

Nutrition at the hospital-community
interface; an investigation of nutritional
risk in community-dwelling older adults

Thesis submitted for the degree of Doctor of Philosophy

Imperial College London

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2019

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Thesis abstract

Undernutrition is a predictor of morbidity and mortality in older adults and those living with conditions of accelerated aging such as COPD. Nutritional screening is recommended to identify at-risk individuals but there are concerns that this initial step in a pathway of nutritional care is not always completed or communicated. In addition, there is little research in community-dwelling older populations regarding how best to organise care at the hospital-community interface. Exploring existing pathways of nutritional care experienced by community dwelling older adults will help us to understand potential determinants of undernutrition that may influence their trajectory of recovery and highlight any gaps in care. The aim of this thesis was to examine nutritional risk, physical function and quality of life in a cohort of community-dwelling older adults.

An observational prospective cohort study of community-dwelling, older adults demonstrated that individuals at medium and high risk of undernutrition were at higher risk of mortality and suffered a worse trajectory of recovery following hospital admission compared to their counterparts at low nutritional risk.

However, cross-sectional analyses using data from a large cohort of COPD patients attending pulmonary rehabilitation between August 2009 and January 2015 showed that whilst medium/high nutritional risk was associated with worse strength and function prior to a period of respiratory rehabilitation, it did not influence performance, with similar benefits observed in low and medium/high nutrition risk groups.

This thesis suggests that irrespective of nutritional status, older adults recently discharged from hospital or attending outpatient rehabilitation programmes exhibited reduced ability to perform activities of daily living, however, that individuals at nutritional risk experience a reduced rate of recovery, suggesting that worse nutritional status may compound adverse effects on physical function and quality of life following hospital admission. However, nutritional support may have the potential to reduce further deterioration in at risk participants.

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Declaration of Originality

The author performed all of the work described in this thesis. Collaborations and assistance are detailed below. The work of others is fully cited, referenced or acknowledged. The author was responsible for the processing and handling of the nutritional data presented in this thesis. All critical appraisal and interpretation presented in this thesis are the opinion of the author.

It should be acknowledged that whilst the author wrote the thesis introduction (chapter 1), she and Professor Mary Hickson had previously co-written a book chapter on the consequences of undernutrition. As a result, section 1.8 'The Consequences of Undernutrition' may share similarities with this work (Hickson and Julian, 2018).

Nutritional risk in chronic obstructive pulmonary disease (Chapter 3): Data was collected by the research team at Harefield hospital, London, led by Dr William Man (Consultant Physician, Royal Brompton and Harefield Trust). Analysis was completed by the author.

Undernutrition at the hospital-community interface: an investigation in to the relationships between undernutrition risk, sarcopenia risk, functional status, quality of life and satisfaction with food-related life (chapter 4): The author jointly developed the study protocol with Professor Mary Hickson (Imperial College London and University of Plymouth) and Dr Elizabeth Weekes (Consultant Dietitian, King's College London). All data was collected by the author and Bogna Nicinska (Research Assistant, Imperial College London).

Nutritional status, energy and protein intakes in community-dwelling older adults (chapter 5): The author adapted the dietary coding protocol from the standard food record coding protocol devised for the Airwave Health Monitoring Study by Rachel Gibson (PhD student, Imperial College London) and Rebeca Eriksen (PhD student, Imperial College London) and trained the three dietary coders Jo Craddock, Alice Gibson and Hannah West (Undergraduate students, University of Plymouth).

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Acknowledgements

I owe a huge thank you to several people who have helped me throughout my PhD journey.

First and foremost Professor Mary Hickson – I don't know how I can ever repay you for all the knowledge and guidance you have given me, and the patience you have shown me! Having such a personable mentor has been invaluable – thank you.

I am also enormously grateful to my second academic supervisor Professor Gary Frost. I have thoroughly enjoyed my time in the Nutrition and Dietetic Research Group at Imperial College and have learnt a vast amount over the last four years.

I would like to thank all the staff at St Mary's who were so supportive during my year of recruitment, and the research team at Harefield Hospital who welcomed me in to the fold and taught me lots about research. Also to my colleague and friend Bogna for assisting on the study, your help was very much appreciated.

In addition, this thesis would not have been possible without the time and effort made by all the study participants, whose contributions I am extremely grateful for.

Finally I would like to thank my wonderful family and friends for helping me through the challenges, particularly my partner Matt.

Glossary of abbreviations

ADL	Activities of daily living
ANOVA	Analysis of Variance
AWGS	American Working Group on Sarcopenia
BAPEN	British Association for Parenteral and Enteral Nutrition
BDA	British Dietetic Association
BIA	Bioelectrical impedance
BMI	Body Mass Index
BMR	Basal metabolic rate
BMRest	Estimated Basal metabolic rate
BW	Body weight
CART	Cocaine- and Amphetamine-Related Transcript
CAT	COPD Assessment Test
CCK	cholecystokinin
CFS	Clinical Frailty Scale
CI	Confidence Interval
CSRI	Client Service Receipt Inventory
COPD	Chronic obstructive pulmonary disease
CRP	C-reactive protein
CSHA	Cardiovascular study of health and aging
CVD	Cardiovascular Disease
DEXA	Dual Energy X-Ray Absorptiometry
DN	District nurse
DNA	Deoxyribonucleic acid
DRG	Diagnosis-related groups
EI	Energy intake
EPIC	European Prospective Investigation into Cancer
EQ-5D-5L UI	Euroqol Quality of Life-5 Domain-5 Level utility index
EQ-5D VAS	Euroqol Quality of Life-5 Domain-5 Level Visual Analogue Scale
ESPEN	The European Society for Clinical Nutrition and Metabolism
EWGSOP	The European Working Group for Sarcopenia in Older People
FBA	Food Benefits Assessment questionnaire
FEV	Forced expiratory capacity
FFM	Fat-free mass
FFMI	Fat-free mass index
FFQ	Food frequency questionnaire
FI	Frailty Index
g	Gram
GI	Glycaemic index
GLMM	General Linear Mixed Model
GLP-1	Glucagon-like polypeptide-1
GP	General practitioner
HADS	Hospital anxiety and depression scale
HGS	Handgrip strength
HR	Hazard Ratio
HRQOL	Health-related quality of life
HSE	Health Survey for England
IADL	Instrumental Activities of Daily Living
IBW	Ideal body weight
ICC	Intraclass correlation coefficient
IL-6	Interleukin-6
IMD	Index of multiple deprivation
IQR	Interquartile range
ISWT	Incremental shuttle walk test
IWGS	International Working Group on Sarcopenia
k	Kappa statistic
Kg	Kilogram

Kcal	Kilocalorie
LCD	Low calorie diet
LDL	Low Density Lipoprotein
LOS	Length of hospital stay
M	Meters
MAC	Mid-arm circumference
MCID	Minimal clinically important difference
MUAC	Mid upper arm circumference
MJ	Millijoules
mmol/L	Millimoles per Litre
MNA	Mini Nutritional Assessment
MNA-SF	Mini Nutritional Assessment–Short Form
MUST	Malnutrition Universal Screening Tool
MRC	Medical Research Council
MST	Malnutrition Screening Tool
NICE	National Institute for Health and Care Excellence
NCD	Non communicable diseases
NDNS	National Diet and Nutrition Survey
NHANES	National Health and Examination Survey
NHI	Nutritional Health Index
NHS	National Health Service
NPV	Negative Predictive Value
NRS 2002	Nutritional Risk Screening 2002
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSP	Non starch polysaccharides
ONS	Oral Nutritional Supplement
OR	Odds ratio
PAL	Physical activity level
PCA	Principle components analysis
POMC	Pro-opiomelanocortin
PPV	Positive Predictive Value
PR	Pulmonary rehabilitation
PYY	Peptide YY
QMVC	Quadriceps maximal voluntary contraction
QoL	Quality of Life
ROC	Receiver operating characteristic
RCT	Randomised Controlled Trial
REC	Research ethics committee
RR	Relative Risk
SACN	Scientific Advisory Committee on Nutrition
SARC-F	Sarcopenia risk screening tool
SD	Standard deviation
SE	Standard error
SF-36	Short form health survey
SGA	Subjective Global Assessment
SGRQ	St George's Respiratory Questionnaire
SNAQ	Short Nutritional Assessment Questionnaire
SOP	Standard operating procedure
SPPB	Short physical performance battery
SPSS	Statistical Package for the Social Sciences
SWFL	Satisfaction with food-related life questionnaire
T2DM	Type 2 Diabetes Mellitus
TEE	Total energy expenditure
TSF	Triceps skinfold thickness
TNF	Tumour Necrosis Factor
UI	Utility Index
UK	United Kingdom
USA	United States of America

VLCD	Very-Low Calorie Diet
Vco₂	Carbon dioxide output
Vo₂	Oxygen output
WC	Waist circumference
WHO	World Health Organisation
WHOQOL-BREF	World Health Organisation Quality of life 'brief'

Chapter 1: Background

1.1 Definitions of undernutrition

Due to a lack of consensus in the literature, several definitions are clarified here. For the purposes of this thesis, undernutrition is defined as “a state of nutrition in which a deficiency or imbalance of energy, protein, and other nutrients causes measurable adverse effects on body shape, size, composition and function, and clinical outcome” (Batres et al., 2007). The aetiology of undernutrition may include nutrient deficiency due to a reduced intake, reduced absorption, increased excretion or an inability to utilise nutrients. Chronic disease causing heightened energy expenditure and tissue catabolism, or acute disease promoting inflammation. In addition, it is important to highlight that this thesis describes ‘risk’ of undernutrition and uses nutrition screening tools to characterise at-risk individuals. Whilst the terms ‘undernutrition’ and ‘risk of undernutrition’ are often used interchangeably in the literature, this is incorrect and it is important to highlight that they are different.

This chapter will discuss specific conditions of undernutrition, namely starvation, sarcopenia and cachexia. As there is no clear definition of older adults, older adults will be considered as those aged 60 years and over.

1.2 Prevalence

Under and over-nutrition coexist in the developed world (Gillespie et al., 2001). Whilst only 2% of world undernutrition can be found in developed countries, this translates to 3 million UK residents (Batres et al., 2007), including 1.3 million people over the age of 65.

Many studies performed over the last four decades have explored the prevalence of undernutrition across the world (Agradi et al., 1984, Cereda et al., 2016, McWhirter and Pennington, 1994, Stratton et al., 2004). Trends show higher prevalence in hospital populations, reaching 62% in a study of 155 patients hospitalised in the Netherlands (Naber et al., 1997). Prevalence in community dwelling populations is significantly lower, ranging from 7-39% in the UK and Ireland (see table 1.1). The cause of these differences in prevalence arise from differences in study designs, variations in the definition of undernutrition and the

methodologies employed to measure it (Corish and Kennedy, 2000, Covinsky et al., 2002). For example, of the studies detailed in table 1.1, the lowest prevalence was found in a large study recruiting participants aged over 60 (mean age was 72) able to attend an outpatient setting (Romero-Ortuno et al., 2011). This compares to the highest prevalence from a relatively small study in an older sample (mean age was 79), all interviewed in their own homes. A large study found a prevalence of 4.1% using body mass index (BMI), 17.1% using arm anthropometry and 27.4% using subjective global assessment (SGA) – a difference of over 23% (Pirlich et al., 2006). Furthermore, differences in the cut point used for anthropometrical data impact the prevalence of undernutrition. For example, BMI thresholds of <18, <18.5, <20, and <21.7kg/m² (Kelly et al., 2000, Landi et al., 2000, McWhirter and Pennington, 1994, Weekes, 1999) have all been utilised in different studies. One systematic review (Cereda et al., 2016) looked exclusively at prevalence determined using the Mini Nutritional Assessment (MNA) tool in older people across different healthcare settings. Prevalence of undernutrition in hospital was 22.0%, outpatients 6.0% and community-living participants 3.1%. Whilst the absolute numbers were different, the prevalence showed a similar trend to other large scale data (Russell and Elia, 2014), with prevalence following the level of dependency demonstrating higher levels of undernutrition in institutions. However, the I² statistic showed extremely high heterogeneity for all settings (87.4-97.2%) and prevalence rates within settings varied up to 6.2% depending on the study's country of origin. This suggests that prevalence of undernutrition may vary with the tool used, but also across different settings, different countries and with different patient groups. Discrepancies between study methods make it impossible to provide a definitive prevalence. Choice of methodology is often dependent on size and setting of the study. For example, larger studies may be restricted by time and cost. In studies of hospital inpatients biochemical markers or specialised equipment may be available, where in long-term care facilities the physical abilities of the residents may dictate the tool used. Screening tools are inexpensive and relatively easy to administer and are often the tool of choice for prevalence studies.

Author	Country	N	Screening tool	Mean age (SD/ IQR)	Prevalence	Study design
Harris et al, 2007	UK	100	MUST	79 (6)	12%	Cross-sectional
O'Dwyer et al, 2009	Ireland	63	MNA	79 (11)	38.5%	Cross-sectional
Power et al, 2014	Ireland	208	MNA	75 (7)	11%	Cross-sectional
Riches and Jeanes, 2014	UK	20	MNA	76 (8)	25%	Cross-sectional
Romero-Ortuno, 2011	Ireland	556	MNA	72 (7)	7.2%	Cross-sectional

UK, United Kingdom; MUST, Malnutrition Universal Screening Tool (Elia, 2003a); MNA, Mini Nutritional Assessment (Vellas et al., 1999).

Table 1.1: Prevalence undernutrition risk in community dwelling older adults from UK and Ireland

Undernutrition is thought to increase during hospital admission, however few studies have explored nutritional status at the point of discharge from hospital. One prospective cohort study (McWhirter and Pennington, 1994) recruited 500 consecutive hospital patients to determine the incidence of undernutrition in this population, recording weight change at discharge. Forty percent were considered undernourished on admission and 75% went on to lose further weight. Unfortunately, only 22% (n=112) were measured at discharge. It is also unclear how long these patients spent in hospital or how the sample was chosen. Another observational study (Kondrup et al., 2002) examined the reasons behind inadequate nutritional care in the ward setting, interviewing nursing staff about their choice of nutritional risk score. Weight loss was similar, but again a minority (7%) of the original sample were followed up at discharge and weight change was recorded but nutritional risk was not re-calculated. A third study captured discharge data for 99 % of participants (n=500) (Liang et al., 2008b), but found no significant changes in the prevalence of nutritional risk over the course of a hospital admission.

In summary, prevalence of undernutrition is higher in hospital or care home populations, and in older patient groups but data vary depending on the methods used.

1.3 Aging and the anorexia of aging

Increases in life expectancy can be attributed to enhanced understanding of disease, medical and public health initiatives and interventions. Projections indicate a rise in the number of people aged 65 and over from 18% in 2000 to 28% in 2036, with the largest increase in individuals age 80 and above (Office for national statistics, 2017). Successful aging has been defined as the preservation of good physical and cognitive function, reduced risk of disease and disease-related problems and participation within society (Rowe and Kahn, 1998). Living without morbidity and maintaining independence for the longest period possible is the goal of healthy aging (Campion, 1998).

Body composition, appetite and dietary intake are affected by age, and changes to both can occur over time, though to varying degrees. Approximately 21% of older, community-living adults experience the anorexia of aging (Landi et al., 2013), where by age-related changes in energy expenditure, reduced exercise levels, sensory changes, comorbidity and polypharmacy combine with social factors and depression to reduce appetite (see figure 1.1).

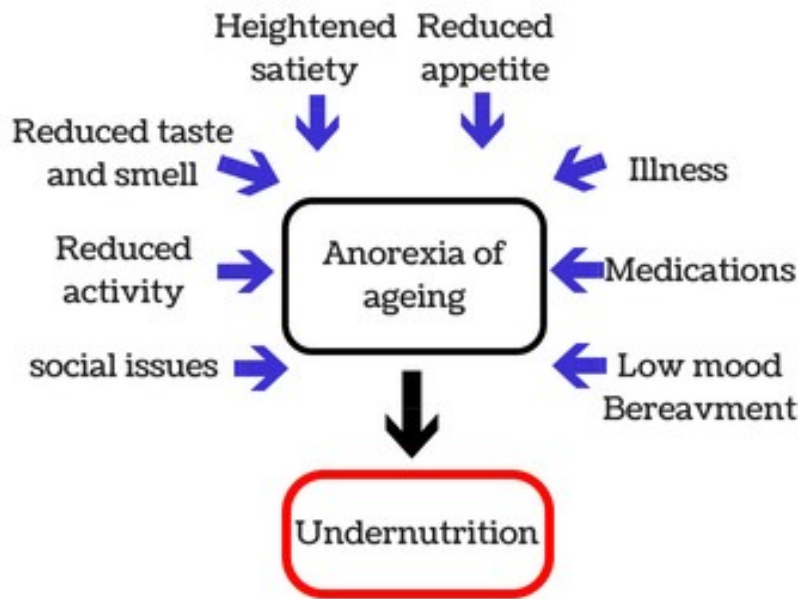


Figure 1.1: The role of anorexia in undernutrition in older adults

The rate of hyposmia, or the reduced ability to smell, increases with increasing age, due to the loss of olfactory neurons and blunted release of odour molecules due to suboptimal chewing (Smoliner et al., 2013). Studies of neurological disease have suggested a role for the entorhinal cortex, with approximately 90% of patients with Alzheimer's disease exhibiting poor odour perception (Thomann et al., 2009, Wilson et al., 2007). However, there is a lack of data examining the relationship between olfaction and nutritional status in older adults. Of the existing studies, several have demonstrated reduced pleasure from food in people with sensory impairment (Duffy et al., 1995, Ferris and Duffy, 1989), resulting in reduced diet quality. A recent secondary analysis of longitudinal dietary data replicated this result, showing reduced diet quality in women with impaired olfaction (Gopinath et al., 2016). However, the study was underpowered, with between group differences indicating the potential selection bias. Additionally, one study has examined undernutrition risk in older adults with poor olfaction, but found no association between undernutrition risk and smell using MNA in a regression analysis. The authors acknowledged that with 39% of participants (n=191)

experiencing hyposomia, power may not be adequate to detect a difference (Smoliner et al., 2013).

Several physiological processes characterise a reduction in the efficiency of appetite homeostasis with age (Roberts et al., 1994). Anorexia is multifactorial, potential causes are discussed in more detail below and include changes to olfactory senses, stretch receptors in the stomach, peripheral hormones, and gut hormones.

In the normal pathway, hunger triggers eating and satiety stops it (Burton-Freeman et al., 1997). In addition to a sensory-specific pathway, hormones play a large role in appetite regulation. Ghrelin is the only peripheral hormone known to promote hunger, and studies have failed to show a consistent reduction with aging (Moss et al., 2012). However, increased plasma insulin and leptin have been associated with reduced impact of ghrelin in older age (Chapman, 2007, Di Francesco et al., 2007). In addition, changes to satiety signalling by cholecystokinin (CCK), Peptide YY (PYY) and glucagon-like polypeptide-1 (GLP-1) have been implicated in the pathogenesis of early satiety, with increasing evidence suggesting higher levels of circulating hormones (Hickson et al., 2016, Moss et al., 2012). One study demonstrated higher levels of CCK in older participants with undernutrition compared to their well-nourished counterparts (Berthélemy et al., 1992). Another showed CCK release occurred at a lower threshold in older participants compared to their younger counterparts (Silver et al., 1989).

Some authors have suggested that a decrease in the rate of gastric emptying occurs as part of the natural aging process (Clarkston et al., 1997, Evans et al., 1981), proposing that a reduction in the capacity of the gastric fundus causes food to move through to the antrum more quickly. This in turn causes the stomach to stretch, triggering the signal to terminate eating and causing the release of hormones to curb appetite (Jones et al., 1997). On the other hand, a review by Soenen et al., (2015) suggested that the rate of gastric emptying remains within the range of younger adults at 1-4 kcal/minute. A meta-analysis (Giezenaar et al., 2016) showed a 25% drop in hunger and 35% increase in fullness over a 50-year period from age

27 to 74 years (Giezenaar et al., 2016). In addition, the mechanisms used to regulate body weight lose efficiency. Two intervention studies (Moriguti et al., 2000, Roberts et al., 1994) have examined age-related differences in the control of food intake between individuals. In the first study (Roberts et al., 1994), a group of older and younger participants were provided with a hypocaloric diet to induce weight loss, then followed up over 7 weeks to document any differences between the two groups once the energy restriction had been lifted. Results showed a marked between-group difference, whereby the younger group regained their lost weight through hyperphagia. On the other hand, the older participants returned to a normal pattern of eating and were unable to recover the lost weight. In addition, when an excess of energy was provided to participants, only the younger group were able to correct for their weight gain once the experimental conditions stopped (Roberts et al., 1994). In the second intervention (Moriguti et al., 2000), a different group of older and younger participants were compared to examine the effects of a hypocaloric diet. The older subjects lost more weight than their younger counterparts, and again failed to regain significant weight at 6 month follow-up. The older subjects also reported lower levels of hunger during the follow-up period, though there was no significant between-group difference in reported satiety levels (Moriguti et al., 2000).

Reduction in food intake and a decrease in activity levels gives rise to a reduction in muscle mass. This process is known as sarcopenia and is discussed in more detail in section 1.6. Unhelpfully, this process places older people at risk of anorexia and further muscle atrophy.

