has your patient been chosen?

We have invited your patient to take part as they have cancer, and attend the Royal Marsden Hospital. We are inviting 180 patients in total, along with their close family and carers, to take part in the study.

What will happen to my patient as part of the study?

Your patient will be visited at home by the researcher and be asked some basic questions about their diagnosis and medications, along with a questionnaire about their symptoms and QoL. They will also be asked about the frequency of home visits from community nurses, carers and yourself, as well as any hospital visits. Their close family member or carer will also be asked some similar questions. We will contact your patient and their carer 4 times over a 3 month period. The first assessment will be a face to face contact in your patient's home and then subsequent contacts will be by telephone at one week, 1 month, and

finally at 3 months. The first visit will take about 45 minutes, and each telephone call after this will take about 30 minutes. The carer or patient will be contacted by telephone weekly for 5 minutes to collate what health services they have used in the previous week.

Your patient may also be asked to participate in a one-to-one interview with the researcher regarding their views about being discharged from the oncologists care and the CC service.

What are the possible disadvantages of taking part?

Taking part in the study will not adversely affect any aspect of your patient's treatment at home or in hospital.

Your patient or their carer will be offered a referral for additional support and assessment if any new issue is uncovered as part of the research.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in various medical journals. If you would like a summary of the results when available please inform your doctor or research nurse.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital.. The study is funded by the Royal Marsden Palliative Care Research Fund. The researchers will not be paid for including you in the study.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study and have given their approval

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

Dr Julia Riley
Consultant
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea, London
0207 808 2761

Dr Clare Smith
Research Fellow

Appendix 7.3.4: Patient Consent Form

Centre Number: RMH
Study Number: CCR3184
Patient Identification for this trial:

CONSENT FORM

Title of Project: **The Hospital2Home Research project**

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Name of Researcher: **Dr Julia Riley**

Please initial

box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to my data being stored or encrypted on password-protected computers at the RMH
5. I agree to take part in the above study

☐☐☐☐☐

Name of patient Date Signature

Name of person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

**When completed - 1 for patient;
1 (original) to be kept in research site file;
1 for medical notes;
1 for CRF.**

Would you like a summary sheet of research findings YES/NO

Appendix 7.3.5: Carer Consent Form

Centre Number: RMH
Study Number: CCR3184
Carer Identification for this trial:

CONSENT FORM

Title of Project: **The Hospital2Home Research project**

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Name of Researcher: **Dr Julia Riley**

box

Please initial

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my loved ones medical notes may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in research.
4. I agree to my data being stored or encrypted on password-protected computers at the RMH
5. I agree to take part in the above study

☐☐☐☐☐

Name of participant Date Signature

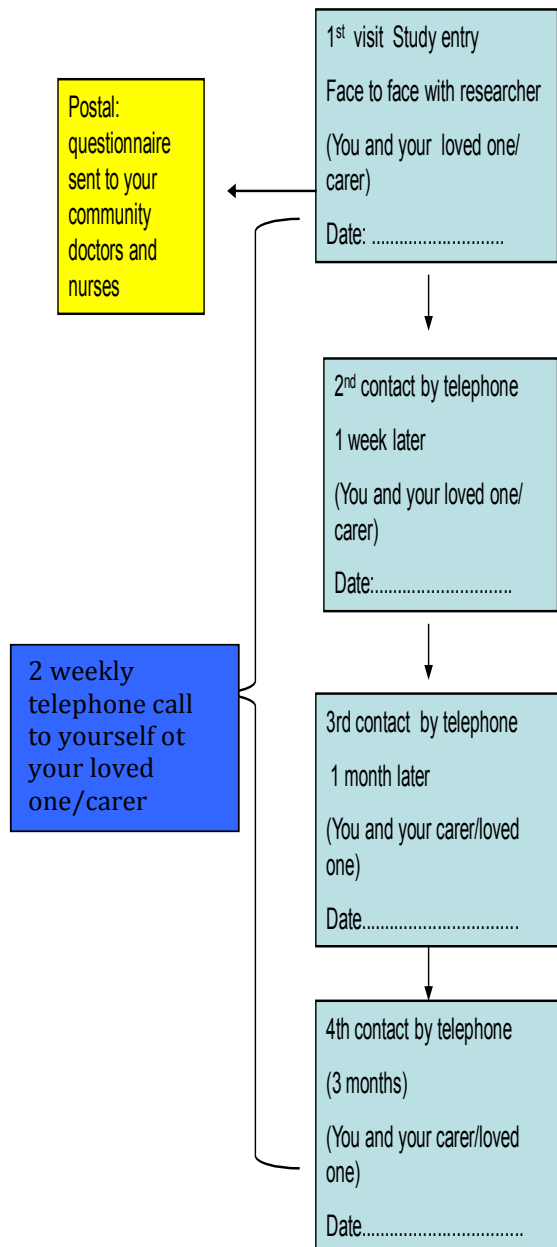
Name of person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

**When completed - 1 for carer;
1 (original) to be kept in research site file;
1 for medical notes;
1 for CRF.**

Would you like a summary sheet of research findings YES/NO

Appendix 7.3.6: Personalised Contact Diagram



**Appendix 7.3.7: The feasibility study QUAN: Patient
Clinical Record File**

**A pragmatic prospective controlled
evaluation comparing a CC model of care
with standard models of care at the
transition between acute and community**

Clinical Record File

Patient

Assessment No 1

Patient identification no:

Date of entry into study:

PI authorisation signature:

Date of signature:

Patient Demographic Data
(most data collected from notes)

Study Number: _____ Date of study entry: _____ Inpatient/Outpatient _____

Age _____

Gender: _____

Address /Postcode _____

Hospital2Home CC: _____ Y _____ N _____

Attendees (please circle) _____ GP _____ CPCT _____ DN _____ Carer _____ Other (please list) _____

If yes:

Reason for referral to hospital2home

- a. offers best supportive care
- b. security in knowing patients' preferences are addressed
- c. helps facilitate difficult conversations
- d. H2H team ensures patients do not have unnecessary readmissions to RMH
- e. being able to offer the patient another form of care once treatment has stopped
- f. improve communication between acute and
- g. other

If No:

Reason for not referring to hospital2home:

- a. don't want to discharge patient from RMH
- b. want patient to come back to RMH regardless of the problem
- c. too strict in referral criteria
- d. don't know what this service is all about
- e. it may cause the patient and family to become distressed
- f. Find it too difficult to have the conversation about discharging patient from RMH
- g. Patient has no complex symptoms
- h. Patient has no complex psychosocial issues
- i. Patient has a good relationship with their CPCT (therefore Hospital2home not beneficial)
- j. other

Factors related to illness

Cancer diagnosis:

Date:

Most recent Cancer treatment:

Date:

Extent of disease at entry into the study: Locally advanced

Metastases

Last Scan Date:

Sites of disease:

Estimated prognosis (asked to lead hospital professional) (in months or weeks)

Number of previous cancer treatments:

Surgery:

Chemotherapy:

Radiotherapy:

Details of anti-cancer treatment in the last 12 months

Surgery

Y/ N

If yes, please fill in details below:

DATE	DESCRIPTION OF SURGERY	REASON	PLACE	DAYS IN HOSPITAL

Chemotherapy (including monoclonal antibody treatment) Y / N
If yes, please fill in details below:

DATE STARTED	CHEMOTHERAPY REGIMEN	NO. OF CYCLES	DATE FINISHED	REASON FOR STOPPING

Radiotherapy Y/N
If yes, please fill in the details below:

DATE	SITE	NO OF FRACTIONS	REASON

Hormone therapy Y/ N

If yes, please fill in the details below;

DATE STARTED	DRUG	DATE FINISHED	REASON FOR STOPPING

Bisphosphonate Treatment Y/ N

DATE STARTED	DRUG/DOSE	PLACE GIVEN	DATE FINISHED	REASON FOR STOPPING

Other past medical history:

PPS on assessment:

Individual factors

Ethnic origin

White -

British	☐	1
Irish	☐	2
Any other White background	☐	3

Please specify.....

Black or Black British -

Caribbean	☐	4
African	☐	5
Any other Black background	☐	6

Please specify.....

Asian or Asian British -

Indian	☐	7
Pakistani	☐	8
Bangladeshi	☐	9
Any other Asian background	☐	10

Please specify.....

Mixed -

White and Black Caribbean	☐	11	
White and Black African	☐	12	
White and Asian	☐	13	
Any other Mixed background	☐		14

Please specify.....

PPC:

Discussed by team	Y	N	Not documented

If yes, circle as appropriate

1st choice

Home	Hospice N/H	Hospital	Other

2nd choice

Home	Hospice N/H	Hospital	Other

Source: (please circle) (if more than one applies circle all that apply)

Patient	Patient Notes	CHCP

PPD

Discussed by team

Y	N	Not documented

If yes, circle as appropriate

1st choice:

Home	Hospice N/H	Hospital	Other

2nd choice:

Home	Hospice N/H	Hospital	Other

Source: (please circle) (if more than one applies circle all that apply)

Patient	Patient Notes	CHCP

Environmental factors**Health care:**

Rural environment	Y	N
Continuing care funding:	Y	N
Known to palliative care team	Y	N (if yes, which and service available)

Social support:

Accommodation type:	House	Flat	Other
Home owner	Y	N	
Living with relatives:	Y	N	
Married:	Y	N	
Extended family support	Y	N (if yes, please list)	
Living with children under 18	Y	N (if yes, please list)	

Date of Death:

Place of Death

Home	Hospice N/H	Hospital	Other

PPS

%	Ambulation	Activity and evidence of disease	Self-care	Intake	Level of consciousness
100	Full	Normal activity No evidence of disease	Full	Normal	Full
90	Full	Normal activity Some evidence of disease	Full	Normal	Full
80	Full	Normal activity with effort Some evidence of disease	Full	Normal or reduced	Full
70	Reduced	Unable to do normal job/work Some evidence of disease	Full	Normal or reduced	Full
60	Reduced	Unable to do hobby/house work Significant disease	Occasional assistance	Normal or reduced	Full or confusion
50	Mainly sit/lie	Unable to do any work Extensive disease	Considerable assistance	Normal or reduced	Full or confusion
40	Mainly in bed	As above	Mainly assistance	Normal or reduced	Full or drowsy or confusion
30	Bed bound	As above	Total care	Reduced	Full or drowsy or confusion
20	As above	As above	Total care	Sips	Full or drowsy or confusion
10	As above	As above	Total care	Mouth care	Drowsy or coma
0	Death	-	-	-	-

Patient's Name _____ Date ____/____/____ ID # _____

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

- I. **INSTRUCTIONS:** Below is a list of symptoms. If you had the symptom **DURING THE PAST WEEK**, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom **DISTRESSED** or **BOTHERED** you.

Check <u>all</u> the symptoms you have had during the PAST WEEK.	→→ IF YES: How much did it DISTRESS or BOTHER you?					
	Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Difficulty concentrating						
Pain						
Lack of energy						
Cough						
Changes in skin						
Dry mouth						
Nausea						
Feeling drowsy						
Numbness/tingling in hands and feet						
Difficulty sleeping						
Feeling bloated						
Problems with urination						
Vomiting						
Shortness of breath						
Diarrhea						
Sweats						
Mouth sores						
Problems with sexual interest or activity						
Itching						
Lack of appetite						
Dizziness						
Difficulty swallowing						
Change in the way food tastes						
Weight loss						

Patient's Name _____ Date ____/____/____ ID # _____

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form [MSAS-SF]

- I. INSTRUCTIONS:** Below is a list of symptoms. If you had the symptom DURING THE PAST WEEK, please check Yes. If you did have the symptom, please check the box that tells us how much the symptom DISTRESSED or BOTHERED you.

Check <u>all</u> the symptoms you have had during the PAST WEEK.	→ → <u>IF YES:</u> How much did it DISTRESS or BOTHER you?					
	Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Hair loss						
Constipation						
Swelling of arms or legs						
"I don't look like myself"						
If you had <u>any other symptoms</u> during the PAST WEEK, please list them below, and indicate how much the symptom DISTRESSED or BOTHERED you.						
1. _____						
2. _____						

- II.** Below are other commonly listed symptoms. Please indicate if you have had the symptom DURING THE PAST WEEK, and if so, how OFTEN it occurred.

Check <u>all</u> the symptoms you have had during the PAST WEEK	→ → <u>IF YES,</u> How <u>OFTEN</u> did it occur?				
	Yes [✓]	Rarely [1]	Occasionally [2]	Frequently [3]	Almost Constantly [4]
Feeling sad					
Worrying					
Feeling irritable					
Feeling nervous					

McGILL QOL QUESTIONNAIRE

Instructions

The questions in this questionnaire begin with a statement followed by two opposite answers.

Numbers extend from one extreme answer to its opposite.

Please circle the number between 0 and 10 which is most true for you.

There are no right or wrong answers.

Completely honest answers will be most helpful

EXAMPLE

I am hungry:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

- If you are not even a little bit hungry, you would circle 0
- If you are a little hungry (you just finished a meal but still have room for dessert), you might circle a 1, 2 or 3
- If you are feeling moderately hungry (because mealtime is approaching), you might circle a 4, 5 or 6
- If you are very hungry (because you haven't eaten all day), you might circle a 7, 8 or 9
- If you are extremely hungry, you would circle 10.

BEGIN HERE:

IT IS VERY IMPORTANT THAT YOU ANSWER ALL QUESTIONS FOR HOW YOU HAVE BEEN
FEELING JUST IN THE PAST TWO (2) DAYS

PART A

Considering all parts of my life – physical, emotional, social, spiritual, and financial –*over the past two (2) days* the quality of my life has been:

very bad 0 1 2 3 4 5 6 7 8 9 10 **excellent**

PART B

- (1) For questions in Part 'B', please list the **PHYSICAL SYMPTOMS OR PROBLEMS** which have been the biggest problem for you over the past **two (2)** days. (Some examples are: pain, tiredness, weakness, nausea, vomiting, constipation, diarrhoea, trouble sleeping, shortness of breath, lack of appetite, sweating, immobility. Feel free to refer to others if necessary).
- (2) Circle the number which best shows how big a problem each one has been for you **OVER THE PAST TWO (2) DAYS**.
- (3) If, over the past two (2) days, you had **NO** physical symptoms or problems, or only one or two, answer for each of the ones you have had and write 'none' for the extra questions in Part B, and then continue to Part C.

1. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)
- no problem** 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**
2. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)
- no problem** 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**
3. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)
- no problem** 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**

4. Over the past two (2) days I have felt:

physically 0 1 2 3 4 5 6 7 8 9 10 **physically**
terrible **well**

PART C

*Please choose the number which best describes your feelings and thoughts
OVER THE PAST TWO (2) DAYS.*

5. Over the past two (2) days, I have been depressed:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

6. Over the past two (2) days, I have been nervous or worried:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

7. Over the past two (2) days, how much of the time did you feel sad?

never 0 1 2 3 4 5 6 7 8 9 10 **always**

8. Over the past two (2) days, when I thought of the future, I was:

not afraid 0 1 2 3 4 5 6 7 8 9 10 **terrified**

9. Over the past two (2) days, my life has been:

utterly 0 1 2 3 4 5 6 7 8 9 10 **very**
meaningless **purposeful**
and without **and**
purpose **meaningful**

10. Over the past two (2) days, when I thought about my whole life, I felt that in achieving life goals I have:

made no 0 1 2 3 4 5 6 7 8 9 10 **progressed**
progress **to complete**
whatsoever **fulfillment**

11. Over the past two (2) days, when I thought about my life, I felt that my life to this point has been:

completely 0 1 2 3 4 5 6 7 8 9 10 **very**
worthless **worthwhile**

12. Over the past two (2) days, I have felt that I have:

no control 0 1 2 3 4 5 6 7 8 9 10 **complete**
over my **control over**
life **my life**

13. Over the two (2) days, I felt good about myself as a person

completely 0 1 2 3 4 5 6 7 8 9 10 **completely**
disagree **agree**

14. To me, the past two (2) days were:

a burden 0 1 2 3 4 5 6 7 8 9 10 **a gift**

15. Over the past two (2) days, the world has been:

an 0 1 2 3 4 5 6 7 8 9 10 **caring and**
impersonal **responsive**
unfeeling place **to my needs**

16. Over the past two (2) days, I felt supported:

not at all 0 1 2 3 4 5 6 7 8 9 10 **completely**

PART D

Please list or describe the things which had the greatest effect on your QoL in the past two (2) days. Please tell us whether each thing you list made your QoL better or worse during this time. If you need more space, please continue on the back of this page.

Satisfaction Questionnaire (week 1 only)

FAMCARE P scale Code B /0

Think about the care that you have received from all the health professionals.

Please answer EACH of the questions below indicating how satisfied you are with the care received: Very Satisfied (5) Satisfied (4)

Undecided (3)

Dissatisfied (2)) Very Dissatisfied (1)

How satisfied are you with:

1. Doctor's attention to your description of symptoms
1 2 3 4 5
2. How thoroughly the doctor assesses your symptoms
1 2 3 4 5
3. Information given about how to manage pain
1 2 3 4 5
4. Information given about side effects
1 2 3 4 5
5. Speed at which symptoms were treated
1 2 3 4 5
6. Information given about your tests
1 2 3 4 5
7. The way tests and treatments are performed
1 2 3 4 5
8. The way tests and treatments are followed up by the doctor
1 2 3 4 5
9. Information given about your prognosis
1 2 3 4 5
10. Answers from health professionals
1 2 3 4 5
11. Referral to specialists
1 2 3 4 5
12. Availability of doctors to answer your questions
1 2 3 4 5
13. Availability of nurses to answer your questions

	1	2	3	4	5
14. The way the family is included in treatment and care decisions	1	2	3	4	5
15. Coordination of care	1	2	3	4	5
16. The availability of doctors to your family	1	2	3	4	5

Hospital2Home service satisfaction questionnaire (if applicable)

(1) How would you describe the length of the CC?

- a. Too short
- b. About right
- c. Too long

(2) Before the CC had you met all the CHCPs?

If not, list below who you met for the first time

(3) Were all the issues you feel are important to your care addressed?

- a. yes all
- b. yes mostly
- c. no, a lot was missing

(4) Did you receive a copy of your individualised care plan?

- a. yes
- b. no
- c. I wasn't offered one
- d. I was offered one but did not want it

If yes, did you understand it?

- e. yes all

f. mostly

g. No

(5) Did any of it's contents surprise you (ie: not mentioned in the CC)

a. yes

b. no

(6) Did any of its contents distress you?

a. yes

b. no

(7) Would you recommend the Hospital2Home CC service to other patients in a similar situation to you?

(8) Any other comments

**Appendix 7.3.8: The feasibility study QUAN: Carer Clinical
Record File**

**A pragmatic prospective controlled
evaluation comparing a CC model of care
with standard models of care at the
transition between acute and community**

Clinical Record File

Carer

Assessment No 1

Patient identification no:
Carer identification no: C

Date of entry into study:

PI authorisation signature:

Date of signature:

Carer Demographic Data

Study number: _____ Date of study entry: _____
(all carers numbers are prefixed by C and correlate with patient study number)

Main carer's name: _____

Relationship with patient: Wife Husband Child Mother/father Other

Age _____

Gender _____

Ethnic origin

White -

British	☐	1
Irish	☐	2
Any other White background	☐	3

Please specify.....

Black or Black British -

Caribbean	☐	4
African	☐	5
Any other Black background	☐	6

Please specify.....

Asian or Asian British -

Indian	☐	7
Pakistani	☐	8
Bangladeshi	☐	9
Any other Asian background	☐	10

Please specify.....

Mixed -

White and Black Caribbean	☐	11
White and Black African	☐	12
White and Asian	☐	13
Any other Mixed background	☐	14

Please specify.....

Medical problems limit the carer: Y N
If yes, please specify: _____

Occupation: _____

Currently working: Y N

Hours per week: _____

Other dependents: Y N
If yes, please specify (who and if they live in the same household) _____

Care giver preferences:

PPC:

Discussed by team Y N Not documented

If yes, circle as appropriate

1st choice

Home Hospice N/H HospitalOther

2nd choice

Home Hospice N/H HospitalOther

PPD

Discussed by team Y N Not documented

If yes, circle as appropriate

1st choice:

Home Hospice N/H HospitalOther

2nd choice:

Home Hospice N/H HospitalOther

Other carer's (please list)

Name	Relationship	Live with patient (Y/N)

MEMORIAL SYMPTOM ASSESSMENT SCALE – Short Form (MSAS-SF)

I. **INSTRUCTIONS:** Below is a list of symptoms. If your family member had the symptom **DURING THE PAST WEEK** please check Yes. If they did have the symptom, please check the box that tells us how much the symptom DISTRESSED or BOTHERED them

Check <u>all</u> the symptoms you have had during the PAST WEEK.	→→ IF YES: How much did it DISTRESS or BOTHER you?					
	Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Difficulty concentrating						
Pain						
Lack of energy						
Cough						
Changes in skin						
Dry mouth						
Nausea						
Feeling drowsy						
Numbness/tingling in hands and feet						
Difficulty sleeping						
Feeling bloated						
Problems with urination						
Vomiting						
Shortness of breath						
Diarrhea						
Sweats						
Mouth sores						
Problems with sexual interest or activity						
Itching						
Lack of appetite						
Dizziness						
Difficulty swallowing						
Change in the way food tastes						
Weight loss						

Check <u>all</u> the symptoms you have had during the PAST WEEK.	→ → IF YES: How much did it DISTRESS or BOTHER you?					
	Yes [✓]	Not at All [0]	A little Bit [1]	Some-what [2]	Quite a Bit [3]	Very Much [4]
Hair loss						
Constipation						
Swelling of arms or legs						
"I don't look like myself"						
If you had <u>any other symptoms</u> during the PAST WEEK, please list them below, and indicate how much the symptom DISTRESSED or BOTHERED you.						
1. _____						
2. _____						

II. Below are other commonly listed symptoms. Please indicate if your family member has had the symptom DURING THE PAST WEEK, and if so, how OFTEN it occurred

Check <u>all</u> the symptoms you have had during the PAST WEEK	→ → IF YES, How OFTEN did it occur?				
	Yes [✓]	Rarely [1]	Occasionally [2]	Frequently [3]	Almost Constantly [4]
Feeling sad					
Worrying					
Feeling irritable					
Feeling nervous					

McGILL QOL QUESTIONNAIRE

Instructions

The questions in this questionnaire begin with a statement followed by two opposite answers.

Numbers extend from one extreme answer to its opposite.

Please circle the number between 0 and 10 which is most true for your family member.

There are no right or wrong answers.

Completely honest answers will be most helpful

EXAMPLE

I am hungry:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

- If you are not even a little bit hungry, you would circle 0
- If you are a little hungry (you just finished a meal but still have room for dessert), you might circle a 1, 2 or 3
- If you are feeling moderately hungry (because mealtime is approaching), you might circle a 4, 5 or 6
- If you are very hungry (because you haven't eaten all day), you might circle a 7, 8 or 9
- If you are extremely hungry, you would circle 10.

BEGIN HERE:

IT IS VERY IMPORTANT THAT YOU ANSWER ALL QUESTIONS FOR HOW YOU HAVE BEEN
FEELING JUST IN THE PAST TWO (2) DAYS

PART A

Considering all parts of your family members life – physical, emotional, social, spiritual, and financial –over the past two (2) days their QoL has been:

very bad 0 1 2 3 4 5 6 7 8 9 10 **excellent**

PART B

For questions in Part 'B', please list the **PHYSICAL SYMPTOMS OR PROBLEMS** which have been the biggest problem to your family member over the past **two (2)** days. (Some examples are: pain, tiredness, weakness, nausea, vomiting, constipation, diarrhoea, trouble sleeping, shortness of breath, lack of appetite, sweating, immobility. Feel free to refer to others if necessary).

Circle the number which best shows how big a problem each one has been for them **OVER THE PAST TWO (2) DAYS**.

If, over the past two (2) days, they had **NO** physical symptoms or problems, or only one or two, answer for each of the ones they have had and write 'none' for the extra questions in Part B, and then continue to Part C.

1. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)

no problem 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**

2. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)

no problem 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**

3. Over the past two (2) days,
one troublesome symptom has been:.....
(write symptom)

no problem 0 1 2 3 4 5 6 7 8 9 10 **tremendous problem**

4. Over the past two (2) days they have felt:

physically 0 1 2 3 4 5 6 7 8 9 10 **physically well**
Terrible

PART C

*Please choose the number which best describes their feelings and thoughts
OVER THE PAST TWO (2) DAYS.*

5. Over the past two (2) days, they have been depressed:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

6. Over the past two (2) days, they have been nervous or worried:

not at all 0 1 2 3 4 5 6 7 8 9 10 **extremely**

7. Over the past two (2) days, how much of the time have they felt sad?

never 0 1 2 3 4 5 6 7 8 9 10 **always**

8. Over the past two (2) days, when they think of the future, they are:

not afraid 0 1 2 3 4 5 6 7 8 9 10 **terrified**

9. Over the past two (2) days, their life has been:

utterly 0 1 2 3 4 5 6 7 8 9 10 **very**
meaningless **purposeful**
and without **and**
purpose **meaningful**

10. Over the past two (2) days, when they think about their whole life, they feel that in achieving life goals they have:

made no 0 1 2 3 4 5 6 7 8 9 10 **progressed**
progress **to complete**
whatsoever **fulfillment**

11. Over the past two (2) days, when they think about their life, they feel that to this point it has been:

completely 0 1 2 3 4 5 6 7 8 9 10 **very**
worthless **worthwhile**

12. Over the past two (2) days, they feel that they have:

no control 0 1 2 3 4 5 6 7 8 9 10 **complete**
over my **control over**
life **my life**

13. Over the two (2) days, they feel good about themselves as a person

completely 0 1 2 3 4 5 6 7 8 9 10 **completely**
disagree **agree**

14. To them, the past two (2) days were:

a burden 0 1 2 3 4 5 6 7 8 9 10 **a gift**

15. Over the past two (2) days, the world has been:

an 0 1 2 3 4 5 6 7 8 9 10 **caring and**
impersonal **responsive**
unfeeling place **to my needs**

16. Over the past two (2) days, they have felt supported:

not at all 0 1 2 3 4 5 6 7 8 9 10 **completely**

PART D

Please list or describe the things which had the greatest effect on your loved ones QoL in the past two (2) days. Please tell us whether each thing you list made their QoL better or worse during this time. If you need more space, please continue on the back of this page.

CAREGIVER QUALITY OF LIFE- CANCER

Below is a list of statements that other people caring for loved ones with cancer have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.