1.4 Disease

Disease can have a huge impact on undernutrition, whether as the cause of new undernutrition or to exacerbate existing undernutrition. Specific diseases are known to have different effects, for example dementia may cause physical, cognitive and behavioural changes to reduce oral intake (Ikeda et al., 2002); liver disease alters glycogen storage and increases energy and protein requirements (Kondrup and Müller, 1997, Krähenbühl et al., 2003). The treatment of disease may also influence nutritional status, with medications interfering with appetite

regulation, promoting catabolism or malabsorption. Hospital admissions can be detrimental to nutritional status, disrupting daily life, limiting access to food and causing prolonged periods of inactivity. Extended admissions, particularly in the older population, have been shown to affect longer-term independence (Dupertuis et al., 2003, Rudberg et al., 1996).

Often a change in nutritional status is the result of not one, but of a combination of factors, including increased macro and micronutrient requirements, reduced dietary intake and increased losses (Norman et al., 2008b). Acute exacerbations of disease such as infection or inflammation have the potential to reduce appetite, promote increases in metabolism, and alter the breakdown or absorption of nutrients (Campbell, 1999). Chronic disease may lead to reductions in food intake over a prolonged period of time and leading to depletion (see figure 1.2).

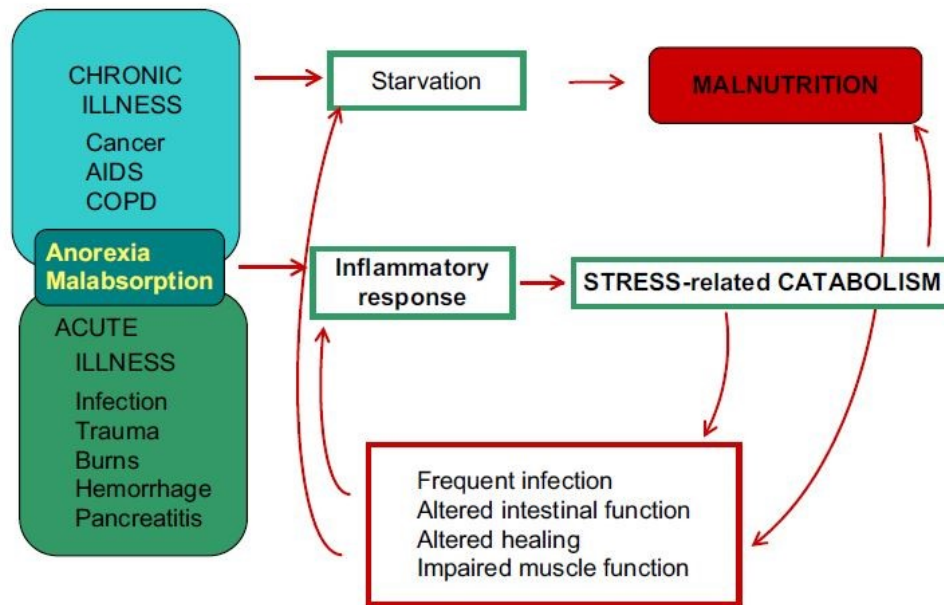


Figure 1.2: Disease related undernutrition from (Norman et al., 2008b)
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Reduced intake may result from a blockage along the gastrointestinal tract, or from dysphagia or odynophagia causing pain and anxiety (Eslick and Talley, 2008, Peterson et al., 2010). Dysphagia and reduced chewing ability may impact on nutritional status either directly by reducing the quality and quantity of food consumed or indirectly, by inducing taste changes. Both dry mouth and chewing ability were associated with undernutrition risk in a cross sectional study (Nykänen et al., 2012). The effect of nausea may reduce intake secondary to its unpleasant nature and food aversions that may form as a result (Dantzer and Kelley, 2007). Vomiting too may exert a psychological influence, but primarily leads to reduced absorption of nutrients.

In disease states, the body may be engaged in an inflammatory response. Inflammation initiates the release of cytokines, glucocorticoids, and catecholamines, a response associated with reduced appetite and poor food intake (Tisdale, 2005). Pro-inflammatory cytokines also contribute to the breakdown of muscle protein (Jensen et al., 2010) and lead to an increase in energy and protein requirements by raising resting energy expenditure (REE) and nitrogen excretion. Acute, critical illness initiates a significant inflammatory response, and leads to the

rapid breakdown of muscle tissue (Puthuchear et al., 2013). Chronic disease may also stimulate inflammatory processes, causing muscle atrophy over time (Londhe and Guttridge, 2015). Both have the potential to reduce both muscle mass and function considerably, but acute disease is often transient, with loss of lean mass ceasing with the resolution of the illness and removal of the inflammatory triggers. Nutritional therapy can help to minimise muscle protein loss during periods of active inflammation, but anabolism is unlikely no matter how much nutritional intake exceeds requirements whilst inflammatory processes remain active (Zoico and Roubenoff, 2002).

1.5 The aetiology of weight loss

Undernutrition is a multifactorial condition with interacting factors that both precipitate and exacerbate one another, making it difficult to separate the causes and the consequences of undernutrition. Some of the common causes are shown in table 1.2, but to find evidence of causal relationships between undernutrition and these listed causes is difficult due to their tangled relationship. Most evidence is observational or epidemiological, so although associations may be established, it may not be possible to determine which event came first. In addition, it is difficult to ascertain the effect of different nutrients from one another when the human diet is so complex and changeable. Vitamins and minerals play a role alongside macronutrients, and real food is a composite mix of these. To prove cause and effect, intervention studies are required, but these come with their own challenges and currently there are few. However, a range of studies have provided evidence of a link between undernutrition and poor outcomes.

Starvation has been described as a simple deficit resulting from a reduced nutritional intake and resulting in a gradual loss of fat mass and muscle mass (Hickson, 2006). Evidence from starvation studies quantifies the effects of undernutrition on the human body. Periods of famine and acts of hunger strike have provided further insight into the mechanisms associated with prolonged fasting. Keys' Minnesota experiments created a model of semi-starvation allowing researchers to study the processes and consequences of weight loss in a controlled

environment. In Keys' study, 32 lean male participants lost an average of 25% body weight over 24 weeks, following a diet designed to produce a deficit of approximately 1 kilogram per week (Keys et al., 1950). Total abstinence from food has generated more acute weight losses, with 18% body weight loss seen over a 43-day period in eight Brazilian prisoners on hunger strike (Faintuch et al., 2000) and at 60-days the average weight loss was 38% in 30 Irish hunger strikers (Allison, 1992). Keys proposed that weight losses over 18% would cause significant disruption to homeostasis, with death highly likely at weight losses of 50%.

Cachexia on the other hand is driven by underlying disease, creating "a complex metabolic syndrome associated with a loss of muscle with or without loss of fat mass" (Muscaritoli et al., 2010). Sarcopenia is strongly associated with aging (Cruz-Jentoft et al., 2010), characterised by a loss of skeletal muscle mass and of function (Cruz-Jentoft et al., 2010). The mechanisms of muscle loss differ substantially and thus each responds to re-nutrition differently. As a straightforward nutritional deficit, starvation-related malnutrition is treated with nutrition support since the cause is lack of food. The processes of disease and aging on the other hand are more complex to treat. In sarcopenia, age-associated hormonal and neuromuscular changes, along with lifestyle and genetic factors affect the ability of the muscle to recover size and function. Sarcopenia is possibly an inevitable part of aging with studies showing the only way to prevent losses is through resistance training, without this muscle is lost with age, even in highly trained athletes. Unlike starvation-related undernutrition, in disease-related undernutrition illness may hinder the ingestion or absorption of nutrients, increasing energy requirements. (Stratton et al., 2003). In these cases the provision of nutrition support may not be enough, and simply providing nutrition support to cachexic or sarcopenic populations will not necessarily treat the condition (Barker et al., 2011)

1.6 The causes of undernutrition

The causes of undernutrition are multifactorial, with age-related changes in body composition, physical activity, taste changes and deteriorating dentition (Hickson, 2006). Undernutrition can impact on physical, social and psychological functions (Keys et al., 1950) Those

considered most at risk are older people (Schols et al., 1998), people living in deprived areas (Collins et al., 2016), those who are socially isolated, people with chronic disorders such as chronic obstructive pulmonary disease or cognitive impairment, and those who were recently hospitalised (Beck et al., 2015, NICE, 2006). The main factors contributing to higher risk of undernutrition are described in table 1.2, and explored in more detail in sections 1.6.1-1.6.3.

Factors	Causes
Physical	Poor appetite
	Poor dentition and oral hygiene
	Reduced smell and taste
	Chronic disease, including respiratory disorders, endocrine disorders, gastrointestinal disorders, neurological disorders
	Acute disease or surgical intervention
	Physical disability
Psychological	Medication interactions and polypharmacy
	Cognitive function
	Culture/food preferences
	Low mood
	Anxiety
Sociological	Bereavement
	Knowledge
	Education
	Loneliness/support
	Social deprivation

Table 1.2: Factors contributing to undernutrition risk (Morley, 2001, Wilson et al., 1998)

1.6.1 The Physiological causes of undernutrition

1.6.1.1 Appetite

Loss of appetite, or anorexia, can be described as a disruption in normal appetite signalling. Several physiological processes act to upset appetite homeostasis with age (Roberts et al., 1994), the causes of which include changes to olfactory senses, a reduction in stomach stretch receptors, changes to the composition of the diet and changes in peripheral and gut hormone levels.

In the feeding pathway, appetite and hunger trigger the eating process and satiety stops it (Burton-Freeman et al., 1997), two processes which are largely controlled by neuropeptides and hormones. In the hypothalamus two groups exist, with opposing roles in appetite regulation. One group includes neuropeptide Y (NPY) and agouti-related protein (AgRP) to promote food intake. The other cluster expresses cocaine- and amphetamine-related transcript (CART) and pro-opiomelanocortin (POMC) to inhibit food intake. In addition, cholecystikinin (CCK) acts to moderate NPY signalling and reduce food intake. Peripheral hormones such as ghrelin, leptin and insulin interact with these neural pathways to regulate appetite.

Ghrelin is the only peripheral hormone known to promote hunger, produced by the stomach during periods of fasting. One study demonstrating reduced circulating levels in older participants compared to younger ones (Nass et al., 2014). A reduced sensitivity has been suggested, with post-prandial ghrelin levels shown to reduce to lesser degree in older people (Bauer et al., 2009). Additionally, increased plasma levels of insulin and leptin have been associated with reducing the impact of ghrelin in older age (Chapman, 2007, Di Francesco et al., 2007). Older age is accompanied by an increase in adiposity and concomitant leptin levels, which may influence background levels of satiety (Moss et al., 2012).

CCK acts peripherally, stimulated by the presence of nutrients in the small intestine, to promote satiety. Several studies have demonstrated higher circulating levels of CCK in older individuals (MacIntosh et al., 1999, Masclee et al., 1988). One study compared a group of older and younger adults' response to CCK. Both groups experienced a reduced intake at a test meal following CCK infusion, but the satiation response of the older cohort was double that of the younger group (MacIntosh et al., 2001). In addition CCK release may be triggered at lower threshold in older participants compared to their younger counterparts (Silver et al., 1989). PYY has also been implicated as a cause of reduced intake in older individuals, with increased postprandial levels thought to prolong satiety (Hickson et al., 2016).

Other factors that affect appetite include those of the sensory-specific pathway. A decrease in the rate of gastric emptying occurs secondary to changes in the stomach, where the fundus has a reduced capacity for storage allowing food to move through to the antrum causing distension (Evans et al., 1981). This stretching of the stomach is the signal to terminate eating, and causes the release of hormones to curb appetite.

1.6.1.2 Changes in sensory perception

In addition to neural and hormonal changes, it has been well documented that the pleasure gleaned from food reduces with age, especially with a background of smoking. Olfaction, a sense integral to taste, declines consistently with age, reducing the desire to eat and altering food choice (Spence, 2015). Following a reduction in the number and size of taste buds, reduced taste sensation may also be present in older age. Zinc deficiency can induce taste changes and is often observed in older people, associated with suboptimal intake long-term, ineffective absorption and chronic disease (Blumberg, 1997). Medications, including certain steroids, antihypertensives and antidepressants, can also alter taste (Doty et al., 2008). These changes may contribute to food choice, food quality and total food intake and result in macro and micronutrient deficiencies (Rolls, 1999).

1.6.1.3 Physical disability and frailty

Reduced body composition, strength and function impact the ability to perform activities of daily living (ADLs), including food shopping, preparation and eating, and lead to reductions in energy intake. Frailty is associated with older age and chronic disease, characterised by a reduced capacity to maintain physical and social activities, “a biologic syndrome of decreased reserve and resistance to stressors, resulting from cumulative decline across multiple systems, and causing vulnerability to adverse outcomes” (Walston et al., 2006). Considered a clinical syndrome, Fried et al (2001b) defined frailty as ≥ 3 of unintentional weight loss, exhaustion, weakness, slow walking speed and low-levels of physical activity. Fried found that 6.9% of community patients in his 2001 study would be considered ‘frail’ according to their description, placing them at higher risk of falls, disability, hospitalisation and mortality.

In addition, frailty is associated with loss of independence. A key phenotypic characteristic of frailty is reduced body cell mass due to muscle wasting, and hence weight loss or ADLs such as meal preparation are used to assess nutritional status in frailty tools. A systematic review (Bell et al., 2013) summarised 17 studies exploring the prevalence of dependency on caregivers for eating in care homes ranged from 11-36% and partial dependence 8-87%. A qualitative study explored changes in dependence in older people, showed falls, infections or chronic conditions led to a reduction in independence (Edfors and Westergren, 2012). Dependence on caregivers for food preparation and eating has been reported to be difficult (Pajalic et al., 2012), involving a loss of control for individuals. Study participants described caregivers unable to locate requested food items, and participants themselves disposing of the meals provided due to an unpalatable appearance, texture, or ingredient (Edfors and Westergren, 2012). Another study in older women living alone showed a decline in the number of cooked meals and frequency of events serving food (Gustafsson and Sidenvall, 2002).

1.6.1.4 Medications

Medication use, triggering a reduction in appetite, taste changes, gastrointestinal problems including nausea and diarrhoea and reduced saliva production have been shown to influence

dietary intake and weight (Visvanathan et al., 2004). Moreover, some studies have suggested the number of daily medications taken by an individual is associated with undernutrition and weight change (Chapman and Nelson, 1994). With one in two community-dwelling older adults taking multiple medications, polypharmacy is prevalent (Haider et al., 2007). The mean number of medications taken by community-dwelling older people has been shown to be between 3.5-6.9 (Jyrkkä et al., 2012). However, there is no consensus on the number of medications that defines polypharmacy; five medications has been suggested by one author (Jyrkkä, 2011) and nine to ten by others (Haider et al., 2009, Kragh et al., 2011). The nutritional screening tools, DETERMINE checklist and MNA (Vellas et al., 1999), both take polypharmacy into consideration, but judge it to influence nutritional risk if individuals take three or more medications. A prospective longitudinal study in community-dwelling older people (Chen et al., 2009) examined the effect of polypharmacy, demonstrating a significant association between number of medications taken and nutritional status, correcting for length of stay, treatment and time (beta coefficient = -0.08, $p=0.0004$). Another study in care home residents (Griep et al., 2000) showed that an increasing number of medications was associated with worse MNA score (beta coefficient = -0.31, $p = 0.008$). Thus, with each 1-unit increase in medications, MNA score decreased by 0.08 or 0.31 respectively. Both studies used MNA as the outcome variable, but as MNA accounts for polypharmacy within its design, there is likely to be interactions that have not been accounted for. In addition, the adverse effects of multiple medications on an individual may be heightened by the presence of undernutrition and weight loss, and the effect of the underlying conditions requiring medication cannot be ignored. As with all studies of an observational nature, cause and effect cannot be elucidated. The current research exploring medication use, polypharmacy and undernutrition is based on a small number of cross-sectional studies with heterogeneous treatment of confounders. More research is required to better understand the relationships between medication use and undernutrition.

1.6.2 Psychological factors associated with undernutrition

1.6.2.1 Depression

The prevalence of depression in older individuals is thought to be between 10% and 20% in outpatients and 22-34% in inpatients (Beekman et al., 1999, Meldon et al., 1997, Raccio- Robak et al., 2002). Studies have suggested a causal role of depression in the development of undernutrition (Morley and Silver, 1988, Wilson et al., 1998), but as undernutrition is a complex concept with interrelated factors, it is impossible to say which of two factors came first precipitating the other. In one study (German et al., 2008) undernutrition risk was found to be significantly higher in inpatients with depression compared to those without (25.0% versus 22.9%). Undernutrition risk as measured by MNA was independently associated with depression following logistic regression analysis (odds ratio = 2.23 (95%CI: 1.04-4.8)) (German et al., 2008). Among the key features of depression are appetite and body weight losses (Morley and Kraenzle, 1994, Polivy and Herman, 1976, Thompson and Morris, 1991). The mechanism of action is not clear, one theory is that depression causes apathy, anhedonia, and reduces motivation to perform helpful behaviours, including food shopping and preparation (Bodnar and Wisner, 2005).

1.6.2.2 Dementia

Several factors have been implicated in the aetiology of undernutrition in dementia. Reduced nutritional intake, changes in behaviour including disruptions to eating behaviour, an increase in energy expenditure, and dysfunctional appetite regulation (Gillette-Guyonnet et al., 2007, Piguet et al., 2011, White et al., 2004). Deteriorating nutritional status was linked to the severity of the dementia. Several analyses have used regression to determine key risk factors that may help to identify older people at risk of undernutrition, including access to food, functional ability to prepare, cook and eat, taking in to account cognitive, behavioural and physical factors (Guerin et al., 2005, Isaia et al., 2011, Spaccavento et al., 2009). Poor cognition may adversely affect functional status leading to disability, dependence and reducing dietary intake (Claggett, 1989). Prevalence data has shown undernutrition risk to be significantly higher in this population compared to the general community-dwelling elderly (Kaiser et al., 2010).

Prevalence of undernutrition ranged from 0% to 6%, and prevalence of risk ranged from 19% to 36%. In two large cross-sectional studies in community dwelling dementia patients, undernutrition prevalence was 3.8 and 5.2% and risk of undernutrition 35 and 42.6% (Gillette-Guyonnet et al., 2003, Roque et al., 2013). A fourfold higher prevalence was seen in dementia with Lewy bodies compared to frontal lobe, vascular, Alzheimer's or mixed types (Roque et al., 2013), attributed to dysphagia as a prominent symptom of Lewy body dementia (Shinagawa et al., 2009).

1.6.3 Social factors associated with undernutrition

As with the other causes of undernutrition, the social influences are often complex involving economic and political factors and as with many variables, cause and consequence are difficult to determine (Campbell, 1991). The next section will consider the effect of poverty, personality and loneliness of undernutrition.

1.6.3.1 Poverty and deprivation

In older adults living in the UK, poverty is associated with undernutrition. Poverty does not just refer to low income, but access to health services and safe water, education level and involvement in decision making (WHO, 1998). Figure 1.3 shows the factors which may contribute to poverty and influence nutritional status. Household food insecurity is the term used when access to food is limited to the extent that the nutritional needs of a family cannot be met or the lives of a household are put at risk (Reutlinger, 1986). Food insecurity may arise from insufficient public health services, poverty or poor sanitation. Figures suggest that one in seven older people live below the breadline (AgeUK, 2014). It is a self-perpetuating cycle whereby poor people are unable to attain adequate quality or quantity of foodstuffs to support health, which in turn results in health problems and potentially physical disability further restricting ability to earn and opportunity for education (Ingutia et al., 2009, Peña and Bacallao, 2002). Education and knowledge are essential in the context of poverty, to ensure the best choices are made for optimal health (Aguirre, 2000). Nutritional status begins utero via

maternal nutrition and may persist through the lifespan, causing chronic undernutrition (Peña and Bacallao, 2002).

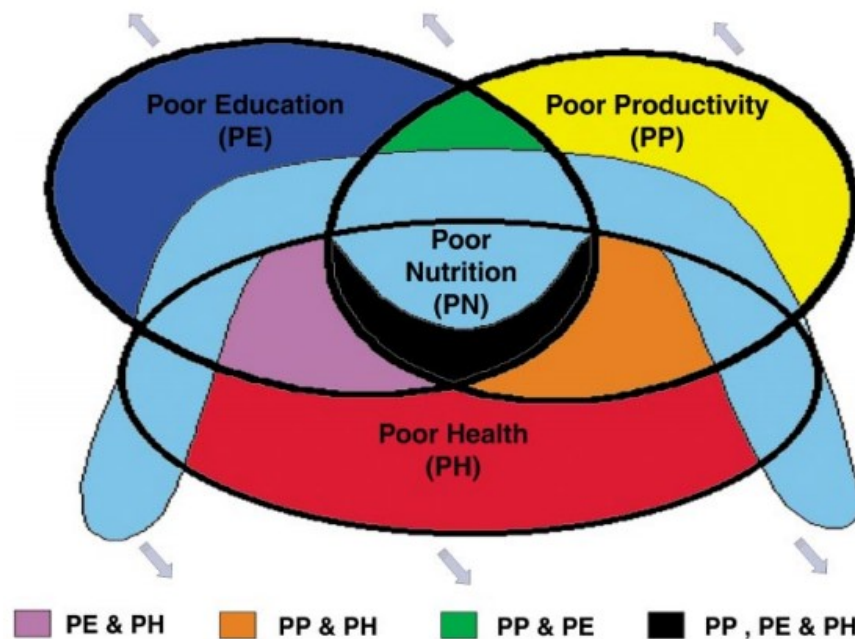


Figure 1.3: Venn diagram showing the relationship between aspects of poverty and poor nutrition (Peña and Bacallao, 2002).

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A recent study in chronic obstructive pulmonary disease (COPD) outpatients (Collins et al., 2016) reported prevalence of undernutrition risk to be 22%, with higher prevalence in the area of higher deprivation (28% vs 17%; $p = 0.004$). Higher rank index of multiple deprivation (IMD) was negatively associated with undernutrition risk ($p = 0.014$) (Collins et al., 2016). Similarly, a study in hospital inpatients (Stratton and Elia, 2006) showed that the prevalence of undernutrition risk increased by a factor of 1.14 (95% CI 1.02, 1.28) for each quartile of IMD rank (Stratton and Elia, 2006).

1.6.3.2 Personality

Personality is considered a stable trait that influences an individual's feelings and behaviours (Derlega et al., 1991). There is likely to be a significant amount of variance in patient outcome that can be explained by personality - for example, when compared to pessimistic people, optimistic individuals describe less physical problems, fewer stressful events and superior functional status (Chang, 2001). A recent review found a positive association between higher levels of certain personality characteristics and health-related quality of life (HRQOL), for example higher levels of extraversion, openness, optimism and self-esteem were associated with a greater HRQOL (Huang et al., 2017). The authors found that personality characteristics were more frequently associated with psychosocial aspects of HRQOL (such as neuroticism or negative affectivity) rather than physical aspects of HRQOL (such as limitation due to physical problems or pain). Interestingly the review found personality to better predict response to HRQOL than age (Cederfjäll et al., 2001), and comorbidity (Nesbitt and Heidrich, 2000). Very few studies explored change in HRQOL over time. Of those that did, pessimism was indicative of stable responses over time (Huang et al., 2017). Measuring personality would be useful, however in practice, the tools used to measure personality can be lengthy. In future research, even a short-form measure could be considered to provide some insight in to the personality traits of participants.

1.6.3.3 Loneliness

Loneliness is a subjective, negative emotion defined as a feeling that occurs when there is disagreement between the expectation and the reality of a person's social relationships (Perissinotto et al., 2012). Descriptions of loneliness have included physical, psychological and social dimensions (Eloranta et al., 2015). Studies performed in community-dwelling populations have reported rates of loneliness among adults aged 65 and over of between 5% and 26% (Chalise et al., 2010, Stessman et al., 2013, Victor et al., 2000, Wenger et al., 1996). Company at meal times has been shown to increase dietary intake in older people (De Castro, 1997, Stroebele and De Castro, 2004). On the other hand, social isolation has been

associated with reduced food intake and thus the development of undernutrition (McIntosh et al., 1989).

1.7 The consequences of undernutrition

The consequences of undernutrition are varied and far-reaching. With pre-existing illness, undernutrition may increase complications, mortality and delay recovery (Stratton et al., 2003). Evidence shows that undernutrition may influence an individual's mood (Cabrera et al., 2007) and quality of life (Hickson and Frost, 2004, Keller et al., 2004, Larsson et al., 1994), affecting independence and increasing reliance on carers and support services (CarersUK, 2011). I will go on to discuss in detail the impact of undernutrition on mortality, hospital admission, muscle mass and function, infective and non-infective complications, psychological problems, cognition and cost.

1.7.1 Mortality

A healthy adult is able to survive for around 70 days without nutrition, in which time 40% of their body weight will be lost (Allison, 1992). This data was obtained from the Irish hunger strike in 1981 when a group of men protested by refusing to eat. After 70 days, mean weight loss in the 30 men was 38% and 10 had died (Allison, 1992). This example of total starvation, where 40% body weight loss is thought to be fatal, compared to semi-starvation where 50% body weight can be lost before death.

Life is not sustainable below a body mass index (BMI) of approximately 13kg/m^2 in males and 11kg/m^2 in females, due to absence of adequate fat stores (Henry, 1990, Keys et al., 1950). In the fasting state fat is utilised as the main energy source. In obese individuals fat can be used to meet 94% of energy requirements, compared to just 78% in lean individuals. Thus during periods where food supply is limited, overweight and obese have a survival advantage. In addition, this mechanism results in a reduced volume of energy being drawn from protein oxidation. This theory was demonstrated in a proof of concept study, showing a rise in leucine metabolism of 230% in lean participants, compared to just 17% in obese individuals after 2-3 days of starvation (Umpleby et al., 1995). Despite fat-free mass (FFM) being higher in obese

individuals to start with, it seems that obesity offers a protein-sparing effect, saving FFM breakdown and reducing overall protein loss during fasting (Elia et al., 1999).

Mortality risk as a consequence of undernutrition is highest in the elderly, following a recent hospital admission, in people with reduced strength and those with poor functional status (Newman et al., 2001). The prospective Cardiovascular Health Study (n=4714) examined mortality rate in weight-gaining versus weight-losing older adults over a four year period. Results showed that participants losing $\geq 5\%$ body weight had a higher mortality risk compared to their weight-gaining counterparts (Hazard Ratio = 1.67, 95% Confidence Interval (CI): 1.29–2.15) (Newman et al., 2001), demonstrating that weight loss is a significant indicator of mortality risk in older adults.

A close relationship between malnutrition and increased mortality has been demonstrated in chronic disease including cancer, chronic liver disease and COPD, but also in acute disease such as stroke, hip fracture and liver transplantation (Norman et al., 2008b). In a large, multicentre study (n=3122) in Australasia, 30-day and 90-day in-hospital mortality rates were 1.5% (n=46) and 2.4% (n=72) respectively. Logistic regression analysis showed that whilst undernutrition determined using SGA was not an independent risk factor for 30-day in-hospital mortality, it doubled the odds of 90-day in-hospital mortality (OR: 1.91, CI: 1.09-3.34, p = 0.023) (Agarwal et al., 2013). 24-hour dietary analysis was used to demonstrate an intake $\leq 25\%$ of food available doubled the risk of 30- and 90-day in-hospital mortality (OR: 2.69, CI: 1.31- 5.52, p = 0.007) (Agarwal et al., 2013). In one study of hospital inpatients, mortality risk was three-fold higher in undernourished individuals according to SGA, 12 months after discharge (10.1 versus 29.7%) (Middleton et al., 2001). A matched case control study (Lim et al., 2012) showed that mortality was more than six times higher in individuals with undernutrition at 1 year (34% vs. 4.1%), and four times higher at 3 years (48.5% vs. 9.9%). Undernutrition remained a significant predictor of mortality after controlling for factors such as diagnosis, age, gender, and ethnicity (adjusted hazard ratio = 4.4, 95% CI 3.3-6.0, p <0.001) (Lim et al., 2012).

The relationship between undernutrition and mortality has been extensively studied in older adults. One study used the Malnutrition Universal Screening Tool (MUST) to demonstrate an increase in mortality with increasing risk of undernutrition according ($p=0.01$) (Stratton et al., 2006). In this study 119 patients were followed up after admission, with data showing mortality at 3 and 6 months to be higher for individuals at nutritional risk (29% at 3 months and 37% at 6 months respectively ($p<0.01$)) compared to those at low risk (5% at 3 months and 13% at 6 months) (Stratton et al., 2006). The individual components of 'MUST' also predicted clinical outcome, with in-hospital mortality twofold greater in individuals with a BMI <20 kg/m² or weight losses greater than 5% (Stratton et al., 2006). Another study followed up patients after a hospital admission, demonstrating that protein energy malnutrition was a strong independent risk factor for mortality one year after discharge from hospital (OR: 1.91, CI:1.09-3.34, $p=0.023$) (Agarwal et al., 2013). In addition, a retrospective analysis of 476 older adults discharged from hospital assessed electronic patient records to determine nutritional status using the MNA. Survival analysis included age, gender, disease classification, mobility and length of stay (LOS) at index admission as covariates to demonstrate increased mortality at 18 months for undernourished individuals. The malnourished group had the highest risk of death (Hazard ratio 3.41 (95% confidence interval: 1.07–10.87; $p=0.038$)), mortality risk was also raised in the nutritionally at-risk group at (Hazard ratio 1.61 (95% confidence interval: 0.52–5.17; $P=0.397$)) (Charlton et al., 2012) and further work showed that this relationship persisted four years post-discharge (Sullivan and Walls, 1998).

The adverse effects of undernutrition are not confined to hospital patients. A systematic review examined mortality in community-dwelling older adults after a period of physical rehabilitation (Marshall et al., 2014). From the five observational studies included, undernutrition was associated with a reduction in functional status and quality of life, increase risk of hospitalisation, care home admission and mortality (Marshall et al., 2014). Heterogeneity of methods and small sample sizes made conclusions regarding mortality more difficult, but study quality was high. These findings have been corroborated by epidemiologic data showing that

weight gain reduces the incidence of death in previously undernourished individuals (Keller, 1995, Newman et al., 2001). The second (Newman et al., 2001), a large observational study, found that weight loss of 5% or more was associated with an increased risk of mortality, hazard ratio 1.67 (95% confidence interval: 1.29-2.15). Another study in community-dwelling older adults. Underweight individuals suffered a twofold increase in mortality at 3 years compared their healthy weight counterparts. In addition, self-reported unintentional weight loss increased mortality 1.67 times (Locher et al., 2007).

Whilst there are several recent systematic reviews of disease related malnutrition and nutritional support, and although nutritional interventions improve energy and protein intake, and body weight, the data remains equivocal on mortality (Bally et al., 2016, Milne et al., 2009). A meta-analysis of RCTs showed that enteral feeding was associated with a 50% reduction in complications and nutritional intervention has been shown to reduce undernutrition-related deaths by 40% (Stratton et al., 2003, Stratton et al., 2006). In addition, systematic reviews in specific patient groups (such as hip fracture and liver transplant patients) have found low-quality evidence for the use of nutritional support in reducing unfavourable outcomes such as complications and mortality (Avenell et al., 2016, Langer et al., 2012). However, the most recent Cochrane systematic review exploring the effect of undernutrition and undernutrition risk on mortality found no clear difference (Feinberg et al., 2017). Including hospitalised adults of any age, the review examined 244 RCTs (n=28,619). Results showed risk of mortality was 12.2% and 13.2% at maximum follow-up (this varied from months to years) in the intervention and control groups respectively. All studies were deemed at risk of bias due to incomplete outcome data including failure to adequately explain missing data, selective outcome reporting, and lack of blinding, with some not adequately controlling for disease and other confounding factors, meaning undernutrition may simply be a marker disease severity. Large, well designed randomised intervention studies are required before consensus can be reached.

1.7.2 Length of stay and readmission

Malnourished patients have been shown to have a length of hospital stay 1.5 to 1.7 times longer than well-nourished patients (Kagansky et al., 2005, Middleton et al., 2001). Observational studies (Kondrup, 2003b) have highlighted a link between higher undernutrition risk and LOS ($p < 0.001$). Results from the Nutrition Care Day Survey 2010 (Agarwal et al., 2013) reported mean LOS for malnourished patients measured by Subjective Global Assessment (SGA) of 15 days compared to 10 days in their well-nourished counterparts (mean age 65 years).

In a recent systematic review (Muscaritoli et al., 2017), only six of 15 studies supported undernutrition as an independent predictor of readmission. Of these, four large prospective cohort studies (Aziz et al., 2011, Benedik et al., 2011, Mudge et al., 2011, Vecchiarino et al., 2004) and two large secondary data studies (Zapatero et al., 2012, Zapatero et al., 2013) demonstrated an association between undernutrition and readmission. In addition, the two more recent studies also showed higher risk of readmission in undernourished individuals (Agarwal et al., 2013, Lim et al., 2012).

Trials using nutrition support have also shown that LOS can be reduced with nutrition intervention. For example, one RCT of ONS during acute illness (Gariballa et al., 2006) found mean LOS was 9.4 and 10.1 days in intervention versus placebo group in their moderately sized trial over six weeks with six month follow-up. However, a systematic review (Muscaritoli et al., 2017) combining nine interventional studies, was unable to show sufficient impact of nutritional therapies on readmission rate. This finding was supported by a meta-analysis (Beck et al., 2013b). Another meta-analysis (Cawood et al., 2012) however, favoured oral nutritional supplements to reduce hospital re-admission. These mixed results are indicative of heterogeneous methods across studies, with changing definitions of undernutrition and consideration of other causal factors. There may be multiple reasons why admission is prolonged in undernourished adults, including functional, social and clinical issues. Multivariable regression goes some way to address confounding factors, however not all

studies use regression analyses and those that do vary in their choice of potential confounders.

1.7.3 Muscle mass and function

Under the condition of starvation, muscle mass is lost relative to the extent of the exposure. In complete starvation muscle catabolism occurs quickly, with daily protein losses of around 75g (Brennan, 1977). For an individual weighing 70kg with 10kg of muscle, this would amount to 15% muscle loss over 10 days, meaning muscle stores would be fully depleted in less than 70 days. However, this rapid muscle depletion only lasts a few days before adaption occurs and fat stores are made available for energy to spare protein. The majority of data for semi-starvation comes from Keys' Minnesota experiments (Keys et al., 1950). Participants were fed a diet low in energy and protein to induce weight losses amounting to 1 kg per week over 6 months. Participants experienced average muscle losses of 18% over 168 days.

Data has also been gained from studies examining body composition and tissue loss in obese subjects undergoing weight loss programmes. One systematic review including low calorie diet (LCD) and very-low calorie diet (VLCD) showed that the degree of energy restriction influenced FFM loss ($r^2=0.31$, $p=0.006$). Median FFM losses were 14% and 23% for LCD and VLCD respectively, with average muscle loss exceeding the recommended maximum level of 22% weight loss from FFM in some interventions (Chaston et al., 2007).

Muscle mass is essential to strength and function, and both undernutrition and muscle depletion have been associated with reduced performance in activities of daily living, lower gait speed and handgrip strength (HGS) (Felder et al., 2015, Keys et al., 1950, Norman et al., 2008a). A systematic review (Bohannon, 2008) showed the value of HGS as an indicator for poor outcome. In healthy individuals age and gender have the greatest impact on performance in HGS, but in the context of disease, many other factors come in to play. These include disease severity, comorbidity score, muscle disuse and inflammation (Budziareck et al., 2008). Low HGS has been associated with increased complications (Guo et al., 1996, Klidjian et al., 1980, Webb et al., 1989) and longer hospital stay (Kerr et al., 2006). It has been

used to predict deterioration in functional status (Humphreys et al., 2002, Kerr et al., 2006) and loss of independence over the ensuing five years (Rantanen et al., 2002). In this functionally independent cohort, those in the lowest third for strength experienced a two to threefold increase in risk of dependence than their counterparts in the highest tertile for strength at five years (Rantanen et al., 2002). Furthermore, HGS is associated with mortality in hospitalised patients (Bohannon, 2008) and death following hospital admission (Bohannon et al., 2004). The literature clearly indicates the important role of adequate muscle stores in adverse conditions, offering protection from morbidity and mortality (Rantanen et al., 2002).

However, nutritional intervention studies have not consistently shown the benefit of supplementary nutrition to improve muscle mass and function. Recent systematic reviews (Bally et al., 2016, Milne et al., 2009) highlight the variance in study outcomes reported, the heterogeneity of study designs and the sub-optimal quality of studies as potential reasons why nutritional intervention alone does not increase muscle mass or improve function. Large-scale intervention studies are recommended before conclusions can be drawn.

Undernutrition adversely affects both muscle strength and endurance, impacting on the functional role played by that muscle group. In addition to its role in skeletal muscle, muscle protein is integral to the function of major organs such as the heart, liver and kidneys, and these protein stores are not immune to the effects of undernutrition. Undernutrition leads to a reduction in whole body protein stores, with loss of skeletal muscle relatively less damaging than loss of organ tissue (Norman et al., 2011). Atrophy of internal organs is a critical feature of undernutrition, affecting the cardiovascular and respiratory systems by reducing muscle size and function. Congestive heart failure is aggravated by undernutrition, with heightened risk of tricuspid regurgitation and right atrial pressure (Carr et al., 1989). Loss of diaphragm mass has been shown to reduce contraction force and increase fatigue, decreasing respiration rate and consequentially oxygen consumption, impacting on recovery following chest infection and weaning from ventilation (Rochester and Esau, 1984). Individuals with COPD and poor nutritional status experience worse clinical outcomes including sub-optimal respiratory

function, reduced ability to expectorate and heightened fatigability. Pneumonia is a common cause of death once muscle mass is reduced to 60% of normal (Rochester and Esau, 1984).

There are various ways to measure functional status (see methods chapter, section 2.7), and although the more objective performance measures might be theoretically superior, they are not preferable to subjective measures (Guralnik et al., 1989, Myers et al., 1993). Reductions in functional performance are associated with the aging process. There is a downward trend in ability to perform activities of daily living (ADLs) with aging (Bowling and Grundy, 1997) and within this various rates of reduction (slight, gradual and rapid). Significant age-related differences are apparent from age 70, with changes in lower limb function reducing movement and limiting activities (Winograd et al., 1994)

One hypothesis is that comorbidity occurs in the later stages of life, with a large proportion of older people living with more than one long-term condition. Whilst the majority of these conditions are not severe, they may cause symptoms which lead to a reduction in ability to carry out activities of daily living (Ettinger et al., 1994, Guralnik, 1997). Polypharmacy has also been linked to reduced ability to perform ADLs (Ward et al., 1995).

In addition to a general decline with aging, there appear to be gender differences. Several longitudinal cohort studies have shown that although women live longer, they suffer more disability (Avlund et al., 2003, Dunlop et al., 1997) and are more at risk of functional decline with increasing age (Fried and Guralnik, 1997). In addition, frail older people have a higher risk of ADL disability compared to non-frail elderly people (Ensrud et al., 2009). A systematic review (Vermeulen et al., 2011) demonstrated that frailty could predict difficulty with ADLs in community-dwelling older adults

The causes of physical disability in the elderly have been explored in many studies using ADL tasks (Avlund et al., 2003, Ettinger et al., 1994, Fried and Guralnik, 1997). Actions are measured either by self-report, indicating the level of difficulty with which a task can be accomplished (no difficulty, slight, moderate or severe difficulty), or by researcher observation

where by the individual performs a task representative of an ADL. Another approach is to observe the participant undertaking ADLs in their own environment, but time, resources and scoring are challenging. Continuous scores that measure ability on a large scale, sensitive to variety of levels within the population, are of value in research to help make predictions based on existing data. Functional limitation is a measure of ability to perform the activity “without reference to situational requirements” where disability includes situational aspects. Ability to carry out ADLs is fundamental for survival, where the ability to perform IADLs is a feature of independent living (Fried et al., 2004). IADL deficits usually precede ADL deficits (Judge et al., 1996). With self-reported measures there are challenges in measuring the construct and separating functional limitation from disability, for example, a test “tying shoelaces” may be designed to measure agility (functional) rather than dressing oneself. Additionally, in participants with cognitive impairment, physical limitation may not be present, but disability is. It is difficult to separate the effects of undernutrition, aging and chronic disease as all have been shown to affect function. Disability leads to other commonly measured outcomes including hospital admission, nursing home admission, and death. In addition, a reduction in function can have a profound effect on quality of life, with relatively small deteriorations in functional ability associated with increased dependence, increased carer time, and increased financial costs (Fried, 2003, Reuben et al., 2003). Another paper (Verbrugge and Jette, 1994) describes a pathway from disease to disability, noting key influencers. The disablement process model demonstrates the changes that occur with age.

The ability, or difficulty, in performing ADLs (such as dressing, toileting) can be used to measure disability, and in older people can be a useful predictor of health and use of health services (Mullner, 2009). Awareness and appreciation of the mobility of older people is hugely important in interventions aiming to enable participation in daily activities (Townsend and Landry, 2005).

Another marker of frailty and reduced mobility in older persons is falling (Moore and Boltong, 2011). Falls have the potential to cause serious injury, subsequently increasing length of

hospital stay, use of medications, equipment, and increasing associated healthcare and personal costs (Drevet et al., 2014, Myers et al., 1993). Falls have been associated with nutritional status, weight and calcium intake. A review (Vellas et al., 1992) discussed the numerous markers of poor nutritional status found in falls patients, including low BMI, low mid-arm circumference (MAC), triceps skinfold thickness (TSF) and calf circumference, as well as reduced biochemical levels of pre-albumin and retinal binding protein. Falls predominately occur in older people, which is likely to indirectly increase undernutrition risk (Moore and Boltong, 2011), but a higher incidence of undernutrition was seen in fractures associated with older individuals, including lumbar spine, pelvis, femur and humeral fractures in one large, prospective study (Ihle et al., 2017). In an observational study of 49 Australian patients who experienced falls during hospitalisation, nearly half (45%) were malnourished according to subjective global assessment (Bauer et al., 2007). This relationship has also been demonstrated in community settings, with 12.2% (11/90) of older adults attending an outpatient falls clinic undernourished with either a BMI $<22\text{kg/m}^2$, MAC or TSF under the 15th percentile in one study (Stolz et al., 2002). Another study showed risk of falling was 1.65 times higher in individuals with undernutrition and receiving home care compared to those without (Visvanathan et al., 2003) and another that care home residents with undernutrition fell more frequently than their well-nourished counterparts (OR 1.78, $p < 0.01$) (Neyens et al., 2013). More recently, a large study across three sites in France followed community-dwelling older adults over a 12 year period to examine the relationship between falls and undernutrition (Torres et al., 2015). Falls data was captured for 6040 participants and showed a 12% prevalence of undernutrition using MNA. The authors went on to demonstrate an association between worse nutritional status and higher falls risk (HR=1.66; 95 % CI 1.35–2.04 in males and HR=1.20, 95 % CI 1.07–1.34 in females) using Cox proportional hazard regression and adjusting for sociodemographic data, age and health indicators. These studies suggest a significant adverse influence of undernutrition on falls risk. In addition, energy and protein intakes were found to be lower in one study of 75 older female inpatients with hip fracture compared to age-matched controls (4.3 vs 5.4 MJ ($p < 0.001$) and 43g versus 54g respectively

($p < 0.001$)) (Lumbers et al., 2001), with fracture patients exhibiting lower weight and BMI than their controls. The study also explored the level of injury sustained (nil vs minor injury), suggesting more serious injury occurred in those with undernutrition (Lumbers et al., 2001). This finding was contradicted by a later study (Bauer et al., 2007), where no relationship was uncovered between the severity of injury and nutritional status, however both were conducted in relatively small samples and underpowered to detect real change.