0	=	Not at all	2	=	Somewhat
1	=	A little bit	3	=	Quite a bit
		4	=		Very much

During the past 7 days:

1.	It bothers me that my daily routine is altered.	0	1	2	3	4
2.	My sleep is less restful.	0	1	2	3	4
3.	My daily life is imposed upon.	0	1	2	3	4
4.	I am satisfied with my sex life.	0	1	2	3	4
5.	It is a challenge to maintain my outside interests.	0	1	2	3	4
6.	I am under a financial strain.	0	1	2	3	4
7.	I am concerned about our insurance coverage.	0	1	2	3	4
8.	My economic future is uncertain.	0	1	2	3	4
9.	I fear my loved one will die.	0	1	2	3	4
10.	I have more of a positive outlook on life since my loved one's illness.	0	1	2	3	4
11.	My level of stress and worries has increased.	0	1	2	3	4
12.	My sense of spirituality has increased.	0	1	2	3	4
13.	It bothers me, limiting my focus to day-to-day.	0	1	2	3	4
14.	I feel sad.	0	1	2	3	4
15.	I feel under increased mental strain.	0	1	2	3	4
16.	I get support from my friends and neighbors.	0	1	2	3	4
17.	I feel guilty.	0	1	2	3	4
18.	I feel frustrated.	0	1	2	3	4

		0	=	Not at all		2	=	Somewhat	
		1	=	A little bit		3	=	Quite a bit	
				4	=	Very much			
19.	I feel nervous.	0	1	2	3	4			
20.	I worry about the impact my loved one's illness has had on my children or other family members.	0	1	2	3	4			
21.	I have difficulty dealing with my loved one's changing eating habits.	0	1	2	3	4			
22.	I have developed a closer relationship with my loved one.	0	1	2	3	4			
23.	I feel adequately informed about my loved one's illness.	0	1	2	3	4			
24.	It bothers me that I need to be available to chauffeur my loved one to appointments.	0	1	2	3	4			
25.	I fear the adverse effects of treatment on my loved one.	0	1	2	3	4			
26.	The responsibility I have for my loved one's care at home is overwhelming.	0	1	2	3	4			
27.	I am glad that my focus is on getting my loved one well.	0	1	2	3	4			
28.	Family communication has increased.	0	1	2	3	4			
29.	It bothers me that my priorities have changed.	0	1	2	3	4			
30.	The need to protect my loved one bothers me.	0	1	2	3	4			
31.	It upsets me to see my loved one deteriorate.	0	1	2	3	4			
32.	The need to manage my loved one's pain is overwhelming.	0	1	2	3	4			
33.	I am discouraged about the future.	0	1	2	3	4			
34.	I am satisfied with the support I get from my family.	0	1	2	3	4			
35.	It bothers me that other family members have not shown interest in taking care of my loved one.	0	1	2	3	4			

Satisfaction Questionnaire (Week1 only)

FAMCARE scale Code B /0

Think about the care that your family member has received from all the health professionals.

Please answer EACH of the questions below indicating how satisfied you are with the care received:

Very Satisfied (**VS**) Satisfied (**S**)

Undecided / Not relevant (**UN**)

Dissatisfied (**D**) Very Dissatisfied (**VD**)

How satisfied are you with:

9. the patient's pain relief
VS S UN D VD
10. information provided about the patient's prognosis
VS S UN D VD
11. answers from health professionals
VS S UN D VD
12. information given about medication side effects
VS S UN D VD
13. referrals to specialists
VS S UN D VD
14. availability of a hospital bed, if/when needed
VS S UN D VD
15. family conferences held to discuss the patient's illness
VS S UN D VD
16. speed with which symptoms are treated
VS S UN D VD
9. doctor's attention to patient's description of symptoms
VS S UN D VD
10. the way tests and treatments are performed
VS S UN D VD
11. availability of doctors to the family
VS S UN D VD
12. availability of nurses to the family
VS S UN D VD

13. coordination of care
VS S UN D VD
14. time required to make a diagnosis(by doctor)
VS S UN D VD
15. the way the family is included in treatment and care decisions
VS S UN D VD
16. information given about how to manage the patient's pain
VS S UN D VD
17. information given about the patient's tests
VS S UN D VD
18. how thoroughly the doctor assesses the patient's symptoms
VS S UN D VD
19. the way tests and treatments are followed up by the doctor
VS S UN D VD
20. availability of the doctor to the patient
VS S UN D VD

Hospital2Home Satisfaction Questionnaire

(1)How would you describe the length of the CC?

- c. Too short
- d. About right
- e. Too long

(2)Before the CC had you met all the CHCPs?

If not, list below who you met for the first time

(3)Were all the issues you feel are important to your care addressed?

- f. yes all
- g. yes mostly
- h. no, a lot was missing

(4) Did you receive a copy of the individualised care plan for your family member?

- i. yes
- j. no
- k. We weren't offered one
- l. We were offered one but did not want it

(5) If yes, did you understand it?

- m. yes all
- n. mostly
- o. No

(6) Did any of its contents surprise you (ie: not mentioned in the CC)

- p. yes
- q. no

(7) Did any of its contents distress you?

- r. yes
- s. no

(8) Would you recommend the Hospital2Home CC service to other patients in a similar situation to you?

(9) Any other comments

Appendix 7.3.9 : The feasibility study QUAN : Service Use Data collection tool

Hospital2Home CC (if applicable)

Date:

Place:

Duration:

ATTENDEES	TICK IF PRESENT (specify number if >1)
Patient	
Carer	
District Nurse	
CPC Nurse	
Hospital2Home Specialist Sister	
GP	
Social worker	
Other	

Scheduled Regular Care Package (AT HOME)

[illegible]

(please specify where from)											
Meals on wheels											
Other (please specify- including private input)											
Other (please specify - including private input)											

Scheduled Regular Package from the local hospice/palliative care team

			Scheduled time (T) and average length (L) of visit/contact									
			1		2		3		4		5	
CONTACTS (SERVICE)	NUMBER OF SCHEDULED VISITS PER WEEK (W) or PER DAY (D)	Date of change	T	L	T	L	T	L	T	L	T	L
Day centre visit												
Art therapy*												
Massage therapy/ Reflexology*												
Relaxation Exercises*												
Music therapy*												
Physiotherapy												
Bisphosphonate infusion*												

(* indicates this service occurs at the hospice unit eg- as part of day centre – please specify if different)

Medications List on entry to the study

Regular medications:

Drug	Dose	Route	Frequency

As required medications:

Drug	Dose	Route	Frequency

Intravenous/Subcutaneous medication/ fluids: Y / N

Drug	Dose	Route	Frequency

Feeding regimen: Y / N

Feed	Dose/Volume	Route	Frequency

Home Oxygen:

Litres prescribed	No.of hours /day	Non-invasive ventilation	If yes, no of hours/day
		Y / N	

Equipment Costs (Frequently used items)

Stock Item	Description	Gross Price £	Tick if Present
MOB632	Walking frame – domestic wheeled 890-960mm	15.62	
MOB819	Tray – plastic moulded, Buckingham Caddy	13.00	
BED206	Community bed – 4 section electric	680.00	
BED251	Cot sides – infill padded	40.00	
BED551	Mattress – overlay eclipse medium with cushion	675.00	
BED294	Table – over bed cantilever adjustable	27.00	
MOB714	Glide sheet – one way	30.06	
MOB716	Glideboard – Samarit Banana	44.50	
MOB771	Sling – Quickfit Deluxe net medium	63.00	
MOB775	Hoist – standard electric	991.25	
MOB514	Sling – Quickfit Deluxe Poly medium	60.00	
MOB707	Hoist – Midi 175 Electric	676.00	
TOI701	Raised toilet seat 102 mm high	6.90	
TOI729	Commode – fixed arms adjustable height	21.75	
TOI730	Commode – adjustable height with detachable arms	26.46	
TOI731	Commode – wheeled Mayfair	70.00	
TOI733	Commode – standard, extra wide heavy duty	96.29	
TOI741	Toilet seat and frame – adjustable extra wide with arms mobile	64.75	
KIT400	Stool with back and arms	19.42	
KIT413	Stool with arms and padded back	21.40	
KIT595	Perching stool with back and arms, adj, extra wide, heavy duty	58.50	
BAT105	Bath board – padded 730 mm	18.45	
BAT170	Bathability 62-82 kg hydraulic bath seat	265.00	
BAT212	Shower chair – Harrogate, adjustable	34.57	
SEA670	Raiser- chair, fixed height 75 mm	40.36	
SEA900	Chair – standard electric riser/recliner	300.00	
BAT191F	Grab rail – offset epoxy coated 715 mm	3.05	
HAR201	Door entry system	98.07	
HAR602	Banister rail – Mopstick	3.58/metre	

Equipment (Other)

Stock Item	Description	Gross Price £	Tick if present
	WALKING AIDS		
MOB533	Net bag for walking frames	3.11	
MOB542	Ramps – portable 1000mm	240.00	
MOB543	Ramps – portable 2000mm	365.00	
MOB544	Ramps – portable 3000mm	445.00	
MOB552	Walking frame – trough with wheels	78.45	
MOB556	Crutch – heavy duty, fixed height	23.77	
MOB557	Crutch – gutter	29.70	
MOB558	Crutch – comfort handles	13.80	
MOB559	Crutch – elbow, closed cuff double adjustable (pair) medium	13.50	
MOB561	Crutch – elbow, closed cuff double adjustable (pair) adult	10.00	
MOB562	Crutch – elbow, closed cuff double adjustable (pair) extra long	11.92	
MOB563	Rollator deluxe – easy fold with basket	79.64	
MOB564	Basket attachment for three wheel walkers	10.00	
MOB565	Three wheel walker with hand brakes	28.60	
MOB566	Three wheel walker with auto brake	28.60	
MOB568	Bag attachment for three wheel walkers	3.75	
MOB572	Walking frame – wheeled narrow small	14.00	
MOB573	Walking frame – slimline small	11.50	
MOB575	Walking frame – domestic 670-750 mm	13.53	
MOB576	Walking frame – domestic 780-860 mm	13.53	
MOB578	Walking frame – slimline medium	11.50	
MOB579	Walking frame – narrow	13.53	
MOB583	Walking frame – wheeled narrow medium	14.00	
MOB584	Walking frame – wheeled narrow large	14.00	
MOB587	Walking frame – folding	24.34	
MOB591	Walking stick – metal, Fischer left handed	5.99	
MOB592	Walking stick – metal, Fischer right handed	5.99	
MOB593	Walking aid – tripod	11.99	
MOB594	Walking aid – tetrapod	11.99	
MOB595	Ferrule – Z type 18 mm grey	0.30	
MOB596	Ferrule – Z type 22 mm Z-type	0.30	
MOB597	Ferrule – Z type 25 mm Grey	0.30	
MOB607	Ferrule 18 mm black	0.30	
MOB608	Ferrule 16 mm ZL	0.30	
MOB609	Ferrule 16 mm Black	0.40	
MOB630	Walking frame – domestic 870-950 mm	13.53	
MOB631	Walking frame – domestic wheeled 680-860 mm	15.62	
MOB641	Walking frame – slimline large	11.50	
MOB648	Walking stick – metal adjustable	4.77	
MOB649	Ferrule – Z type 19 mm Z-Type	0.30	
MOB650	Stick – wooden 965 mm	3.14	
MOB651	Stick – wooden 1016	3.33	
MOB652	Stick – wooden 1067 mm	3.25	
MOB660	Wheels for walking frames (pair)	6.39	
MOB661	Wheels for JMC walking frames	4.05	
	BEDS, COTSIDES, MATTRESSES		
BED200	Back rest	9.99	

BED202	Foam wedge – medium	44.56	
BED207	Community bed – 2 section electric	525.00	
BED208	Monkey pole – community bed	54.00	
BED209	Cot sides – cantilever, community bed	41.99	
BED210	Mattress elevator – single bed	224.00	
BED211	Mattress elevator – double bed	256.00	
BED213	Pillow lift	242.00	
BED217	Grab rail – Easyrail, single slatted beds	29.48	
BED220	Bed blanket cradle	8.00	
BED224	Bed leaver – Liftwell	26.99	
BED226	Straps – Liftwell bed lever	6.23	
BED227	Grab rail – Easyleaver with straps	28.00	
BED228	Grab rail – Easyleaver, heavy duty	35.29	
BED238	Ellison Bed – standard, adjustable height	133.00	
BED239	Bed aid – floor fixed	35.00	
BED260	Bed raiser – Langham 102 mm (pair)	13.40	
BED266	Bed raiser – Exmouth (pair)	45.28	
BED267	Bed raiser – Exmouth with castors (pair)	46.94	
BED270	Leg lifter	4.05	
BED290	Bed board – single	23.50	
BED295	Lifting pole – free standing	99.07	
BED296	Rope ladder	5.60	
BED300	Mattress – Propad plus dura cover, double	57.63	
BED301	Mattress- Propad plus dura cover, single	95.29	
BED302	Mattress- softform single	98.00	
BED322	Bed raiser – Alexander round	42.70	
BED323	Bed raiser – twin cup adjustable (pair)	15.70	
BED325	Bed raiser – adjustable, square cup	14.85	
BED550	Mattress – phase 2 alternating replacement with cushion	1800.00	
BED552	Mattress – repose, air filled static overlay single	72.00	
BED272	Tights aid – gutter style	3.06	
BED275	Button hook	2.48	
BED276	Dressing stick	2.04	
BED279	Shoe horn – long handled	1.05	
BED286	Lace – elastic brown	2.46	
BED287	Lace – elastic black	2.46	
BED289	Block – bed handle (pair)	23.00	
BED309	Table – over bed no wheels	25.00	
BED332	Stocking aid – gutter style	1.38	
BED346	Zip pull with built up handle	2.50	
BED471	Sock aid – Soxon	5.00	
BED472	Lace – elastic spring white	3.75	
BED473	Lace – coiler black	3.61	
BED474	Lace – coiler brown	3.61	
HAR305	Handiplug	7.99	
HAR306	Socket raiser – handisocket	24.97	
HAR311	Plug pull	1.53	
HAR329	Tapturn turner (pair)	2.86	
HAR330	Tap turner – crosshead and crystal	5.12	
HAR331	Tap turners	6.27	
HAR339	Scissors	5.11	
HAR347	Plug pull	3.06	
HAR350	Contour turner – multi-purposer	5.09	
HAR356	Pen grip (pack of 3)	1.52	
HAR357	Key turner – single	1.80	
HAR358	Reacher – pick up	4.08	

HAR360	Grip mat – medium	4.07	
HAR367	Reacher – medium	2.67	
HAR368	Reacher – long	2.81	
HAR406	Key turner – double	2.17	
HAR407	Key turner – Yale	1.58	
HAR530	Roll – Dycem blue	15.59	
HAR531	Roll – Dycem red	14.84	
HAR532	Roll – Dycem green	15.59	
VACUAIDE	Suction machine – mains with battery back up	204.75	
	HOIST, SLINGS, MOVING AND HANDLING EQUIPMENT		
MOB717	Turning disc	49.20	
MOB718	Leg support frame – ATO form	119.50	
MOB719	Maxi mover	50.00	
MOB729	Sling – full back paediatric	69.00	
MOB730	Sling – full back small	78.00	
MOB731	Sling – full back medium	75.00	
MOB732	Sling – full back large	72.00	
MOB740	Sling – Oxford transport, Standard medium	96.00	
MOB741	Sling – Oxford, Standard medium	54.00	
MOB761	Patient turner	126.75	
MOB770	Sling – Quickfit deluxe net small	60.00	
MOB772	Sling – Quickfit deluxe net large	66.00	
MOB791	Turntable	45.93	
MOB792	Transfer board – plastic	15.76	
SEA622	T roll small	70.00	
SEA623	T roll medium	81.00	
BED270	Leg lifter	4.05	
MOB400	Sling – universal fast fit poly small	49.11	
MOB401	Sling – universal fast fit poly medium	49.11	
MOB402	Sling – universal fast fit poly large	49.11	
MOB412	Sling – universal fast fit mesh small	54.13	
MOB413	Sling – universal fast fit mesh medium	54.13	
MOB414	Sling – universal fast fit mesh large	54.13	
MOB415	Sling – universal fast fit mesh with head support/padded legs S	79.83	
MOB416	Sling – universal fast fit mesh with head support/padded legs M	79.83	
MOB417	Sling – universal fast fit mesh with head support/padded legs L	79.83	
MOB418	Sling – toileting/dressing mesh small	73.74	
MOB419	Sling – toileting/dressing mesh medium	73.74	
MOB420	Sling – toileting/dressing mesh large	73.74	
MOB421	Sling – toileting/dressing mesh with head support/pad legs S	108.51	
MOB422	Sling – toileting/dressing mesh with head support/pad legs M	108.51	
MOB423	Sling – toileting/dressing mesh with head support/pad legs L	108.51	
MOB424	Sling – muscular dystrophy mesh with head support/pad legs S	103.12	
MOB425	Sling – muscular dystrophy mesh with head support/pad legs M	103.12	
MOB426	Sling – muscular dystrophy mesh with head support/pad legs L	103.12	
MOB427	Sling – amputee mesh small	101.41	

MOB428	Sling – amputee mesh medium	101.41	
MOB429	Sling – amputee mesh large	101.41	
MOB430	Sling – paediatric fast fit with head support	76.49	
MOB431	Sling – paediatric fast fit without head support	46.75	
MOB455	Sling – fast fit with padded legs small	70.11	
MOB456	Sling – fast fit with padded legs medium	70.00	
MOB457	Sling – fast fit with padded legs large	70.11	
MOB465	Sling – Quickfit mesh small	45.00	
MOB466	Sling – Quickfit mesh medium	51.00	
MOB467	Sling – Quickfit mesh large	54.00	
MOB510	Sling – access poly medium	78.00	
MOB511	Sling – Quickfit poly small	42.00	
MOB512	Sling – Quickfit poly medium	45.00	
MOB513	Sling – Quickfit poly large	51.00	
MOB527	Sling – Quickfit deluxe poly small	57.00	
MOB528	Sling – Quickfit deluxe poly large	63.00	
MOB536	Sling – access poly small	75.00	
MOB538	Sling – access poly large	81.00	
MOB611	Sliding sheet small	12.97	
MOB612	Sliding sheet medium	13.77	
MOB613	Sliding sheet large	16.87	
MOB616	Transfer belt – maxi	19.46	
MOB706	Hoist – mini 140 electric	568.75	
MOB708	Hoist – major 190 electric	822.25	
	TOILET AIDS		
TOI700	Raised toilet seat 51 mm high	6.75	
TOI710	Bed pan	12.87	
TOI712	Urinal – female	4.91	
TOI713	Urinal – male	3.36	
TOI714	Adapter – non-spill for male urinal (TOI713)	6.35	
TOI721	Floor fixing kit	7.36	
TOI722	Toilet frame – adjustable extra wide heavy duty with arm rests	37.19	
TOI724	Floor fixing kit for extra wide toilet frame	39.00	
TOI725	Bottom wiper	6.72	
TOI727	Fixed floor attachments – commode	7.36	
TOI735	Chemical commode	26.46	
TOI737	Bucket – commode 20 litre	4.50	
TOI738	Pot – commode	1.80	
TOI743	Toilet seat and frame – adjustable extra wide with arms fixed	65.12	
TOI760	Fluid – Elsan Green 1 litre	3.66	
TOI771	Toilet seat and frame – Stirling	41.79	
TOI771F	Floor fixing kit for Stirling toilet seat and frame	15.41	
TOI772	Toilet frame – Cumbria	16.40	
TOI772F	Floor fixing kit for Cumbria toilet frame	7.36	
	KITCHEN		
HAR302	Tin opener – bench electric	15.34	
HAR303	Kettle – electric mini jug	15.66	
HAR351	Jar opener – twister	1.89	
HAR354	Jar opener – spillnot	10.43	
KIT401	Stool with arms	17.17	
KIT402	Stool without back and arms	14.92	
KIT410	Trolley – Etwell small	45.65	
KIT411	Trolley – Etwell standard	39.85	

KIT412	Trolley – Swedish	28.50	
KIT420	Kettle tipper – jug	7.59	
KIT424	Spread board – plastic	3.11	
KIT429	Kettle tipper – cordless jug	12.81	
KIT430	Kettle tipper – standard	12.00	
KIT432	Mug – insulated	3.89	
KIT439	Plate surround – incurve	1.96	
KIT441	Bread board	9.85	
KIT446	Ultralite cutlery knife small	6.65	
KIT447	Ultralite cutlery form small	5.11	
KIT448	Ultralite cutlery spoon small	5.11	
KIT478	Straw – Pat Saunders	5.09	
KIT479	Peeler/grater – Clyde	16.18	
KIT500	Kings cutlery knife	2.36	
KIT501	Kings cutlery fork	2.36	
KIT502	Kings cutlery spoon	2.36	
KIT503	Kings cutlery junior spoon	2.36	
KIT504	Kings cutlery teaspoon	2.36	
KT507	Kings handles – double ended lightweight	3.88	
KIT508	Kings handles – oval varigrip	2.39	
KIT509	Kings cutlery – splayed Nelson knife	2.36	
KIT510	Kings cutlery – angled knife	2.36	
KIT512	Kings cutlery – angled fork right	2.36	
KIT513	Kings cutlery – angled spoon left	2.36	
KIT514	Kings cutlery – angled spoon right	2.36	
KIT516	Kings cutlery – angled fork left	2.36	
KIT517	Kings cutlery – splayed fork	2.36	
KIT518	Kings cutlery – splayed rocker knife	4.84	
KIT519	Kings cutlery – splayed rocker knife small	2.36	
KIT520	Kings handles – standard built-up standard	1.77	
KIT521	Kings handles – standard built-up slim	1.27	
KIT522	Kings handles – standard built-up contoured	1.89	
KIT523	Kings handles – standard built-up mushroom	1.99	
KIT524	Kings handles – standard built-up customised	5.02	
KIT526	Kings spoon – soft spoon	3.76	
KIT527	Kings spoon – soft teaspoon	3.44	
KIT530	Kings handles – standard built-up heavyweight	2.49	
KIT531	Kings handles – small contoured varigrip	2.69	
KIT532	Kings handles – large contoured varigrip	2.81	
KIT533	Kings handles – lightweight small	3.00	
KIT534	Kings handles – lightweight large	3.29	
KIT535	Utralite handle small	9.60	
KIT536	Ultralite handle large	10.21	
KIT543	Caring cutlery knife	3.01	
KIT563	Jar opener – Dycem	1.82	
KIT565	Tray – lap with bean bag	16.57	
KIT570	Reflex knife – carving	8.93	
KIT572	Tray – freehand with non slip mat	14.37	
KIT585	Cooking basket	9.73	
KIT589	Can opener – safety	8.07	
KIT650	Belliclamp	19.14	
KIT654	Kings handles – doubled ended standard	2.93	
KIT655	Reflex knife – Chef	7.63	
KIT670	Ultralite cutlery knife large	6.65	
KIT671	Ultralite cutlery fork large	4.59	
KIT672	Ultralite cutlery spoon large	4.59	
KIT673	Ultralite cutlery knife large	9.18	

KIT675	Caring cutlery fork	3.01	
KIT676	Caring cutlery spoon	3.01	
KIT680	Cup – two handled with spout lid	4.15	
KIT700	Jar opener – Strongboy	5.79	
KIT703	Ring pull tin opener	1.36	
	BATHING AIDS		
BAT104	Bath board – padded 673 mm	17.55	
BAT106	Bath board – metal	16.00	
BAT110	Shower board 660 mm	11.20	
BAT111	Shower board 711 mm	11.20	
BAT120	Bath seat – slatted Merlin 152 mm	9.30	
BAT121	Bath seat – slatted Merlin 203 mm	9.30	
BAT124	Bath seat – plastic /metal	13.00	
BAT125	Bath seat – padded, plastic/metal	28.25	
BAT128	Bath seat – slatted Merlin 305 mm	9.30	
BAT129	Tap rail – contoured	16.68	
BAT151	Bath mat – non slip	4.11	
BAT152	Shower mat	3.24	
BAT153	Sponge – long handled	2.40	
BAT158	Bath step – plastic, adjustable height	13.40	
BAT168	Bathability 38-63 kg	265.00	
BAT171	Bathability 63-102 kg	265.00	
BAT200	Paddle caps – Rentwood	6.13	
BAT203	Toe washer	4.61	
BAT213	Bath seat – adjustable height	12.00	
BAT216	Bath lift – Neptune	295.00	
BAT216P	Side flap protectors – Neptune bath lift	3.11	
BAT235	Bath lift – AquaJoy Premier Plus	249.00	
BAT235RC	Replacement covers – AquaJoy Premier Plus Bath Lift	21.00	
BAT250	Bath board – Savannah slatted 660 mm	10.15	
BAT251	Bath board – Savannah slatted 711 mm	10.51	
BAT253	Bath board handle – Savannah	2.17	
BAT310	Shower chair – extra wide with back	75.31	
BAT311	Swivel bather – Myco	85.00	
BAT313	Shower seat – adjustable height	20.16	
	CHAIRS		
BED553	Repose foot protector	54.00	
SEA615	Castellated foam cushion	15.34	
SEA620	Footstool – T framed adjustable	24.00	
SEA625	Chair – Capital 18	98.00	
SEA626	Chair – Capital 20	100.00	
SEA627	Board – chair	4.00	
SEA630	Chair – Seville, adjustable height	76.50	
SEA640	Raiser – chair adjustable	12.10	
SEA663	Raiser – Langham Grip-ons 25 mm	12.18	
SEA664	Raiser – Langham Grip-ons 38 mm	12.75	
SEA665	Raiser – Langham Grip-ons 50 mm	14.52	
SEA672	Raiser – chair/settee adjustable	46.20	
SEA673	Raiser – settee fixed height	41.83	
SEA703	Raiser – chair, round	40.20	
SEA850	Cushion – Flotech Solution	120.98	
SEA851	Cushion – Repose Air Filled	36.00	
	RAILS FOR WALL		
BAT137F	Devon Mk II rail – folding wall mounted 762 mm	29.62	

BAT138F	Devon Mk II rail – folding wall mounted 546 mm	28.63	
BAT139F	Devon rail with drop down leg	52.26	
BAT140F	Grab rail – plastic 300 mm	4.04	
BAT141F	Grab rail – plastic 450 mm	4.10	
BAT142F	Grab rail – plastic 600 mm	4.82	
BAT143F	Grab rail – metal 715 mm	2.24	
BAT144F	Grab rail – metal 890 mm	2.75	
BAT146F	Rail – Newel left handed	4.47	
BAT147F	Rail – Newell right handed	4.47	
BAT149F	Grab rail – metal 445 mm	2.24	
BAT187F	Grab rail – plastic fluted	9.94	
BAT190F	Grab rail – offset epoxy coated 445 mm	1.99	
BAT195F	Grab rail – metal 1200 mm	5.18	
BAT204F	Devon Rail – folding floor mounted	62.98	
BAT334	Swedish rail – epoxy coated	30.35	
	VISUAL IMPAIRMENT		
HARS325	Clofield silent alert paging system – trickle charger	30.84	
HARS343	Telephone – clear sound big button	29.47	
HARS344	Alarm clock – vibrating	22.38	
HARS346	Alarm clock – VC10	26.91	
HARS413	Flash receiver – Bellman	61.11	
HARS475	Bellman visit paging system – telephone alert	16.88	
HARS475	Telephone – very high amplification	62.28	
HARS476	Telephone ringer with bright light	15.55	
HARS478	Link box	17.00	
HAR372	Liquid level indicator – short stem	5.79	
HAR513	Guide – signature black/white	0.52	
HAR514	Pound coin holder	0.75	
HARS11	Watch – black talking	6.96	
HARS12	Watch – easy to see	12.01	
HARS18	Telephone – BT big button plus	19.15	
HARS51	Lamp – fluorescent Livall	24.17	
HARS56	Timer – easy to see	9.76	
HARS70	Cassette recorder – Sony TCM-200DV	27.04	
HARS71	Cane – 4 section symbol reflective 700 mm	7.99	
HARS72	Cane – 4 section Ambutech reflective 900 mm	14.50	
HARS73	Cane – 4 section Ambutech reflective 950 mm	14.50	
HARS74	Cane – 4 section Ambutech reflective 1000mm	14.50	
HARS75	Cane – 4 section Ambutech reflective 1050 mm	14.50	
HARS76	Cane – 4 section Ambutech reflective 1100 mm	14.50	
HARS77	Cane – 4 section Ambutech reflective 1150 mm	14.50	
HARS79	Cane – 4 section Ambutech folding long 1270 mm	19.02	
HARS80	Cane – 4 section Ambutech folding long 1370 mm	19.02	
HARS95	Cane – 4 section Ambutech folding long 1320 mm	19.02	
HARS96	Cane – 4 section Ambutech folding long 1220 mm	19.02	
HARS98	Guide – envelope	1.04	
HARS138	Diary – large print	4.98	
HARS139	Address book – large print	4.59	
HARS145	Typoscope – pack of four	4.00	
HARS163	Cane – 4 section Ambutech reflective 850 mm	14.50	
HARS166	Cane – 4 section Ambutech folding long 1070 mm	19.02	
HARS168	Cane – 4 section Ambutech folding long 1170 mm	19.02	
HARS171	Walking stick – Coopers adjustable aluminium	5.10	
HARS172	Replacement tip – Canadian centre Louis-Herbert	8.19	
HARS210	Watch – tactile quartz large gents	29.79	
HARS218	Knife – Dux carving with guard right handed	21.11	

HARS218L	Knife – Dux carving with guard left handed	21.11	
HARS229	Calendar – large print	2.50	
HARS232	Timer – easy to see tactile mechanical	11.08	
HARS237	Watch – Unisex easy to see	12.01	
HARS241	Alarm clock – Braille	17.19	
HARS243	Mat – Dycem oblong large red	7.70	
HARS246	Tacti-Mark – marking fluid black	3.30	
HARS247	Replacement tape – red	3.79	
HARS250	Telecane – 5 section 750 mm	16.17	
HARS251	Cane – 3 section symbol Ambutech 700 mm	8.29	
HARS252	Cane – 3 section symbol Ambutech 1000 mm	8.29	
HARS257	Cane – 4 set Ambutech graphite folding long roller tip 1120 mm	23.70	
HARS258	Cane – 4 set Ambutech graphite folding long roller tip 1220 mm	23.70	
HARS259	Cane – 4 set Ambutech graphite folding long roller tip 1320 mm	23.70	
HARS261	Replacement tip – Ambutech hook style while roller	8.19	
	SENSORY IMPAIRMENT		
Hars270	Measuring cups – set of 4 stainless steel	4.00	
HARS271	Cup holder – moulded	3.00	
HARS280	Loc dots – labelling	0.96	
HARS285	Alarm clock/calendar – talking	31.95	
HARS292	Lamp with flexi-arm	32.13	
HARS293	Glasses – anti-glare polarising	12.50	
HARS294	Talking mini memo	5.45	
HARS295	Kitchen scales – talking	37.95	
HARS296	Microwave – talking	195.00	
HARS301	Alarm clock – square talking	13.79	
HARS306	Arm bands – reflexite	4.40	
HARS404	TV magnifier for 23-26" screen	99.99	
HARS405	Coin holder – multi pack	2.75	
HARS409	Clamp – standing lamp	6.74	
HARS410	Flexi light – floor standing	42.40	
HARS412	Calculator – talking	20.85	
HARS415	Mat – Dycem round yellow	4.00	
HARS417	Mat – Dycem oblong yellow	4.00	
HARS422	Board – chopping translucent yellow	3.00	
HARS425	Talking tin – starter pack of 3	9.99	
HARS426	Bumps – on – pack of mixed colours	2.00	
HARS427	Bumps – on – pack of mixed shapes	1.84	
HARS434	Cane – 4 section Ambutech graphite folding long roller tip 1170 mm	23.70	
HARS436	Cane – 4 set Ambutech graphite folding long roller tip 1270 mm	23.70	
HARS437	Cane – 4 section revolution advantage folding	18.50	
HARS443	Gloves – coolskin	22.95	
HARS447	Cane – 4 section Ambutech graphite folding long roller tip 1070 mm	23.70	
HARS448	Cane – 4 section Ambutech graphite folding long roller tip 1370	23.70	
HARS449	Telecane – 3 section 450 mm	13.40	
HARS461	Watch – talking bracelet	6.75	
HARS462	Watch – easy to see bracelet	7.95	
HARS467	Colour detector – talking	49.95	
HARS468	Label reader – Voila talking	149.95	

HARS470	Braille Dymo gun	27.99	
HARS473	Replacement tip – Ambutech hook style jumbo roller	8.19	
HARS474	Replacement tip – Ambutech hook style metal glide	3.03	
HARS479	Replacement tip – Ambutech hook style rolling ball	5.10	
HARS500	Cane – 4 section symbol reflective 850 mm	7.99	
HARS501	Cane – 4 section symbol reflective 1000 mm	7.99	
HARS502	Cane – 4 section symbol reflective 1050 mm	7.99	
HARS510	Telecane – 5 section (deaf/blind)	18.99	
HARS520	Eye shields – UV one size wrap around	12.60	
HARS521	Eye shields – UV small fit over 32% medium grey	5.76	
HARS522	Eye shields – UV small fit over 49% orange	11.36	
HARS525	Clock – radio controlled large easy to see wall	23.97	
HARS526	Watch – talking with stop watch	9.37	
HARS528	Watch – easy to see jumbo chrome leather strap	12.01	
HARS529	Watch – easy to see jumbo chrome self grip strap	12.01	
HARS530	Watch – easy to see gold coloured	16.96	
HARS531	Watch – tactile quartz small ladies	29.79	
HARS532	Writing frame – blue A4 rigid lines	3.50	
HARS534	Bump-ons large round clear	3.00	
HARS535	Bump-ons flat round orange	3.00	
HARS536	Dymo tape clear 12 mm	1.20	
HARS537	Dymo tape clear 9 mm	1.20	
HARS540	Telephone – phone easy	11.84	
HARS542	Double spatula	6.47	
HARS543	Tongs – extra long goodgrips	6.07	
HARS544	Magnifying mirror	18.01	
HARS550	Money detector	17.00	
HARS551	Watch – ladies single button talking leather strap	23.00	
HARS552	Watch – ladies single button talking bracelet	23.00	
HARS553	Watch – gents single button talking leather strap	23.00	
HARS554	Watch – gents single button talking bracelet	23.00	
HARS555	Watch – talking strap	10.75	
HARS556	Watch – easy to see leather strap	12.95	
HARS560	Alarm clock – travel talking	9.95	
HARS561	Accessory pack – Voila talking label reader	40.00	
HARS562	Audible labelling device – Voxcom II	80.00	
HARS563	TVi	355.00	
HARS564	Alarm clock – talking	5.12	
MOB910	Walking stick – adjustable white folding	13.50	
HAR375	Door entry alert – Mountcastle	53.53	
HARS18	Telephone – large button	19.15	
HARS24	Door chime – courier portable	29.10	
HARS24D	Mains adaptor – portable door chime	5.88	
HARS37	Loop system – domestic	53.90	
HARS39	Phone flash	24.70	
HARS44	Doorbell – Mountcastle silent bell 91D system single light circuit	72.56	
HARS45	Doorbell – Mountcastle silent bell 91D system double light circuit	90.87	
HARS47	Call indicator switch – Mountcastle	57.50	
HARS48	Teleflash	22.21	
HARS100	Crescendo 20/5 with steto clips	44.55	
HARS101	Crescendo 20/5 with neckloop	44.55	
HARS104	Minicom – textphone Ultratech 6000	170.72	
HARS107	Telephone amplifier – Ameriphone	14.63	
HARS115	Bellman visit paging system – phone/person to person transmitter	25.50	

HARS116	Transmitter – doorbell	36.36	
HARS117	Bellman visit paging system – baby cry transmitter	63.36	
HARS121	Uniphone	199.99	
HARS123	Bellman visit paging system – Ionization smoke alarm transmitter	45.81	
HARS124	Bellman visit paging system – optical smoke alarm transmitter	65.89	
HARS125	Bellman visit paging system – pager	90.77	
HARS126	Bellman alarm clock and bed shaker	44.07	
HARS134	Bed shaker – Bellman visit paging system	9.58	
HARS135	Connection lead for Bellman visit paging system	4.30	
HARS143	Bellman visit paging system – charging cradle	29.92	
HARS178A	Mini tech with headset	54.50	
HARS178B	Mini tech with neckloop	54.50	
HARS185	Fax machine – plain paper	69.99	
HARS200	Loop system	76.50	
HARS201	Loop system and pad	87.75	
HARS202	Loop pad	17.55	
HARS203	Loop system with yellow knobs	81.00	
HARS204	Infralight system	89.00	
HARS205	Infralight system with neckloop	107.10	
HARS206	Scart loop Amplifier with pad	76.50	
HARS207	Pager system – bellman home visit pack B	188.32	
HARS208	Minicom – compact portable	228.00	
HARS209	Textphone – pro8000	331.79	
HARS211	Crescendo 20/2	44.55	
HARS212	Alarm clock – shake awake vibrating portable	15.00	
HARS213	Door Beacon	23.00	
HARS216	Loop system – domestic with two microphones	58.00	
HARS311	Clofield silent alert paging system – pager unit	62.07	
HARS312	Clofield silent alert paging system – alarm clock charger	61.20	
HARS313	Clofield silent alert paging system – vibrating pillow pad	16.88	
HARS319	Clofield silent alert paging system- movement monitor	74.39	

Health Economic Data Collection Tool

(researcher to check for any changes 2 weekly and complete)

Study ID:

Week No:

Date:

Changes to Scheduled Regular Care Package (AT HOME) since last assessment

		Scheduled time (T) and average length of visits (L)									
		1		2		3		4		5	
CONTACTS (SERVICE)	NUMBER OF SCHEDULED VISITS PER WEEK (W) or PER DAY (D)	T	L	T	L	T	L	T	L	T	L
GP											
District Nurse											
Carers											
CPC Nurse (visit)											
CPC Nurse (tele)											
Marie Curie Night Nurses											
Day Sitters (please specify where from)											
Meals on wheels											
Other (please specify- including private input)											
Other (please specify - including private input)											

Changes to Scheduled Regular Package from the local hospice/palliative care team since last assessment

			Scheduled time (T) and average length (L) of visit/contact									
			1		2		3		4		5	
CONTACTS (SERVICE)	NUMBER OF SCHEDULED VISITS PER WEEK (W) or PER DAY (D)	Date of change	T	L	T	L	T	L	T	L	T	L
Day centre visit												
Art therapy*												
Massage therapy/ Reflexology*												
Relaxation Exercises*												
Music therapy*												
Physiotherapy												
Bisphosphonate infusion*												

(* indicates this service occurs at the hospice unit eg- as part of day centre – please specify if different)

The Number of transport journeys related to health care since last assessment

Type of transport	Number of journeys	Approximate Distance for each journey (miles)				
		1	2	3	4	5
999 Ambulance						
Booked non urgent ambulance						
Booked urgent ambulance						
Hospital taxi						
Hospital transport						
Own car						
Public transport						

Changes to Medications List since last assessment

Regular medications:

Drug	Dose	Route	Frequency

As required medications:

Drug	Dose	Route	Frequency

Intravenous/Subcutaneous medication/ fluids: Y / N

Drug	Dose	Route	Frequency

Feeding regimen: Y / N

Feed	Dose/Volume	Route	Frequency

Home Oxygen:

Litres prescribed	No.of hours /day	Non-invasive ventilation	If yes, no of hours/day
		Y / N	

Changes to Equipment since last assessment (Frequently used items)

Stock Item	Description	Gross Price £	Tick if added	Tick if removed
MOB632	Walking frame – domestic wheeled 890-960mm	15.62		
MOB819	Tray – plastic moulded, Buckingham Caddy	13.00		
BED206	Community bed – 4 section electric	680.00		
BED251	Cot sides – infill padded	40.00		
BED551	Mattress – overlay eclipse medium with cushion	675.00		
BED294	Table – over bed cantilever adjustable	27.00		
MOB714	Glide sheet – one way	30.06		
MOB716	Glideboard – Samarit Banana	44.50		
MOB771	Sling – Quickfit Deluxe net medium	63.00		
MOB775	Hoist – standard electric	991.25		
MOB514	Sling – Quickfit Deluxe Poly medium	60.00		
MOB707	Hoist – Midi 175 Electric	676.00		
TOI701	Raised toilet seat 102 mm high	6.90		
TOI729	Commode – fixed arms adjustable height	21.75		
TOI730	Commode – adjustable height with detachable arms	26.46		
TOI731	Commode – wheeled Mayfair	70.00		
TOI733	Commode – standard, extra wide heavy duty	96.29		
TOI741	Toilet seat and frame – adjustable extra wide with arms mobile	64.75		
KIT400	Stool with back and arms	19.42		
KIT413	Stool with arms and padded back	21.40		
KIT595	Perching stool with back and arms, adj, extra wide, heavy duty	58.50		
BAT105	Bath board – padded 730 mm	18.45		
BAT170	Bathability 62-82 kg hydraulic bath seat	265.00		
BAT212	Shower chair – Harrogate, adjustable	34.57		
SEA670	Raiser- chair, fixed height 75 mm	40.36		
SEA900	Chair – standard electric riser/recliner	300.00		
BAT191F	Grab rail – offset epoxy coated 715 mm	3.05		
HAR201	Door entry system	98.07		
HAR602	Banister rail – Mopstick	3.58/metre		

Changes to Equipment since last assessment (Other)

Stock Item	Description	Gross Price £	Tick if added	Tick if removed
	WALKING AIDS			
MOB533	Net bag for walking frames	3.11		
MOB542	Ramps – portable 1000mm	240.00		
MOB543	Ramps – portable 2000mm	365.00		
MOB544	Ramps – portable 3000mm	445.00		
MOB552	Walking frame – trough with wheels	78.45		
MOB556	Crutch – heavy duty, fixed height	23.77		
MOB557	Crutch – gutter	29.70		
MOB558	Crutch – comfort handles	13.80		
MOB559	Crutch – elbow, closed cuff double adjustable (pair) medium	13.50		
MOB561	Crutch – elbow, closed cuff double adjustable (pair) adult	10.00		
MOB562	Crutch – elbow, closed cuff double adjustable (pair) extra long	11.92		
MOB563	Rollator deluxe – easy fold with basket	79.64		
MOB564	Basket attachment for three wheel walkers	10.00		
MOB565	Three wheel walker with hand brakes	28.60		
MOB566	Three wheel walker with auto brake	28.60		
MOB568	Bag attachment for three wheel walkers	3.75		
MOB572	Walking frame – wheeled narrow small	14.00		
MOB573	Walking frame – slimline small	11.50		
MOB575	Walking frame – domestic 670-750 mm	13.53		
MOB576	Walking frame – domestic 780-860 mm	13.53		
MOB578	Walking frame – slimline medium	11.50		
MOB579	Walking frame – narrow	13.53		
MOB583	Walking frame – wheeled narrow medium	14.00		
MOB584	Walking frame – wheeled narrow large	14.00		
MOB587	Walking frame – folding	24.34		
MOB591	Walking stick – metal, Fischer left handed	5.99		
MOB592	Walking stick – metal, Fischer right handed	5.99		
MOB593	Walking aid – tripod	11.99		
MOB594	Walking aid – tetrapod	11.99		
MOB595	Ferrule – Z type 18 mm grey	0.30		
MOB596	Ferrule – Z type 22 mm Z-type	0.30		
MOB597	Ferrule – Z type 25 mm Grey	0.30		
MOB607	Ferrule 18 mm black	0.30		
MOB608	Ferrule 16 mm ZL	0.30		
MOB609	Ferrule 16 mm Black	0.40		
MOB630	Walking frame – domestic 870-950 mm	13.53		
MOB631	Walking frame – domestic wheeled 680-860 mm	15.62		
MOB641	Walking frame – slimline large	11.50		
MOB648	Walking stick – metal adjustable	4.77		
MOB649	Ferrule – Z type 19 mm Z-Type	0.30		
MOB650	Stick – wooden 965 mm	3.14		
MOB651	Stick – wooden 1016	3.33		
MOB652	Stick – wooden 1067 mm	3.25		
MOB660	Wheels for walking frames (pair)	6.39		
MOB661	Wheels for JMC walking frames	4.05		
	BEDS, COTSIDES, MATTRESSES			

BED200	Back rest	9.99		
BED202	Foam wedge – medium	44.56		
BED207	Community bed – 2 section electric	525.00		
BED208	Monkey pole – community bed	54.00		
BED209	Cot sides – cantilever, community bed	41.99		
BED210	Mattress elevator – single bed	224.00		
BED211	Mattress elevator – double bed	256.00		
BED213	Pillow lift	242.00		
BED217	Grab rail – Easyrail, single slatted beds	29.48		
BED220	Bed blanket cradle	8.00		
BED224	Bed leaver – Liftwell	26.99		
BED226	Straps – Liftwell bed lever	6.23		
BED227	Grab rail – Easyleaver with straps	28.00		
BED228	Grab rail – Easyleaver, heavy duty	35.29		
BED238	Ellison Bed – standard, adjustable height	133.00		
BED239	Bed aid – floor fixed	35.00		
BED260	Bed raiser – Langham 102 mm (pair)	13.40		
BED266	Bed raiser – Exmouth (pair)	45.28		
BED267	Bed raiser – Exmouth with castors (pair)	46.94		
BED270	Leg lifter	4.05		
BED290	Bed board – single	23.50		
BED295	Lifting pole – free standing	99.07		
BED296	Rope ladder	5.60		
BED300	Mattress – Propad plus dura cover, double	57.63		
BED301	Mattress- Propad plus dura cover, single	95.29		
BED302	Mattress- softform single	98.00		
BED322	Bed raiser – Alexander round	42.70		
BED323	Bed raiser – twin cup adjustable (pair)	15.70		
BED325	Bed raiser – adjustable, square cup	14.85		
BED550	Mattress – phase 2 alternating replacement with cushion	1800.00		
BED552	Mattress – repose, air filled static overlay single	72.00		
BED272	Tights aid – gutter style	3.06		
BED275	Button hook	2.48		
BED276	Dressing stick	2.04		
BED279	Shoe horn – long handled	1.05		
BED286	Lace – elastic brown	2.46		
BED287	Lace – elastic black	2.46		
BED289	Block – bed handle (pair)	23.00		
BED309	Table – over bed no wheels	25.00		
BED332	Stocking aid – gutter style	1.38		
BED346	Zip pull with built up handle	2.50		
BED471	Sock aid – Soxon	5.00		
BED472	Lace – elastic spring white	3.75		
BED473	Lace – coiler black	3.61		
BED474	Lace – coiler brown	3.61		
HAR305	Handiplug	7.99		
HAR306	Socket raiser – handisocket	24.97		
HAR311	Plug pull	1.53		
HAR329	Tapturn turner (pair)	2.86		
HAR330	Tap turner – crosshead and crystal	5.12		
HAR331	Tap turners	6.27		
HAR339	Scissors	5.11		
HAR347	Plug pull	3.06		
HAR350	Contour turner – multi-purposer	5.09		
HAR356	Pen grip (pack of 3)	1.52		
HAR357	Key turner – single	1.80		

HAR358	Reacher – pick up	4.08		
HAR360	Grip mat – medium	4.07		
HAR367	Reacher – medium	2.67		
HAR368	Reacher – long	2.81		
HAR406	Key turner – double	2.17		
HAR407	Key turner – Yale	1.58		
HAR530	Roll – Dycem blue	15.59		
HAR531	Roll – Dycem red	14.84		
HAR532	Roll – Dycem green	15.59		
VACUAIDE	Suction machine – mains with battery back up	204.75		
	HOIST, SLINGS, MOVING AND HANDLING EQUIPMENT			
MOB717	Turning disc	49.20		
MOB718	Leg support frame – ATO form	119.50		
MOB719	Maxi mover	50.00		
MOB729	Sling – full back paediatric	69.00		
MOB730	Sling – full back small	78.00		
MOB731	Sling – full back medium	75.00		
MOB732	Sling – full back large	72.00		
MOB740	Sling – Oxford transport, Standard medium	96.00		
MOB741	Sling – Oxford, Standard medium	54.00		
MOB761	Patient turner	126.75		
MOB770	Sling – Quickfit deluxe net small	60.00		
MOB772	Sling – Quickfit deluxe net large	66.00		
MOB791	Turntable	45.93		
MOB792	Transfer board – plastic	15.76		
SEA622	T roll small	70.00		
SEA623	T roll medium	81.00		
BED270	Leg lifter	4.05		
MOB400	Sling – universal fast fit poly small	49.11		
MOB401	Sling – universal fast fit poly medium	49.11		
MOB402	Sling – universal fast fit poly large	49.11		
MOB412	Sling – universal fast fit mesh small	54.13		
MOB413	Sling – universal fast fit mesh medium	54.13		
MOB414	Sling – universal fast fit mesh large	54.13		
MOB415	Sling – universal fast fit mesh with head support/padded legs S	79.83		
MOB416	Sling – universal fast fit mesh with head support/padded legs M	79.83		
MOB417	Sling – universal fast fit mesh with head support/padded legs L	79.83		
MOB418	Sling – toileting/dressing mesh small	73.74		
MOB419	Sling – toileting/dressing mesh medium	73.74		
MOB420	Sling – toileting/dressing mesh large	73.74		
MOB421	Sling – toileting/dressing mesh with head support/pad legs S	108.51		
MOB422	Sling – toileting/dressing mesh with head support/pad legs M	108.51		
MOB423	Sling – toileting/dressing mesh with head support/pad legs L	108.51		
MOB424	Sling – muscular dystrophy mesh with head support/pad legs S	103.12		
MOB425	Sling – muscular dystrophy mesh with head support/pad legs M	103.12		
MOB426	Sling – muscular dystrophy mesh with head support/pad legs L	103.12		

MOB427	Sling – amputee mesh small	101.41		
MOB428	Sling – amputee mesh medium	101.41		
MOB429	Sling – amputee mesh large	101.41		
MOB430	Sling – paediatric fast fit with head support	76.49		
MOB431	Sling – paediatric fast fit without head support	46.75		
MOB455	Sling – fast fit with padded legs small	70.11		
MOB456	Sling – fast fit with padded legs medium	70.00		
MOB457	Sling – fast fit with padded legs large	70.11		
MOB465	Sling – Quickfit mesh small	45.00		
MOB466	Sling – Quickfit mesh medium	51.00		
MOB467	Sling – Quickfit mesh large	54.00		
MOB510	Sling – access poly medium	78.00		
MOB511	Sling – Quickfit poly small	42.00		
MOB512	Sling – Quickfit poly medium	45.00		
MOB513	Sling – Quickfit poly large	51.00		
MOB527	Sling – Quickfit deluxe poly small	57.00		
MOB528	Sling – Quickfit deluxe poly large	63.00		
MOB536	Sling – access poly small	75.00		
MOB538	Sling – access poly large	81.00		
MOB611	Sliding sheet small	12.97		
MOB612	Sliding sheet medium	13.77		
MOB613	Sliding sheet large	16.87		
MOB616	Transfer belt – maxi	19.46		
MOB706	Hoist – mini 140 electric	568.75		
MOB708	Hoist – major 190 electric	822.25		
	TOILET AIDS			
TOI700	Raised toilet seat 51 mm high	6.75		
TOI710	Bed pan	12.87		
TOI712	Urinal – female	4.91		
TOI713	Urinal – male	3.36		
TOI714	Adapter – non-spill for male urinal (TOI713)	6.35		
TOI721	Floor fixing kit	7.36		
TOI722	Toilet frame – adjustable extra wide heavy duty with arm rests	37.19		
TOI724	Floor fixing kit for extra wide toilet frame	39.00		
TOI725	Bottom wiper	6.72		
TOI727	Fixed floor attachments – commode	7.36		
TOI735	Chemical commode	26.46		
TOI737	Bucket – commode 20 litre	4.50		
TOI738	Pot – commode	1.80		
TOI743	Toilet seat and frame – adjustable extra wide with arms fixed	65.12		
TOI760	Fluid – Elsan Green 1 litre	3.66		
TOI771	Toilet seat and frame – Stirling	41.79		
TOI771F	Floor fixing kit for Stirling toilet seat and frame	15.41		
TOI772	Toilet frame – Cumbria	16.40		
TOI772F	Floor fixing kit for Cumbria toilet frame	7.36		
	KITCHEN			
HAR302	Tin opener – bench electric	15.34		
HAR303	Kettle – electric mini jug	15.66		
HAR351	Jar opener – twister	1.89		
HAR354	Jar opener – spillnot	10.43		
KIT401	Stool with arms	17.17		
KIT402	Stool without back and arms	14.92		
KIT410	Trolley – Etwell small	45.65		