Interventions aiming to reduce falls risk have been performed with some success. In one study of undernourished older adults in long-term care, the cohort receiving nutritional intervention, the number of participants who fell was reduced in comparison to that of the undernourished group without nutritional intervention (OR 0.738; $p = 0.056$) (Neyens et al., 2013). A combination of vitamin D and calcium minimises bone degradation and muscle strength losses, and thus has been studied in relation to reducing falls risk in older people. A systematic review of studies using vitamin D and calcium supplementation showed relative risk (95% CI) of falling was 0.83 (0.73–0.95) with supplementation, based on two heterogeneous studies in women only (Health Quality Ontario, 2008). In summary, the prevalence of undernutrition was higher in populations of fallers than in the general population, and risk of falls higher in undernourished cohorts. Further research is required to explore the effect of undernutrition on the severity of injury sustained from a fall.

1.7.4 Immunity and infection

Nutritional status affects non-specific and specific immunity, with poor nutrition impacting physical barriers, such as skin and mucous membranes, acting as the first line defence to protect the body from infection. Suboptimal nutrient availability reduces the barrier function of the skin so that infection risk is increased (Correia and Waitzberg, 2003). The presence of undernutrition reduces immunoglobulin secretion, compromising the epithelial cells of the respiratory tract, small intestine and urinary tract. In addition, lysozymes, complement cell and T-lymphocytes numbers are reduced, reducing the efficacy of the immune response (Marcos et al., 2003).

In a relatively small study, incidence of urinary tract and respiratory infections in undernourished inpatients was twice that of their well-nourished counterparts following stroke (50% versus 24%, $p=0.0017$) (Dávalos et al., 1996). In addition, a retrospective cohort study in Brazil used logistic regression (adjusted for diagnosis) to demonstrate that inpatients with undernutrition suffered 10% more infectious complications than their well-nourished counterparts (Correia and Waitzberg, 2003). Interventions have also been shown to improve immunity. One RCT in malnourished patients with COPD patients demonstrated improvements in hypersensitivity reactions and lymphocyte count with nutritional support using oral supplements (Fuenzalida et al., 1990). However, several other studies have failed to show improvement in lymphocyte counts or T-helper/T-suppressor ratio indicative immunological changes (Knowles et al., 1988, Otte et al., 1989, Whittaker et al., 1990)

1.7.5 Non-infectious complications

Undernutrition also increases the risk of non-infectious complications (Correia and Waitzberg, 2003). Substantial epidemiological evidence supports an association between undernutrition and prevalence of pressure sores, with low body weight and poor dietary intake both displaying independent associations with pressure sore formation. Incidence of pressure sores is 3-66% in the hospital setting, with older people and those with reduced mobility at highest risk (Stratton et al., 2005). In the absence of a full nutrient supply and suboptimal fat stores, skin loses its ability to repair. In addition, undernutrition adversely affects wound integrity with the potential for chronic, poorly-healed wounds (Stechmiller, 2010). With fat and muscle losses there is a loss of protective mass and a reduced ability to dissipate pressure, the layers of the skin weaken allowing sores to develop. An Australian study showed the odds of developing a pressure sore were twice as high for undernourished participants compared to their well-nourished counterparts (Banks et al., 2010). A meta-analysis combining four RCTs examining pressure sores development in at-risk populations demonstrated a lower incidence of pressure sores in participants receiving nutritional support compared to those receiving usual care ($n=1224$; odds ratio (OR) 0.75, 95% CI 0.62–0.89) (Stratton et al., 2005). However, these studies were generally short-term and in older adults with many confounders. Studies

exploring the effect of nutrition support on subjects with existing pressure ulcers are limited and with a lack of randomised controlled trials, firm conclusions on the effect of nutrition support on pressure sore healing are not possible.

1.7.6 The psychological impact of undernutrition

1.7.6.1 Quality of life

Quality of life has been described as “an individual’s perceptions of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns” (World Health Organisation, 1995). An extension of quality of life is health-related quality of life (HRQoL) which considers the dimensions pertaining specifically to physical, mental, and social functioning, and their influence on quality of life (Bullinger and Hasford, 1991). It is widely recognised as a complicated and multifaceted concept (WHO, 1995) making it difficult to quantify. Due to the inconsistencies in reporting quality of life between different people, measuring HRQoL brings challenges and some approaches have received criticism (Leplege and Hunt, 1997).

The literature demonstrates an adverse relationship between quality of life in specific conditions such as cancer (Lis et al., 2012) and amongst those receiving treatment such as haemodialysis (Oliveira et al., 2012). Change in physical functioning is a primary determinant of quality of life in old age; even relatively modest declines in functioning capabilities are associated with loss of independence, increased caregiver burden, and greater financial expenditures (Fried, 2003; Reuben, 2003).

The relationship between undernutrition and HRQoL is complex. As a multidimensional construct, HRQoL likely results from a number of the physical and functional changes detailed above; for example from the increased the risk of complications, of hospital admission and dependence (Norman et al., 2006, Rasheed and Woods, 2013b). Apathy and lethargy as effects of undernutrition have been documented by Keys (1950), with Keys highlighting low mood and lack of interest within the Minnesota cohort, exemplified by participants’ withdrawal from university classes as body weight and energy and protein intakes reduced. A systematic

review of 15 studies (Rasheed and Woods, 2013b) exploring the relationship between nutritional status and quality of life in older adults demonstrated higher quality of life in well-nourished participants (OR: 2.85; 95% CI: 2.20–3.70, $p < 0.001$). The authors also showed that nutritional intervention to treat undernutrition improved quality of life (Rasheed and Woods, 2013a). The authors included both interventional and observational data, and only used studies which employed validated techniques to measure quality of life, but found evidence of publication bias and limitations in the design of studies (Rasheed and Woods, 2013b). However, more recent studies continue to suggest that there is a link between nutritional status and quality of life, in specific patient groups (Brinksma et al., 2015).

1.7.6.2 Mood, depression and anxiety

The relationship between undernutrition and mood is difficult to determine. Low mood and depression are often discussed as determinants of undernutrition (as discussed in section 1.7.2.1), but also as potential consequences of undernutrition. For example, a systematic review of undernutrition in care home residents (Tamura et al., 2013) demonstrated a link between depression and poor nutritional status, but could not prove the direction of the association. Similarly, a systematic review of observational studies (Rahe et al., 2014) investigating the relationship between dietary patterns and depression in healthy adults hypothesised that diet as a modifiable lifestyle factor, could be manipulated to reduce depression. While observational studies indicate that a relationship between dietary intake and depression exists, the underlying mechanisms are not sufficiently understood and RCTs are required to confirm the direction of the relationship and elucidate whether the effects of dietary change on depression are causal. One RCT of community-dwelling older adults (Endeveldt et al., 2011), showed positive results of comprehensive nutritional intervention on depression scores. However sample size was, small and the study underpowered, and there has been little since.

1.7.7 Cognitive function

Cognitive function encompasses the areas of memory, psychomotor ability, processing speed, visual attention, and executive function. A recent systematic review highlighted a lack of agreement between studies examining the effect of nutritional deficits on domains of cognitive impairment (Benau et al., 2014). Under conditions of short-term fasting, reaction time, processing time and executive function showed modest reductions, but the authors found it difficult to unpick the role of lethargy and motivation within these effects. In addition, methods were heterogeneous and the majority of studies did not report age or consider age or gender amongst confounders. Memory was examined most frequently, but did not appear to be impacted by fasting. Understanding the short-term effects of fasting on cognition in healthy adults may improve understanding of the potential implications of undernutrition on cognition (Benau et al., 2014).

The relationship between cognitive function and several dietary factors has been explored, including whole diet interventions, fatty acids, antioxidants, and B vitamins. Whilst epidemiological evidence supports an association between antioxidants, fatty acids, and B vitamins are associated and higher cognitive functioning, RCTs have been unable to corroborate these findings. Studies are limited and more research required.

1.7.8 The economic impact of undernutrition

The economic costs arising from undernutrition are attributable to increased length of hospital stay, repeat admissions, higher complication rates and prolonged recovery. The overall costs of disease-related malnutrition are estimated to be \$432 billion in Europe (Inotai et al., 2012) and \$157 billion in the USA (Snider et al., 2014). Both estimates were derived from morbidity and quality-adjusted life years lost, mortality, with the remainder attributable to direct medical costs. Whilst both analyses drew from published literature, the USA data was based on NHANES data and are therefore in a community-dwelling population. They acknowledge that their data are likely an underestimate of the total cost of disease-related malnutrition.

The most recent data for England suggests costs of £19.6 billion (Elia, 2015), but the methods used to calculate this figure are not comparable to those for Europe and the USA. Still, the costs absorbed by health and social care are significant, and as a treatable condition, tackling malnutrition could make substantial savings to the National Health Service (NHS) (Elia, 2015). A UK study showed that the costs of managing an individual with undernutrition was twofold higher than the cost of managing a well-nourished individual (Guest et al., 2011), attributable to greater use of healthcare resources including health professional visits, hospital outpatient appointments (Abizanda et al., 2016, Guest et al., 2011).

1.8 The pathways of nutritional care

Length of hospital stays have reduced over time due to new technologies and techniques, and changes in the economic environment (Organisation for Economic Co-operation and Development, 2015). For example, between 2002 and 2012 average length of stay in a UK hospital reduced by 14% to seven days (Organisation for Economic Co-operation and Development, 2015). Supply and demand factors result in some variability in length of stay, but admissions are kept to a minimum for a number of reasons. These include patient wishes, bed shortages, in addition to the financial costs of a hospital stay (Asher, 1947, Clarke, 1996).

At discharge from hospital people are still in the recovery phase from the acute illness which caused them to be admitted, this places them at risk of other problems. Krumholz (2013) suggested a critical 30-day period where this risk is elevated. At this time the body may be weak physically, nutritionally depleted with muscle and fat losses, affecting the immune system (Cosquéric et al., 2006, Lieffers et al., 2012). In a study of Medicare patients discharged from the hospital, 19.6% were readmitted within 30 days (Jencks et al., 2009). The authors showed that in 60% of cases it was not recurrence of the same illness which caused the admission in the first instance, but a complication (Jencks et al., 2009).

Hospital admission can cause huge interruption to normal routine, with patients removed from their usual environment. Pain, discomfort and unfamiliarity can influence sleep and circadian rhythms; altered bowel habit and digestive discomfort may be experienced. Procedures and medications may affect cognition and physical function, and patients may experience “deconditioning” due to inactivity and poor nutrition - all placing significant stress on the individual. A longitudinal study performed in the U.S. took anthropometric and clinical values, and explored functional status in a regression analysis, to show that weight loss after discharge predicted readmission within 30 days (Friedmann et al., 1997). In addition, the authors showed a 75% increase in the odds of readmission with every kilogram of weight loss experienced. The study looked at a cohort of older patients at discharge, one week, four weeks and 12 weeks post-discharge.

A frequent cause of weight loss is poor intake (Tamura et al., 2013). In the hospital setting suboptimal intake may reflect unattractive or unfamiliar food or surroundings (Dupertuis et al., 2003), or isolation during mealtimes (Simmons et al., 2001). Hospital admissions themselves have been associated with gastrointestinal disturbance and sleep disturbance (Krumholz, 2013), which may affect eating behaviours and diet quality (Chaput, 2014, Feinle-Bisset et al., 2004). Fatigue, discomfort and pain may all play a physical and psychological role in the aetiology of reduced food intake (Ravasco et al., 2003). In addition, nutritional problems may arise from interruptions for tests and procedures and the fasting process which accompanies these. For individuals with swallowing difficulties or illness which does not allow adequate nutrition, decisions may be delayed whilst assessment is performed or a decision to provide nutrition via an alternative route is made. In addition, organisational factors such as lack of nutritional screening and assessment, poor staff knowledge and training, and inadequate feeding assistance (Kubrak and Jensen, 2007).

Undernutrition may affect physical, social and psychological functions (Keys et al., 1950) influencing mood (Cabrera et al., 2007) and quality of life (Hickson and Frost, 2004, Keller et al., 2004, Larsson et al., 1994), affecting independence and increasing reliance on carers and support services (UK, 2011). This is costly both to the individual and the NHS (Guest et al., 2011). With these influences undernutrition may affect day-to-day activities and other interventions designed to support people living with chronic illness - for example individuals undergoing a programme of rehabilitation. A reduced level of independence is not uncommon following a period illness. Supervision and support may be required during this period of acclimatisation following an admission. Delirium may be a feature of the illness or medication or confusion may be an issue with "information overload" as patients meet many different staff members and the environment changes frequently. This again may reduce an individual's performance in the activities of daily living or affect their ability to retain information and effectively monitor for problems on discharge – for example to monitor their dietary intake or

weight. Medications including sedatives and pain relief may reduce awareness and increase falls risk.

There are services in place across England, designed to maintain or improve health, and promote independence and self-care. A collaborative approach between service-users, carers, GPs and other health and social care professionals exists to minimise hospital admissions (NHS England, 2014). This organisation of care across the interface between general practice and secondary care providers is central in ensuring to both high quality care and in making the best use of clinical time and NHS resources in both settings (Banks et al., 2011). Following a hospital admission, individuals in England are entitled to free intermediate care, reablement or aftercare regardless of income for a maximum of six weeks (Which?, 2018). This is different across the world. A lack of continuity exists within and between countries, with formal pathways between phases of care either non-existent, incomplete, or variable (Reyes and Ouslander, 2019). This is due to different organisational structures, and different levels of resources. Approximately 85% of older adults admitted to U.S. hospitals are discharged home, and any support with activities of daily living is provided by home health agencies or family members (Robert Wood Johnson Foundation, 2018), but there is limited free health care in reablement and intermediate care (Centers for Medical and Medicare, 2018). Similarly, Medicare and many insurance plans do not automatically cover nutrition services.

It is well known that undernutrition takes significant time to reverse particularly in older people (Miller and Wolfe, 2008) and therefore interventions commenced in hospital can be considered a starting point only. However, few studies have explored nutritional status at the point of discharge and little work has been published on how best to organise care at the acute-community care interface. The NICE Quality Standard 24 (NICE, 2012) states that “all people who are screened for the risk of undernutrition have their screening results and nutrition support goals (if applicable) documented and communicated in writing within and between

settings". In addition, with length of stay for hospital patients becoming shorter, the opportunity to treat malnutrition in hospital is also reduced (Muscaritoli et al., 2017).

Research into the detection and management of undernutrition has been most visible in acute and care home settings. For example, numerous nutrition care pathways exist, but often focus on the acute hospital setting, or are condition specific. (Atkins et al., 2018). They tend to be implemented based on consensus opinion and evaluated through auditing compliance or change in practice (Andersen et al., 2015, Atkins et al., 2018). Much of the literature describes the application of existing, pathways such as the guidance from NICE (2006) in COPD (Hodson, 2016) or The American Society for Parenteral and Enteral Nutrition guidelines (McClave et al., 2009) in critical care (VanBlarcom and McCoy, 2018). One key nutritional care pathway (Keller et al., 2015) used the Delphi technique to amass expert opinion (Goodman, 1987). Methods incorporated a literature search, then targeted key stakeholders through questionnaires and focus groups. Pathway evaluation showed significant improvement amongst staff knowledge and practice ($p < 0.001$) (Laur et al., 2018), although compliance with each step in the pathway had not been audited. The pathway advises nutrition recommendations be made as part of discharge communications from hospital to relevant community health care professionals where the patient is malnourished (mild, moderate or severe undernutrition as determined by SGA).

The pathways that link nutritional care across the hospital-community interface have not been well examined, but poor cross-boundary communication has been cited as an issue (Bavelaar et al., 2008, Elia et al., 2010) and recent guidelines refer to this as an area for future exploration (NICE, 2012, NICE, 2013). It is essential for good patient care that there is clear and timely communication on discharge from hospital, this includes a discharge summary sent to the GP within 24 hours after every discharge from inpatient, day case or A&E care (NHS England, 2014).

The key nutritional care pathway used in the U.K., outlined by NICE (NICE, 2006) forms part of the clinical guideline and is incorporated in to guidance by organisations such as BAPEN.

The pathway highlights opportunities for the optimal organisation of nutrition support, then outlines the role of screening, choosing an appropriate intervention and monitoring to determine changes in nutritional status. It provides information on appropriate tools to use in the screening and assessment of undernutrition, and signposts to guidance on the type of interventions that could be utilised. It also advises that where the service user is transferred to another care setting, this nutritional information should follow them (NICE, 2006). In addition, interactive guidelines such as A Guide to Managing Adult Malnutrition in the Community (Malnutrition Pathway Panel, 2017) support the implementation of recommendations in the NICE guideline on nutrition support for adults within community settings.

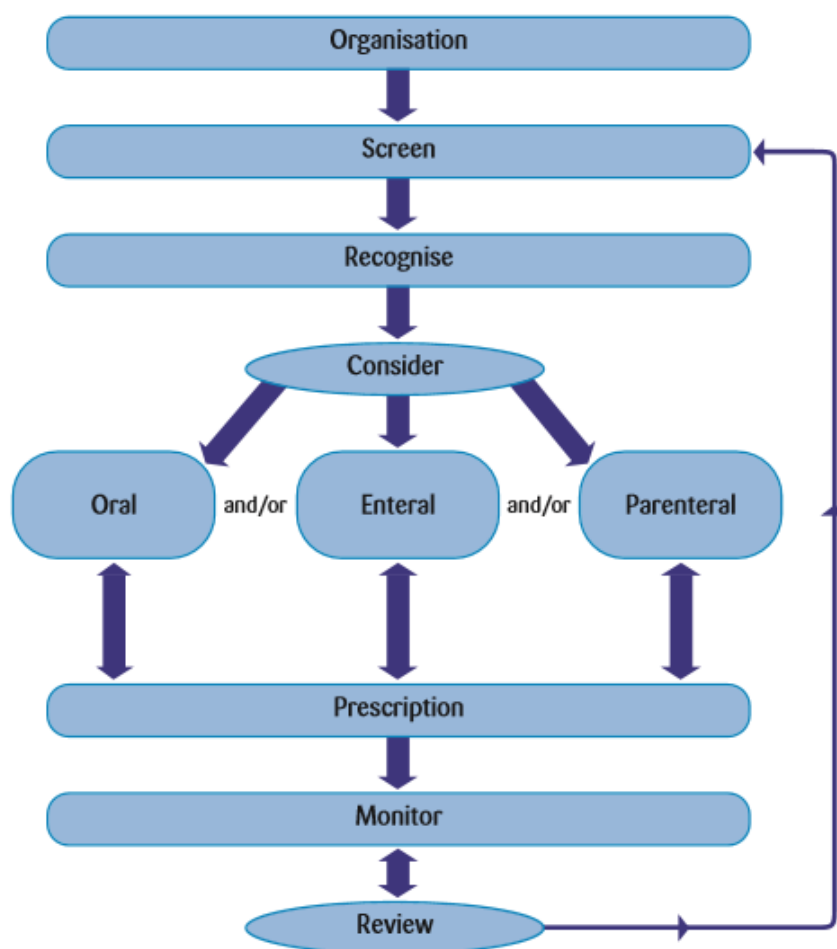


Figure 1.4: NICE Clinical Guideline 32: Nutritional support in adults (NICE, 2006)

1.9 Summary

This chapter aimed to provide an overview of undernutrition risk in an aging population, the size of the problem, those considered most at risk, and the costs associated with undernutrition. From the influences discussed, it is clear that undernutrition has the potential to affect interventions designed to support people living in the community with chronic illness. I wanted to better understand whether undernutrition risk was likely to affect patients' capacity for treatment. To achieve this, I chose to examine the participant characteristics associated with undernutrition risk in a large dataset of COPD outpatients accessing pulmonary rehabilitation. As COPD is a disease of accelerated aging, this patient group are likely to share physiological and functional similarities with an older population, and therefore offer useful insights in to the relationship between undernutrition risk and the rehabilitation potential of older people.

Following on from this initial study exploring undernutrition risk in chronic disease, I wanted to examine the characteristics associated with nutritional risk in older people following an acute stressor. Understanding that the risk of undernutrition is raised following a hospital admission, and that older people are particularly vulnerable, I had the idea to create a longitudinal study exploring the impact of undernutrition risk over the 12 months following a hospital stay. Again my focus was on community-dwelling individuals as little is known regarding their recovery and, as undernutrition has the potential to affect performance in their day-to-day activities. As the study was designed to investigate person-centred outcomes, I wanted to produce data applicable to a range of patients with varying health states that would be classed as 'older adults' in normal clinical practice. I also felt it was important to use practical measures which could be reproduced in normal practice, so that any interventions arising from the work would be feasible in clinical contexts.