KIT411	Trolley – Etwell standard	39.85		
KIT412	Trolley – Swedish	28.50		
KIT420	Kettle tipper – jug	7.59		
KIT424	Spread board – plastic	3.11		
KIT429	Kettle tipper – cordless jug	12.81		
KIT430	Kettle tipper – standard	12.00		
KIT432	Mug – insulated	3.89		
KIT439	Plate surround – incurve	1.96		
KIT441	Bread board	9.85		
KIT446	Ultralite cutlery knife small	6.65		
KIT447	Ultralite cutlery form small	5.11		
KIT448	Ultralite cutlery spoon small	5.11		
KIT478	Straw – Pat Saunders	5.09		
KIT479	Peeler/grater – Clyde	16.18		
KIT500	Kings cutlery knife	2.36		
KIT501	Kings cutlery fork	2.36		
KIT502	Kings cutlery spoon	2.36		
KIT503	Kings cutlery junior spoon	2.36		
KIT504	Kings cutlery teaspoon	2.36		
KT507	Kings handles – double ended lightweight	3.88		
KIT508	Kings handles – oval varigrip	2.39		
KIT509	Kings cutlery – splayed Nelson knife	2.36		
KIT510	Kings cutlery – angled knife	2.36		
KIT512	Kings cutlery – angled fork right	2.36		
KIT513	Kings cutlery – angled spoon left	2.36		
KIT514	Kings cutlery – angled spoon right	2.36		
KIT516	Kings cutlery – angled fork left	2.36		
KIT517	Kings cutlery – splayed fork	2.36		
KIT518	Kings cutlery – splayed rocker knife	4.84		
KIT519	Kings cutlery – splayed rocker knife small	2.36		
KIT520	Kings handles – standard built-up standard	1.77		
KIT521	Kings handles – standard built-up slim	1.27		
KIT522	Kings handles – standard built-up contoured	1.89		
KIT523	Kings handles – standard built-up mushroom	1.99		
KIT524	Kings handles – standard built-up customised	5.02		
KIT526	Kings spoon – soft spoon	3.76		
KIT527	Kings spoon – soft teaspoon	3.44		
KIT530	Kings handles – standard built-up heavyweight	2.49		
KIT531	Kings handles – small contoured varigrip	2.69		
KIT532	Kings handles – large contoured varigrip	2.81		
KIT533	Kings handles – lightweight small	3.00		
KIT534	Kings handles – lightweight large	3.29		
KIT535	Utralite handle small	9.60		
KIT536	Ultralite handle large	10.21		
KIT543	Caring cutlery knife	3.01		
KIT563	Jar opener – Dycem	1.82		
KIT565	Tray – lap with bean bag	16.57		
KIT570	Reflex knife – carving	8.93		
KIT572	Tray – freehand with non slip mat	14.37		
KIT585	Cooking basket	9.73		
KIT589	Can opener – safety	8.07		
KIT650	Belliclamp	19.14		
KIT654	Kings handles – doubled ended standard	2.93		
KIT655	Reflex knife – Chef	7.63		
KIT670	Ultralite cutlery knife large	6.65		
KIT671	Ultralite cutlery fork large	4.59		
KIT672	Ultralite cutlery spoon large	4.59		

KIT673	Ultralite cutlery knife large	9.18		
KIT675	Caring cutlery fork	3.01		
KIT676	Caring cutlery spoon	3.01		
KIT680	Cup – two handled with spout lid	4.15		
KIT700	Jar opener – Strongboy	5.79		
KIT703	Ring pull tin opener	1.36		
	BATHING AIDS			
BAT104	Bath board – padded 673 mm	17.55		
BAT106	Bath board – metal	16.00		
BAT110	Shower board 660 mm	11.20		
BAT111	Shower board 711 mm	11.20		
BAT120	Bath seat – slatted Merlin 152 mm	9.30		
BAT121	Bath seat – slatted Merlin 203 mm	9.30		
BAT124	Bath seat – plastic /metal	13.00		
BAT125	Bath seat – padded, plastic/metal	28.25		
BAT128	Bath seat – slatted Merlin 305 mm	9.30		
BAT129	Tap rail – contoured	16.68		
BAT151	Bath mat – non slip	4.11		
BAT152	Shower mat	3.24		
BAT153	Sponge – long handled	2.40		
BAT158	Bath step – plastic, adjustable height	13.40		
BAT168	Bathability 38-63 kg	265.00		
BAT171	Bathability 63-102 kg	265.00		
BAT200	Paddle caps – Rentwood	6.13		
BAT203	Toe washer	4.61		
BAT213	Bath seat – adjustable height	12.00		
BAT216	Bath lift – Neptune	295.00		
BAT216P	Side flap protectors – Neptune bath lift	3.11		
BAT235	Bath lift – Aquajoy Premier Plus	249.00		
BAT235RC	Replacement covers – Aquajoy Premier Plus Bath Lift	21.00		
BAT250	Bath board – Savannah slatted 660 mm	10.15		
BAT251	Bath board – Savannah slatted 711 mm	10.51		
BAT253	Bath board handle – Savannah	2.17		
BAT310	Shower chair – extra wide with back	75.31		
BAT311	Swivel bather – Myco	85.00		
BAT313	Shower seat – adjustable height	20.16		
	CHAIRS			
BED553	Repose foot protector	54.00		
SEA615	Castellated foam cushion	15.34		
SEA620	Footstool – T framed adjustable	24.00		
SEA625	Chair – Capital 18	98.00		
SEA626	Chair – Capital 20	100.00		
SEA627	Board – chair	4.00		
SEA630	Chair – Seville, adjustable height	76.50		
SEA640	Raiser – chair adjustable	12.10		
SEA663	Raiser – Langham Grip-ons 25 mm	12.18		
SEA664	Raiser – Langham Grip-ons 38 mm	12.75		
SEA665	Raiser – Langham Grip-ons 50 mm	14.52		
SEA672	Raiser – chair/settee adjustable	46.20		
SEA673	Raiser – settee fixed height	41.83		
SEA703	Raiser – chair, round	40.20		
SEA850	Cushion – Flotech Solution	120.98		
SEA851	Cushion – Repose Air Filled	36.00		
	RAILS FOR WALL			

BAT137F	Devon Mk II rail – folding wall mounted 762 mm	29.62		
BAT138F	Devon Mk II rail – folding wall mounted 546 mm	28.63		
BAT139F	Devon rail with drop down leg	52.26		
BAT140F	Grab rail – plastic 300 mm	4.04		
BAT141F	Grab rail – plastic 450 mm	4.10		
BAT142F	Grab rail – plastic 600 mm	4.82		
BAT143F	Grab rail – metal 715 mm	2.24		
BAT144F	Grab rail – metal 890 mm	2.75		
BAT146F	Rail – Newel left handed	4.47		
BAT147F	Rail – Newell right handed	4.47		
BAT149F	Grab rail – metal 445 mm	2.24		
BAT187F	Grab rail – plastic fluted	9.94		
BAT190F	Grab rail – offset epoxy coated 445 mm	1.99		
BAT195F	Grab rail – metal 1200 mm	5.18		
BAT204F	Devon Rail – folding floor mounted	62.98		
BAT334	Swedish rail – epoxy coated	30.35		
	VISUAL IMPAIRMENT			
HARS325	Clofield silent alert paging system – trickle charger	30.84		
HARS343	Telephone – clear sound big button	29.47		
HARS344	Alarm clock – vibrating	22.38		
HARS346	Alarm clock – VC10	26.91		
HARS413	Flash receiver – Bellman	61.11		
HARS475	Bellman visit paging system – telephone alert	16.88		
HARS475	Telephone – very high amplification	62.28		
HARS476	Telephone ringer with bright light	15.55		
HARS478	Link box	17.00		
HAR372	Liquid level indicator – short stem	5.79		
HAR513	Guide – signature black/white	0.52		
HAR514	Pound coin holder	0.75		
HARS11	Watch – black talking	6.96		
HARS12	Watch – easy to see	12.01		
HARS18	Telephone – BT big button plus	19.15		
HARS51	Lamp – fluorescent Livall	24.17		
HARS56	Timer – easy to see	9.76		
HARS70	Cassette recorder – Sony TCM-200DV	27.04		
HARS71	Cane – 4 section symbol reflective 700 mm	7.99		
HARS72	Cane – 4 section Ambutech reflective 900 mm	14.50		
HARS73	Cane – 4 section Ambutech reflective 950 mm	14.50		
HARS74	Cane – 4 section Ambutech reflective 1000mm	14.50		
HARS75	Cane – 4 section Ambutech reflective 1050 mm	14.50		
HARS76	Cane – 4 section Ambutech reflective 1100 mm	14.50		
HARS77	Cane – 4 section Ambutech reflective 1150 mm	14.50		
HARS79	Cane – 4 section Ambutech folding long 1270 mm	19.02		
HARS80	Cane – 4 section Ambutech folding long 1370 mm	19.02		
HARS95	Cane – 4 section Ambutech folding long 1320 mm	19.02		
HARS96	Cane – 4 section Ambutech folding long 1220 mm	19.02		
HARS98	Guide – envelope	1.04		
HARS138	Diary – large print	4.98		
HARS139	Address book – large print	4.59		

HARS145	Typoscope – pack of four	4.00		
HARS163	Cane – 4 section Ambutech reflective 850 mm	14.50		
HARS166	Cane – 4 section Ambutech folding long 1070 mm	19.02		
HARS168	Cane – 4 section Ambutech folding long 1170 mm	19.02		
HARS171	Walking stick – Coopers adjustable aluminium	5.10		
HARS172	Replacement tip – Canadian centre Louis-Herbert	8.19		
HARS210	Watch – tactile quartz large gents	29.79		
HARS218	Knife – Dux carving with guard right handed	21.11		
HARS218L	Knife – Dux carving with guard left handed	21.11		
HARS229	Calendar – large print	2.50		
HARS232	Timer – easy to see tactile mechanical	11.08		
HARS237	Watch – Unisex easy to see	12.01		
HARS241	Alarm clock – Braille	17.19		
HARS243	Mat – Dycem oblong large red	7.70		
HARS246	Tacti-Mark – marking fluid black	3.30		
HARS247	Replacement tape – red	3.79		
HARS250	Telecane – 5 section 750 mm	16.17		
HARS251	Cane – 3 section symbol Ambutech 700 mm	8.29		
HARS252	Cane – 3 section symbol Ambutech 1000 mm	8.29		
HARS257	Cane – 4 set Ambutech graphite folding long roller tip 1120 mm	23.70		
HARS258	Cane – 4 set Ambutech graphite folding long roller tip 1220 mm	23.70		
HARS259	Cane – 4 set Ambutech graphite folding long roller tip 1320 mm	23.70		
HARS261	Replacement tip – Ambutech hook style white roller	8.19		
	SENSORY IMPAIRMENT			
Hars270	Measuring cups – set of 4 stainless steel	4.00		
HARS271	Cup holder – moulded	3.00		
HARS280	Loc dots – labelling	0.96		
HARS285	Alarm clock/calendar – talking	31.95		
HARS292	Lamp with flexi-arm	32.13		
HARS293	Glasses – anti-glare polarising	12.50		
HARS294	Talking mini memo	5.45		
HARS295	Kitchen scales – talking	37.95		
HARS296	Microwave – talking	195.00		
HARS301	Alarm clock – square talking	13.79		
HARS306	Arm bands – reflexite	4.40		
HARS404	TV magnifier for 23-26" screen	99.99		
HARS405	Coin holder – multi pack	2.75		
HARS409	Clamp – standing lamp	6.74		
HARS410	Flexi light – floor standing	42.40		
HARS412	Calculator – talking	20.85		
HARS415	Mat – Dycem round yellow	4.00		
HARS417	Mat – Dycem oblong yellow	4.00		
HARS422	Board – chopping translucent yellow	3.00		
HARS425	Talking tin – starter pack of 3	9.99		
HARS426	Bumps – on – pack of mixed colours	2.00		
HARS427	Bumps – on – pack of mixed shapes	1.84		
HARS434	Cane – 4 section Ambutech graphite folding long roller tip 1170 mm	23.70		
HARS436	Cane – 4 set Ambutech graphite folding long	23.70		

	roller tip 1270 mm			
HARS437	Cane – 4 section revolution advantage folding	18.50		
HARS443	Gloves – coolskin	22.95		
HARS447	Cane – 4 section Ambutech graphite folding long roller tip 1070 mm	23.70		
HARS448	Cane – 4 section Ambutech graphite folding long roller tip 1370	23.70		
HARS449	Telecane – 3 section 450 mm	13.40		
HARS461	Watch – talking bracelet	6.75		
HARS462	Watch – easy to see bracelet	7.95		
HARS467	Colour detector – talking	49.95		
HARS468	Label reader – Voila talking	149.95		
HARS470	Braille Dymo gun	27.99		
HARS473	Replacement tip – Ambutech hook style jumbo roller	8.19		
HARS474	Replacement tip – Ambutech hook style metal glide	3.03		
HARS479	Replacement tip – Ambutech hook style rolling ball	5.10		
HARS500	Cane – 4 section symbol reflective 850 mm	7.99		
HARS501	Cane – 4 section symbol reflective 1000 mm	7.99		
HARS502	Cane – 4 section symbol reflective 1050 mm	7.99		
HARS510	Telecane – 5 section (deaf/blind)	18.99		
HARS520	Eye shields – UV one size wrap around	12.60		
HARS521	Eye shields – UV small fit over 32% medium grey	5.76		
HARS522	Eye shields – UV small fit over 49% orange	11.36		
HARS525	Clock – radio controlled large easy to see wall	23.97		
HARS526	Watch – talking with stop watch	9.37		
HARS528	Watch – easy to see jumbo chrome leather strap	12.01		
HARS529	Watch – easy to see jumbo chrome self grip strap	12.01		
HARS530	Watch – easy to see gold coloured	16.96		
HARS531	Watch – tactile quartz small ladies	29.79		
HARS532	Writing frame – blue A4 rigid lines	3.50		
HARS534	Bump-ons large round clear	3.00		
HARS535	Bump-ons flat round orange	3.00		
HARS536	Dymo tape clear 12 mm	1.20		
HARS537	Dymo tape clear 9 mm	1.20		
HARS540	Telephone – phone easy	11.84		
HARS542	Double spatula	6.47		
HARS543	Tongs – extra long goodgrips	6.07		
HARS544	Magnifying mirror	18.01		
HARS550	Money detector	17.00		
HARS551	Watch – ladies single button talking leather strap	23.00		
HARS552	Watch – ladies single button talking bracelet	23.00		
HARS553	Watch – gents single button talking leather strap	23.00		
HARS554	Watch – gents single button talking bracelet	23.00		
HARS555	Watch – talking strap	10.75		
HARS556	Watch – easy to see leather strap	12.95		
HARS560	Alarm clock – travel talking	9.95		
HARS561	Accessory pack – Voila talking label reader	40.00		
HARS562	Audible labelling device – Voxcom II	80.00		
HARS563	TVi	355.00		

HARS564	Alarm clock – talking	5.12		
MOB910	Walking stick – adjustable white folding	13.50		
HAR375	Door entry alert – Mountcastle	53.53		
HARS18	Telephone – large button	19.15		
HARS24	Door chime – courier portable	29.10		
HARS24D	Mains adaptor – portable door chime	5.88		
HARS37	Loop system – domestic	53.90		
HARS39	Phone flash	24.70		
HARS44	Doorbell – Mountcastle silent bell 91D system single light circuit	72.56		
HARS45	Doorbell – Mountcastle silent bell 91D system double light circuit	90.87		
HARS47	Call indicator switch – Mountcastle	57.50		
HARS48	Teleflash	22.21		
HARS100	Crescendo 20/5 with steto clips	44.55		
HARS101	Crescendo 20/5 with neckloop	44.55		
HARS104	Minicom – textphone Ultratech 6000	170.72		
HARS107	Telephone amplifier – Ameriphone	14.63		
HARS115	Bellman visit paging system – phone/person to person transmitter	25.50		
HARS116	Transmitter – doorbell	36.36		
HARS117	Bellman visit paging system – baby cry transmitter	63.36		
HARS121	Uniphone	199.99		
HARS123	Bellman visit paging system – Ionization smoke alarm transmitter	45.81		
HARS124	Bellman visit paging system – optical smoke alarm transmitter	65.89		
HARS125	Bellman visit paging system – pager	90.77		
HARS126	Bellman alarm clock and bed shaker	44.07		
HARS134	Bed shaker – Bellman visit paging system	9.58		
HARS135	Connection lead for Bellman visit paging system	4.30		
HARS143	Bellman visit paging system – charging cradle	29.92		
HARS178A	Mini tech with headset	54.50		
HARS178B	Mini tech with neckloop	54.50		
HARS185	Fax machine – plain paper	69.99		
HARS200	Loop system	76.50		
HARS201	Loop system and pad	87.75		
HARS202	Loop pad	17.55		
HARS203	Loop system with yellow knobs	81.00		
HARS204	Infralight system	89.00		
HARS205	Infralight system with neckloop	107.10		
HARS206	Scart loop Amplifier with pad	76.50		
HARS207	Pager system – bellman home visit pack B	188.32		
HARS208	Minicom – compact portable	228.00		
HARS209	Textphone – pro8000	331.79		
HARS211	Crescendo 20/2	44.55		
HARS212	Alarm clock – shake awake vibrating portable	15.00		
HARS213	Door Beacon	23.00		
HARS216	Loop system – domestic with two microphones	58.00		
HARS311	Clofield silent alert paging system – pager unit	62.07		
HARS312	Clofield silent alert paging system – alarm clock	61.20		
HARS313	Clofield silent alert paging system – vibrating pillow pad	16.88		
HARS319	Clofield silent alert paging system- movement monitor	74.39		

Extra service contacts since last assessment (To be completed from assessment 2 onwards)

Please give details of any time you have had extra contact with the following services in the last week

[illegible]

grade) (Home visit)										
Other palliative care doctor (specify grade) (tele)										
Oncologist (tele) (specify grade)										
24 hour advice line										
Day centre visit										
Day centre nurse contact (tele)										
Art therapy*										
Massage / Reflexology*										
Music therapy*										
Relaxation*										
Blood tests (please specify where)										
Blood transfusion										
Day Case (specify where)										
Chiropodist										
Dietician										
Physiotherapist										
Psychologist										
Counsellor										
Occupational therapist										
Social worker										
Home help/care worker										
Meals on wheels										
Self help group										
Other (please specify)										

(* this additional service is assumed to be part of hospice care ie: at the hospice/day centre unless otherwise stated)

Hospital/Hospice Outpatient Appointments (since last assessment)

Date	Speciality	Hospital/Hospice	Extra procedures during visit (please list)

Hospital/Hospice Inpatient Stays (since last assessment)

Date Admitted	Date Discharged	Number of Days	Hospital/Hospice	Reason for admission

Hospital2Home service contacts

<u>Date</u>	<u>Reason</u>	<u>Face to face or Telephone</u>	<u>Contact with (please give HCP or patient)</u>	<u>Outcome</u>

Appendix 7.3.10: Bereavement pack H2H Study QUAN

Invitation letter to bereaved relative for post bereavement questionnaire (The feasibility study QUAN)

Dear *(Insert name here)*

Thank you for participating in our research study to improve the care and support for cancer patients in the community.

I am writing to you to invite you to take part in the final questionnaire part of the study. You may remember that when you entered the study it included a questionnaire at approximately 3 months after the death of your loved one with the researcher who knows you best.

This is to help us develop a full picture of your views about, and experiences of your loved ones care at the end of their life.

Before you decide, it is important for you to understand why the research is being done so I have attached another copy of the information sheet (attach appendix 1b) Please read it carefully and discuss it with friends, relatives if you wish

If you decide that you no longer wish to participate in the final questionnaire please return the form below in the stamped address envelope provided or contact the palliative care secretary on 0207 808 2761

If we have not heard from you within 3 weeks of the date of this letter we will assume you still wish to participate in the study and a member of the research team will contact you by telephone to arrange a time and place convenient to you for the questionnaire

Thank you for your time

Yours sincerely

Dr Julia Riley

.....

**I am no longer willing to participate in the questionnaire
Please do not contact me**

PRINT NAME:

SIGNATURE:

DATE:

Post Bereavement Questionnaire (prospective study)

Name of person completing the questionnaire:

Name of your deceased relative:

Carer Identification Number: C

These questions will be read out to the bereaved relative in an interview, at a location of the bereaved choice (ie: their home or hospital) by the researcher that has had regular contact with them throughout their loved ones illness

Regarding your loved on, and their place of death and preferences

(1) Where did he/she die?

- a. home
- b. hospital
- c. hospice or palliative care unit
- d. In a nursing or residential home
- e. Elsewhere (please say where):

If he/she died in a hospital, hospice, palliative care unit, nursing or residential home how long had he/she been there before he/she died?

(1) Did you ever talk about where your loved one would have chosen to die?

- a. Yes
- b. No

(2) If yes, where would they have chosen to die?

- a. home
- b. hospital (please specify which one)
- c. hospice or palliative care unit
- d. In a nursing or residential home
- e. Elsewhere (please say where):

(3) Did you have a preference?

- a. Yes
- b. No

(4) If you did, where would you have preferred your loved one die?

- a. home
- b. hospital (please specify which one)
- c. hospice or palliative care unit

- d. In a nursing or residential home
- e. Elsewhere (please say where):

Think about the care that your family member has received from all the health professionals.

Please answer EACH of the questions below indicating how satisfied you are with the care received:

Very Satisfied (VS) Satisfied (S)

Undecided / Not relevant (UN)

Dissatisfied (D) Very Dissatisfied (VD)

How satisfied are you with:

- 1 the patient's pain relief
VS S UN D VD
- 2 information provided about the patient's prognosis
VS S UN D VD
- 3 answers from health professionals
VS S UN D VD
- 4 information given about medication side effects
VS S UN D VD
- 5 referrals to specialists
VS S UN D VD
- 6 availability of a hospital bed, if/when needed
VS S UN D VD
- 7 family conferences held to discuss the patient's illness
VS S UN D VD
- 8 speed with which symptoms are treated
VS S UN D VD
9. doctor's attention to patient's description of symptoms
VS S UN D VD
- 10 the way tests and treatments are performed
VS S UN D VD
11. availability of doctors to the family
VS S UN D VD
12. availability of nurses to the family
VS S UN D VD
13. coordination of care

VS S UN D VD

14. time required to make a diagnosis(by doctor)
VS S UN D VD
15. the way the family is included in treatment and care decisions
VS S UN D VD
- 16 information given about how to manage the patient's pain
VS S UN D VD
- 17 information given about the patient's tests
VS S UN D VD
- 18 how thoroughly the doctor assesses the patient's symptoms
VS S UN D VD
- 19 the way tests and treatments are followed up by the doctor
VS S UN D VD
- 20 availability of the doctor to the patient
VS S UN D VD

***Thank you for completing this questionnaire, if any of these questions have caused you distress and you would like some extra support please leave us a contact number in the space provided below
Alternatively please feel free to call the palliative research team at any time if you would like to discuss any of these issues. (0207 808 2761)***

I would like some extra support, and my contact telephone number is below:

Name:

Contact telephone no:

**Appendix 7.3.11 – Condolence letter to informal carer –
The feasibility study QUAN**

Letter of Condolence to the Informal Carer

Dear *(Insert carer participant name here)*

We are writing to send you our condolences after the recent death of *(Insert patient participant name here)*. Our thoughts are with you and your family at this time.

We would also like to thank you for participating in our research study

If you have any queries or questions about this research study please do not hesitate to contact us

Thank you again for your participation and time

Yours Sincerely

Dr Julia Riley
Consultant
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea, London
0207 808 2761

Dr Clare Smith
Research Fellow

Appendix 7.3.12: Patient information sheet The feasibility study QUAL

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

'We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

*Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Thank you for reading this'*

What is the purpose of the study?

This study is trying to find out how doctors and nurses from the hospital communicate with patients and their families at crucial time points in their illness.

We are studying patients like you who are cared for by the Royal Marsden Hospital who are being discharged from the hospital back to their GP or CPCT through the Hospital2Home service.

This study will look at the your views and feelings, along with the hospital doctors views on this important time in your illness. The aim of the study is to learn from the experiences of patient's like yourself in order to improve care and services in the future

Why have I been chosen?

You have been invited to take part because you are a patient with cancer attending hospital who has been referred to the Hospital2Home service. We are inviting other patients in a similar situation to you to take part in the study.

Do I have to take part?

It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

You will be visited at home (or elsewhere if more convenient to you) by the researcher and be asked some basic questions about yourself and then you will be interviewed specifically regarding your feelings and views about being discharged from the oncologists care and any feedback you can give about the Hospital2Home service. This interview will be audiotaped and is likely to last between 45 minutes to one hour.

What are the possible disadvantages of taking part?

Taking part in the study will not adversely affect any aspect of your treatment at home or in hospital. Sometimes being asked about your feelings may be difficult to answer. If so, you do not have to continue or answer anything you do not feel comfortable with. You can stop the interview at any time and if you do not wish to continue the audio recording the recording will be erased and the information provided will not be included in the study. If you feel after answering our questions you need more support to deal with any emotions you have we will arrange this for you.

What are the possible benefits of taking part?

You will be offered a referral for additional support and assessment if necessary. These interviews are part of a larger study looking at the possible benefits of the Hospital2Home service.

The study will help people in the future by making health professionals more aware of the problems or experiences of patients who have cancer.

Will my taking part in this study be kept confidential?

If you consent to take part in the research, any of your medical records may be looked at by a member of the research team or regulatory authority. Your name, however, will not be disclosed. You will not be identified in any report or publication that arises as a result of the study. Your audiotape recording will be anonymised and stored securely. Sections of your interviews may be transcribed and used in publications including academic medical education journals and/or conference presentations however anonymity will always be preserved.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in

various medical journals. If you would like a summary of the results when available please inform your doctor or research nurse.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital. The study is funded by the Royal Marsden Palliative Care Research Fund. The researchers will not be paid for including you in the study.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study, and given their approval

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

**Dr Julia Riley and Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London
0207 808 2761**

**Appendix 7.3.13: Patient Consent Form- The feasibility
study QUAL**

Centre Number: RMH

Study Number:

Patient Identification for this trial: QUAL

CONSENT FORM

Title of Project: The Hospital2Home Research project

**(A pragmatic prospective controlled evaluation comparing a CC model of
care with standard models of care at the transition between acute and
community)**

Name of Researcher: **Dr Julia Riley**

Please initial box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I understand that my participation will be audio taped
5. I understand that sections of my interviews will be transcribed and used in publication including academic medical education journals and/or conference presentations and that my anonymity will be preserved.
6. I understand that I can stop the interview at any time if I do not wish to continue the audio recording and that the recording will be erased and the information provided will not be included in the study.

☐☐☐☐☐☐

- 7 I understand that audio/video tapes will be treated as strictly confidential and will be kept in accordance with research governance policies and that any raw data on which the results of the project depend will be retained in secure storage in accordance with the Data Protection Act (1998)
8. I agree to take part in the above study

☐☐

Name of patient Date Signature

Name of person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

**When completed - 1 for patient;
1 (original) to be kept in research site file;
1 for medical notes;**

Would you like a summary sheet of research findings YES/NO

**Appendix 7.3.14: Patient Clinical Record File: The
feasibility study QUAL**

QUALITATIVE PATIENT CLINICAL RECORD FILE AND TOPIC GUIDE

Study Identification Number:

PI Authorisation:

Date:

Signature:

Patient Demographic Data
(most data collected from notes)

Study Number:

Date of study entry:

Quantitative Study No (if applicable):

Inpatient/Outpatient

Age

Gender:

Address /Postcode

Factors related to illness

Cancer diagnosis:

Date:

Most recent Cancer treatment:

Date:

Extent of disease at entry into the study:

Locally advanced		Metastases

Last Scan Date:

Sites of disease:

Number of previous cancer treatments:

Surgery:

Chemotherapy:

Radiotherapy:

Details of anti-cancer treatment in the last 12 months

Surgery

Y/ N

If yes, please fill in details below:

DATE	DESCRIPTION OF SURGERY	REASON	PLACE	DAYS IN HOSPITAL

Chemotherapy (including monoclonal antibody treatment)
If yes, please fill in details below:

Y / N

DATE STARTED	CHEMOTHERAPY REGIMEN	NO. OF CYCLES	DATE FINISHED	REASON FOR STOPPING

Radiotherapy

Y/N

If yes, please fill in the details below:

DATE	SITE	NO OF FRACTIONS	REASON

Hormone therapy

Y/ N

If yes, please fill in the details below;

DATE STARTED	DRUG	DATE FINISHED	REASON FOR STOPPING

Bisphosphonate Treatment

Y/ N

DATE STARTED	DRUG/DOSE	PLACE GIVEN	DATE FINISHED	REASON FOR STOPPING

Other past medical history:

Individual factors

Ethnic origin

White -

- British ☐ 1
Irish ☐ 2
Any other White background ☐ 3

Please specify.....

Black or Black British -

- Caribbean ☐ 4
African ☐ 5
Any other Black background ☐ 6

Please specify.....

Asian or Asian British –

Indian	☐	7
Pakistani	☐	8
Bangladeshi	☐	9
Any other Asian background	☐	10
Please specify.....		

Mixed - White and Black Caribbean	☐	11
White and Black African	☐	12
White and Asian	☐	13
Any other Mixed background	☐	14
Please specify.....		

Environmental factors**Health care:**

Rural environment	Y	N
Continuing care funding:	Y	N
Known to palliative care team	Y	N (if yes, which and service available)

Social support:

Accommodation type: House	Flat	Other
Home owner	Y	N
Living with relatives:	Y	N
Married:	Y	N
Extended family support	Y	N (if yes, please list)
Living with children under 18	Y	N (if yes, please list)

PPS

%	Ambulation	Activity and evidence of disease	Self-care	Intake	Level of consciousness
100	Full	Normal activity No evidence of disease	Full	Normal	Full
90	Full	Normal activity Some evidence of disease	Full	Normal	Full
80	Full	Normal activity with effort Some evidence of disease	Full	Normal or reduced	Full
70	Reduced	Unable to do normal job/work Some evidence of disease	Full	Normal or reduced	Full
60	Reduced	Unable to do hobby/house work Significant disease	Occasional assistance	Normal or reduced	Full or confusion
50	Mainly sit/lie	Unable to do any work Extensive disease	Considerable assistance	Normal or reduced	Full or confusion
40	Mainly in bed	As above	Mainly assistance	Normal or reduced	Full or drowsy or confusion
30	Bed bound	As above	Total care	Reduced	Full or drowsy or confusion
20	As above	As above	Total care	Sips	Full or drowsy or confusion
10	As above	As above	Total care	Mouth care	Drowsy or coma
0	Death	-	-	-	-

Appendix 7.3.14 Patient Topic Guide: The feasibility study QUAL

Topic Guide: Patient

Topic A: Discharge from oncology services

I want you to think carefully about your last meeting with the oncologist when they discharged you from their care and referred you to the Hospital2Home service.

Tell me in your own words about what happened, What did it mean to you?

At the time, tell me in your own words how did it make you feel?, How do you feel about it now?

For you, in what ways did it go well and why?

What didn't go so well, and why?

Explain to me, what were your main concerns at the time?

Have they been alleviated or are they still your concerns now?

Explain to me any of your concerns now

Topic B: Co-ordination of care and views on Hospital2Home

As you see things who is responsible for your care now?

What has been good about this?, What has not been so positive/good about this, and why?

I want you to think about the Hospital2Home team and the service they provide. Think about this from the first time they met or spoke to you to the last time.

Explain to me your understanding of the service, Talk me through what has happened in your case

For you, what has gone well? What didn't go so well, and why?

I'd like you now to think about the meeting in your home. Describe to me what happened

Was this as you expected it to be, and why?

At the time, how did this meeting make you feel? Now, looking back how do you feel about the meeting?

Overall, describe to me what you think was good about this service?

What do you think is not so good about the service, and why?

Thinking about your experience so far, what advice would you give to others in a similar situation?

Do you have any suggestions on how anything could have been improved for you?

TOPIC C: Experience of completing this research interview

Tell me how you have felt about participating in this research interview

Did you find it upsetting in any way?. If so, in what ways/why was it upsetting?

Did you find it helpful in any way? If so, in what way/why was it helpful to you?

Do you have any suggestions about how we can improve research interviews like this in the future?

Any other issues you would like to discuss

Appendix 7.3.15 Invitation Letter and Information Sheet
HCP: The feasibility study QUAL

Dear *(Insert consultants name here)*

I am writing to invite you to take part in a one to one interview as part of a research study the palliative care department are conducting at the Royal Marsden Hospital.

We are conducting a study looking at the care our patients receive within the hospital towards the EoL. We are approaching consultants and their patients to participate in individual interviews about their experience of the Hospital2Home service and discharge from the Royal Marsden Hospital.

I have attached a copy of the information sheet (attach appendix 11b) for you to read.

Once you have made a decision about whether to participate I would be most grateful if you could either email me at clare.smith@rmh.nhs.uk or contact the palliative care secretary on 0207 808 2761 to let us know your decision

If you wish to participate, once we receive a reply form you we will contact you to arrange a convenient time and place for the interview.

If we have not heard from you within 2 weeks from the date of this letter we will contact you by telephone to remind you about the study and arrange an interview time if you are willing to participate

Thank you for your time

Yours sincerely

Dr Clare Smith
Palliative Care research fellow
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London
0207 808 2761

Health professional information sheet: The feasibility study QUAL

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

'We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.'

Please take time to read the following information and please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this'

What is the purpose of the study?

This study is trying to find out how doctors from the hospital communicate with patients and their families at crucial time points in their illness.

We are particularly interested in studying the consultation when oncologists inform patients that there is no further active anti-cancer treatment available to them, and subsequently discharge the patient from their care. The reason we are interested in this interaction is because it is a consultation that both doctors and patients often agree is important but find difficult.

This study will look at the views and feelings of patients and their oncologist/palliative care teams at this important time, including feedback on the Hospital2Home service. The aim of the study is to learn from these experiences in order to improve care in the future, particularly in relation to developing the Hospital2Home service.

Why have I been chosen?

You have been invited to take part because you are a health professional working at the Royal Marsden Hospital. We are also interviewing patients regarding their opinions.

Do I have to take part?

It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

What will happen to me if I take part?

You will be interviewed by the researcher at a time and place convenient to you. The interview will be audiotaped. The interview will be semi-structured and contain questions specifically regarding your feelings and views about the process of discharging patients with advanced disease from the hospital and your views on the Hospital2Home service. The interview is likely to last between 45 minutes to one hour.

Will my taking part in this study be kept confidential?

If you consent to take part in the research your identity will be kept strictly confidential. You will not be identified in any report or publication that arises as a result of the study. Your audiotape recording and raw data taken from the audiotapes will be anonymised and stored securely. Sections of your interviews may be transcribed and used in publications including academic medical education journals and/or conference presentations however anonymity will always be preserved.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in various medical journals. If you would like a summary of the results when available please inform the researcher.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital. The study is funded by the Royal Marsden Palliative Care Research Fund.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study and given their approval.

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

**Dr Julia Riley and Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London
0207 808 2761**

**Appendix 7.3.16: Healthcare professional Consent Form:
The feasibility study QUAL**

Centre Number: RMH

Study Number:

HCP Identification for this trial: QUAL

CONSENT FORM

Title of Project: The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Name of Researcher: **Dr Julia Riley**

Please initial box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.
4. I understand that my participation will be audio taped
5. I understand that sections of my interviews will be transcribed and used in publication including academic medical education journals and/or conference presentations and that my anonymity will be preserved.
6. I understand that I can stop the interview at any time if I do not wish to continue the audio recording and that the recording will be erased and the information provided will not be included in the study.

☐☐☐☐☐

- 7 I understand that audio/video tapes will be treated as strictly confidential and will be kept in accordance with research governance policies and that any raw data on which the results of the project depend will be retained in secure storage in accordance with the Data Protection Act (1998)
8. I agree to take part in the above study

☐☐

Name of participant Date Signature

Name of person taking consent Date Signature
(if different from researcher)

Researcher Date Signature

**When completed - 1 for the HCP participant;
1 (original) to be kept in research site file**

Would you like a summary sheet of research findings YES/NO

**Appendix 7.3.17: HCP Record File and Topic Guide: The
feasibility study QUAL**

HCP CLINICAL RECORD FILE AND INTERVIEW SCHEDULE

Study Identification Number:

PI Authorisation:

Date:

Signature:

HCP Demographic Data

Study Number:

Date of study entry:

Job Title

Age

Gender:

Number of years experience in current role:

Number of years working in health care:

Previous regular use of the Hospital2Home service: Y N
(Regular in defined as referring to the Hospital2Home service on a monthly basis)

Topic Guide: HCP

Topic A: Discharge from oncology and prognostication

Think about the times when you/colleagues have discharged patients who have no active treatment options available from the oncology service

Can you tell me in your own words what factors contribute to making this decision?

Thinking about these factors in what way does each of them affect when or how the decisions are made?

Can you tell me about determining prognosis in these patients?

Do you use any specific tools or aids to guide you when estimating prognosis?

Do difficulties in determining prognosis affect when and at what stage you/colleagues might consider discharging patients from oncology?

I'd like you to think specifically about the last patient you discharged/observed being discharged from clinic to the care of the community or the palliative care team because there are no further oncology treatments available

What went well, and why? Why do you think this went well?

What didn't go so well, and why? Why do you think it didn't go so well?

How did you feel at the time? How do you feel about it now?

Thinking about worries you may have when discharging patients to the community/palliative care team, can you describe these to me?

Topic B: The Hospital2Home service

I want you to think about the Hospital2Home team and the service they provide.

Explain to me your understanding of the service

Talk me through in your own words what happens when you refer to the service (think about both the patient and your interaction with the Hospital2Home team)

I'd like you to think about when you refer to the service, what does it mean to you?

What does it mean to the 'patient'?

What works well about the service? What doesn't work so well about the service, and why?

Thinking about why professionals do not use the service, can you explain to me your thought on this?

Thinking about why patients might decline the service, can you explain your thoughts on this?

Do you have any suggestions on how anything in the discharge process and referral to Hospital2Home can be improved?

Topic C: Experience of completing this interview

Tell me how you have felt about participating in this research

Any other issues you would like to discuss?

*The wording of this Topic guide was adapted for the H2H SS interviews by changing the word 'you' in each question to 'the oncologist'

**Appendix 7.3.18: Invitation letter, Information Sheet and
'Opt in' Form Bereaved relatives: IP Study**

Patient Study No: RD.....

Dear *(Insert name here)*

I am writing to you to invite you to take part in a questionnaire as part of a research study at the Royal Marsden Hospital.

From our records, it appears that *(Insert name here)* died recently on the ward at the Royal Marsden Hospital.

I am contacting you as the documented next of kin for *(Insert name here)*.

We are conducting a study looking at the care our patients receive within the hospital towards the EoL, and we are approaching relatives or next of kin of patients who have recently died in the Royal Marsden Hospital to complete a short questionnaire which we will send to you through the post.

This is to help us develop a full picture of your views about, and experiences of your loved one's/ relative's care at the end of their life.

Before you decide, it is important for you to understand why the research is being done so I have attached a copy of the information sheet (attach appendix 8b) Please read it carefully and discuss it with friends and relatives if you wish

Once you have made a decision about whether to participate or not then I would be most grateful if you could complete the reply slip attached and post it back to us in the stamped address envelope provided or alternatively contact the palliative care secretary on 0207 808 2761 and let her know your decision

If you wish to participate, once we receive your reply we will send you the questionnaire to complete along with a consent form

If we have not heard from you within 1 month of the date of this letter we will assume you do not wish to participate in the study and you will not be contacted further.

Thank you for your time

Yours sincerely

Dr Julia Riley

Dr Clare Smith

Bereaved Relative Information sheet: IP Study

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Protocol number: 3.0

'We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

*Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Thank you for reading this'*

What is the purpose of the study?

This study is trying to find out how doctors and nurses from the hospital can best help GPs and community nurses to care for people with cancer in their place of choice, which is most commonly home, and how we can stop people being admitted to hospital unnecessarily.

We are studying patients who are cared for by the Royal Marsden Hospital. Currently GPs of patients at the Royal Marsden Hospital are kept informed about their patients care through letters from clinic and discharge summaries with or without a CC meeting held in your home.

This study will compare these two methods and will also look at the care of patients who die whilst an inpatient at the Royal Marsden Hospital. The aim is to find the best way hospital teams can keep look after their patients towards the end of their life.

Why have I been chosen?

You have been invited to take part because you are the next of kin of a patient who has recently died in the Royal Marsden hospital

Do I have to take part?

It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep, and you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in anyway.

What will happen to me if I take part?

If you wish to take part we would either like you to return the reply slip enclosed or contact us by telephone on 0207 808 2761 to confirm you wish to take part. Once we receive this, a questionnaire will be sent to you through the post to complete and return to us. A consent form for you to sign will also be sent with this.

The questionnaire will take approximately 15 minutes to complete and will include questions about your next of kin's place of death, any preferences they might have had, and your views on the care they received.

If you find a question too difficult to answer please leave it blank and move onto the next one.

What are the possible disadvantages of taking part?

Sometimes being asked about your feelings may be difficult to answer. If so, you do not have to continue or answer anything you do not feel comfortable with. If you feel after answering our questions you need more support to deal with any emotions you have we will arrange this for you.

What are the possible benefits of taking part?

You will be offered a referral for additional support and assessment if necessary. The study will help people in the future by making health professionals more aware of the problems or experiences of patients who have cancer, and their carers.

This will lead to deciding how support can be organised best between the hospital and the community to improve current practice.

Will my taking part in this study be kept confidential?

If you consent to take part in the research, any of next of kin's medical records may be looked at by a member of the research team or regulatory authority. Your name and their name however, will not be disclosed. You will not be identified in any report or publication that arises as a result of the study.

What will happen to the results of the research study?

The results of the study will not be available for about 2 years. The researchers will write a report, which will be publicised at various medical meetings, and in various medical journals. If you would like a summary of the results when available please inform us by ticking the relevant box on the consent form.

Who is organising and funding the research?

The study is being organised by the Department of Palliative Medicine at the Royal Marsden Hospital. The study is funded by the Royal Marsden Palliative Care Research Fund. The researchers will not be paid for including you in the study.

Who has reviewed the study?

The Royal Marsden Hospital/ Institute of Cancer Research's Research and Local Ethics Committee have reviewed the study, and have given their approval

Contact for further information:

If you would like further information about the study, then please contact the researchers (see below)

Thank you for reading this information sheet, and for considering taking part in this research.

**Dr Julia Riley and Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London
0207 808 2761**

‘Opt in’ reply slip: IP Study

Patient Study No: RD.....

I have read the information leaflet about your study

I am willing to participate in your questionnaire

(please circle as appropriate)

YES

NO

Name (in capital letters).....

Signature.....

Date.....

Appendix 7.3.19: Bereavement Pack: IP Study

Hospital2Home Research Project

**A pragmatic prospective controlled evaluation comparing a
CC model of care with standard models of care at the
transition between acute and community**

Bereaved Relative Pack

**(to be sent out on receipt of an opt in slip or
consenting telephone call)**

Patient Study No: RD.....

Date:

Bereaved Relatives:-Covering Thank you letter : IP Study

Patient Study No: RD.....

Dear *(Insert name here)*

Thank you for agreeing to complete the enclosed questionnaire about *(Insert name here)* care at the Royal Marsden Hospital

Within this pack you should have received the questionnaire, a consent form and a stamped addressed envelope

If you are still willing to participate, please complete the consent form and questionnaire and return it to us in the stamped addressed envelope provided

If you would like a summary of the research findings please tick the relevant box on the consent form and these will be sent to you when the study is complete, in approximately 2 years

If any of the contents of this pack are missing, you wish to discuss any aspect of the study with me or after completing the questionnaire you feel you need professional support please don't hesitate to call the palliative care secretary on 0207 808 2761, and ask to speak to Dr Clare Smith
I would be more than willing to answer any questions.

Thank you again for agreeing to participate

Yours Sincerely

**Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London**

Bereaved Relatives:- Consent form: IP Study

Centre Number: RMH

Study Number:

Patient Identification for this trial:

CONSENT FORM

Title of Project: The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community care)

Name of Researcher: **Dr Julia Riley**

Please initial

box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my next of kins medical notes may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to my data being stored or encrypted on password-protected computers at the RMH
5. I agree to take part in the above study

☐☐☐☐☐

Name of next of kin Date Signature

Researcher Date Signature

Would you like a summary sheet of research findings YES/NO

When completed - 1 for next of kin;
 1 (original) to be kept in research site file;
 1 for medical notes;
 1 for CRF.

Bereaved Relatives: Postal Questionnaire: IP Study

Name of person completing the questionnaire:

Name of your deceased relative:

Part 1: Regarding your loved one, and their place of death and preferences

Please circle one option for each question

(1) Where did he/she die?

- a. home
- b. hospital
- c. hospice or palliative care unit
- d. In a nursing or residential home
- e. Elsewhere (please say where):

If he/she died in a hospital, hospice, palliative care unit, nursing or residential home how long had he/she been there before he/she died?

(2) Did you ever talk about where your loved one would have chosen to die?

- a. Yes
- b. No

(3) If yes, where would they have chosen to die?

- a. home
- b. hospital (please specify which one)
- c. hospice or palliative care unit
- d. In a nursing or residential home
- e. Elsewhere (please say where):

(4) Did you have a preference?

- a. Yes
- b. No

(5) If you did, where would you have preferred your loved one die?

- a. home
- b. hospital (please specify which one)
- c. hospice or palliative care unit
- d. In a nursing or residential home
- e. Elsewhere (please say where):

Part 2: FAMCARE scale

Think about the care that your family member has received from all the health professionals.

Please answer EACH of the questions below indicating how satisfied you are with the care received:

Very Satisfied (**VS**) Satisfied (**S**)

Undecided / Not relevant (**UN**)

Dissatisfied (**D**) Very Dissatisfied (**VD**)

How satisfied are you with:

- 1 the patient's pain relief
VS S UN D VD
- 2 information provided about the patient's prognosis
VS S UN D VD
- 3 answers from health professionals
VS S UN D VD
- 4 information given about medication side effects
VS S UN D VD
- 5 referrals to specialists
VS S UN D VD
- 6 availability of a hospital bed, if/when needed
VS S UN D VD
- 7 family conferences held to discuss the patient's illness
VS S UN D VD
- 8 speed with which symptoms are treated
VS S UN D VD
- 9 doctor's attention to patient's description of symptoms
VS S UN D VD
- 10 the way tests and treatments are performed
VS S UN D VD
11. availability of doctors to the family
VS S UN D VD
12. availability of nurses to the family
VS S UN D VD
13. coordination of care
VS S UN D VD

14. time required to make a diagnosis(by doctor)
VS S UN D VD
15. the way the family is included in treatment and care decisions
VS S UN D VD
- 16 information given about how to manage the patient's pain
VS S UN D VD
- 17 information given about the patient's tests
VS S UN D VD
- 18 how thoroughly the doctor assesses the patient's symptoms
VS S UN D VD
- 19 the way tests and treatments are followed up by the doctor
VS S UN D VD
- 20 availability of the doctor to the patient
VS S UN D VD

Part 3:

Please use the space provided below to tell us anything else you feel is important about the care your family members received (please use extra sheets of paper if necessary)

***Thank you for completing this questionnaire, if any of these questions have caused you distress and you would like some extra support please leave us a contact number in the space provided below
Alternatively please feel free to call the palliative research team at any time if you would like to discuss any of these issues. (0207 808 2761)***

I would like some extra support, and my contact telephone number is below:

Name:

Contact telephone no:

**Appendix 7.3.20: Bereaved Relative Reminder Letter: IP
Study**

The Hospital2Home Research project

**(A pragmatic prospective controlled evaluation comparing a CC model of
care with standard models of care at the transition between acute and
community)**

Patient Study No: RD.....

Dear *(Insert name here)*

Thank you for agreeing to participate in postal questionnaire about your
satisfaction with *(Insert name here)* care at the Royal Marsden Hospital

To date we have not received your completed questionnaire through the post. If
you have posted the questionnaire back to us within the last week then please
ignore this letter. However, if you have not yet returned the questionnaire and
you are still willing to participate then please do so in your own time.

If you are unable to return the questionnaire because some of the contents of the
original pack were missing, you wish to discuss any aspect of the study or you
posted your questionnaire back sometime ago and are concerned it may not have
arrived then please do not hesitate to call the palliative care secretary on 0207
808 2761, and ask to speak to Dr Clare Smith
I would be more than willing to answer any questions or queries you may have.

Thank you again for agreeing to participate

Yours Sincerely

**Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London**

**Appendix 7.3.21: Bereaved Relative Returned
Questionnaire Thank you letter: IP Study**

The Hospital2Home Research project

(A pragmatic prospective controlled evaluation comparing a CC model of care with standard models of care at the transition between acute and community)

Patient Study No: RD.....

Dear *(Insert name here)*

Thank you for completing the satisfaction questionnaire about *(Insert name here)* care at the Royal Marsden Hospital.

I am writing to confirm that I have received your completed questionnaire through the post and also to thank you once again for your participation. Please find enclosed a copy of your consent form for you to keep for your reference.

Thank you again

Yours Sincerely

**Dr Clare Smith
Palliative Care Research Team
Department of Palliative Medicine
Royal Marsden NHS Foundation Trust
Chelsea,
London**

Appendix 7.3.22: Process for support for bereaved relatives involved study: H2HF and IP Study

Background

There are two parts of this research study that involve bereaved relatives

- (a) Bereaved relatives of patients enrolled in the prospective Hospital2Home research study (patients are most likely to die outside the Royal Marsden Hospital)
- (b) Bereaved relatives of patients who died as inpatients at the Royal Marsden Hospital who have participated in a satisfaction questionnaire. This is a postal questionnaire, where the relative can indicate if they wish to have further support

Process to be followed to access support:

- (a) Bereaved relatives of patients dying outside Royal Marsden Hospital (group a above)
 - a. Once the need for support has been identified
 - b. Refer the bereaved relative to their GP and the SPCT responsible for the patient's care
 - c. Annotate this on EPR and in the CRF log
- (b) Bereaved relatives of patients who die as inpatients at the Royal Marsden Hospital (group b above)
 - a. Once the need for support has been identified
 - b. Researcher to contact the bereaved relative and
 - c. Refer the bereaved relative to PALS (Patient advice and liaison service), giving them the contact no 0800 783
 - i. have contact numbers for local bereavement services
 - d. If this has already previously been accessed contact the chaplaincy service for further advice

The chief investigator should be aware of any bereaved relatives requiring any of the above referrals

Appendix 7.3.23: Factors influencing place of death

Factors influencing place of death service evaluation proposal form

	THE ROYAL MARSDEN NHS FOUNDATION TRUST SERVICE EVALUATION PROPOSAL FORM v1		SE Number: SE29 Version 1 QA Team ST

Please complete this form as a 'Word' document and return it by e-mail attachment to the QA Team secretary / PA to Head of QA at least **4 weeks** before the paper deadline for the intended CAC meeting. **Note:** * trust Statistician involvement is **MANDATORY**
 Refer to the Service Evaluation Policy on the trust intranet for full guidance on the submission process, including design of Clinical Report Forms (data collection tools) and spreadsheets
 Please contact the QA staff on Extensions given below (see footer) if you have any queries in relation to the process for reviewing SE projects.
 Thank You. Miss F MacNeil, Chair, Clinical Audit Committee. Shaded boxes are for QA/Statistics office use only.

Service Evaluation Title: Retrospective Study of factors influencing place of death for patient treated at the Royal Marsden Hospital in 2006 -2007 and 2010-2011			
Is this required for a PhD?	Yes	If Yes, date M.Sc report required	
Regd. Date received by QA	26 May 11	Branch	Trustwide /
Other Sites involved: No	If Yes, UK / International / Both	Data collection: Retrospective	
CQC sections (office use only) 1.1, 1.2, 2.4, 2.5, 5.16 etc	(1) 5.16	(2)	(3) (4)
On SEval Forward Plan?	NA (No FP in 2011)	Date on Fwd Plan	
Has proposal prev.been submitted to a trust Statistician?	Yes / No	If No, new Date to Statistician	
Date sent to SE Review Committee		SE Review Committee decision	SE / Research / Audit
If Research, Date proposal forwarded to CCR Admin.		SE:Date to Clinical Reviewer(s)	
If SE, is Ethics approval needed?	Yes / No	1st CAC Date (month / year)	
Name / Designtn: Clin. Reviewer 1			
Name / Designtn: (if) Reviewer 2			
Name: PALS Reviewer (Quresh).			
Proposer Divn / Directorate	Clinical Services		
Proposer: Name:	Dr Clare Smith	Contact No: 02078082761	
Designation:	Research Fellow	Unit/ Dept: Palliative Medicine	
Data Manager (Name)			
Trust statistician (Name)	Mohammed Kabir		
Co- Investigator(s) (List all)	Dr Julia Riley, Dr Joy Ross, Prof Nick Bosenquat		
FULL postal address for CAC response	Department of Palliative Medicine The Royal Marsden NHS Foundation Trust		Chelsea
Planned Start Date:			Date report anticipated:
Is a questionnaire involved?	No	Is this a patient or staff questionnaire?	Patient / Staff / Other
'Other' questionnaire please specify			
Proposer Declaration and signature	I confirm that I have completed the following actions prior to submitting this proposal to the Clinical Audit Committee (CAC): i) obtained the involvement of a named trust statistician ii) sought and obtained approval for this evaluation from the clinical audit lead for my Unit / Department, who has seen and signed a copy of this proposal iii) sought and obtained approval for this evaluation from my Head of Department who has seen and signed a copy of this proposal		
Signed (Proposer)		Date:	

The following template can be used as a starting point for service evaluations. Text in blue has been written as a guide to completing the template – all the blue text should be replaced with your own text as appropriate to your study. The completed protocol should act as a blueprint or 'recipe book' to conducting your evaluation: that is, a reasonably well-informed person should be able to use the protocol (and only the protocol) as a set of instructions which are comprehensive enough to enable them to carry out the study from start to finish.