As little is known about how best to organise nutritional care at the hospital-community interface, the final study intended to explore the proportion of the cohort receiving nutritional care and what that care looked like. I designed a study using both self-reported data and

patient notes to examine the processes employed to communicate and to manage undernutrition risk following hospital discharge. This information will allow me to identify gaps in the care pathway as sites for future research.

1.10 Hypothesis

Older adults recently discharged from hospital who are at risk of undernutrition have poorer person-centred outcomes and deficiencies in the care pathway exacerbate this situation.

1.11 Research questions

1. What is the prevalence of undernutrition risk in community-dwelling individuals with stable COPD?
2. Which phenotypic characteristics are associated with risk undernutrition in the outpatient COPD population?
3. What are the nutritional, quality of life and functional characteristics of older people leaving hospital, how do these characteristics change during 1 year follow-up?
4. How does food intake and nutritional status [and factors influencing nutritional status] change over a 12 month period, in older adults after a hospital admission?
5. What is the process of discharge from the acute to the community sector in the context of nutritional care?
6. What is the trajectory of the care process from discharge to 12 months post-discharge in terms of nutritional care for older people?

Chapter 2: Methods

This chapter aims to address the methodological and theoretical considerations of the studies included in this PhD thesis, with evidence in support of their use. It will outline the methods used in answering the research questions of the two studies undertaken, including aspects of the study design including participant selection, data collection, data management and methods of statistical analysis. Each study incorporates different methods, so the main measures and constructs will be discussed here with additions provided in each specific chapter.

2.1 Ethics

Both studies 1 and 2 were categorised as research and therefore required ethical approval. Study 1 'Nutritional risk in chronic obstructive pulmonary disease' had approval from West London (11/H0707/2) and London Camberwell St Giles (11/LO/1780) research ethics committees prior to my involvement in the project. A favourable ethical review was granted by National Research Ethics Committee Yorkshire & The Humber Leeds East for study 2 entitled 'An observational study to investigate the impact of nutrition risk status on utilisation of health and social care resources and patient-centred outcomes in older people living in the community' (REC reference 15/YH/0094 and IRAS ID 171279). See appendix 9.1 for copies of these letters.

As observational studies, no participant risk was anticipated. Consideration was given to consent procedures, confidentiality, sampling of the study and research methods. Consent procedures were designed to meet the requirements of the Helsinki Declaration, ensuring that consent was both informed and given without persuasion. In study 2, it important not to exclude older adults with cognitive impairment in order to capture a representative sample. The Mental Capacity Act (2005) states that a person cannot give consent on behalf of another adult, therefore where a prospective participant was unable to consent themselves, a representative (most likely next-of-kin), was approached to act as a personal consultee. Where uncertainty existed as to an individual's capacity, an assessment consistent with the Mental Capacity Act 2005 was made.

The process for inviting participants to take part in study 1 is outlined in chapter 3 and for study 2 in chapter 4. Examples of the consent form, declaration form for consultees and the patient and consultee information booklets have been included in appendix 9.2.

2.2 Outcome measures

Outcome measures can be used to map changes in health status over time. For observational studies, this includes the description of certain characteristics with exposures and risk factors (The British Dietetic Association, 2016). A key issue with observational studies is the influence of confounding factors which may have an effect on both the dependent and independent variables, making interpretation of results difficult. In these studies where the inclusion criteria were large, it was as important to identify these factors (for example age, severity of acute disease, number of long-term conditions) as it was to measure our variables of interest so that they could be accounted for in the analysis of the study.

For study 1, methods had been designed and data collected prior to my involvement in the study. The primary outcome measure was nutritional status measured using the Malnutrition Universal Screening Tool (MUST). The aim of the study was to examine nutritional risk in outpatients with COPD prior to a programme of pulmonary rehabilitation. A sub-study then explored change in nutritional risk following pulmonary rehabilitation.

For study 2, the primary end points were function and quality of life. The aims of the study were to explore differences in recovery following a hospital admission between older adults at medium or high risk of undernutrition and older adults at low risk. This included four time points; at hospital discharge (baseline), 3 months, 6 months and 12 months.

2.2.1 Anthropometric measurements

Anthropometry involves the systematic measurement of the human body. Important in nutritional assessment, anthropometry is used in the identification and monitoring of undernutrition (Tomkins, 1994). Error in anthropometrical measures influence not only the measurement, but the interpretation of nutritional status. For example, measurement errors

may affect the deviation from the 'actual' value and influence the ability to measure variance over time.

Error may be caused by a number of factors including equipment fault, investigator inaccuracy, for example due to a lack of skill or care, and circadian variation in height (Bland and Altman, 1996, Reilly et al., 1984). Chronic disease and dehydration may skew anthropometrical measurements (McNeil et al., 1975). To limit instrument error, equipment was calibrated (see individual measurement for details). To minimise human error and ensure consistency and reliability between investigators it was important that all members of the research team undertook training and followed the same validated procedures to measure participants. As prospective studies, data for study 1 and 2 were collected by trained investigators and assistants following standardised protocols. The investigators were responsible for ensuring the participant's height and weight were recorded accurately; following the standard operating procedures (SOP) for each measurement technique.

2.2.1.1 Height

Height was collected along with weight to determine body mass index and nutritional status. The gold standard is to measure standing height using a stadiometer, however this can be difficult in older adults. Loss of height is a recognised consequence of aging, due to changes in bone, muscle and joints, with losses of ≤ 5 cm for men and ≤ 8 cm for women by 80 years of age (Sorkin et al., 1999). The presence of osteoporosis, arthritis, kyphosis and scoliosis is associated with even greater losses (Hansen et al., 1991). Despite this, measured height is considered gold standard in both younger and older adults. Alternatives include using knee-height, demi-span and arm-span to estimate standing height, or self-reported height (Chumlea and Guo, 1992), but surrogate measures are likely to over-estimate height in the older population, thus underestimating BMI (Hickson and Frost, 2003). A systematic review concluded that height was over-reported, but that large standard deviations suggested variation between participants (Gorber et al., 2007). Studies specifically examining the self-reported height in older populations have shown relatively high levels of accuracy with

intraclass correlation coefficients ranging from 0.85 to 0.92 (Fillenbaum et al., 2010, Yong and Saito, 2012). In view of this information current height was obtained for all participants able to stand without stooping and use reported height for those unable to stand or where height was visibly affected.

Height was measured using portable stadiometer (Hopkins, Michigan) placed on a flat, non-carpeted surface. The procedure was explained to the participant and the participant asked to remove any outdoor clothing, hats or headwear, shoes or slippers. Standing with their feet together on the tab of the stadiometer, upper back, buttocks and heels aligned, the participant's head was placed in the Frankfort plane, achieved when the Orbitale is on the same horizontal plane as the Tragon. Participants were asked to take a breath in and the height measurement rule was lowered until the head gauge rested on top of the participants head, flattening any hair to ensure an accurate reading. All height measurements were recorded in metres to two decimal places following the format 1.60 m, or 1.47 m.

2.2.1.2 Weight

Weight is a simple and efficient way of classifying and monitoring nutritional status, most commonly as part of calculation of BMI or nutritional risk status.

Reporting bias has been associated with existing weight, with studies showing a higher rate of under-reporting in overweight individuals and over-reporting in underweight individuals (Cawley et al., 2015, Rowland, 1990). Age and gender also affected accurate reporting of weight, with males over-reporting weight, compared to females who more frequently under-report (Kuczmarski et al., 2001). Older participants underestimated weight more than their younger counterparts (<60 years) (Kuczmarski et al., 2001) Self-reported measures are practical and cheap, however they are at risk of reporting bias as participants may not accurately recall or provide a socially desirable response (Singleton Jr et al., 1993). Therefore I chose to use measured weight taken according to the following protocol.

Weight was measured using calibrated digital scales. In study 1, all participants were able to stand on standardised scales. For study 2, and where participants were able to stand, the

same set of portable scales (Tanita UM-081 Digital Weight standing scales) were used, placed on a flat, non-carpeted surface. Additional in study 2, participants who were unable to weight bear were weighed using Marsden M-220 chair scales. The procedure was explained to the participant and the participant asked to remove any excess clothing, shoes or slippers, and to empty pockets. Where excess clothing could not be removed, it was recorded to ensure it contributed a similar weight at each study visit. Other items that contribute to weight were removed where possible, for example weight was taken once catheters had been removed, and stoma bags emptied. The start key was used to zero the scales ready to weigh the participant. The participant then stood on the scales, distributing weight evenly. Where suitable, calibrated scales were unavailable, mid-upper arm circumference was taken (see section 2.1.1.4). Weight result, clothing and equipment details were recorded on the data collection tool. Weight measurements were recorded in kilograms (kg) to one decimal place following the format: 40.1 kg or 68.0 kg. The study scales were calibrated against a known weight; portable scales weekly and seated scales prior to each use. Seated scales were marked to show evidence of annual calibration by the Trust Clinical Engineering department.

Judgement and guidance was used to account for casts, amputations and ascites or oedema. A cast for the lower leg weighs 0.9 - 4.5kg depending on the material and site (Todorovic et al., 2003). Weight adjustment for amputation was made from knowledge of the weight of missing limb segments: upper limb 4.9% of body weight (upper arm 2.7%; forearm 1.6%; hand 0.6%); lower limb 15.6% (thigh 9.7%; lower leg 4.5%; foot 1.4%) (Osterkamp, 1995). For mild oedema, a dry weight was estimated by subtracting 2-5 kg from the measured weight (Elia, 2003a). MAC was also used as an indicator of BMI when oedema in the lower body prevented an accurate weight being taken, but the arms remained free of excess fluid.

2.2.1.3 Body mass index

Body mass index (BMI) is an indicator of weight-for-height, used to categorise body fatness in adults (WHO, 1995). As height and weight can be easily and cheaply measured, BMI is frequently used in both research and clinical practice to gauge body fatness. The challenges

associated with using BMI are that whilst BMI shares a linear relationship with body fat percentage (and additionally is inversely related to contribution of weight from lean mass), the norms vary with gender and age. For example, age-associated losses of lean mass alongside increases in fat mass after middle-age, alter body composition - particularly in men. The resultant change in BMI value may be variable, with an predicted increase of 0.7-2.6kg/m² between the age of 60-80 years (Sorkin et al., 1999). Several BMI cut points have been used to define undernutrition in adults, these are listed in table 2.1. Many studies have used BMI as a measure of undernutrition with cut points ranging from <17 kg/m² to <22 kg/m² or <25th BMI centile (Stratton et al., 2003). Due to age-related changes in body composition, research in older populations suggests that the value of standard BMI ranges in older individuals is limited, potentially underestimating adiposity and overestimating lean mass (Zamboni et al., 2005). Nevertheless, BMI remains a commonly used measure in both research and clinical practice. Research exploring the relationship between BMI and mortality has shown a significant association between BMI and all-cause mortality (de Hollander et al., 2012, Kvamme et al., 2012). In a large study of adults aged 70-75 (n= 1,970), BMI range 21.1-31.4 kg/m² was associated with reduced mortality, with a BMI of 27.1 kg/m² carrying the lowest risk of mortality (de Hollander et al., 2012). Another large study of adults aged 65 and over (n=16,711), demonstrated a BMI range of 25-29.9 kg/m² was associated with lowest mortality risk (Kvamme et al., 2012). BMI was calculated by dividing weight in kilograms by the square of the height in metres (kg/m²).

Table 2.1: Categories of BMI for identifying undernutrition risk in adults (FerroLuzzi et al., 1995)

BMI cut point (kg/m ²)	Weight category	Interpretation
<18.5	Underweight	Chronic malnutrition probable
18.5-20	Underweight	Chronic malnutrition possible
20-25	Desirable weight	Chronic malnutrition unlikely
25-30	Overweight	Chronic overnutrition probable with increased risk of associated complications
>30	Obese	Moderate (30-35 kg/m ²), high (35-40 kg/m ²) or very high (>40 kg/m ²) risk of associated complications

2.2.1.4 Fat-free mass index

The drawback of using BMI in older people or conditions of accelerated aging is that the body composition is not examined. For example, inadequate fat-free mass (FFM) may be masked by a high fat mass (Heber et al., 1996). The use of fat-free mass index (FFMI) fat-free mass index (FFMI) calculated as $FFM/height^2$ (VanItallie et al., 1990), as an adjunct to the information provided by BMI may be useful in the classification of both overweight and underweight participants. In a large study of COPD patients, one quarter of participants had a FFMI lower than the lowest 10th percentile of the general population despite a normal BMI (Vestbo et al., 2006). Both BMI and FFMI were significant predictors of mortality, independent of relevant covariates. FFMI was also shown to be an independent predictor of survival in individuals with COPD (relative risk: 0.90; 95% CI: 0.84,0.96; $p=0.003$) (Schols et al., 2005). The risk of altered body composition is high in individuals with COPD. BMI and weight change used in screening tools such as MUST cannot differentiate between the types of tissue present, therefore there is a strong argument for measuring FFMI. In addition, individuals at risk of undernutrition often exhibit an optimal BMI, when measures of body composition reveal lean mass losses (Ingadottir et al., 2017).

2.2.1.5 Mid upper arm circumference

As discussed in section 2.2.2, weight can be difficult to measure in an older, frail population, particularly using portable scales, where poor mobility and impaired balance may prevent

ability to stand stably and thus obtain an accurate weight reading. Numerous studies have shown that mid upper arm circumference (MUAC) correlates well with BMI in adult populations (Collins, 1996, Ferro-Luzzi and James, 1996). MUAC can be used as a surrogate to estimate BMI and nutritional status. Studies undertaken in an older population are limited (Tsai et al., 2007), but demonstrate a significant association between low MUAC and undernutrition (<23.5 cm in men and <22 cm in women). This result is supported by other studies in adults showing robust associations between low MUAC (<23 cm) and a BMI <18.5kg/m². Therefore, where it was not possible to obtain a reliable weight measurement MUAC was measured according to the following protocol (Todorovic et al., 2003):

The participant was directed to bend their non-dominant arm at a 90 degree angle and place it across their chest. Using a non-stretch tape measure (CMS Weighing Ltd, London, UK), the distance between the acromion and the olecranon process was measured. A small mark was made to indicate the mid-point of the arm. Again using the tape measure, the arm circumference at the mid-point was measured, ensuring the participant's arm was relaxed, hanging loose by their side with the palm facing inwards. The tape was pulled firmly around the circumference of the arm, taking care not to compress the tissue with the tape. Loose skin around the upper arm can make this difficult in older subjects, but care was taken to include all arm tissue in the measurement and to make a measurement without gaps between the skin and the tape measure. For participants who were unable to mobilise into the required position, a measurement was taken from the supine position (Jensen et al., 1981). The mid-point was identified as above, then a pillow used to raise the arm palm facing up, allowing the researcher to measure the circumference.

Two readings within 0.1cm were taken and an average calculated. The MUAC measurement was compared to BMI cut points for interpretation, with a MUAC ≤23.5cm indicative of a BMI <20kg/m² or underweight; a MUAC 23.6-31.9cm indicative of a BMI of 20-30kg/m² and considered healthy to overweight and a MUAC measurement ≥32.0cm indicative of a BMI >30 kg/m² or obesity (Todorovic et al., 2003).

2.3 Nutritional screening tools

Nutrition screening is the first step in the nutritional care pathway, and is a process through which at-risk individuals are identified and, where appropriate, referred to a registered dietitian for nutrition assessment and intervention (Skipper, 2008). Nutrition screening is generally conducted by other people involved in patient care and is different from nutrition assessment. Nutrition screening identifies those at risk; nutrition assessment diagnoses existing nutritional issues and advises a route for treatment. It has been defined as “a comprehensive approach to diagnosing nutrition problems that uses a combination of the following: medical, nutrition and medication histories; physical examination; anthropometric measurements and laboratory data” (Teitelbaum et al., 2005).

Of the screening tools that exist, most rely on two variables commonly used to evaluate undernutrition; percentage weight loss and change in food intake, due to their relationship with clinical outcome. Recent weight loss has been described as a key factor in the diagnosis of undernutrition and as such is included as a component of nutritional screening tools. Whilst BMI provides a measure of nutritional status over the longer term, recent weight loss indicates more current nutritional problems. Whilst no reference range is gold standard, a consensus is 5-10% weight loss over 3-6 month period due to its adverse effect on physical activity levels (Keys et al., 1950, Stratton et al., 2003).

For a nutrition screening tool to be accurate and useful, it has to be valid (Charney, 2008). Validity refers to the degree to which the instrument measures what it proposes it measures, thus screening tools should be validated in the population which they intend to measure. In addition, all screening tools require an appropriate level of sensitivity and specificity, when compared with other methods of measuring nutritional risk status (Rush, 1993). Sensitivity and specificity are terms to describe the effectiveness or construct validity of a tool. Sensitivity is the number of true positives correctly classified by the tool, in this case the ability to identify those who are at risk of malnutrition, whilst specificity is the number of true negatives correctly classified by the tool (Altman and Bland, 1994). In validating nutritional screening tools

anthropometric measures and the assessment tools Mini nutritional Assessment (MNA) (Guigoz, 1994) and Subjective Global Assessment (SGA) (Baker et al., 1982) have all been utilised as reference measures. One of the limitations of nutritional screening tools is the subjective nature of the data, for example, reported appetite, nutritional intake and weight loss may be subject to interpretation by the participant and therefore could be seen as ambiguous. It is clear from the literature that different screening tools have been validated in different countries, settings and used different reference standards. A systematic review demonstrated the variety of techniques used to test validity of ten nutritional screening tools used in older, community-dwelling populations. The tools differed in the quality of the validation process, with MNA, MUST and SCREEN II tools rated good.

There are many nutritional screening tools in use across the world, but no international consensus on a single 'best tool'. Some are also specific to specific populations and diseases. The Malnutrition Universal Screening Tool (MUST) was chosen for use in studies 1 and 2 as a tool commonly used in clinical practice within in the UK.

2.3.1 The Malnutrition Universal screening tool

The Malnutrition Universal Screening Tool (MUST) is the most commonly used screening tool in the UK and is advocated by The British Association for Enteral and Parenteral Nutrition to screen for undernutrition in all patient groups, and by The European Society for Parenteral and enteral Nutrition for use in community populations (Kondrup, 2003a). MUST incorporates BMI, percentage weight loss and severe change in food intake to assess nutritional risk (appendix 3.1).

The MUST tool demonstrated excellent reproducibility when undertaken by different assessors ($k=0.8-1.0$) and good concurrent validity when compared to other nutritional screening tools (Elia, 2003a). Two studies have validated MUST against nutritional assessment methods. In the original development study (Elia and BAPEN, 2000), MUST showed good levels of construct validity when compared to subjective global assessment (SGA) ($\kappa=0.78$) and dietitian assessment ($\kappa=0.77$ to 0.81) in 412 hospitalised adult patients.

The second study (Almeida et al., 2012) conducted in 300 surgical inpatients, compared MUST and SGA with positive results. Sensitivity and specificity of the tool were reported to be good (85% and 95% respectively), with a high positive predictive value of 89% and negative predictive value of 93%. Validation studies in older populations are limited, with the one existing study showing fair-good validity ($\kappa=0.4-0.75$ - (Landis and Koch, 1977)) when compared to the Mini Nutrition Assessment (MNA) (Stratton et al., 2004) and excellent agreement with the NRS-2002 (Stratton et al., 2004). The MUST was one of only two tools validated in an outpatient setting, in which it showed fair validity (Neelemaat et al., 2008). Fair validity was defined as a performance rating 0.7-0.8 on the academic point system.

2.3.2 Nutrition Risk Screening tool

The Nutrition Risk Screening Tool-2002 (NRS) was developed taking into account that both disease severity and degree of undernutrition both play a role in determining nutritional risk. By doing so it aims to include those vulnerable to malnutrition secondary to disease. As a result, the NRS tool (see appendix 3.2) has been recommended for use in hospitalised patients by ESPEN (Kondrup, 2003a). It is a two phase tool: The initial step includes four questions examining nutritional risk, each with a yes or no response. If any question receives a positive response, the screen moves to step 2 where a score is calculated taking into account BMI, weight loss history and food intake. The patients are classified as 'at nutritional risk' (score ≥ 3) or 'no nutritional risk' (score < 3) (Kondrup, 2003b). Including a score for old age (>70 years) it is different to other screening instruments, but the scoring is open to interpretation and may cause inconsistencies. In their validation study, the authors demonstrated that dietary recording using quartiles to document percentage intake agreed relatively well with calculations by a dietitian (Kondrup et al., 2003). Four additional studies have explored the construct validity of the NRS compared to nutritional assessment (Almeida et al., 2012, Kyle et al., 2006, Neelemaat et al., 2011b, Westergren et al., 2011). Sensitivity was between 37% and 94% and specificity 79% to 93% across the four studies. Positive and negative predictive values (PPV and NPV) were calculated in three of the studies (Almeida et al., 2012, Kyle et al., 2006, Westergren et al., 2011), with scores ranging from 71% to 87%

and 46% to 100% for PPV and NPV respectively. Looking at the studies conducted in an older adult population (Neelemaat et al., 2011b, Westergren et al., 2011), sensitivity of the NRS ranged from 36% to 92%. This shows variability, even within studies of similar populations.