NOTE : All Sections of the following pages are MANDATORY for completion

Julia Tan, Clinical Effectiveness & Audit Facilitator Ext 9044/9009 Wendy Christie, Quality Improvement Auditor Ext 2626

	THE ROYAL MARSDEN NHS FOUNDATION TRUST SERVICE EVALUATION PROPOSAL FORM v1	SE Number: SE29 Version 1 QA Team ST

Background Information

In the United Kingdom (UK) over 500,000 people die each year[1]. This is projected to rise to 530,000 by the year 2030[2]. Place of death is often used as a surrogate marker of a good quality death.

In 2007 over 54% of complaints to the Care Quality Commission concerning acute hospital trusts related to the care of the dying or bereaved[3]. Hence, place of death represents a significant problem for health service providers.

A systematic review of qualitative evidence published in 2000 concluded that the majority (49-78%) of advanced cancer patients would prefer die at home [4]. Since this review, numerous studies have replicated these findings [5-13]. Studies specifically in the cancer population[13] or terminally ill [12] have found home death preferences from 50-61%.

The National End-of-life Care Intelligence Network, commissioned by the Department of Health (DOH), published its first review of variations in place of death in England in August 2010[14]. Based on Office of National Statistics data this has shown that currently fifty six percent of people die in hospital and only 19% die at home [14]. These data vary depending upon where people live within the UK, with the proportion of people dying in hospital being highest in London (65.7%). London also has the lowest proportion of home deaths (17.6%).

The observation that most deaths occur in institutions is not limited to the UK. Data from the United States of America, Western Australia and Belgium show hospital death rates of 49.5% [15], 48.7%[16], and 52-63% [17] respectively. Some western countries show different trends, such as the Netherlands where between 31-35% of deaths occur in hospital[17].

Currently there is a mismatch between where the majority of people die (hospital)[1] and where they want to die (home)[2]. The question is why is there such a mismatch.

A systematic review of factors influencing place of death [18] published in 2006 identified six factors strongly associated with home death:

- ☐ low functional status
- ☐ patient preference
- ☐ home care and its intensity
- ☐ living with relatives
- ☐ extended family support

Other evidence [19] supports the importance of these factors. A systematic review concentrating on end-of-life cancer patients found that the most influential factors in place of death are social support, health care inputs and patient preferences.

The need to provide good end of life care has been highlighted as a national priority in the government white paper 'Our health, our choice, our say' [20], the National Institute of Clinical Excellence guidance [21], the National Cancer plan [22] and the Department of Health's End of life strategy [3]. However, despite these initiatives over 50% of patients still die in acute hospitals. Further research into current trends and practice is required to provide insight into factors and trends that result in hospital deaths and prevent community deaths.

The Royal Marsden Hospital (RMH) is a tertiary referral cancer centre based in London, UK. In the year 2006-2007 two thousand six hundred and fifty three adult patients known to the Royal Marsden Hospital died. The place of death for these patients was known for 1841 patients, of these 40% died in hospital, 32% in a hospice and 23% at home (data taken from an ongoing audit). In 2007 the Hospital2Home service was introduced for patients with no active oncological treatments available to them. The aim of the Hospital2Home service is to co-ordinating care between hospital and home in order to enable patients to die in their preferred place.

This retrospective study will aim to:

Colin Tan Clinical Effectiveness & Audit Facilitator Ext 3044/1803 Wendy Claxton Quality Improvement Auditor Ext 3676

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Determine whether factors in the literature known to influence place of death have a similar effect in patients treated at the Royal Marsden Hospital. It will also test other chosen clinical factors that may impact on place of death specifically in the Royal Marsden Hospital population.
Describe changes in trends in place of death between 2006-07 and 2010-11 for RMH patients

Currently there is a mismatch between where the majority of people die (hospital)[1] and where they want to die (home)[2]. The question is why is there such a mismatch.

A systematic review of factors influencing place of death [18] published in 2006 identified six factors strongly associated with home death:

- ☐ low functional status
- ☐ patient preference
- ☐ home care and its intensity
- ☐ living with relatives
- ☐ extended family support

Other evidence [19] supports the importance of these factors. A systematic review concentrating on end-of-life cancer patients found that the most influential factors in place of death are social support, health care inputs and patient preferences.

The need to provide good end of life care has been highlighted as a national priority in the government white paper 'Our health, our choice, our say' [20], the National Institute of Clinical Excellence guidance [21], the National Cancer plan [22] and the Department of Health's End of life strategy [3]. However, despite these initiatives over 50% of patients still die in acute hospitals. Further research into current trends and practice is required to provide insight into factors and trends that result in hospital deaths and prevent community deaths.

The Royal Marsden Hospital (RMH) is a tertiary referral cancer centre based in London, UK. In the year 2006-2007 two thousand six hundred and fifty three adult patients known to the Royal Marsden Hospital died. The place of death for these patients was known for 1841 patients, of these 40% died in hospital, 32% in a hospice and 23% at home (data taken from an ongoing audit). In 2007 the Hospital2Home service was introduced for patients with no active oncological treatments available to them. The aim of the Hospital2Home service is to co-ordinating care between hospital and home in order to enable patients to die in their preferred place.

AIMS

This retrospective study will aim to:

Determine whether factors in the literature known to influence place of death have a similar effect in patients treated at the Royal Marsden Hospital. It will also test other chosen clinical factors that may impact on place of death specifically in the Royal Marsden Hospital population.

	THE ROYAL MARSDEN NHS FOUNDATION TRUST SERVICE EVALUATION PROPOSAL FORM v1	SE Number: SE29
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SE Objectives: Primary Objective

- ☐ To determine factors that significantly influence the place of death of RMH patients in the year 2010-2011

SE design

The study is a retrospective analysis (service evaluation) of data held on the Royal Marsden Hospital Electronic Patient Record system.

A search will identify patients known to the RMH who died between the 1st April 2010-31st March 2011 inclusive. These dates have been chosen because the Hospital2Home service began in October 2007 reaching full capacity for the year 2010, and therefore any changes in trends due to the implementation of the service can be examined. Data for all patients meeting the eligibility criteria will be analysed

Eligibility for inclusion in the SE

- ☐ RMH patients known to have died between the dates of 1st April 2010-31st March 2011
- ☐ Age over 18 years old

b) Exclusion criteria

- ☐ Patients in whom the place of death is documented as outside the United Kingdom
- ☐ Patients who had treatment management planned at RMH but received their final course of treatment elsewhere or whom only visited RMH for a second opinion, and patients who have never received any anti-cancer treatment at RMH
- ☐ Patients in whom the last RMH contact prior to death was greater than 6 months ago
- ☐ Diagnosis of superficial skin cancers (SCC/BCC)

Planned methodology

Data Collection between (dates)	1 st April 2006- 31 st March 2007, and 1 st April 2010-31 st March 2011
Data source(s) to be used	RMH Electronic Patient Record

The RMH information analysts will help the researcher identify all potential participants known to the RMH who died between the 1st April 2010-31st March 2011. The researcher will apply the eligibility criteria and collate the demographic information and clinical information as shown in the appendix 1. This will either be directly transferred from the EPR to a spreadsheet or manually entered onto the spreadsheet (see Appendix 1 for spreadsheet headings). Where place of death is missing all reasonable effort (from national databases enquires and contact with GP surgeries) will be made to ascertain this information.

Statistical considerations

Endpoints

This is a retrospective analysis of data already stored on the RMH Electronic Patient Record. The majority of data will be collated and analysed from the existing database however where place of death is missing this will be ascertained from national databases or a telephone contact with the GP surgery. As this is not a prospective study there is no end of study time point for participants. The primary end point will be;

Simon Tan Clinical Effectiveness & Audit Facilitator Ext 3044/1803 Wendy Claxton Quality Improvement Auditor Ext 2676

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- ☐ Factors that significantly influence place of death (i.e. Hospital death (any hospital) compared to death outside hospital) in 2010-2011.

Analysis methods

Binary logistic regression will be used to investigate factors that influence the place of death (Hospital versus other). The factors to investigate include: age, gender, ethnicity, marital status, main team involved, palliative care involved, Hospital2Home team involved, last anti-cancer treatment and type of last RMH contact. Each factor will be tested on its own first and all factors found to have p value of ≤ 0.20 in the univariate analysis will be used in the multivariate analysis to determine independent predictors of place of death. For the multivariate analysis a p value of <0.05 will be considered significant

Descriptive statistics will be reported for RMH patients dying in each of the three main locations (home, hospice and hospital) in 2010-2011 using tables with numbers and percentages. The number of deaths and locations for the two periods will be presented in graphs. Statistical comparisons of the two populations will be by the chi-square method.

Sample size

The primary objective of the study is to determine the factors influencing the place of death of RMH patients. The analysis will include all patients known to the Royal Marsden Hospital that died within one year (from 1st April, 2010 – 31st December, 2011), about 2, 200 patients are expected to be identified. However, the study will exclude any patient in whom the last hospital contact was greater than 6 months prior to death as well as those who attended for a second opinion only. The number is expected to reduce to approximately 1, 500 patients.

Study organisation: Who does what

The study will be conducted in accordance with good clinical practice and the relevant national legislation. The study is being submitted to the Royal Marsden Audit committee. The chief investigator will be responsible for overseeing the conduct of the study and for dissemination of the study results.

The RMH information analyst will assist the research fellow to identify all potential patients from the RMH EPR database. The research fellow will be responsible for collating and analysing the study database.

The research fellow will be responsible for ensuring timely response to any problems that arise with practicalities of the study conduct. The researcher will undertake the statistical analysis under the guidance of a statistician.

Data storage and data handling

All data relating to the study will be treated as confidential via the Data Protection Act 1998. Computer generated files will be backed up according to the Royal Marsden's back up policy and all the data relating to patients details will be password protected and made anonymous with all patients being allocated a study number. The computer files will be kept for a minimum of 5 years after the end of the study. The investigators will permit study related monitoring, audits and regulatory inspections providing direct access to source data and documents for this purpose.

References

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SE Number:

SE29

Version 1

QA Team ST

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APPENDIX 1: Location of Death Analysis

Primary outcome measure is binary: Place of death
Hospital / Out of hospital

Coding: Hospital =1, Out of hospital =0 , and repeat analysis Coding: Home=1, Out of hospital =0

Clinical information to be entered directly onto a spreadsheet

ID

Factor	Range
Age: 2 columns for this variable.	Insert actual value
SPSS variable name: Column 1 :Age Column 2: Ageband	Categories used by Gomes et al: Column 1: continuous variable age (no decimal places) Column 2: SPSS responses 1= <40 2= 40-59 3= 60-79 4=80+
Ethnicity: 1 column for this variable This variable is categorical (14 categories) as per right hand column SPSS variable name: ethnico	SPSS response 1 – White British 2 – White Irish 3 – White other 4 – Black Caribbean 5 – Black African 6 – Black other 7 – Asian Indian 8 – Asian Pakistani 9 – Asian Bangladeshi 10 – Asian other 11 – Mixed white and black Caribbean 12 – Mixed white and black African 13 – White and Asian mixed 14 – Any other mixed background 15 - other 99-not disclosed/missing
Gender: binary/categorical SPSS variable name : Sex	1 - Male 2 - Female
Living alone : 1 column – binary/categorical This is derived as follows: Lives alone: No 1)if the NOK details are the same address as the patient 2) NOK details different but documentation in EPR that living with family member up to 6 months from date of death Lives alone: Yes – all others SPSS variable name: livalone	0 – N or N (NH) 1 – Y
Marital Status: 1 column – categorical	1 - Married 2 – Widowed/surviving civil partner

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SPSS variable name: martstat	3 - Single 4 - Divorced/separated 5 - Cohabiting/other 6 - not disclosed
Postcode (First 4 digits only) This variable has been used to assign each patient a deprivation score based on their postcode from IMD 2010 income deprivation data (for a full description of this see separate deprivation sheet) 1 column – categorical (ordered)	1- 1 most deprived 2 - 2 nd most deprived 3 - 3 rd most deprived 4 - 4 th most deprived 5 - 5 least deprived 99- missing
SPSS variable name: deptscore PCT funding 4 columns here 3 Column for analysis is the spending per death in quartiles, spending per head in quartiles, actual spend per death (£, 2 decimals) This variable is ordinal categorical SPSS variable names: Spend per head quartile: pctspeheadq Spend per death (£): pctspedeact Spend per death quartile: pctspedeactq	1 – quartile 1 (least spending) 2 – quartile 2 3 – quartile 3 4 – quartile 4 (most spending) 99 – missing Missing for actual spend =9999
Place of death This is the dependent variable – it is binary Use descriptive statistics to demonstrate the proportion of patients dying in each location (Column 1) SPSS variable name: deathplacall Binary dependent variable for outcome of logistic regression (Column 2) SPSS variable name: deathplace	SPSS response for deathplacall 1 - Hospital 2 - Nursing home 3 - Home 4 - Hospice 5 - Other 99 - missing SPSS responses for deathplace 1- Hospital 0- Usual residence/hospice/other 99 - missing
Date of death SPSS variable name: dod	
Main RMH site involved 1 column Categorical variable SPSS variable name: mainsite	1 - Chelsea 2 - Sutton 3 - Kingston
Hospital Palliative Care involved 1 column dichotomous categorical variable SPSS variable name: hospc	1- Yes 0 - No
Hospital2Home team involved 1 column dichotomous categorical variable SPSS variable name: h2h	1 - Yes 0 - No
Type of last RMH contact 1 column categorical variable (not ordered)	1- Inpatient 2 -MDU visit/WA 3 – Outpatient



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SPSS variable name: lastcon	4 - Daycase
Date of last contact	Column 1: continuous in days
This column is used to calculate the column – time from last contact to death There are 2 columns for this in the dataset	Column 2: 1 = < 1 month 2 = < 3 months 3 = 3-6 months
Column 1: This is a continuous variable (measured in time= days)	
Column 2: This is an ordered categorical variable	
SPSS variable name: Actual date: datelastcon Time from last contact actual : lastcontime (days) Band/categorical from last contact: lastconband	
Last anti-cancer treatment	1 - Surgery
1 column: nominal categorical	2 - Chemotherapy
	3 - Radiotherapy/Brach
	4 - Hormone
SPSS variable name: lasttreat	
Date of last treatment	Column 2: 1 = < 1 month 2 = < 3 months 3 = 3-6 months 4 = 6-12 months 5 = 1-2 years 6 = > 2
This has 2 columns Column 1: This is a continuous variable (measured in time=days)	
Column 2: This is an ordered categorical variable	
As time from last anti-cancer treatment to death decreases the likelihood of a patient dying in hospital increases	
SPSS variable name: Actual date: lasttreatedate Time (continuous): lasttretime (days) Band (categorical): lasttreband	
Treatment intent (at last contact)	1 - Adjuvant
	2 - Curative
This is a nominal categorical variable	3 - Palliative
SPSS variable name: lasttreintent	
Functional Status (at last contact) PS	0 = 0
	1
This is an ordered categorical variable	2
	3
	4
SPSS variable name: ps	99 - Missing

Diagnosis	diagcon SPSS response
This is a nominal categorical variable	1- Bladder/TCC 2- Brain/cns 3- Breast
Column 2: condensed/grouped diagnosis	



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SPSS variable name: diagcon % %	4F Colorectal% 5F Endometrial/vulva/vagina/cervix% 6F Germ cell% 7F Haematological% 8F Head and neck/Thyroid% 9F Hepatobiliary/Pancreas% 10FLung/pleura/mesothelioma% 11FMelanoma% 12FOther/unknown% 13FOvary/peritoneal% 14FProstate% 15FRenal% 16FSarcoma% 17FUpper GI% % %
Date of diagnosis for cancer being treated 2 columns Actual date SPSS variable name: diagdate % Column: This is a continuous variable (time in days) SPSS variable name: diagtime % Column: This is an ordered categorical variable SPSS variable name: diagband %	Column: % 1=3 months 2=6 months 3=12 months 4=12 years 5=15 years 6=5 years %
Number of MH inpatient admissions in the last 6 months prior to death % 1 column: This is a continuous variable SPSS variable name: admis %	
Known to community palliative care team % This is a nominal categorical variable SPSS variable name: xpct %	N/Unknown = 0 Y = 1

Appendix 7.3.24 Approval letters for study from RMFT research and development and London Ethics committee

Central London REC 1
Level 7N019, Maternity Block
Northwick Park Hospital
Watford Road
Harrow
Middx
HA1 3UJ

Telephone: 020 8869 3775
Facsimile: 020 8869 5222

06 May 2010

Dr Clare Smith
The Royal Marsden NHS Foundation Trust
Fulham Road
Chelsea
London
SW3 6JJ

Dear Dr Smith

Study Title:	The Hospital2 Home Research Project: A pragmatic prospective observational controlled evaluation comparing a case conference model of care with standard models of care at the transition between acute and community end of life care
REC reference number:	10/H0718/24
Protocol number:	2.2

The Research Ethics Committee reviewed the above application at the meeting held on 28 April 2010. Thank you for attending to discuss the study.

Ethical opinion

- a. The Committee asked you to explain your reasons for carrying out this study. You explained that there is a discrepancy of where patients choose to die 50% - 79% want to die at home, and you want to find out how this can be achieved for patients at the Royal Marsden and for patients all over the UK, you explained that you intend to pilot a service so patients can stay at home who do not require chemotherapy or radiotherapy. Patients will meet a nurse separately from the oncologist. A case conference will then take place with the patients GP Carer and consultant and they will put together an action plan.
- b. You were asked by the Committee if you intend to ask the question "Where do you want to die". You replied that you would not ask. Asked how you will know if you do not ask, You explained that you will know by what has been documented already from the lead health professional and from the patients notes or in their care plan. This will be available in 9/10 cases. When asked if patients could change their mind you confirmed that they could.
- c. The Committee commented that the patient information sheet was very detailed and too broad. You explained the secondary outcome of the study; that if you shift care into the community you will just pass the burden onto the carer.
- d. You were asked if you had any previous experience with this and you answered that you had not piloted the questionnaire yourself but a study by Dr Shipman had previously carried out mock questionnaires with advanced lung cancer and GI sufferers. The report back was that patients preferred face to face contact rather than telephone contact. You added that the length of the interview would be approximately 35-40 minutes with the patient and 30 minutes with the carer.

- e. The Committee felt that 30 questions on subsequent visits will be too much. You confirmed that the number of questions reduce on subsequent visits although you would like to keep the service questionnaire in as you feel this is of vital importance.
- f. You were asked why the patient information sheet does not mention death but the GP information sheet does. You replied that patients in standard care may not have been told of their outcome, and thought it too harsh to include into the patient information sheet.
- g. You were asked if you thought that patients in denial should be left out of the study and if so would this invalidate the research. You said that if patients have a case conference arranged that this could invalidate the study and it would make comparing complicated.
- h. Members said to you that it is not informed consent if patients are included in the study and they do not know their fate. You replied that there is a secondary outcome to the study as well.
- i. The Committee asked about selection sites. You informed the Committee that the statistician needs two sites Kingston and the Royal Marsden main site for comparison and demographic purposes. It was not possible to randomise.
- j. asked if patients are treated at Kingston and the findings were dramatically lower how would you proceed with the study. You said that you will take the figures back to Dr Riley and then they may have to end the study early.
- K Asked if you questionnaires were validated you confirmed that they were.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary. Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		09 March 2010
REC application		08 March 2010
Protocol	2.2	15 February 2010
Investigator CV		25 March 2009
Student CV		
Participant Information Sheet	2.2	15 February 2010

Participant Information Sheet: Informal Carer	2.2	15 February 2010
Participant Information Sheet: Community Health Care Professional	2.2	15 February 2004
Participant Consent Form	2.2	15 February 2010
Participant Consent Form: Informal Carer	2.2	15 February 2007
Participant Consent Form		
Personalised Flow Diagram	2.2	
Letter of invitation to participant	2.2	15 February 2010
clinical record file/Questionnaire for community health care	2.2	15 February 2010
Appendix 5 Patient assessment no. 1	2.2	15 February 2010
Appendix 6 Clinical Record File Assessment 2 Onwards	2.2	15 February 2010
Appendix 7 Invitation letter to bereaved relative	2.2	15 February 2010
Appendix 8 Royal Marsden Inpatient deaths	2.2	15 February 2010
appendix 9a Invitation letter to bereaved relatives	2.2	15 February 2010
Relatives Information Sheet	2.2	15 February 2010
Appendix 9c Bereaved relatives reply slip	2.2	15 February 2010
appendix 10	2.2	15 February 2010
Appendix 10a Thank you letter Bereaved inpatients	2.2	15 February 2010
Appendix 10b Bereaved Relatives consent form	2.2	15 February 2010
Appendix 10c Bereaved Relatives Postal Questionnaire	2.2	15 February 2010

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0718/24	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project
Yours sincerely

Dr John Keen
Chair

Dr Julia Riley
Palliative Care
Royal Marsden NHS Trust
Fulham Road
Chelsea
London
SW3 6JJ

11 December 2009

Dr Julia Riley

**ID: CCR3184
study**

conventional

**Hospital2Home Pilot Project (A non-randomised control
comparing a case conference model of care with
models of care for cancer patients in the community**

Thank you for your application to the Committee for Clinical Research. The Committee thanked Dr

Clare Smith for presenting the resubmission application. The Committee approved the application and granted RMH sponsorship subject to satisfactory response to the points listed below:

- It is recommended that a TMG rather than IDMC is established
- Please include standard care group in protocol
- Old protocol mentioned the primary endpoint analysis for looking at proportion of patients via chi2 tests etc. It would be useful to include this in the revised protocol
- How will you deal with missing data in the questionnaire?
- Are they going to adjust for questionnaires scores over time?
- Will you use some adjustment for multiple testing?
- The power should be 80% rather than the 90% quoted otherwise numbers do not make sense

When you are ready to submit your NHS REC Application Form, please contact Simone Morris (REC coordinator) at The Royal Marsden Research Ethics Committee, St George's University of London, South London REC Office (1), Room 1.13, 1st Floor Jenner Wing, Blackshaw Road, Tooting, London, SW17 0RE. Tel: 0208 725 0252. Fax: 0208 725 1897. Email: royalmarsden.rec@stgeorges.nhs.uk to arrange submission of your REC Application Form.

You are reminded that your project must be conducted in accordance with the Research Governance

Framework for Health and Social Care and that all members of the research team must be aware of and understand their responsibilities under this Framework.

NB: This letter is part of the approval process but is not the final R&D approval. Please remember that you must have received the full R&D approval letter and have your study activated on the Hospital information System (HIS) before you can recruit patients and commence this study.

Yours sincerely

Prof David Dearnaley

Chairman of the Committee for Clinical Research

cc: Dr Clare Smith

Copy to: Dr Clare Smith,

Appendix 7.4: RESULTS

Appendix 7.4.1 RESULTS: Quantitative Analysis: Symptom burden, QoL and Satisfaction

This appendix follows on from Section 4.3.2.2 in the results chapter. It details the Week 1 individual items scores for MSAS-SF and McGill questionnaires.