2.4 Quality of life

Measures of health-related quality of life (HRQOL) are increasingly used in health research, allowing researchers to focus not only on hard outcomes such as mortality and morbidity, but on the impact *health* status has on *quality of life*. Two tools are used in this thesis: St George's Respiratory Disease Questionnaire (SGRQ) in study 1 (chapter 3), and the ED-5D in study 2 (chapter 4).

2.4.1 EuroQoL-5D

The EQ-5D is a widely used tool made up of a descriptive component which can be presented as a utility index (UI) and a visual analogue scale (VAS) (Rabin and Charro, 2001) (see appendix 9.3.3). The descriptive component includes self-reported scales for five dimensions of health: mobility, self-care, usual activities, pain and discomfort and anxiety and depression. Each domain is given a score based on a 5 point Likert scale, producing a 1-digit number expressing the level rating for the dimension based on "no problems," "slight problems," "moderate problems," "severe problems," and "extreme problems". The combination of these five ratings is then combined into a single score where values less than 0 are worse than death and higher values represent increasingly better quality of life. The tool can be used to describe quality of life in the single dimensions where the data is reported as a health profile showing each level of each dimension, stratified nutritional risk group, it can also be used to demonstrate quality of life as a total using a summary utility index (UI) score (Szende et al., 2007). EQ-5D-5L health profiles, can be converted into a single index value (Dolan, 1997) where each dimension score is summarised into a 1-digit number on a utility index anchored at 1 (full health). This is performed using value sets created by the EUROQOL group. In each case, lower values indicate a worse HRQOL. Summarising the EQ-5D data in this manner introduces bias, based on the value set that is used.

In addition to the EQ-5D profile which is restricted to five distinct domains, data on patients overall health is captured using the EQ-5D-5L VAS. The VAS requires the participant to score their health on a scale ranging from 0 (worst imaginable health) to 100 (best imaginable health) (Rabin and Charro, 2001). Collecting accurate and reliable data requires that every respondent hears exactly the same questions read in exactly the same way. Changes in the way a question is asked can affect the way a respondent answers and therefore affect results.

Information regarding quality of life is generally self-reported due to the idiosyncratic nature of the information provided (Buckley et al., 2012). This poses a challenge in individuals with dementia, as cognitive ability reduces as the dementia becomes more severe. In these cases self-reported HRQOL is not reliable and an alternative measure is required (Albert et al., 1996, Logsdon et al., 2002, Lopez et al., 1994). However, this presents its own methodological issues.

Measuring HRQOL is complex, attempting to gauge information on the physical, social and psychological elements of a person's life (Felce and Perry, 1995). The EQ-5D-5L authors developed a tool which could be completed by a patient proxy. One study that compared participants with and without dementia and their carers found that carers attributed lower scores in all groups. Repeated-measures ANOVA showed that both self-reported and carer-reported total quality of life scores decreased with dementia severity ($F = 371.537$, $p < 0.001$), but proxy-reported scores were significantly lower than the self-reported scores of the participants irrespective of group ($F = 146.098$, $p < 0.001$) (Jacob et al., 2017). A systematic review suggested that the discrepancies between self-reported and proxy-reported data may be due to traits of the participant or the carer, for example, higher levels of agreement were apparent when the health of the participant was prominently good or bad. Additionally, the approach adopted by the proxy may influence the answer provided. For example, the proxy may try to answer the question as if they were the participant, or they may apply their own values to answer. Studies suggest variation in the nature of the proxy relationship, such as the duration and closeness, influence this.

2.4.2 St George's Respiratory Disease Questionnaire

The SGRQ (Jones et al., 1991) is a 50-item questionnaire designed to measure health-related quality of life in people with chronic respiratory problems, and was used only study 1 (see chapter 3). The index covers three domains (symptoms, activity and impact) asking a variety of general and time-specific questions to explore symptoms of disease, the activities which cause breathlessness and the impact this has on the participants' everyday life. The questionnaire uses a combination of Likert scales and true or false questions. The overall score is a sum of all 50 questions and ranges from 0 to 100, with higher scores indicating more severe limitations. Studies have shown good internal consistency (Cronbach's $\alpha = 0.87$), small ceiling and floor effects, and good convergent and discriminant validity when compared to other measures of disease severity and quality of life, such as the World Health Organization Quality of Life-Bref (WHOQOL-BREF) instrument (Liang et al., 2008a). This tool measures physical and psychological health, and social relationships in a variety of many populations. The SGRQ was provided to the participant for self-completion within the research facility. Participants were asked to complete the questionnaire as honestly as possible, asking the researcher where questions arose. For participants with literacy issues, the researcher read the questions aloud and documented their responses.

2.4.3 Satisfaction with food-related life

The domains included in general health related quality of life measures, such as the EQ-5D, focus on health and do not provide information on food or nutrition, it was therefore prudent to include an additional set of questions relating to this aspect of quality of life in study 2. Many studies into the effects of nutrition on health exist (Veenhoven, 2008), including several exploring quality of life in chronic diseases (Buckner and Dwyer, 2003, Gucciardi et al., 2009), older adults (Hickson and Frost, 2004) but minimal on the interaction between food or eating and quality of life (Veenhoven, 2008). Several authors have produced tools to explore HRQOL in food allergy (Goossens et al., 2011, van der Velde et al., 2012). Other tools are specific to certain medical conditions, for example Goldberg et al (2005) designed a chemosensory questionnaire focussing on taste and smell in head and neck cancer patients. One nine-

question instrument was constructed for a population at risk of undernutrition and weight loss, but investigates weight very specifically and for participants with HIV (Rabeneck et al., 1998, Wagner and Rabkin, 1999). Other tools have been designed as broad measures of food-related quality of life within a nutrition background. such as the 'QF' - Quality of Life Factors Questionnaire (Corle et al., 2001). The QF questionnaire combines statements from other quality of life tools, showing good levels of construct validity assessed using factor analysis and internal consistency using Cronbach's alpha. Coefficient values were all ≥ 0.7 for each item except one - the health action domain, justified as low because it includes individual, broad statements. It was, however, unclear whether alpha coefficients had been calculated for the study or recycled from previous data. It is designed for self-administration using Likert scales for each of the 51-items. In Corle's original study, participants were recruited from the Polyp Prevention Trial with a mean age of 60 years. This intervention (and one subsequent unrelated study (Pakiz et al., 2005)) required an instrument sensitive to changes in food behaviours relating to fruit and vegetable intake and the adoption of a low fat diet. Guyonnet et al (2008) developed and validated the 'food benefits assessment (FBA) questionnaire', designed to assess the impact food makes on HRQOL in the general adult population. The 7-dimension tool aims to investigate participants' vitality, digestive comfort, disease prevention, physical appearance, well-being, aesthetics and snacking. Validation was carried out in France using healthy adults aged 18-65; 130 'normal weight' and 67 'overweight' participants, the authors have since used the tool in gastroenterology patients. Construct validity was assessed by principal components analysis (PCA), concurrent validity using the Short Form-36 scale (sf-36)(Ware and Sherbourne, 1992) - both of which achieved good scores. Internal consistency tested using Cronbach's alpha, demonstrated reliability. Stable reliability was also shown using test-retest reproducibility over a one week period. However this 41-item questionnaire was long and impractical for the study needs.

Due to the mix of clinical conditions in the recruited population, it was important to use a quality of life tool non-specific to disease, but which related to nutrition allowing assessment of the

impact of food on quality of life. A suitable tool meeting these criteria is the Satisfaction with food related life (SWFL) questionnaire. Grunert (2007) looked specifically at food-related behaviours to produce a tool measuring general satisfaction with food-related life. The tool includes five statements, with no timescale, to be answered on a scale of 1-7. The tool was validated across eight European countries, including the UK, using 96-105 community-dwelling older adults for each sample. As a result it considers not just enjoyment of food and mealtimes, but other important factors such as food preparation. Construct validity was measured using the Nutritional Health Index (NHI) and the SF-36, convergent validity by comparison to interview. The correlation between the SWFL tool and satisfaction with food related life as assessed by in depth interview and measured by Pearson correlation was weak to moderate ($r=0.44-0.53$, $p<0.001$). However, when compared to satisfaction with food-related life from a specified, seven day period, correlation was poor ($r=0.32-0.46$). Correlation of the SWFL tool and overall satisfaction with life, again measured using SF-36 and NHI, was found to be 0.36 ($p<0.001$), showing a low level of positive correlation between the two constructs. Internal consistency was tested using Cronbach's alpha with coefficients of 0.71-0.89 showing that the scale had adequate levels of consistency. In addition, reliability using test-retest reproducibility of the SWFL was established through a repeat of the study using 441 of the same participants after 6 months, and found to be moderate ($r=0.60$, $p<0.001$) (Schnettler et al., 2013). Despite the low validity with other measures of quality of life, this tool was felt to be the most appropriate because it was short, simple and easily completed by participants, adding minimal burden to the study process.

2.4.4 Standard operating procedure for questionnaires

Interviews were conducted in a quiet space with the participant on their own where possible. Each questionnaire was introduced to the participant as dictated by the predefined script. A show-card was used for multiple-choice answers to guide the participant through the possible responses.

Throughout the interview it was imperative to maintain a neutral tone, ensuring nothing in the interviewer's words or behaviour expressed surprise, approval or disapproval of the answers given by the participant. Each question was read exactly as worded. In cases where the respondent did not hear the question, or did not understand the question, the entire question was re-read. If the participant asked for help with the question it was redirected back to the participant.

The researcher read all questions out loud to the participant, supplying the participant with the options for each answer. Each chosen response was recorded on the data collection tool. Where the participant lacked the capacity to complete the assessments, the consultee provided answers. For the EQ-5D-5L, a proxy version of the questionnaire was completed. Whilst there are clear challenges using a proxy to provide information on HRQOL, the researcher can influence the accuracy of the tool. In order to make this tool as accurate as possible the following decisions were made. Firstly, that the consultee providing information (the proxy) must know the participant well enough to provide information relating to quality of life. Secondly, by providing sufficient detail to the proxy prior to them answering the question so it was answered consistently. The proxy was asked to answer the question as if they were the participant, i.e. consider what rating the patient would give were they able to communicate it accurately.

2.5 Comorbidities

2.5.1 Charlson comorbidity index

Chronic diseases, were recorded from the self-reporting of the participants physical health from a list of 22 possible conditions (Charlson et al., 1987), and were coded as having been diagnosed (yes=1) or never been diagnosed (no=0). Respondents were asked whether a physician had ever diagnosed them with heart conditions-heart attack, myocardial infarction or congestive heart failure, hypertension, diabetes or high blood sugar, arthritis or rheumatism, lung disease, cancer, or stroke. The age-adjusted comorbidity index was then calculated by

adding 1 point per decade to all participants upwards from 2 points for participants between 60 and 69 years (Charlson et al., 1994) (see appendix 9.3.3).

2.6 Frailty

Several screening tools and monitoring instruments have been developed to identify frailty. De Vries et al (2011) conducted a systematic review of existing tools used to measure frailty. Using a predetermined method they reviewed the content of studies within the categories nutritional status, physical activity, mobility, energy, strength, cognition, mood and social support. The review looked for evidence of reproducibility, agreement, validity and responsiveness in each instrument, scoring each using an assessment scale (Terwee et al., 2007). Two of the most common multidimensional tools with used to assess frailty (Fried et al., 2001a) are the Frailty Phenotype and the Frailty Index (FI) (Rockwood et al., 2007b, Rockwood et al., 2006). The Frailty Phenotype is assessed by the participant performing simple activities, including handgrip strength and gait speed. A score for each activity is assigned based on a 6-level Likert scale ranging from 0 to 5. These scores are then totalled and the individual classified as robust (0), pre-frail (1-2) and frail (≥ 3). Measuring gait speed presented practical problems for this study as the space was not available to conduct this test. In addition, disability and cognitive impairment affect the reliability of the assessment, so it was felt this assessment may be unsuitable for a large proportion of our participants. At this point the decision was made to characterise frailty through self-report and researcher assessment methods only. Of 20 tools examined in the systematic review, only one instrument could be used to gain information on the full 8 frailty factors; the FI (Rockwood et al., 2007b, Rockwood et al., 2006).

The FI is a list of 70 possible deficits which, when summarised, can help to diagnose frailty and predict poor health outcomes. Items included the presence and severity of current diseases, ability in the activities of daily living, and physical and neurological signs from the clinical examinations. Whilst comprehensive, this method of working through 70 characteristics presents practical difficulties. For the purposes of our study, a quick, self-report

instrument exploring psychological, social and physical domains of frailty was required. Two tools were identified for potential use in the study, both semi-quantitative, self-report instruments, providing a score to reflect several domains of frailty and requiring no specialist staff or equipment. The first, Groningen's Frailty index (Steverink et al., 2001) is a 15-item questionnaire addressing 8 frailty indicators: mobility, physical fitness, vision, hearing, nutrition, morbidity, cognition and psychosocial factors. The participant is assigned a score between 0 and 15, with a score ≥ 4 indicative of moderate to severe frailty. The second was the Clinical Frailty Scale (CFS) and is described in section 2.6.1. The CFS was the final choice due to its ease of use, and reduced participant burden.

2.6.1 The Clinical Frailty Scale

The Clinical Frailty Scale (CFS) is a 7-point scale exploring physical, psychological and social domains of frailty to provide a global score ranging from 1 (very fit) to 7 (terminally ill) (Rockwood, 2005). The tool was designed to provide a straight-forward method of classifying frail individuals using simple clinical descriptors. The development study conducted in a large cohort of older adults (Rockwood, 2005) showed high levels of correlation ($r = 0.80$) with the more comprehensive but onerous FI, providing an effective measure of frailty with greater ease of use (Chong et al., 2017, Rockwood, 2005). The CFS combines comorbidity, disability and cognitive impairment to make an assessment of overall frailty, correlating with existing tools including for comorbidity (Cumulative Illness Rating Scale, $r=0.43$), functional ability (CSHA Function Score, $r=0.78$) and cognition (the 3MS measure, $r=0.58$). One criticism of the tool is its lower sensitivity to frail people without disability or cognitive impairment (Rockwood et al., 2007a) As the scale is subjective, requiring the researcher to make a judgement based on the participant over the duration of the assessment. The full CFS instrument can be found in appendix 9.3.4.

2.7 Sarcopenia

Sarcopenia as a syndrome had been described frequently in the literature, referring to age-associated, loss of muscle mass and strength with prevalence ranging from 1% to 30%

depending on the population, age and methods chosen to measure muscle mass and function (Cruz-Jentoft et al., 2014). Sarcopenia is a health concern due to its association with reduced function, dependency and reduced quality of life (Goodpaster et al., 2006). The European Working Group for Sarcopenia in Older People (EWGSOP) recommends using the presence of both low muscle mass and low muscle function (strength or performance) for the diagnosis of sarcopenia (Cruz-Jentoft et al., 2014). The relationship between age, muscle loss and reduced function is central to the definition of sarcopenia, and the international consensus statement emphasises the loss of muscle function in addition to mass in the diagnosis of the condition. The aetiology of sarcopenia is multifactorial, with inflammatory pathways, neuromuscular changes, hormones and environmental factors implicated (Clark and Manini, 2008). Pro-inflammatory cytokines, C-reactive protein (CRP) and tumour necrosis factor-alpha (TNF- α) are thought to create an environment of chronic, low-grade inflammation specific to older age and chronic disease (Schaap et al., 2006, Thomas, 2007, Thomson and Gordon, 2006). In a cohort of participants from the Framingham study (Payette et al., 2003), IL-6 levels were significantly higher in older participants compared to their younger counterparts, particularly where CRP was raised. Muscle mass is expected to reduce by 30% between the ages of 20 and 80 years, with infiltration of non-contractile tissue reducing function (Frontera et al., 2000, Goodpaster et al., 2001).

A number of techniques can be used to assess muscle mass including magnetic resonance imaging (MRI), dual energy x-ray absorptiometry (DEXA) and bioelectrical impedance (BI). Additionally two tools have been designed to assess sarcopenia; the Short Portable Sarcopenia Measure (SPSM) (Miller et al., 2009) and the SARC-F (Strength, Assistance with walking, Rise from a chair, Climb stairs, and Falls) (Malmstrom and Morley, 2013). Ease of use, availability and associated cost dictated the suitability of assessment measures. MRI DEXA are expensive and impractical, BI and the SPSM tool require the transport of equipment. Therefore the SARC-F tool was chosen.

2.7.1 The SARC-F tool

As a result of these practical limitations of MRI and DEXA, a simple questionnaire was created to allow the diagnosis of sarcopenia without costly and impractical measures (Malmstrom et al., 2016, Malmstrom and Morley, 2013). The SARC-F questionnaire was chosen for use in study 2 to provide insight in to the prevalence of sarcopenia in the study cohort. The SARC-F tool encompasses 5 domains: Strength, assistance with walking, rise from a chair, climbing stairs and falls. A score of 0 to 2 points is given for each domain to provide a total score between 0 and 10. The score is then dichotomised with a score ≥ 4 indicative of sarcopenia. The complete SARC-F instrument can be found in Appendix 9.3.5. Tested in the outpatient setting with 4000 community-dwelling Chinese adults, the SARC-F showed good construct validity against three definitions of sarcopenia (International Working Group on Sarcopenia, European Working Group on Sarcopenia in Older People, and the Asian working group for sarcopenia). The tool demonstrated good specificity (94.2–99.1%), but poor sensitivity (3.8–9.9%) depending on gender and reference definition (Bokhorst-de van der Schueren et al., 2014, Woo et al., 2014).

2.8 Functional measurements

A decline in physical function has the potential to reduce quality of life dramatically, associated with an increase in dependence, an increase in health and social care needs, and higher financial costs (Guralnik et al., 1994). Assessment of functional status is therefore an essential component of the examination of older people. Issues can be identified by asking questions about the ability to carry out tasks from basic self-care activities to essential every day chores, and through to more complex tasks. Alternatively, functional abilities can be examined using measures of physical performance, whereby the individual performs a set of objective tests designed to replicate ADLs. There are several ways to measure function including self-reported measures and physical performance tests.

2.8.1 Self-reported functional measures

Specific physical performance tests can be time consuming, require specialist resources and test only limited aspects of function. Self-reported measures can be quick, efficient and

inexpensive methods for data collection, but are also subjective and reliant on the individual to accurately assess their current level of function. Self-reported measures of function most commonly rely on Likert-scales to score ability to perform ADLs. Participants provide a score within a range, but this has no real meaning. Furthermore, as with all self-report methods, answers can be influenced by previous experience or attitude, or by social desirability. There is a tendency to avoid the extreme values at either end of a scale with a clustering around middle values (Lewin, 2005).

Some tools measuring self-reported function are disease-specific, others more generic instruments. As the study population was heterogeneous, a generic tool was required. Two of the most common generic, self-report functional measurement tools are the Barthel Index and the Katz index. The Barthel was developed in 1965 (Mahoney and Barthel, 1965) for use in the hospital setting. It includes a series of ten questions relating to an individual's performance in the dimensions of feeding, bathing, dressing, grooming, continence of bowels and bladder, transferring to and from the toilet, moving from chair to bed, walking on a level surface and going up and down stairs. It is designed to measure a person's function in the activities of daily living. It is quick and easy to perform, and can be administered during patient interviews (Hsieh et al., 2012). To gain baseline data or monitor change in function over time. Its validity and reliability has been checked (Wade and Collin, 1988) and agreement found when compared with more extensive tools such as the Functional Independence Measure (Fricke and Unsworth, 1997).

The Katz index of independence in activities of daily living was developed by Katz et al (Katz et al., 1963). It differs from the Barthel index in that there are only two possible outcomes: independent or dependent. Used frequently in clinical practice, predictive validity has been demonstrated in a review (Cabañero-Martínez et al., 2008), but few studies exploring other aspects of validity exist. Both tools may be considered too crude, with poor sensitivity to small changes and exhibiting ceiling effects in a community-dwelling population (Saito et al., 2017).

Study 2 comprised of community-dwelling individuals following a hospital admission, with a broad range of functional abilities. A tool was required to detect changes in function within both dependent and independent older adults and to examine pre-hospital function over the 3-6 months preceding the study, which could not be obtained using performance measures. A review (Coman and Richardson, 2006) found reasonable (moderate to large effect) correlation between performance-based, observational assessment and self-reported tools to evaluate functional status.

2.8.1.1 The modified Townsend activities of daily living scale

Study 2 used the Modified Townsend index (Bowling and Grundy, 1997). The tool is a modified version of the Townsend disability scale (Townsend, 1979) and includes a series of 19 questions pertaining to an individual's performance in the dimensions of mobility, personal care and domestic activities. It is simple and easy to administer and suitable for a community-dwelling population, using example activities with the intention that participants can relate to them. Each Likert-scale item provides six responses, scored from 0 and 5, with a total score between 0 and 95. Greater scores are indicative of dependence. For example, a score of 0 signals full independence and a score of 95 complete dependence with all tasks requiring significant assistance. The Index can be used to obtain baseline information and monitor change in function over time. The tool has been validated in two large cohorts of older people living in London and Essex, and found to have good validity and reliability (Bowling and Grundy, 1997). Internal reliability was measured using the split half method, and demonstrating good correlation ($r=0.78-0.91$). Acceptable to high levels of internal consistency were determined by Cronbach's alpha ($0.70-0.89$). In addition, the tool correlated well with dressing, stairs and walking as measured by Nottingham Health profile (Hunt et al., 1981) ($0.4-0.6$, $p<0.01$) and statements from the scale correlated highly with the physical health problems reported by participants and health service use suggesting construct validity (Bowling and Grundy, 1997). The questionnaire was delivered as part of each participant interview in study 2.

2.8.2 Performance and strength measures

The short physical performance battery (SPPB) (Guralnik et al., 2000) and the incremental shuttle walk test (ISWT) (Singh et al., 1992) were chosen as markers of exercise performance for study 1 (chapter 3). Exercise performance tests have been shown to accurately benchmark an individual's physical capability and to predict future outcomes, including morbidity and mortality (Cooper et al., 2010) and response to interventions such as pulmonary rehabilitation (Larsson et al., 2018), and have been validated in older people and people living with chronic disease such as those with COPD (Freiberger et al., 2012). Extrapulmonary manifestations, sarcopenia and skeletal muscle weakness are prevalent in older populations and those living with chronic disease (Maddocks et al., 2016), but outcome measures such as forced expiratory volumes fail to capture these global effects. Performance tests provide a way to measure the impact of disease on a person's physical ability to perform ADLs (Peruzza et al., 2003).

Both physical performance tests measure a specific component of physical function. Validated against laboratory tests, physical performance tests are simple field tests, allowing more practical outcome measures, minimising medical equipment and potentially reducing stress on the participant by using everyday measures.

Relevant to function, muscle strength is a valuable measure which can be used to diagnose muscle weakness and sarcopenia and predict future outcomes (Cruz-Jentoft et al., 2010). Muscle strength is key in the performance of ADLs in older adults (Goodpaster et al., 2006). Fixed dynamometry has been established as the preferred technique for the quantification of muscle power and strength with high levels of reliability and validity; however, isokinetic hand dynamometry is expensive and immobile restricting its' use (Mijnarends et al., 2013). Study 1 (chapter 3) took place in a research facility, allowing quadriceps maximal voluntary contraction (QMVC) to be measured. The second study (chapter 4) required a mobile tool to measure muscle strength in ward, clinic and homely settings, so handgrip dynamometry was chosen. The measure of handgrip is discussed further in section 2.8.2.4.

2.8.2.1 The short physical performance battery

The purpose of the short physical performance battery (SPPB) (Guralnik et al., 2000, Guralnik et al., 1995b, Guralnik et al., 1994) is to evaluate lower extremity function, and provide a marker of disease severity. Developed by the National Institute on Aging, the SPPB is frequently used to measure physical performance in studies of both aging and chronic disease to measure effect over time and the impact of interventions (Larsson et al., 2018). The test is quick and easy to run with non-specialist staff who have been trained to conduct the SPPB, requiring a chair, a stopwatch and a four metre flat surface only, it takes less than 5 minutes to complete. The assessment is made up of 3 individually validated performance tests; standing balance, usual gait speed and ability to stand from a chair. The SPPB has been used as a predictive tool for possible disability and can aid in the monitoring of function in older people. Due to the combination of tests, the SPPB can categorise level of function across the full spectrum of disability, overcoming floor and ceiling effects (Seeman et al., 1994). The scores range from 0 (worst performance) to 12 (best performance). The SPPB has been shown to have predictive validity showing a gradient of risk for disability, service use, nursing home admission and mortality (Guralnik et al., 1995a, Guralnik et al., 1994, Lester et al., 2019).

A recent cross-sectional study in patients with COPD provided evidence for the validity of the performance test battery as a tool to assess mobility (Bernabeu-Mora et al., 2015). Following analysis using receiver operating characteristic (ROC) curves, the authors showed good discrimination between those with and without mobility problems as assessed by self-report (area under the curve (AUC) SPPB score was 0.75 (95% confidence interval [CI]: 0.66–0.85). A cut point of 10 was shown to be the most accurate in classifying mobility problems.

The 3 tests that make up the SPPB (standing balance, usual gait speed and five times sit to stand) are described below. Each was completed in a research facility under the supervision of 1-2 investigators to ensure reliability.

- The standing balance test

The standing balance test is a set of three stances to measure static standing ability and balance at increasing levels of difficulty i.e. with narrowing base of support. Balance is an important component of function that, when lost, leads to falls and fall-related injuries (Berg et al., 1992).

To test standing balance participants were directed to maintain a side-by-side, semi-tandem, and tandem stance for 10 seconds each. The positions required for each stand are shown in figure 2.1. Each stand was demonstrated by the researcher prior to the test, along with strategies to aid balance. Stands were timed using a stopwatch (Fastime, Pyramid Technologies, Connecticut, U.S.) to the nearest hundredth of a second, starting when the participant was ready and finishing either when the task was complete and the participant had completed 10 seconds in the required position, or when the task was stopped as the participant moved their feet or reached out to hold on for balance. The researcher was able to assist the participant assuming the correct stand position, but did not provide any physical support to participants once the test had begun. Each test commenced when the start position had been adopted and the researcher said “ready, begin”. Participants who are unable to hold the stand for less than 10 seconds were given a score of 0 for this element of the SPPB. The participants successful in this first position (position held ≥ 10 seconds) were asked to complete a stand in the semi-tandem position. The semi-tandem position required the participant to maintain a position with one foot to the side of the bottom of the large toe on the other foot. If the participant moved their feet or reached out to hold on for balance timing was stopped. If the participant was successful in this second stand, they were instructed to participate in the final tandem stand, holding the position for 10 seconds. Again, if the participant moved their feet or reached out to hold on for balance the stopwatch was stopped and the time recorded. A score was awarded based on the participant’s ability to complete a test at each difficulty level. A score of 0 was given when the participant failed to complete any of the tests; 1 when the participant completed the standing test with feet together only; 2 when the participant completed the semi-tandem standing test but either could not attempt the tandem standing

test or held the stand for ≤ 2 seconds only; 3 when the participant held the tandem standing test from 3-9 seconds but did not complete the task; and 4 when the participant was able to hold the tandem standing test to completion.

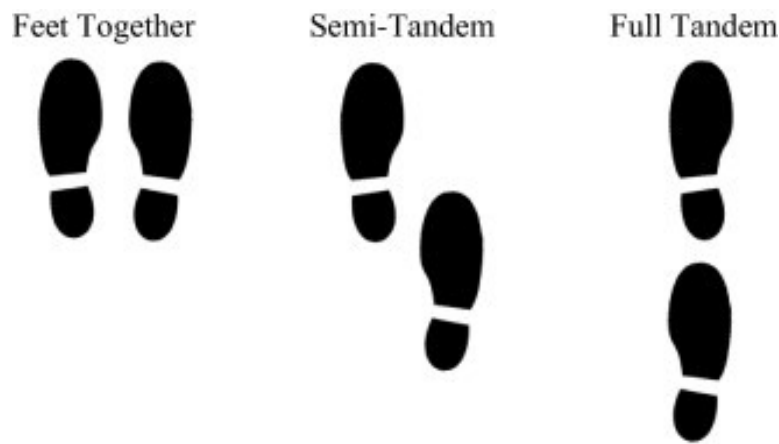


Figure 2.1: Feet positions for standing balance test (Eriksen et al., 2015)

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- **The 4-metre gait speed test**

The 4-metre gate speed test (4MGS) has been described as a marker of wellbeing in older adults (Cesari and Scarlata, 2014). It has been validated in community-dwelling older adults, and in a cohort of COPD patients (Kon et al., 2013). In a cohort of stable COPD patients, 4MGS was significantly correlated with measures of exercise capacity, health status and dyspnoea. Results were dichotomised with a 4MGS < 0.80 m/s considered sub-optimal and a 4MGS of ≥ 0.80 m/s, function intact (Muscaritoli et al., 2010). In addition, the 4MGS demonstrated excellent reliability, suggesting it did not incur a learning effect common in other performance measures. Gait speed over a relatively short distance of 4 metres was chosen for this study due to ease of use in community and home settings (Simonsick et al., 1997). It is now the most widely used distance in the literature making comparisons easier. The 4MGS is not a maximal walking test, but tests normal walking speed. It therefore has a ceiling effect in better functioning patients, but minimal floor effect in poorer functioning patients making it a useful component of a more comprehensive battery of tests.

A course 4 metres in length was pre-measured and marked out in a straight line with tape. Participants were asked to walk at their self-determined usual speed from one end of the course to the other by the researcher using standardised instructions: “I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the shops. Walk all the way past the other end of the tape before you stop. Ready...begin”. Participants were shown the course prior to the test commencing, but did not trial it themselves.

Assistive devices were used if required by the participant. The researcher timed the task using a stopwatch, starting when the participant removed their first foot from the floor and stopping when they crossed the line at the end of the course. Each participant was given two attempts with no recovery in between, the faster of two attempts was recorded in m/s. A score of 0-4 was assigned to the participant, 0 where the participant was unable to complete the course, 1-4 depending on the predetermined time taken to complete the course (Guralnik et al., 2000) (table 2.2).

Time (seconds)	Score
Incomplete	0
>8.70	1
6.21-8.70	2
4.82-6.20	3
<4.82	4

Table 2.2: Scoring system for 4-metre gait speed (Guralnik et al., 2000)

- The 5 times sit to stand test

The sit to stand chair rise assesses the participant’s leg strength without the use of their arms. It is considered the most biomechanically demanding of the performance measures (Riley et al., 1991), requiring a greater range of motion compared to gait or stair climbing exercises. As a result it has large floor effect, but is responsive to improvement and provides a good additional measure in more physically able participants as part of the SPPB.

The participant was asked to sit in a straight-backed chair with arms folded across their chest. Each was given a practice where the participant was asked to rise from the chair to a standing position, then return to the seat as quickly as possible without using their hands. If able, the participant then moved on to the test, repeating this procedure a total of five times. The researcher used a stopwatch (Fastime, Pyramid Technologies, Connecticut, U.S.) to time the test. The time was started when the participant was in the initial sitting position and instructed to start, to the end of the fifth stand. A score of 0-4 was assigned to the participant, 0 where the participant was unable to complete the course, a score of 1-4 relative to the predetermined quartile of time taken to complete the test (see table 2.3).

Time (seconds)	Score
Incomplete	0
16.70 – 60.00	1
13.70-16.69	2
11.20-13.69	3
< 11.20	4

Table 2.3: Scoring system for 5 times sit to stand test (Guralnik et al., 2000)

Participants completed a performance test battery consisting of the three tasks listed above: standing balance, 4-metre gait speed and the 5-sit-to-stand test in the order listed. The sum of the three components comprised the final SPPB score with a possible range from 0 to 12 (12 indicating the highest degree of lower extremity functioning). Norms have been developed to allow clinical comparisons to be drawn – these are explored in the chapter 3.

2.8.2.2 The Incremental Shuttle Walk test

The Incremental Shuttle Walk test (ISWT) was used in study 1 as a standardised walking assessment to examine function in patients with chronic respiratory problems (Singh et al., 1992). It has been well validated against VO₂max with a strong relationship with functional capacity (Singh et al., 1994). Commonly used as an outcome measure, it is a simple field test designed to mimic the lab treadmill test to measure maximal oxygen uptake (Roca et al., 1997), whereby the participant is asked to walk shuttles of a 10 metre course, with the final

measure expressed as distance walked. Contrary to self-pace measures such as the 6-minute walk test, the ISWT is externally paced. This creates a work rate, allowing accurate comparison between individuals and over time (Jones et al., 1987). It is also progressive, differentiating between individuals with a wide spectrum of ability levels, and in the development study (Singh et al., 1992) the researchers demonstrated a graded cardiovascular response.

An ISWT course was set up with two cones set in a straight line, 10 metres apart and inset 0.5 metres from each end. Participants were instructed to walk between the two cones while an audio tape was played to provide pacing. The audio consisted of single bleep sounds at regular intervals. Additionally, every 60 seconds, a triple-bleep sound signalled an increase in pace. The initial pace was set at 20 seconds per shuttle, meaning the participant had to walk at a speed of 0.5m/s to complete the first three shuttles within 60 seconds. After this point, a triple bleep signalled that an increase in pace was required. Completion of a shuttle was judged by the researcher. The researcher walked with the participant for the first three shuttles to help set pace, but then withdrew, providing no encouragement to promote continuity. The test was symptom limited and was halted when either 1) the patient failed to complete a shuttle (e.g. was not at the correct end of the course when the bleep signalled time), 2) shortness of breath prevented the participant from continuing, or 3) the heart rate of the participant reached 85% of their predicted maximum using the formula $\geq(210-0.65 \times \text{age})$. The ISWT was performed on two occasions 30 minutes apart and the best distance recorded in metres to the nearest completed length (Singh et al., 1992).

2.8.2.3 Quadriceps maximal voluntary contraction

The quadriceps muscle is a large muscle fundamental for many functional activities using the lower extremities. Quadriceps maximal voluntary contraction (QMVC) is a measure of maximal muscle contraction (Swallow et al., 2007). Used routinely in research; it provides a measure of lower limb strength and is associated with the sit-to-stand movement, and is important for ADLs such as getting up and down from a chair, up and down stairs and in and out of a bath

(Canavan et al., 2015). Weakness of the quadriceps muscle has been associated with sarcopenia, reduced exercise tolerance, and increased mortality (Gosselink et al., 1996, Jones et al., 2015, Swallow et al., 2007).

QMVC was measured for study 1 only. QMVC measurement was taken in the strongest leg to achieve an optimal result. Participants were seated in a purpose-built chair with their torso secured with adjustable belts and ankle connected to a strain gauge (Edwards et al., 1977). The participant's arms were folded out of the way. Sitting with legs relaxed down to the floor, the participant was directed to flex the knees to a 90-degree angle, holding for several seconds each time. The participant was first asked to perform four contractions at approximately 50% effort and four at 75% effort by way of a warm up and practice prior to the test. Following a minimum rest period of 20 seconds, they were then instructed to perform six attempts at maximal effort. Of the six repetitions conducted, the greatest attempt over 1 second was recorded as the maximal force (kg). In order to compare the QMVC measurement to minimal clinically important difference (MCID) cut-offs, QMVC was normalized to height squared ($QMVC/height^2$) (Canavan et al., 2015). Cut off points of 8.30 and 5.99 kg/m² were used to describe failure to stand (Canavan et al., 2015).

2.8.2.4 Hand grip dynamometry

Handgrip dynamometry was performed in both studies 1 and 2. Handgrip strength (HGS), a measure of the maximum voluntary contraction force of the hand, is valid, reliable, and practical (Guerra and Amaral, 2009, Massy-Westropp et al., 2004). In addition, handheld dynamometers have been developed and validated in numerous cohorts including community dwelling populations, older adults and patients with COPD. In one study (Bohannon, 1998), handgrip dynamometry acted as a valid proxy measure of upper extremity strength in older adults, showing good construct validity ($r=0.778-0.848$). In a reliability study (Schaubert and Bohannon, 2005), Intraclass correlation coefficient (ICC) was reported at 0.94-0.98 suggesting excellent reliability of hand grip strength using a Jamar hydraulic dynamometer. However, the study was small and did not reach statistical power. The American Society of Hand Therapists

describes specific procedures for the assessment of grip strength using the Jamar hydraulic dynamometer. This instrument is the recommended and preferred tool, considered to be the gold standard handheld for grip strength. Studies comparing brands of hydraulic dynamometer demonstrated concurrent validity, including between Jamar and Baseline brands (Mathiowetz, 1990, Mathiowetz et al., 2000). Inter-instrument reliability was tested using ICC, demonstrating excellent inter-instrument ICC 0.95 and 0.94 in male and female participants respectively (Watkins and Portney, 2009). A small difference was observed between mean HGS scores between the two instruments in females, but this was considered clinically insignificant at <5.6% standard error of measurement for HGS (Mathiowetz et al., 2000). As the majority of studies have used the hydraulic dynamometer and several datasets exist with which to draw comparisons, this was chosen as the instrument of choice. As the choice of brand was not clinically important, the Baseline dynamometer was chosen due to its cost-effectiveness

Handgrip dynamometry using a hydraulic dynamometer is a valid bedside measure, frequently used as a measure of upper body strength (Jenkins et al., 2014). HGS is a quantitative measure, commonly used in studies due to its ease and associations with morbidity and mortality (Kilgour et al., 2013), with suboptimal grip strength predictive of disability and early mortality (Bohannon, 2008). Grip strength has shown consistent relationships with gender and age, with males and younger adults demonstrating stronger grip strength than females and older adults.

Handgrip strength dynamometry was performed using the Baseline isometric dynamometer (Fabrication Enterprises, Inc., Irvington, NY). Prior to testing, any contraindications to using the dynamometer were checked with the participant, for example paralysis or injury of the hand or wrist. Where the participant was unable to use their dominant hand, the usability of the other hand was assessed. The subject was directed to sit upright in a straight-backed chair with their feet flat on the floor. Where this was not possible, notes were made in the data collection tool. The handle of the dynamometer was adjusted so that the back rested in the heel of the palm and the handle rested in the middle joint of the four fingers of the participant.

The participant was asked to hold their forearm at a right angle and to exert maximal grip force. Participants were directed not to lean or rest their arm. Where this was not possible it was documented on the case report form. Three contractions were performed, the highest of which was used for the analysis. Values are expressed as force (kg).

2.9 Measures of food intake

Successful assessment of undernutrition involves the exploration of body composition and dietary adequacy. Several methods have been used to measure dietary intake, collecting either observational or self-reported data. Evidence to support observed assessment is generally limited to institutions such as hospital and schools due to the practical and resource issues with observing participants in the community setting (De Vries et al., 2009). Self-report approaches are by far the most commonly used source of dietary data, however the limitations are widely acknowledged (Schoeller, 1995).

The three main strategies for collecting self-reported data are food frequency questionnaires (FFQs), food diaries and 24-hour recall (24HR). Food frequency methods include a list of foods where the participant identifies the frequency with which they consume specified food and beverages. Details regarding the portion size and preparation of food can be limited. In addition, FFQs can be complex, promoting repetition and overestimation where composite foods are eaten (Coulston et al., 2017). Moreover, using a finite list of foods may exclude key foods. Dietary records and recalls are not restricted by this finite list, their open nature allowing less common and cultural foods to be included. Dietary records are used to track foods and beverages at the time of consumption. The participant is provided with a pro forma and asked to log everything consumed over a specified period. To gain accurate records, participants need to receive sufficient instruction in portion sizes, preparation methods and recipes. However, the process does place a high burden on the participant as they must remember to complete extensive records at the time of consumption, and this may influence their choice of what they eat and drink (Black et al., 1993). Studies show this approach may be accurate for up to four days, but interest and motivation is lost after this time and the burden becomes high

(Gersovitz et al., 1978). In addition, using food records requires literacy skills and the physical ability to read and write. Literacy issues can be avoided by using trained investigators to perform 24HR. In addition, as the recall is performed retrospectively it should not influence food choice prior to interview, but relies on the ability of the participant to accurately recall their food and drink. In all self-report approaches omission of foods is common, with underreporting of 4-37% in food records, 3-34% in 24HR and 12-23% in multiple pass 24HR methods respectively (Carter et al., 1981, Karvetti and Knuts, 1985, Prentice et al., 2011, Subar et al., 2003) when compared to doubly-labelled water and observational approaches.

This discrepancy may occur purely as a result of memory, but has been associated with age, gender, intelligence and mood (Campbell and Dodds, 1967). Social desirability is also a factor, and may lead to reactivity bias with changes in the food type and size consumed (Hebert et al., 1995). Studies have repeatedly shown that people with lower intakes tend to over-report, where as those with higher than average intakes under-report (Madden et al., 1976). New technologies have been utilised to increase the accuracy of existing methods of dietary data collection, for example using cameras (Arab and Winter, 2010), but these had not been explored in older populations until the development of the Novel Assessment of Nutrition and Ageing (NANA) (Timon et al., 2015). NANA works as a platform to record food and fluid intake using a tablet with a webcam, and offers prompts to promote compliance. However, the validation study found no increased benefit of using the NANA. Research has shown that older adults are less accepting of technology than younger adults (Smith, 2014), therefore researchers face barriers in using technology to measure food intake in older populations (Fletcher and Jensen, 2015).

Several studies have explored different dietary assessment method in older people. One study comparing three dietary assessment methods to total energy expenditure (TEE) measured using the doubly-labelled water technique in a sample of older (n=10) and younger healthy women (n=10) (Sawaya et al., 1996). The three dietary assessment methods, weighed food intake, 24HR and FFQ, showed that reported energy intake was similar between cohorts of

older and younger adults, but all energy intakes were significantly lower than measured TEE, suggestive of under-reporting. Another study (McAvay and Rodin, 1988) examined the variability of dietary data obtained from the 24HR of older adults (n=220) divided into two age categories: (62-72 years and 73+ years). The analysis found no difference in reported between the age groups (McAvay and Rodin, 1988). Other studies too have not found age-related differences (Lührmann et al., 2001). In their study, Shahar et al highlighted that one of the challenges in an elderly population is poor intake. After correlating weight loss with intake, 30% of participants previously classified as under-reporters (43% of total) were reclassified as under-eaters (Shahar et al., 2010). The study design, population characteristics and availability of resources, including time, money and personnel, were all taken in to account and 24HR was decided as the tool of choice for this study (De Vries et al., 2009), using a three pass technique to optimise accuracy.