Week 1 Individual item symptoms scores

Total population Week 1 prevalence and severity of physical symptoms (MSAS-SF) n=65

Symptom	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Difficulty concentrating	28 (43.8)	(31-56)	9 (14.1)	(5-23)	0
Pain	43 (67.8)	(55-79)	19 (29.7)	(18-41)	0
Lack of energy	54 (84.4)	(75-94)	26 (40.6)	(28-53)	0
Cough	26 (40.6)	(28-53)	5 (7.8)	(1-15)	0
Changes in skin	16 (25)	(14-36)	2 (3.1)	(-1-8)	0
Dry mouth	35 (54.7)	(42-67)	6 (9.4)	(2-17)	0
Nausea	12 (18.8)	(9-29)	3 (4.7)	(0-10)	0
Feeling drowsy	45 (70.3)	(59-82)	15 (23.4)	(13-34)	0
Numbness/tingling in hand and feet	23 (36.5)	(24-49)	10 (15.8)	(7-25)	1
Difficulty sleeping	26 (40.6)	(28-53)	7 (11)	(3-19)	0
Feeling bloated	21 (32.8)	(21-45)	6 (9.4)	(2-17)	0
Problems with urination	12 (19.0)	(9-29)	4 (4.8)	(0-13)	1
Vomiting	5 (7.8)	(1-15)	1 (1.6)	(-2-5)	0
Shortness of breath	37 (57.8)	(45-70)	20 (31.2)	(20-43)	0
Diarrhoea	15 (23.4)	(13-34)	4 (6.3)	(0-12)	0
Sweats	15 (23.4)	(13-34)	2 (3.2)	(-1-8)	0
Mouth sores	4 (6.3)	(0-12)	0 (0.0)	0	0
Problems with sexual interest and activity	8 (12.9)	(4-21)	6 (9.7)	(2-17)	2
Itching	12 (18.8)	(9-29)	0 (0.0)	0	0
Lack of appetite	33 (51.6)	(39-64)	12 (18.7)	(9-29)	0
Dizziness	17 (26.6)	(15-38)	2 (3.2)	(-1-8)	0
Difficulty swallowing	9 (14.1)	(5-23)	1 (1.6)	(-1-5)	0
Changes in the way food tastes	22 (34.4)	(22-46)	4 (6.4)	(0-13)	1
Weight loss	21 (32.8)	(21-45)	7 (10.9)	(3-19)	0
Hair loss	4 (6.3)	(0-12)	2 (3.2)	(-1-8)	0
Constipation	24 (37.5)	(25-50)	5 (8.0)	(1-15)	1
Swelling of arms or legs	16 (25.0)	(14-36)	4 (6.3)	(0-12)	0
'I don't look like myself'	18 (28.1)	(17-39)	5 (7.8)	(1-15)	0

Table 6.1 b Total population Week 1 prevalence and severity of psychological symptoms (MSAS-SF) n=65

Symptom	Overall prevalence		Frequency of Severe Symptoms (distressing the participant 'frequently' or 'almost constantly')		Missing data
	Number (%)	95% confidence intervals		95% confidence intervals	
Feeling sad	35 (54.7)	(42-67)	6 (9.4)	(2-17)	0
Worrying	32 (50.0)	(37-63)	8 (12.5)	(4-21)	0
Feeling irritable	31 (48.4)	(36-61)	5 (7.8)	(11-15)	1
Feeling nervous	23 (35.9)	(24-48)	5 (7.8)	(11-15)	0

Comparison of Week 1 physical symptom prevalence in Hospital2Home study group and All control group

Symptom	Hospital2Home (n=24)					All controls (n=41)				
	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data	Overall prevalence		Prevalence of Severe Symptoms (distressing the participant 'quite a bit' or 'very much')		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals		Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Difficulty concentrating	15 (62.5)	(42-83)	4 (16.8)	(1-33)	0	13 (32.5)	(17-48)	5 (12.5)	(2-23)	0
Pain	17 (70.8)	(51-90)	9 (37.5)	(17-58)	0	26 (65.0)	(50-80)	10 (25.0)	(11-39)	0
Lack of energy	19 (79.2)	(62-97)	12 (50.0)	(28-72)	0	35 (87.5)	(77-98)	14 (35.0)	(20-50)	0
Cough	9 (37.5)	(17-58)	1 (4.2)	(-4-13)	0	17 (42.5)	(26-59)	4 (10.0)	(0-20)	0
Changes in skin	7 (29.2)	(10-49)	1 (4.2)	(-4-13)	0	9 (22.5)	(9-36)	1 (2.5)	(-3-8)	0
Dry mouth	12 (50.0)	(28-72)	3 (12.5)	(-2-27)	0	17 (57.5)	(41-74)	3 (7.5)	(-1-16)	0
Nausea	7 (29.2)	(10-49)	1 (4.2)	(-4-13)	0	5 (12.5)	(2-23)	2 (5.0)	(-2-12)	0
Feeling drowsy	18 (75.0)	(56-94)	8 (33.3)	(13-54)	0	27 (67.5)	(52-83)	7 (17.5)	(5-30)	0
Numbness/tingling in hand and feet	11 (47.8)	(26-70)	4 (17.4)	(0-34)	1	12 (30.0)	(15-45)	6 (15.0)	(3-27)	0
Difficulty sleeping	13 (54.2)	(33-76)	2 (8.3)	(-4-20)	0	13 (32.5)	(17-48)	5 (12.5)	(2-23)	0
Feeling bloated	9 (37.5)	(17-58)	3 (12.5)	(-1-27)	0	12 (30.0)	(15-45)	3 (7.5)	(-1-16)	0
Problems with urination	6 (25.0)	(6-44)	3 (12.5)	(-2-27)	0	6 (15.4)	(4-27)	1 (2.5)	(-3-8)	1
Vomiting	3 (12.5)	(-2-27)	0 (0.0)	0	0	2 (5.0)	(-2-12)	1 (2.5)	(-3-8)	0
Shortness of breath	14 (58.3)	(37-80)	10 (41.6)	(20-63)	0	23 (57.5)	(41-74)	10 (25.0)	(11-39)	0
Diarrhoea	7 (29.2)	(10-49)	1 (4.2)	(-4-13)	0	8 (20.0)	(7-33)	3 (7.5)	(-1-16)	0
Sweats	6 (25.0)	(6-44)	2 (8.3)	(-4-20)	0	9 (22.5)	(9-36)	0 (0.0)	0	0
Mouth sores	3 (12.5)	(-2-27)	0 (0.0)	0	0	1 (2.5)	(-3-8)	0 (0.0)	0	0
Problems with sexual interest and activity	5 (20.8)	(3-38)	4 (16.7)	(1-33)	0	3 (7.9)	(-1-17)	2 (5.0)	(-2-13)	2
Itching	7 (29.2)	(10-49)	0 (0.0)	0	0	5 (12.5)	(2-23)	0 (0.0)	0	0
Lack of appetite	12 (50.0)	(28-72)	5 (20.8)	(3-38)	0	21 (52.5)	(36-69)	7 (17.5)	(5-30)	0
Dizziness	7 (29.2)	(10-49)	0 (0.0)	0	0	10 (25.0)	(11-39)	2 (5.0)	(-2-12)	0
Difficulty swallowing	5 (20.8)	(3-38)	1 (4.2)	(-4-13)	0	4 (10.0)	(0-20)	0 (0.0)	0	0
Changes in the way food tastes	8 (33.3)	(13-54)	2 (8.3)	(-4-20)	0	14 (35.0)	(20-50)	2 (5.0)	(-2-12)	0
Weight loss	10 (41.7)	(20-63)	3 (12.5)	(-1-27)	0	11 (27.5)	(13-42)	4 (10.0)	(0-20)	0
Hair loss	2 (8.3)	(-4-20)	1 (4.2)	(-4-13)	0	2 (5.0)	(-2-12)	1 (2.5)	(-3-8)	0
Constipation	10 (41.7)	(20-63)	1 (4.2)	(-4-13)	0	14 (35.0)	(20-50)	4 (10.3)	(0-20)	0
Swelling of arms or legs	6 (25.0)	(6-44)	3 (12.5)	(-2-27)	0	10 (25.0)	(11-39)	1 (2.5)	(-3-8)	0
'I don't look like myself'	7 (29.2)	(10-49)	1 (4.2)	(-4-13)	0	11 (27.5)	(13-42)	4 (10.0)	(0-20)	0

Comparison of Week 1 psychological symptom prevalence in Hospital2Home study group and All control group

Symptom	Hospital2Home (n=24)					All controls (n=41)				
	Overall prevalence		Frequency of Symptoms (‘almost constantly’ or ‘frequently’)		Missing data	Overall prevalence		Frequency of Symptoms (‘almost constantly’ or ‘frequently’)		Missing data
	Number (%)	95% confidence intervals	Number (%)	95% confidence intervals		Number (%)	95% confidence intervals	Number (%)	95% confidence intervals	
Feeling Sad	14 (58.3)	(37-80)	2 (8.3)	(-4-20)	0	21 (52.5)	(36-69)	4 (10.0)	(0-20)	0
Worrying	11 (45.8)	(24-67)	2 (8.3)	(-4-20)	0	21 (52.5)	(36-69)	6 (15.0)	(3-27)	0
Feeling irritable	14 (58.3)	(37-80)	3 (13.0)	(-2-28)	0	17 (42.5)	(26-59)	2 (5.0)	(-2-12)	0
Feeling nervous	9 (37.5)	(17-58)	2 (8.3)	(-4-20)	0	14 (35.0)	(20-50)	3 (7.5)	(-1-16)	0

Week 1 QoL Individual Item scores (n=65)

				Total						H2H						All Control		
MQOL Item	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Considering all parts of my life-physical, emotional, social, spiritual and financial-the quality of my life has been (0= very bad, 10 = excellent)	62	6.34	2.489	6.00	0-10	3	22	6.41	2.720	6.5	0-10	2	40	6.30	2.388	6.0	2-10	1
Over the past two days, I have felt: (0= physically terrible, 10= physically well)	63	6.13	2.196	5.00	0-10	2	23	6.13	2.379	7.0	0-10	1	40	6.13	2.115	5.0	0-10	1
Over the past two days, I have been depressed: (10=not at all, 0= extremely)	63	7.98	2.618	10.00	0-10	2	23	8.22	2.522	10.0	0-10	1	40	7.85	2.694	9.5	0-10	1
Over the past two days, I have been nervous or worried: (10= not at all, 0=extremely)	63	8.43	2.340	10.00	0-10	2	23	8.35	2.690	10.0	0-10	1	40	8.48	2.148	9.0	2-10	1
Over the past two days, how much of the time did you feel sad? (10=never, 0=always)	63	8.17	2.446	9.00	0-10	2	23	8.17	2.691	10.0	0-10	1	40	8.18	2.330	9.0	2-10	1
Over the past two days, when I thought of the future, I was (10= not afraid, 0= terrified)	63	7.19	2.911	8.00	0-10	2	23	8.30	2.548	10.0	0-10	1	40	6.55	2.943	6.5	0-10	1
Over the past two days, my life has been: (0= utterly meaningless and without purpose, 1=very purposeful and meaningful)	63	6.35	2.766	7.00	0-10	2	23	6.30	3.022	7.0	0-10	1	40	6.38	2.648	7.0	0-10	1
Over the past two days, when I thought about my whole life, I felt that in achieving life goals I have: (0=made no progress whatsoever, 1=progressed to complete fulfilment)	62	7.29	2.459	8.00	0-10	3	23	6.83	2.964	8.0	0-10	1	39	7.56	2.100	8.0	2-10	2
Over the past two days, when I thought about my life, I felt that my life to this point has been: (0=completely worthless, 1=very worthwhile)	63	7.86	2.361	8.00	0-10	2	23	7.09	3.059	7.0	0-10	1	40	8.30	1.742	9.0	5-10	1
Over the past two days, I have felt that I have: (0=no control over my life, 10=complete control over my life)	62	6.23	2.825	6.00	0-10	3	23	6.35	3.284	7.0	0-10	1	39	6.15	2.560	5.0	0-10	2
Over the past two days, I felt good about myself as a person (0=completely disagree, 10=completely agree)	62	7.06	2.598	8.00	0-10	3	23	6.78	3.133	8.0	0-10	1	39	7.23	2.253	8.0	3-10	2
To me, the past two days were: (0= a burden, 10= a gift)	62	6.97	2.897	8.00	0-10	3	23	6.52	3.146	7.0	0-10	1	39	7.23	2.748	8.0	0-10	2
Over the past two days, the world has been:	60	7.33	2.685	8.00	0-10	5	21	7.05	3.383	8.0	0-10	3	39	7.49	2.258	8.0	1-10	2

(0= an impersonal unfeeling place, 10=caring and responsive to my needs)																		
Over the past two days, I have felt supported: (0=not at all, 10= completely)	63	8.5	2.278	10.00	0-10	2	23	8.09	2.729	9.0	0-10	1	40	8.73	1.974	10.0	1-10	1

.Individual difference from T0-T1 (ie: calculating difference between T1-T0 for each participant and then comparing groups

	Hospital2Home Group (A)	All Control Group (B)	Statistical Analysis comparing A & B)		Mean difference across study groups (95% CI)	Clinical Significance
T0 MSAS Subscales	Mean (SD)	Mean (SD)	T Test	P value		
Global Distress Index	1.44 (0.628)	1.11 (0.650)	-2.26	0.03	-0.33 (-0.63, -0.040)	
Physical Symptom Subscale	1.31 (0.583)	1.03 (0.639)	-1.97	0.05	-0.28 (-0.56, 0.00)	
Psychological Symptom Subscale	0.997 (0.732)	0.724 (0.695)	-1.69	0.09	-0.273 (-0.59, 0.48)	
Total MSAS Score	1.01 (0.488)	0.81 (0.498)	-1.78	0.08	-0.205 (-0.44, 0.02)	
T1 MSAS Subscales						
Global Distress Index	1.31 (0.789)	1.24 (0.616)	-0.412	0.68	-0.07 (-0.43, 0.29)	
Physical Symptom Subscale	1.10 (0.687)	0.99 (0.524)	-0.66	0.51	-0.10 (-0.41, 0.21)	
Psychological Symptom Subscale	1.05 (0.867)	0.83 (0.743)	-1.06	0.29	-0.22 (-0.63, 0.19)	
Total MSAS Score	0.91 (0.560)	0.77 (0.390)	-1.12	0.27	-0.14 (-0.39, 0.11)	
Mean difference (T1-T0)						
Global Distress Index	0.15 (0.55)	-0.10 (0.36)	-2.18	0.03		
Physical Symptom Subscale	0.19 (0.62)	0.02 (0.38)	-1.23	0.23		
Psychological Symptom Subscale	0.11 (0.59)	-0.05 (0.52)	-1.14	0.26		
Total MSAS Score	-0.16 (0.36)	-0.04 (0.26)	1.43	0.16		

Extra information regarding AUC summary statistic: The MSAS-GDI Time adjusted AUC summary measure has a Kolmogorov-Smirnov test statistic of 0.189, with a p value of 0.032 for the Hospital2Home group therefore the Mann-Whitney U test statistic is quote Total MQOL Score Time adjusted AUC summary measure has a Kolmogorov-Smirnov test statistic of 0.082, with a p value of 0.2 for the All comparator group, however the Hospital2Home group has a test statistic of 0.214, p value 0.04 violating the assumptions of normality therefore the Mann Whitney U test statistic is quoted.

Comparison of Patient FAMCARE satisfaction individual item scores at Week 1 for Total Population, H2H and All comparator study groups

	Total Population (n=65)						Hospital2Home Study Group (n=24)						All Comparator Study Group (n=41)					
	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Doctors attention to your description of symptoms	61	4.2	0.9	4.0	1-5	4	21	4.3	0.9	5.0	2-5	3	40	4.2	0.9	4.0	1-5	1
How thoroughly the doctor assesses your symptoms	61	4.1	1.0	4.0	2-5	4	21	4.2	1.0	5.0	2-5	3	40	4.0	1.0	4.0	2-5	1
Information about how to manage pain	58	4.0	0.9	4.0	2-5	7	22	4.4	0.9	5.0	2-5	2	36	3.7	0.9	3.5	2-5	5
Information given about side effects	60	3.7	0.9	4.0	1-5	5	22	3.9	0.9	4.0	2-5	2	38	3.6	1.0	3.0	1-5	3
Speed at which symptoms are treated	62	3.9	1.0	4.0	1-5	3	22	4.1	1.0	4.0	1-5	2	40	3.9	1.0	4.0	1-5	1
Information given about your tests	61	3.9	1.1	4.0	1-5	4	22	4.3	0.9	5.0	2-5	2	39	3.7	1.2	4.0	1-5	2
The way tests and treatments are performed	60	4.3	0.9	4.0	1-5	5	22	4.5	0.9	5.0	2-5	2	38	4.2	0.9	4.0	1-5	3
The way tests and treatments are followed up your doctor	59	4.1	1.1	4.0	1-5	6	21	4.1	1.1	4.0	2-5	3	38	4.1	1.1	4.0	1-5	3
Information provided about your prognosis	61	3.9	0.9	4.0	2-5	4	21	4.0	0.9	4.0	2-5	3	40	3.8	0.9	4.0	2-5	1
Answers from health professionals	59	4.2	1.0	4.0	1-5	6	21	4.4	1.1	5.0	1-5	3	38	4.1	0.9	4.0	2-5	3
Referrals to specialists	55	4.1	0.9	4.0	1-5	10	21	4.3	0.8	5.0	3-5	3	34	4.0	1.0	4.0	1-5	7
The availability of the doctor to answer your questions	60	3.9	1.0	4.0	1-5	5	20	4.1	1.1	4.0	1-5	4	40	3.9	1.0	4.0	2-5	1
The availability of nurses to answer your questions	61	4.2	0.9	4.0	1-5	4	21	4.2	1.1	5.0	1-5	3	40	4.1	0.8	4.0	3-5	1
The way the family is included in treatment and care decisions	58	4.4	0.7	5.0	3-5	7	20	4.5	0.8	5.0	3-5	4	38	4.4	0.8	5.0	3-5	3
Coordination of care	61	4.0	1.0	4.0	1-5	4	21	4.3	0.8	4.0	2-5	3	40	3.9	1.0	4.0	1-5	1
Availability of doctors to your family	58	3.9	0.9	4.0	2-5	7	20	4.1	0.8	4.0	3-5	4	38	3.8	1.0	4.0	2-5	3

How satisfied are you with.....

Comparison of Carer FAMCARE satisfaction individual item scores at Week 1 for Total Population, H2H and AC study groups

How satisfied are you with.....

	Total population (n=33)						Hospital2Home (n=11)						All Comparator (n=22)					
	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Doctors attention to your description of symptoms	32	3.88	1.39	4.0	1-5	1	10	4.09	0.83	4	3-5	0	21	3.76	1.61	5.0	1-5	2
How thoroughly the doctor assesses your symptoms	32	4.22	0.98	4.0	1-5	1	10	4.18	0.60	4.0	3-5	0	21	4.24	1.14	5.0	1-5	2
Information about how to manage pain	31	3.87	1.02	4.0	2-5	2	10	4.18	0.75	4.0	3-5	0	20	3.70	1.13	3.5	2-5	3
Information given about side effects	33	4.06	1.00	4.0	2-5	0	10	3.82	0.98	4.0	2-5	0	22	4.18	1.0	4.5	2-5	1
Speed at which symptoms are treated	32	3.88	1.39	4.0	1-5	1	10	4.09	0.70	4.0	3-5	0	21	3.76	1.41	4.0	1-5	2
Information given about your tests	30	4.10	0.88	4.0	2-5	3	9	4.10	0.74	4.0	3-5	1	20	4.10	1.14	5.0	1-5	3
The way tests and treatments are performed	31	4.32	0.94	5.0	1-5	2	10	4.27	0.65	4.0	3-5	0	20	4.35	1.09	5.0	1-5	3
The way tests and treatments are followed up your doctor	31	4.07	1.12	4.0	1-5	2	10	4.27	0.65	4.0	3-5	0	20	3.95	1.32	4.5	1-5	3
Information provided about your prognosis	32	3.84	1.11	4.0	2-5	1	10	3.82	1.17	4.0	2-5	0	21	3.86	1.11	4.0	2-5	2
Answers from health professionals	33	4.06	1.12	4.0	1-5	0	10	4.27	0.90	5.0	3-5	0	22	3.95	1.21	4.0	1-5	1
Referrals to specialists	30	3.90	1.30	4.0	1-5	3	10	4.36	0.92	5.0	2-5	0	19	3.63	1.42	4.0	1-5	4
The availability of the doctor to answer your questions	32	4.19	0.97	4.0	2-5	1	10	4.36	0.67	4.0	3-5	0	21	4.10	1.09	4.0	2-5	2
The availability of nurses to answer your questions	32	4.0	1.02	4.0	1-5	1	10	4.18	0.87	4.0	3-5	0	21	3.91	1.09	4.0	1-5	2
The way the family is included in treatment and care decisions	32	4.16	0.77	4.0	3-5	1	10	4.18	0.60	4.0	3-5	0	21	4.14	0.85	4.0	2-5	2
Coordination of care	32	4.03	1.06	4.0	2-5	1	10	4.36	0.67	4.0	3-5	0	21	3.86	1.20	4.0	2-5	2
Availability of doctors to your family	31	3.90	1.19	4.0	1-5	2	9	4.10	0.74	4.0	3-5	1	21	3.81	1.36	4.0	3-5	2
Pain relief	31	4.19	0.95	5.0	2-5	2	10	4.36	0.81	5.0	3-5	0	20	4.10	1.02	4.5	2-5	3
Availability of a bed	31	3.81	1.08	4.0	1-5	2	10	3.73	1.1	3.0	2-5	0	20	3.85	1.09	4.0	1-5	3
Family conferences	28	3.46	0.92	3.0	2-5	5	10	3.82	0.88	4.0	3-5	0	17	3.24	0.90	3.0	2-5	6
Time to Diagnosis	29	3.59	1.48	4.0	1-5	4	10	4.09	1.04	4.0	2-5	0	18	3.28	1.64	4.0	1-5	5

Appendix 7.4.2 RESULTS: Service Use – Standardised Service Use and Cost comparison – Standardised by time in the study

CONTINUATION: Comparison of Community Service Use for A) Total population, B) H2H study group and C) All comparator group for those who died during 12 week follow up

Contacts per week in study				
Total GP contacts/week				
Mean (SD)	0.78 (1.02)	1.10 (1.32)	0.46 (0.44)	Z=-1.04
Median (Range)	0.38 (0-5)	0.31 (0-5)	0.38 (0-2)	p=0.3
Total District Nurse contacts/week				
Mean (SD)	1.02 (1.61)	1.47 (2.10)	0.57 (0.65)	Z=-1.29
Median (Range)	0.48 (0-8)	0.56 (0-8)	0.4 (0-2)	p=0.2
Total CPCT contact/week				
Mean (SD)	0.93 (1.10)	0.99 (1.45)	0.88 (0.62)	Z=-0.95
Median (Range)	0.59 (0-7)	0.54 (0-7)	0.6 (0-2)	p=0.3
Total Community contacts/week				
Mean (SD)	2.73 (2.77)	3.57 (3.59)	1.9 (1.18)	Z=-1.20
Median (Range)	2.13 (0-14)	2.19 (0-14)	1.97 (0-4)	p=0.2

The table shows that mean standardised total community costs were higher per day in the H2H group with more variation across the group (H2H mean £25.13/day (SD 27.65), median £12.67/day range £0-£90, AC mean £13.59/day (SD 8.62), median £13.94/day range 0-30) although median costs per day were similar across the study groups. Standardised Inpatient costs were marginally higher in the AC group (AC mean £59.68/day (SD 95), median £23.94, range £0-£379.79, H2H mean £57.69 (SD 92.61), median £0, range £0-£343.27). This is likely the result of a large proportion of the AC group dying in a hospice. Overall, Total EOLC costs per day were higher in the H2H group although this was not statistically significant (H2H median £58.38/day, range £7.54-£350.05), AC median £40.61, range £0-£381.21, p=0.5).

Comparison of Community Service Cost per day for A) Total population, B) H2H study group and C) All comparator group

Community Service Costs (£)/day	A) Total population	B) H2H study group	C) All control study group	Statistical comparison of B) & C)
GP Cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	9.36 (15.16) (0-69.83)	13.27 (20.22) 4.35 (0-69.83)	5.46 (5.41) 5.84 (0-22.54)	Z=-0.69 p=0.49
DN Cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	3.77 (6.53) (0-35)	5.45 (8.67) 2.80 (0-35)	2.09 (2.46) 1.14 (0-9.71)	Z=-0.77 p=0.44
CPCT Cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	6.22 (7.42) (0-39.67)	6.42 (8.18) 4.52 (0-39.67)	6.03 (6.76) 3.75 (0-30)	Z=-0.17 p=0.87
Total Community Cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	19.36 (21.07) 13.37 (0-90)	25.13 (27.65) 12.67 (0-90)	13.59 (8.62) 13.94 (0-30)	Z=-0.58 p=0.6
Inpatient cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	58.69 (92.77) 3.86 (0-379.79)	57.69 (92.61) 0 (0-343.27)	59.68 (95.00) 23.94 (0-379.79)	Z=-0.69 p=0.5
Total EOLC cost/day <i>Mean (SD)</i> <i>Median (Range)</i>	80.73 (92.85) 46.41 (0-381.2)	88.19 (92.86) 58.38 (7.54-350.5)	73.27 (94.33) 40.61 (0-381.2)	Z=-0.67 p= 0.5

The table below details the EOLC cost per day by location of death in each study group. Overall, for the total population the average (median) cost per day of a PPD death was very similar to the cost per day of death in a location other than PPD (PPD= £47.15 (0-381), Not PPD= £45.25 (9-167)). However when considering each study group the median cost per day of a PPD death is higher (double) in the H2H group (£72.66 (8-351)) compared to the AC group (£35.25 (0-381)). Overall, the median cost per day of EOLC resulting in a home death was considerably lower than the cost per day for other locations (Total population Home death median £28.17 (0-281), other location £63.45 (7-381)). However, the median cost of a home death in the H2H group was higher (double) than the AC group cost per day (H2H £46.51 (10-239), AC £21.17 (0-281)).

Comparison of EOLC cost/day for death by location in each study group

EOLC Cost/Day (£)	Total Population (n=46)	H2H group (n=23)	All comparator group (n=23)
PPD Achieved <i>n</i> <i>Mean (SD)</i> <i>Median (Range)</i>	32 90.24 (105.45) 47.15 (0-381)	16 108.70 (103.11) 72.86 (8-351)	16 71.79 (107.81) 35.28 (0-381)
PPD Not Achieved <i>n</i> <i>Mean (SD)</i> <i>Median (Range)</i>	14 59.00 (50.95) 45.25 (9-167)	7 41.32 (36.77) 34.65 (9-110)	7 76.66 (59.54) 69.25 (12-167)
Home Death <i>n</i> <i>Mean (SD)</i> <i>Median (Range)</i>	24 67.23 (83.17) 28.17 (0-281)	12 89.82 (86.49) 46.51 (10-239)	12 44.63 (76.60) 21.17 (0-281)
Death in another location <i>n</i> <i>Mean (SD)</i> <i>Median (Range)</i>	22 95.46 (102.29) 63.45 (7-381)	11 86.41 (103.60) 62.27 (7-351)	11 104.51 (105.18) 69.25 (12-381)

Appendix 7.4.6: RESULTS: Bereavement component

Appendix 7.4.6.1 The feasibility study bereaved relative individual FAMCARE item scores

Bereaved relatives FAMCARE individual item scores for Total population, H2H and the All comparator study group

	Total population (n=19)					
	N	Mean	SD	Median	Range	Missing
Doctors attention to your description of symptoms	19	4.05	0.97	4.0	2-5	0
How thoroughly the doctor assesses your symptoms	19	3.58	1.43	4.0	1-5	0
Information about how to manage pain	19	4.11	1.1	4.0	2-5	0
Information given about side effects	19	3.84	0.83	4.0	2-5	0
Speed at which symptoms are treated	19	3.95	1.08	4.0	2-5	0
Information given about your tests	19	4.05	1.13	4.0	1-5	0
The way tests and treatments are performed	19	4.11	0.99	4.0	2-5	0
The way tests and treatments are followed up your doctor	19	4.05	1.03	4.0	2-5	0
Information provided about your prognosis	18	4.0	1.09	4.0	2-5	1
Answers from health professionals	18	3.89	1.37	4	1-5	1
Referrals to specialists	18	3.44	1.42	4.0	1-5	1
The availability of the doctor to answer your questions	19	4.16	0.96	4.0	2-5	0
The availability of nurses to answer your questions	19	4.47	1.02	5.0	1-5	0
The way the family is included in treatment and care decisions	19	4.11	1.1	4.0	1-5	0
Coordination of care	19	3.79	1.23	4.0	1-5	0
Availability of doctors to your family	19	3.84	1.02	4.0	2-5	0
Pain relief	19	4.32	1.00	5	2-5	0
Availability of a bed	19	3.58	1.02	3	1-5	0
Family conferences	19	3.84	1.30	4.0	1-5	0
Time to Diagnosis	18	2.44	1.34	2.0	1-5	1

Comparison of individual FAMCARE items scores in H2H group and AC group

	Hospital2Home (n=9)						All Comparator (n=10)					
	N	Mean	SD	Median	Range	Missing	N	Mean	SD	Median	Range	Missing
Doctors attention to your description of symptoms	9	4.00	0.87	4.0	3-5	0	10	4.10	1.1	4.5	2-5	0
How thoroughly the doctor assesses your symptoms	9	3.56	1.33	4.0	1-5	0	10	3.60	1.56	4.0	1-5	0
Information about how to manage pain	10	3.89	1.1	4.0	2-5	0	10	4.3	1.1	5.0	2-5	0
Information given about side effects	9	3.44	0.73	4.0	2-4	0	10	4.2	0.79	4.0	3-5	0
Speed at which symptoms are treated	9	3.67	1.23	4.0	2-5	0	10	4.2	0.92	4.0	2-5	0
Information given about your tests	9	4.0	1.0	4.0	2-5	0	10	4.10	1.29	4.5	1-5	0
The way tests and treatments are performed	9	4.33	0.71	4.0	3-5	0	10	4.10	0.99	4.0	2-5	0
The way tests and treatments are followed up your doctor	9	3.78	0.97	4.0	2-5	0	10	4.30	1.1	5.0	2-5	0
Information provided about your prognosis	8	4.13	1.13	4.5	2-5	1	9	3.0	1.1	4.0	2-5	1
Answers from health professionals	9	3.78	0.97	4	2-5	0	9	4.0	1.73	5.0	1-5	1
Referrals to specialists	8	3.75	1.04	4.0	2-5	1	10	3.20	1.69	3.50	1-5	0
The availability of the doctor to answer your questions	9	4.22	0.83	4.0	3-5	0	10	4.10	1.10	4.5	2-5	0
The availability of nurses to answer your questions	9	4.22	1.3	5.0	1-5	0	10	4.70	0.68	5.0	3-5	0
The way the family is included in treatment and care decisions	9	4.22	0.83	4.0	3-5	0	10	4.0	1.3	4.5	1-5	0
Coordination of care	9	3.56	1.51	4.0	1-5	0	10	4.0	0.94	4.0	2-5	0
Availability of doctors to your family	9	4.33	0.71	4.0	3-5	0	10	3.40	1.08	3.0	2-5	0
Pain relief	9	4.33	1.12	5	2-5	0	10	4.30	0.95	4.5	2-5	0
Availability of a bed	9	4.0	0.87	4.0	3-5	0	10	3.20	1.03	3.0	1-5	0
Family conferences	9	4.33	0.87	5.0	3-5	0	10	3.40	1.51	3.5	1-5	0
Time to Diagnosis	9	2.44	1.13	2.0	1-5	0	9	2.44	1.59	2.0	1-5	1

Appendix 7.4.6.2 Bereaved relatives (IP) Qualitative comments

This appendix leads on from section 4.7.3.5 and presents the qualitative analysis of the written free text comments from bereaved relatives of patients who died in the cancer centre. The results provide context to the quantitative FAMCARE satisfaction scores in reported in Section 4.7.3.4 to more fully answer objectives 13 & 14.

Objective 13: To describe and compare the bereaved family members satisfaction with care in the H2H study with those of family members of patients who died in the hospital

Objective 14: To determine if the degree of satisfaction with care is related to any patient clinical, demographic, or preferences factors

Forty-two (42/88, 47.7%) bereaved relatives provided additional free text comments. Analysis revealed four main themes; PPD, importance of communication, excellence in care and concerns about care. I will now present the results of each theme.

Theme 1: PPD

A number of participants expressed a known preference for place of death. The majority explained how home was the PPD for both the patient and the carer. In the participants accounts home death was associated with dignity in dying.

'She wanted to die with dignity at home.' BR099

'Although the care could not be faulted it would have been nice to have been offered a chance to take Barb home to die or had someone explain why we weren't offered that service or opportunity' BR088

'We both hoped Ray would be able to pass away at home as I had been able to nurse him all along at home with wonderful backup from our District Nurses as well as the hospice contact. This was a whole new experience for

us both and our family. We did meet very many caring and kind people on our journey and made many friends, thank you.' BR075

However, one participant spoke of how hospital was the PPD and that a home death would have been wrong for the patient. The bereaved wife found her husband's death away from the family home as a positive experience which allowed her to contain her grief.

'Laurence himself never wanted to die at home and hated the idea of everybody crowding around his death bed. For myself, although I was by myself in a strange place surrounded by strangers, I think I was actually stronger emotionally because of it. Now, 7 months later, familiar surroundings here do not provoke any sad memories of that day- they are all a long way away in London.' BR279

In a similar manner, other participants who had expressed home as the patient and their PPD reflected, in hindsight, that hospital was the 'right acceptable place'. In these accounts the reason for hospital being the right location centred around the perception that the patient received more prompt symptom control with medication when needed and a high level of nursing care that could not be expected at home.

'Our preference would have been for Brian to die at home, but he was too ill to move from hospital to home. Looking back hospital was the right place as the access to medical care and drugs were immediate' BR043

'that I would have preferred Trevor to die at home. That is because he loved our home and garden and it would have seemed right for him to die there. Trevor died within 4 weeks of a diagnostic report that he had metastatic bile duct adenocarcinoma and deteriorated very quickly . His condition continued to deteriorate and therefore it was a blessing that he was cared for at the Royal Marsden in Sutton'. BR255

*'Although Mark requested to die at home, I chose to bring him to RMH as I believed it would be far more appropriate and would be better able to control his final symptoms and pain. Mark had 2 very difficult nights on a ward . I was thankful I was allowed to stay with him throughout the nights.'*BR233

Theme 2 – Importance of listening and communicating with family

The second theme emerging from the free text comments was the importance of listening and communicating with the family, within this were two subthemes: balance between truth and hope, and the importance of listening to the family.

Balance between truth and hope

There was a dichotomy within the free text comments about honesty and truth at the EoL. A number of participants expressed the importance of honesty whilst others described concern that too much honesty erodes hope. Bereaved relative 134 felt more honesty was beneficial:

'no complaints about the kindness of the nursing staff, though a bit more honesty and less up-beat but unrealistic attitude would have been helpful from those higher-up.' BR134

As did bereaved relatives 192 and 203:

'The second area relates to communication. It wasn't until days before his death that we had an open and honest discussion about the severity of his condition. I must say that the doctor was fantastic at such a difficult time but it is hard to believe that we were not given more information at a much earlier stage' BR203

'It took far too long to get a diagnosis and the truth would have been better than 'economical' half truths and his inability to move food down to his stomach should have been dealt with much earlier- at least he would have been able to eat. Some people need the truth to be able to adjust mentally and deal with things.' BR192

In contrast, bereaved relatives 195 and 299 expressed concern that complete honesty was detrimental to the patient at the EoL

"We were concerned about the balance between the need to tell the patient the truth (re: prognosis) & maintaining the patient's sense of hope for the coming few months/weeks/days. Once hope in recovery is lost then the will to live disappears & QoL is eroded completely. The patient needs to know that there is point in carrying on living today & that prognoses are not always right. A young patient such as Jacob (21) cannot fully live their last days 'in the moment' if all hope has been taken away from them in an over zealous attempt to be brutally honest about 'the truth' as the consultant sees it.' BR195

And,

'Somehow balancing preparing someone for what has to happen next with a sense of optimism if that is what the patient needs, is critical and not achieved.' BR299

Importance of listening to the family

Bereaved relatives frequently described the importance of feeling listened too and involved in the decision making about the patients care. This empowered bereaved relative 158 with strength to continue organising important issues after the patient's death

'The medical staff discussed all decisions with me & in this way I was able to maintain control over events. Nothing was done without my consent. As I had remained in control throughout his death this gave me the confidence and resolve to continue with the same determination to get things 'right' in the organising of his funeral & farewell to all his friends.' BR158

However, although the minority, there were examples where relatives did not feel listened to:

'I had said she was a very private person & did not want strangers to touch her & had to get again assertive to get her to stop. At no time did she respect me or my family's wishes.' BR099

Theme 3: Excellent care

Overall, the majority of participants recounted 'excellent' EoLC. Excellence was judged to be treating the patient with dignity, care and compassion alongside staff dedication and trusted HCPs. These attributes were a comfort to the bereaved relatives. The comments about excellent EoLC are presented below in the following subthemes: (1) Dignity, care and compassion, (2) Staff dedication, (3) Symptom control at the EoL.

Dignity, care and compassion

Bereaved relative 169 expressed confidence in the caring and compassionate staff:

'The Drs and the team were caring and considerate at all times and my husband had great faith in them.' BR169

Whilst others described the importance of professionalism from all staff:

*'I can't praise enough the professionalism of doctors and all the staff who were very attentive and showed Nancy much love and care. Both myself and the family found their attitude very comforting.'*BR236

And the observation that staff cared for the patient in a dignified manner:

'On the whole Nicki's diagnosis, treatment and eventual death were handled with real dignity.' BR248

'We feel that everything was carried out with care and sensitivity and with consultation with us, his family. He was allowed to keep his dignity and be pain free which is so important. We believe everything possible was done to make his passing as dignified as possible and have nothing but praise and thanks to all the staff involved.' BR192

Staff dedication and patient confidence

A number of bereaved relatives praised the dedication of staff from all disciplines to provide good care, and this made relatives feel that their dying family member was important to everyone. For example BR 197 described the dedication of staff to ensure her husband had good symptom control at the EoL:

'Everything possible was done by the doctors as well as the team of dedicated nurses, to ensure he was not in pain and was as comfortable as possible. I personally believe that he could not have received better care anywhere, and I shall always be glad that he died in the hands of such caring and dedicated people.' 'Ivan had confidence in the people who looked after him in the Royal Marsden; they tried to ensure the very best for him, and I shall always be grateful for the care he received.' BR 197

Bereaved relative 229 recounted how important it was that all hospital workers, not just trained staff, worked with professionalism:

'It is enough to say that while he was there I have never seen such compassion, dedication, skill and professionalism. Nor did I ever see or hear or even pick up any hint of any worker – doctor, nurse, cleaner, receptionist, porter having any negative vibes about the hospital' BR229

Symptom control at EoL

Overall, the majority of comments reported good symptom control at the EoL in often difficult circumstances. These efforts at optimising symptom control were seen by bereaved relatives as more evidence that the patient was treated with dignity at the EoL. Three examples are given below:

'Every effort and support to facilitate and alleviate stress, pain and humane touch was met with dignity and respect by one and all members of the care staff' BR244

'Once my mum was admitted to the palliative care ward she was treated amazingly. As a devastated family we were very pleased with how she was treated by the staff and how well her pain was controlled. We couldn't have asked for better care.' BR284

'His final hours were extremely difficult, not only for Ivan, and for James and I, but also for those who nursed him. His oesophageal tumour erupted and brought up much blood, but the speed and gentleness with which he was dealt was reassuring at what was an extremely distressing time. At this point he was given additional sedation and his passing was peaceful.' BR197

Theme 3: Poor care and concerns about care

The accounts of poor care described three issues relating to poor care: late recognition of dying and over medicalization of EoL, staff shortages, and lack of psychological support. These subthemes will now be discussed:

Recognition of dying and overmedicalisation of EoL

The views regarding over medicalization and investigation at the EoL describe 'pointless' investigations and treatment. Some bereaved relatives felt this caused suffering and harm when the outcome was inevitable, and this approach offered false hope:

'Throughout the last few days she was put on yet another chemo drug and then stopped because her battered frail veins would not allow a port to be inserted. Her white blood cell count was plummeting badly which apparently was a result of the final, pointless chemo effort → neutropenic sepsis' BR134

'We witnessed conflict between the ICU consultant and Paul's consultant which was difficult. They both had differing view on his life expectancy and in the end Paul felt (wrongly) very strongly that his consultant was on 'his side' but that ICU were 'out to get him'. BR299

Bereaved relative 100 and 236 described how additional 'pointless' tests near the EoL had affected them, the memory of which had encroached on their bereavement:

'I realise that Graham did not have much longer to live, but surely a very sick man should have been spared that last discomfort of an x-ray, most especially in the middle of a meal. Eating was uncomfortable at the best of times because of his distended stomach and abdomen. Our last time together was unnecessarily shortened by this x-ray and by my not being called earlier. I find it very difficult to get all this out of my mind.' BR100

'I and the family were very disappointed when 3 days before Nancy passed away the hospital decided to go ahead with a scan for bone cancer, which had not been cancelled knowing that the end for Nancy was very near. Putting Nancy through the scan was very upsetting for her and us. Even though the scan had been booked but not cancelled common sense should have been used by those responsible and the scan cancelled at the last minute.' BR236

Staff shortages

Two bereaved relatives made comments about the level of staff, and that they felt the EoLC of the patient had been suboptimal due to lack of staff. The weekends and shift change times were a particular concern for bereaved relative 299

'A particular vulnerability is when things are changing. The quality of care and availability of nursing staff during the ward changes due to refurbishment of Granard House was marked, especially at weekend. The day my husband died I had to leave him, in distress and scour the corridors looking for help – in the end asking someone myself to contact ICU outreach' BR299

Whilst bereaved relative 100 recounts how she felt ignored when asking for assistance for her husband:

'He was told that he must not change his position without help – obviously they were afraid of him falling again. He must ring his buzzer if he needed to move up or down. The average response to his ringing was twenty minutes! I can verify this because this happened on several occasions when I was there. Twice I went out to find a nurse, without success.' BR100

Lack of psychological emotional support for family

The final issue that requires improvement in the future, was the perceived lack of psychological support for the family. The family members most concerned were those with young children. The relatives felt strongly that this type of psychological support was crucial for their children's grieving process:

'A lack – Paul, I or our children were never proactively offered any form of support or counselling. I asked for us to be referred and we had one appointment. I think it is important that since his death no one from that team has made contact and that we have not been offered any psychological support or follow-up. I have done this myself and the children are doing well but I imagine many bereaved parents would feel unable to reach out at such a time and ask for help.' BR299

Bereaved relative 233 described a potential solution, a written information sheet that describes what to expect at the EoL and what support was available during that time:

'It would have been helpful perhaps to have a leaflet explaining what would happen and what was available once it was clear that Mark's end was near. After Mark passed away, the hospital was very helpful in providing information helping me know what to do. As I say, it might have helped to understand a bit more about what to expect and what was available a little earlier in the process.' BR233

Appendix 7.4.7: RESULTS: Factors influencing place of death

This appendix follows on from Section 4.8.5 to give detail of the univariate analysis of factors influencing death in hospital compared to other locations

Hospital Deaths Univariate analysis

The personal and social variables with a p value < 0.2 were: age, gender, ethnicity, and living alone, deprivation quintile and Primary Care Trust spend per death (PCT/death) quartile. The illness related variables were: cancer diagnosis, time from diagnosis to death, last appointment type, time from last appointment to death, last treatment type, last treatment intent, time from last treatment to death, performance status, number of admissions, known to CPCT and known to the H2H team. Performance status was excluded from further analysis due to the high number of missing cases (n=1247); treatment intent was also excluded due to high collinearity with other variables in the model. The remaining 15 variables were subject to forward step multiple logistic regressions.

Factors influencing place of death (Hospital): Univariate analysis of variables influencing place of death (continues over page)

<i>Number (%)</i>	Hospital death (A) (n=518)	Other location death (B) (n=949)	Chi-squared*
PERSONAL AND SOCIAL FACTORS			
AGE IN YEARS			Overall p=0.1
16-44	48 (39.7)	73 (60.3)	0.1
45-64	176 (31.5)	383 (68.5)	0.02
65-74	156 (38.0)	254 (62.0)	0.17
75+	138 (36.6)	239 (63.4)	0.54
GENDER			p=0.2
Male	266 (36.9)	454 (63.1)	
Female	252 (33.7)	495 (66.3)	
ETHNICITY			p=0.06
White British	396 (33.9)	771 (66.1)	
Other	93 (40.4)	137 (59.6)	
MARITAL STATUS			p=0.4
Married	295 (34.4)	563 (65.6)	
Other	223 (36.6)	386 (63.4)	
LIVING ALONE			p=0.2
Yes	117 (38.5)	187 (61.5)	
No	401 (34.5)	761 (65.5)	
ENVIRONMENTAL FACTORS			
IMD DEPRIVATION QUNITILE			Overall p= 0.03
1 (most deprived)	62 (40.5)	91 (59.5)	0.03
2	103 (42.4)	140 (57.6)	0.15
3	89 (32.0)	189 (68.0)	0.01
4	116 (34.8)	217 (65.2)	0.21
5 (least deprived)	144 (31.9)	308 (68.1)	0.86
PCT SPEND/DEATH QUARTILE			Overall p=0.02
1 (least spending)	64 (28.1)	164 (71.9)	0.02
2	171 (34.1)	331 (65.9)	0.52
3	189 (36.9)	323 (63.1)	0.30
4 (most spending)	72 (42.6)	97 (57.4)	0.03
KNOWN TO CPC			p<0.01
Yes	237 (23.1)	787 (76.9)	
No	281 (63.4)	162 (36.6)	
HOSPITAL2HOME SERVICE INVOLVED IN CARE			p<0.01
Yes	20(15.4)	110 (84.6)	
No	498 (37.2)	839 (62.8)	
ILLNESS FACTORS			
TREATMENT SITE			Overall p=0.22
Chelsea	162 (34.5)	307 (65.5)	
Sutton	344 (36.2)	605 (63.8)	
Kingston	12 (24.5)	37 (75.5)	
CANCER DIAGNOSIS			Overall p<0.01
Lung	72 (32.1)	152 (67.9)	
Gastrointestinal	119 (36.7)	205 (63.3)	
Urological	70 (36.1)	124 (63.9)	
Breast	63 (35.6)	114 (64.4)	
Haematological	65 (61.9)	40 (38.1)	
Sarcoma	32 (32)	68 (68.0)	
Gynaecological	21 (22.3)	73 (77.7)	
Other	76 (30.5)	173 (69.5)	
TIME FROM DIAGNOSIS TO DEATH			Overall p<0.01
1-3 months	50 (59.5)	34 (40.5)	
3-6 months	42 (32.3)	88 (67.7)	
6-12 months	87 (33.3)	174 (66.7)	
1-2 years	111 (33.4)	221 (66.6)	
2-5 years	107 (31.3)	235 (68.7)	

>5 years	121 (38.1)	197 (61.9)	
LAST APPOINTMENT TYPE			Overall p<0.01
Outpatient	272 (30.3)	625 (69.7)	<0.01
Inpatient	199 (43.9)	254 (56.1)	0.25
Ward Attender/Day Services	47 (40.2)	70 (59.8)	<0.01
TIME FROM LAST APPOINTMENT TO DEATH			Overall p<0.01
< 1 month	365 (48.3)	391 (51.7)	
1-3 months	104 (20.5)	403 (79.5)	
3-6 months	49 (24.0)	155 (76.0)	
LAST TREATMENT TYPE			Overall p<0.01
Chemotherapy	285 (35.2)	525 (64.8)	
Radiotherapy	176 (37.0)	300 (63.0)	
Hormonal treatment	19 (20.4)	74 (79.6)	
Surgery	28 (36.8)	48 (63.2)	
Stem Cell Transplant	10 (83.3)	2 (16.7)	
LAST TREATMENT INTENT			p<0.01
Adjuvant/Curative	107 (60.8)	69 (39.2)	
Palliative	411 (31.8)	880 (68.2)	
TIME FROM LAST TREATMENT TO DEATH			Overall p<0.01
< 1 month	210 (56.1)	164 (43.9)	
1-3 months	164 (30.8)	368 (69.2)	
3-6 months	65 (19.9)	261 (80.1)	
6-12 months	39 (27.1)	105 (72.9)	
1-2 years	19 (40.4)	28 (59.6)	
>2 years	21 (47.7)	23 (52.3)	
PERFORMANCE STATUS (WHO) (n=279)			Overall p<0.01
0/1	28 (56.0)	22 (44.0)	
2	35 (50.7)	34 (49.3)	
3	41 (35.3)	75 (64.7)	
4	12 (27.3)	32 (72.7)	
NUMBER OF ADMISSIONS			p=0.08
Mean (SD)	1(1.6)	1 (1.5)	
Range	0-9	0-13	
KNOWN TO HOSPITAL PALLIATIVE CARE			p=0.98
Yes	180 (35.4)	329 (64.6)	
No	338 (35.3)	620 (64.7)	

*p values in bold indicate factors was taken forward into multivariate analysis

Hospital Deaths: Multivariate analysis

The forward multivariate binary logistic regression analysis identified eight variables as independent factors associated with the likelihood of dying in hospital. These variables can be split into personal (age), illness related (last contact type, time from last contact, last treatment type and time from last treatment) and environmental (PCT spend/death quartile, known to CPCT and know to the H2H team).

Personal factors

- Age – In comparison to the reference age range (16-44) , those aged between 45-64 were a fifth less likely to die in hospital (OR 0.8, 0.48-1.32) however, those age above 64 were a third more likely to die in hospital than patients aged between 16-44 (75+ OR 1.28, 0.74-2.2). The confidence intervals cross 1 and therefore the odds ratio should be considered with caution.

Illness factors

- Last contact type- Outpatients were a third less likely to die in hospital compared to the reference category of last contact –inpatient admission (OR 0.62, 0.45-0.85).
- Time from last contact to death- In comparison to the reference category of last contact less than a month prior to death, those last seen between 1-3 months (OR 0.32, 0.22-0.45) or 3-6 months prior to death (OR 0.30, 0.18-0.51) were two thirds less likely to die in hospital.
- Last treatment type- Those whose last treatment was a stem cell transplant were nearly 6 times more likely to die in hospital than chemotherapy patients, although the confidence intervals for this were wide due to the low number of patients in the group (OR 5.67, 0.95-33.87). Chemotherapy and radiotherapy patients were twice as likely to die in hospital than those patients on hormone treatment alone (OR 0.53, 0.28-0.98)
- Time from last treatment to death- the reference category here was treatment less than one month before death. Interestingly, as time from

treatment increases the likelihood of dying in hospital decreases up to the 1-year point. Those whose last treatment was between 6-12 months were a third less likely to die in hospital than those treated within the month prior to death (OR 0.63, 0.36-1.12). After one year from treatment the likelihood of dying in hospital increases and those patients whose last recorded treatment was over 2 years ago were as likely to die in hospital as those treated within the month prior to death (OR 1.09, 0.5-2.35). The confidence intervals for all categories cross 1 therefore these trends should be interpreted with caution.

Environmental factors

- PCT spending per death – The higher the PCT spend on palliative care/per death the more likely the patient was to die in hospital. Patients living in the PCTs spending the most on palliative care (Quartile 4) were over twice as likely to die in hospital than those living in the PCT with the least spend (OR 2.35, 1.42-3.88).
- Known to CPC- Those not known to CPC were nearly 6 times more likely to die in hospital (OR 5.6, 4.2-7.7)
- H2H- Those with no input from the H2H team were twice as likely to die in hospital as those patients who received a H2H (face-to-face or telephone).

Factors influencing place of death: Multivariate forward binary logistic regression analysis of factors influencing place of death

	Hospital n=518 n (%)	Other location n=949 n (%)	Odds Ratio	95% CI	p value
PERSONAL FACTORS					
AGE IN YEARS	16-44	48 (40)	73 (60)	1	p=0.02
	45-64	176 (32)	383 (68)	0.80	(0.48-1.32) 0.39
	65-74	156 (38)	254 (62)	1.32	(0.79-2.22) 0.29
	75+	138 (37)	239 (63)	1.28	(0.74-2.20) 0.38
TREATMENT FACTORS					
LAST CONTACT					
Inpatient	272 (30.3)	625 (69.7)	1		p<0.01
Ward Attender	199 (43.9)	254 (56.1)	1.06	(0.63-1.78)	p=0.84
Outpatient	47 (40.2)	70 (59.8)	0.62	(0.45-0.85)	p=0.03
TIME FROM LAST CONTACT					
< 1 month	365 (48.3)	391 (51.7)	1		p<0.01
1-3 months	104 (20.5)	403 (79.5)	0.32	(0.22-0.45)	p<0.01
3-6 months	49 (24.0)	155 (76.0)	0.30	(0.18-0.51)	p<0.01
LAST TREATMENT					
Chemotherapy	285 (35.2)	525 (64.8)	1		p=0.03
Surgery	176 (37.0)	300 (63.0)	0.68	(0.36-1.29)	p=0.24
Radiotherapy	19 (20.4)	74 (79.6)	1.14	(0.84-1.55)	p=0.41
Hormone Treatment	28 (36.8)	48 (63.2)	0.53	(0.28-0.98)	p=0.04
Stem Cell Transplant	10 (83.3)	2 (16.7)	5.67	(0.95-33.87)	p=0.06
TIME FROM LAST TREATMENT					
< 1 month	210 (56.1)	164 (43.9)	1		p=0.01
< 3 months	164 (30.8)	368 (69.2)	0.60	(0.43-0.85)	p<0.01
3-6 months	65 (19.9)	261 (80.1)	0.53	(0.34-0.84)	p<0.01
6-12 months	39 (27.1)	105 (72.9)	0.63	(0.36-1.12)	p=0.12
1-2 years	19 (40.4)	28 (59.6)	1.01	(0.46-2.23)	p=0.97
> 2years	21 (47.7)	23 (52.3)	1.09	(0.50-2.35)	p=0.83
ENVIRONMENTAL FACTORS					
PCT SPENDING QUARTILE					
Quartile 1 (least spending)	64 (28.1)	164 (71.9)	1		P<0.01
Quartile 2	171 (34.1)	331 (65.9)	1.55	(1.01-2.37)	p=0.04
Quartile 3	189 (36.9)	323 (63.1)	1.85	(1.22-2.82)	p<0.01
Quartile 4 (most spending)	72 (42.6)	97 (57.4)	2.35	(1.42-3.88)	p<0.01
KNOWN TO CPC					
No					p<0.01
Yes	237 (23.1)	787 (76.9)	5.6	(4.2-7.7)	p<0.01
	281 (63.4)	162 (36.6)	1		
H2H					
No	20(15.4)	110 (84.6)	2.1	(1.2-3.7)	p<0.01
Yes	498 (37.2)	839 (62.8)	1		

8 References

8 References

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