2.9.1 Multiple-pass 24-hour recall

The multiple-pass technique for 24HR is widely used, including in large national studies including NHANES III (Briefel et al., 1995). Designed to reduce underreporting, the multiple-pass method was devised by the U.S. Department of Agriculture (Raper et al., 2004). The more detailed 24HR design uses probing questions and memory cues to increase estimates of macronutrient intake (Campbell and Dodds, 1967, Krall et al., 1988) (see Appendix 9.4.1). Practical and easy to administer, the structured interview is complete in around 20-25 minutes per participant (Johnson et al., 1996). A study (Johnson et al., 1996) compared multiple-pass 24HR with the gold-standard comparison measurement doubly labelled water. The method accurately assessed energy expenditure within the cohort as a whole, however individual differences were noted with limits of agreement ranging from -1102 to 807 kcal/day excluding its accuracy as a measure for changes in individual participants. This suggests that 24HR is an effective method for capturing average consumption in cohort studies, but should not be used to measure intake on an individual level. To establish the mean nutrient intake of a population, a single 24HR from a sample population is considered adequate. However, multiple or 'repeat' recalls where the same 24HR protocol is applied over separate occasions

has been recommended to increase accuracy. In one study four 24-hour recalls were used to accurately capture nutrient intake (Holmes et al., 2008). The data requirement can vary from three days 24HR to accurately measure macronutrients, compared to several weeks for micronutrient intake (Forouhi et al., 2018). In addition, the interval between multiple recalls should be adapted to suit the study aim, for example several 24HRs spread through the year are likely to give a better indication of mean nutrient intake than one single recall.

Training on protocols is important to ensure consistency is maintained throughout the process of data collection. Collecting accurate and reliable data requires that every respondent hears exactly the same questions read in exactly the same way with a neutral, professional tone. Even small changes in the way questions are asked may affect the way a respondent answers and therefore affect results. To collect information on the participant's food and fluid intake over the preceding 24 hours, the participant was informed of the purpose of the recall to collect information about everything consumed in the last 24 hours, from first thing in the morning until the time they went to bed (see appendix 9.4.1). The first pass of the 24HR was used to gain general information about the food and drinks consumed in list format. The second pass was used to ask about forgotten foods and the third for time and occasion, the fourth pass included a detailed recount of the food items in the quick list, including portion size and cooking methods, use of condiments, and brand of foods where appropriate. The final pass was used to probe for anything else consumed. A photographic resource (Cheyette and Balolia, 2010) was used with the participant to clarify the quantities of food eaten. In a study by Turconi et al (2005) portion-size photographs presented to the participant to aid identification of their portion size were associated with the actual portion consumed independent of age, gender and BMI (Turconi et al., 2005). Similarly, a study (Howat et al., 1994) found improvement in the accuracy of data collection with the use of food photographs. Estimating energy intake using food photography to portion sizes were closer to the median intakes as assessed by 24-hour recalls (Ocke et al., 1997).

Following the 24HR, data was analysed using Dietplan 7 software (Forrestfield Software Limited, Horsham, UK). It was fundamental that all members of the research team used the same procedure to enter and analyse participant dietary data to ensure consistency and reliability, therefore a standard operating procedure (SOP) was followed, training was provided and inter and intra-reliability checks were carried out throughout the analysis period. The procedure is outlined in more detail in appendix 9.4.2 adapted from diet record coding procedures and cross-sectional evaluation of dietary energy intake reporting in The Airwave Health Monitoring Study (Gibson et al., 2017).

2.10 Data entry and analysis

Each study utilised different methods of collating and analysing data, each of which will be discussed in the relevant study chapters. In addition, data management themes common to both studies are discussed below. Good data management is important in all aspects of processing the data, working with database systems to collect, clean and organise study data.

2.10.1 Data Collection

For study 1, data was collected by the research team and entered directly in to a database. For study 2, a case report form was designed to record the questionnaire and other data collected during the assessments. The order of the questionnaires and other measurements was pre-determined to provide structure to the assessment and this was used by all researchers on the project to ensure consistency.

2.10.2 Data entry

Data for study 1 were managed using an Excel database (Excel for windows 2013, Microsoft, Minnesota, USA). For study 2, data were entered into a purpose built Access database (Access for windows 2013, Microsoft, Minnesota, USA) for storage. Following training, a database was designed with feedback from the wider research team. During the design of the database, restriction settings were applied to tables and forms to prevent incorrect data from being entered. For example, the programme allowed me to set validation rules limiting the range of values from 0-5 in Likert scales, or permitting a dichotomous answer only (e.g.

yes/no) to improve data quality and reliability. In addition, labels and titles were chosen for the data which could be directly transferred in to a SPSS database. These processes helped to minimise errors upon data entry. Each case report form was examined for errors by myself prior to manual entry in to the database, and again following entry for quality checking.

For all analyses, the dataset was exported to SPSS Version 24 (IBM Corp, 2015) and summary data produced and checked to ensure all variables were present and correct. The range for each variable was checked to confirm the values were within the specified range or human norms. Outliers were examined and rechecked with the original case report form if required. If the mistake was clearly due to human error, it was corrected. Where the value could not be verified, but was out with the clear scale range, it was omitted and treated as missing. Missing data was labelled in SPSS to identify it.

Variables that had been calculated manually were re-calculated using formulae to ensure no error had been made, for example BMI, MUST score, sum totals of self-reported measures etc. New variables were also created, for example, change in weight over time. Box and whisker plots, scatter plots and histograms were then created to examine residuals for outliers and explore the data distribution.

2.10.3 Data analysis

2.10.3.1 Statistical analysis

Assumptions regarding normality and variance homogeneity were assessed using the Shapiro-Wilk test and by visual inspection of normality plots and histograms. Where the data was distributed normally, it is presented using the mean and standard deviation (SD). Non-normally distributed data is presented using the median and interquartile range (IQR). Between-group comparisons to compare the two nutritional risk categories (low risk and medium/high risk) were made using Mann-Whitney U test, student's T test, and Chi-squared test depending on data type and distribution. Further details of specific analyses are given in the relevant chapters.

Chapter 3: Nutritional risk in Chronic Obstructive Pulmonary Disease: Prevalence and phenotypic characteristics

3.1 Introduction

Poor nutritional status is commonly cited as an extrapulmonary manifestation of chronic obstructive pulmonary disease (COPD) (Schols et al., 1993a). Undernutrition, defined as the imbalance between nutrient intake and nutritional requirements which leads to metabolic change, reduced body mass and impaired function (Kinosian and Jeejeebhoy, 1995), has been reported to be present in as many as 45% of COPD patients (Stratton et al., 2003).

3.1.1 Aetiology of chronic obstructive pulmonary disease

Global epidemiological data shows that the prevalence of COPD is 9-10% in those over 40 years of age (Vestbo et al., 2013). COPD occurs primarily as a consequence of cigarette smoking, but can be a result of air pollution (Bloemsma et al., 2016, Song et al., 2014) and aging (Jarad, 2011). In the first example, smoking or pollutants irritate the lungs leading to inflammation. Persistent inflammation induces changes in the pulmonary vasculature, over-inflation of the lungs, smooth muscle contraction and oedema result in fibrosis which in turn limits airflow. Compensatory mechanisms include increase in cardiac output leading to hypertension. Pulmonary hypertension may lead to hepatomegaly.

Age associated changes may result in a similar loss of elasticity. The lungs operate optimally from age 20-35 years, deteriorating thereafter (Sharma and Goodwin, 2006). Determining an exact rate is not possible, but longitudinal studies suggest a nonlinear decline with increasing age, and show a more rapid decline after 70 years (Burrows et al., 1986, Ware et al., 1990). Diaphragm strength reduces (Tolep et al., 1995) and hyperinflation occurs (Gillooly and Lamb, 1993). Low grade inflammation as a condition of aging causes damage to the lung over time, reducing the number of alveoli available for gas exchange. It is this chronic inflammation which has been implicated in sarcopenia and which characterises COPD as a disease of advanced aging (Mercado et al., 2015). Aging is driven by mechanistic changes in important physiological processes, adversely affecting function and increasing risk of death. Patients

with COPD exhibit telomere attrition, reduced tissue repair and increased protein expression indicative of DNA damage and cell cycle termination (Ito and Barnes, 2009).

3.1.2 Treatment of COPD

A recent Cochrane review showed reduced hospital readmission, improvements in exercise capacity and in quality of life in people with COPD following pulmonary rehabilitation (PR) (Puhan et al., 2016). Of eight studies exploring readmission in COPD patients (n=810), meta-analysis demonstrated an overall reduction in readmission in favour of PR (OR 0.44, 95% CI 0.21 to 0.91). Evidence was of moderate quality with marked heterogeneity between studies due to variance in PR programmes ($I^2 = 77\%$). More extensive PR programmes were associated with positive effects. Exercise capacity was measured by performance tests, with high quality evidence indicating an improvement in shuttle walk distance (mean difference 48 metres 95% CI -1 to 97). In addition, this difference was above the minimum change considered clinically important (MCID) (Jaeschke et al., 1989). High levels of heterogeneity were apparent, with smaller effects seen in trials at low risk of bias. Again, more extensive PR programmes were associated with better outcomes. PR also appeared to have a positive effect on quality of life, with eight studies using the SGRQ (n=846) all reporting a statistically significant effect on total score above the MCID (mean difference -7.80, 95% CI -12.12 to -3.47) (Schünemann et al., 2003). More intensive PR appeared to show an enhanced effect on quality of life.

Data exploring adherence to PR is lacking. Several characteristics have been associated with non-completion of PR, including smoking, depression, previous hospital admission, higher Medical Research Council (MRC) dyspnoea score and longer commute to PR centre (Sabit et al., 2008). Low BMI, age, gender, co-morbidity and quality of life at baseline did not influence completion of a PR programme (Sabit et al., 2008).

3.1.3 Undernutrition and COPD

The majority of studies examining undernutrition in people with COPD have focussed on hospital inpatients, with few studies exploring undernutrition in outpatients. One landmark

paper described the prevalence of nutritional depletion as 25% in outpatients with moderate airflow obstruction, rising to 40-50% in patients when severe disease was present (Schols et al., 1993b). Another more recent study, and one of the few to use the Malnutrition Universal Screening Tool (MUST), classified 22% of participants to be at nutritional risk (Collins et al., 2016). As discussed in section 1.7, multiple factors contribute to a poor nutritional status including reduced appetite, frequent hospital admissions and depression. Age is also a key factor in undernutrition, with the majority of 'at risk' patients in the older population secondary to physiological processes that occur naturally over time. Similarly, there is evidence for a close relationship between aging and chronic inflammatory disease. Conditions such as cardiovascular disease, Alzheimer's disease and COPD are characterised by chronic, low grade inflammation (Shivshankar et al., 2011, Toba et al., 2015). This inflammation is in turn influenced by age-related changes in hormone levels and metabolism, and higher frequency of cell death (Fontana et al., 2013). Infection is more common in advancing age, for example incidence and severity of influenza and pneumonia are higher in older adults (Shivshankar et al., 2011).

The causes of undernutrition in the COPD population are still not fully understood. Some weight-losing COPD patients have a dietary intake equal to if not higher than their counterparts without COPD, and therefore weight loss has been attributed to hypermetabolism (Hunter et al., 1981). Hypermetabolism is common in COPD, with evidence indicating that resting energy expenditure (REE) may be 20% higher in people with COPD compared to healthy individuals. One study used indirect calorimetry to explore BMR in 16 patients with stable COPD over a 24-hour period (Hugli et al., 1996), demonstrating a BMR of $120 \pm 7\%$ in COPD patients versus $108 \pm 12\%$ in the control group ($p < 0.01$), despite a higher fat-free mass (FFM) in the controls. The same study (Hugli et al., 1996) showed no significant difference in energy intake between individuals with and without COPD. However, the authors showed that energy intake was significantly higher than expenditure in the participants with COPD compared to their healthy counterparts, in a controlled environment for indirect calorimetry. It seemed that participants

compensated for higher BMR with a reduction in physical activity levels and related energy expenditure. This was illustrated in a study (Baarends et al., 1997) using the doubly labelled water technique to compare participants with stable COPD and higher REE to those with stable COPD and lower REE. Results showed no difference in total energy expenditure (Baarends et al., 1997). This result has been replicated in other studies of participants with COPD (Bossenbroek et al., 2011, Vorrink et al., 2011, Watz et al., 2009).

In addition to lower physical activity levels, there is some evidence that the quality of diet in individuals with COPD is lower than in healthy controls. Studies have demonstrated higher saturated fat and cholesterol, low fibre and insufficient fruit and vegetable intakes (Grönberg et al., 2005, Rodríguez-Rodríguez et al., 2016, van den Borst et al., 2012). Vitamin A, and C were lower than in healthy controls, and below recommended levels (Agler et al., 2011, Sargeant et al., 2000, Van de Bool et al., 2014). Protein intakes were also suboptimal (Cochrane and Afolabi, 2004, Grönberg et al., 2005) due to low intakes of high quality protein such as meat and fish. This reduced intake was attributed to both chewing ability and cost (Grönberg et al., 2005). This is interesting considering a high-carbohydrate intake may increase V_{CO_2} and reduce oxygen uptake in people with COPD (Kuo et al., 1993).

Nonetheless, weight-losing individuals with COPD may have a lower energy intake when compared to weight-stable controls (Laudisio et al., 2016, Schols et al., 1991). The mechanisms contributing to this suboptimal intake include anorexia due to reduced appetite (Creutzberg et al., 2000), depression (Grönberg et al., 2005), and dyspnoea (Schols et al., 1991). Hypoxaemia in COPD patients has been shown to increase dyspnoea during a meal, deterring sufferers from eating (Schols et al., 1991). Medications have been shown to influence appetite, and several bronchodilators including ipratropium, fluticasone and salmetrol, have been associated with bitter taste and dry mouth (Douglass and Heckman, 2010). In one study (Chapman-Novakofski et al., 1999), underweight individuals with COPD reported a reduced sensitivity to bitter taste than their counterparts with COPD, but of normal weight ($p=0.016$). The mean FEV% predicted was considerably higher in the underweight

group suggesting greater disease severity could actually be causing the changes in taste. However, other confounding factors such as smoking were not considered. One study (Koehler et al., 2007) used a visual analogue scale to measure appetite in 103 patients with COPD (age 59.8 ± 1.3 years, FEV1 $38.3 \pm 1.7\%$). The authors demonstrated a 36% reduction in appetite when individuals with COPD were compared to healthy controls ($p = 0.001$). Individuals with COPD and cachexia had the lowest appetite scores (-44% , $p < 0.001$) (Koehler et al., 2007). Another study used questionnaire and interview data to explore the reasons behind poor food intake in stable COPD patients (Grönberg et al., 2005). The most common reason was anorexia, but interestingly fear of weight gain and slimming were also raised in fourteen normal weight and four underweight female participants. This subjective information can be used in conjunction with data from trials exploring hormonal appetite regulation, a process which is affected in patients with COPD (Raguso and Luthy, 2011). Leptin, ghrelin, and adenosine monophosphate activated protein kinase peptides play a role in appetite, helping to control energy balance, but higher levels of circulating leptin have been associated with increased systemic inflammation and consequential reduced food intake in COPD patients (Schols et al., 1999). In addition, the efficiency of insulin and growth hormone appears to be diminished (Raguso and Luthy, 2011).

The consequences of disease-related undernutrition are discussed in detail in section 1. COPD associated changes in fat-free mass are at the root of declines in functional ability and the onset of disability. Initial problems affect the respiratory system, but progression of the disease may cause multi-systemic dysfunction affecting circulatory and neurological systems, skeletal muscle and bones (Barnes and Celli, 2009) and lead to functional limitations, intensifying symptoms of breathlessness and reducing performance in ADLs (Okubadejo et al., 1997, Pinto-Plata et al., 2007). The adverse effects of undernutrition are seen in whole-body wasting, inclusive of ventilatory and peripheral muscle, and correcting nutritional deficits has been shown to improve the strength and endurance of both respiratory and skeletal muscle in mobile COPD patients (Efthimiou et al., 1988).

Exacerbations of COPD promote reductions in muscle mass and function known as sarcopenia (Spruit et al., 2003). Sarcopenia affects 15% of patients with stable COPD and impairs exercise capacity, functional performance and health status, but was found not to limit response to pulmonary rehabilitation (Jones et al., 2015). In undernourished individuals with COPD, lean body mass, muscle mass and bone mineral density are very likely to be reduced (Graat-Verboom et al., 2009), correlating with an increased risk of physical disability, poor health status and poor prognosis, independent of the stage of the disease (Landbo et al., 1999, Schols et al., 1998). Undernutrition is associated with reduced immune function and higher incidence of infection (Norman et al., 2008b, Wilson et al., 1989).

Three systematic reviews have demonstrated that dietary intervention, including nutritional supplementation, is effective in improving nutritional status, resulting in weight gain in individuals with COPD - particularly in the presence of undernutrition, and consequently respiratory function (Baldwin and Weekes, 2012, Collins et al., 2013, Ferreira et al., 2012). To explore the impact of nutritional support on pulmonary function, FEV1, maximal inspiratory (PI max) and expiratory (PE max) pressures were studied (Collins et al., 2013). In 10 studies, nutritional intervention was not associated with any improvement in FEV1. However, improvements in PE max were seen using meta-analysis of 4 studies (+13.06 SE 5.81 cm H₂O, $p=0.025$), with all four studies favouring the intervention group.

The impact of nutritional intervention on function was measured in six studies, using walking as a measure of functional performance to show low quality evidence for improvement from baseline of walk distance (Collins et al., 2013). Of the six, three demonstrated a beneficial effect of the intervention (DeLetter, 1991, Efthimiou et al., 1988, Rogers et al., 1992, Steiner et al., 2003) with participants improving by an average of 12-28% compared to 0-1% ($p<0.05$) in the first three studies (DeLetter, 1991, Efthimiou et al., 1988, Rogers et al., 1992). In the fourth study (Steiner et al., 2003) participants walked an additional 60.0 m and 42.6m (29% and 19%) in the intervention group and control group respectively. Whilst this was an improvement for both groups, the between-group difference was not significant ($p=0.182$).

Similarly, Schols et al. demonstrated improvement in walking distance in individuals with COPD undergoing pulmonary rehabilitation, comparing undernourished versus nourished participants to show no significant differences between groups (29% versus 24% respectively). The final study using (Otte et al., 1989) reported no significant changes in the 12-minute walking distance in either group – interestingly this was one of the highest quality studies identified in a systematic review (Collins et al., 2013). Performance in the 6MWT and 12MWT is associated with maximum exercise capacity and mortality. The MCID or “the smallest difference in score that patients perceive to be beneficial” (Jaeschke et al., 1989) is 26 metres in severe COPD (Puhan et al., 2011). This figure was ascertained from a study of 372 respiratory patients undergoing pulmonary rehabilitation. The mean difference following a period of rehabilitation, independent of baseline score, was 65.9 metres (CI: 58.9-72.9) with a mean improvement in exercise tolerance to feel ‘slightly better’ and ‘better’ at 47.5 metres (CI: 38.6-56.5) and 78.7 metres (CI 70.5-86.9) respectively (Puhan et al., 2011). In order to explore improvement, the researchers used a 5-point Likert scale which had to be answered retrospectively.

Four studies and a total of 156 COPD patients were used to examine the effect of oral nutritional supplements on peripheral muscle strength, using HGS as a measure of strength (Efthimiou et al., 1988, Rogers et al., 1992, Steiner et al., 2003, Weekes et al., 2009). Interventions lasted between 7 and 13 weeks, excluding the study by Weekes et al. (2009) which was 6 months in duration. Mean change in HGS from baseline was +1.41 SE 0.66 kg, $p=0.032$ (range 0.3–5.2 kg (1.3–18.5%) in favour of the intervention group).

Quality of life was explored using a validated tool in three studies (Steiner et al., 2003) (van Wetering et al., 2010, Weekes et al., 2009). Two studies ($n=67$) using the SGRQ showed statistically and clinically significant differences in quality of life following intervention with oral nutritional supplements (mean difference -6.55; 95% CI -11.7 to -1.41) (van Wetering et al., 2010, Weekes et al., 2009). One of the studies using SGRQ reported a significant 18% improvement in total score in favour of the intervention group (Weekes et al., 2009); the

second (van Wetering et al., 2010), an improvement of 4.06 (1.39), $p=0.004$. An additional study (Steiner et al., 2003) described an improvement in health-related quality of life assessed using the self-reported Chronic Respiratory Questionnaire) in both the control and intervention groups, but found no between-group difference (Steiner et al., 2003).

Nutritional screening using a validated screening tool is recommended in COPD patients with the aim of identifying at risk individuals and initiating nutritional treatment, with evidence that nutritional support can prevent or help to reverse the problems associated with undernutrition (Thorsdottir et al., 2001). The Malnutrition Universal Screening Tool (MUST) is the most commonly used screening tools in the UK (Elia and BAPEN, 2000). Guidelines written by the European Society for Clinical Nutrition and Metabolism (ESPEN) advise the use of MUST in outpatients (Kondrup, 2003a). The British Thoracic Society (BTS) recommend that a pulmonary rehabilitation programme provides opportunity to screen for nutritional issues (Bolton et al., 2013) and the National Institute of Health and Care excellence (NICE) advises that BMI is calculated in all patients with COPD using a validated screening tool such as 'MUST' (NICE, 2010).

Much of the focus within the COPD population has focussed on inpatients, there is limited data exploring risk of undernutrition in outpatients with stable COPD and the impact of this nutritional risk. It is important to understand not only the prevalence of stable COPD in this population, but the characteristics of individuals with stable COPD at nutritional risk and the implications of their nutritional status when entering in to a programme of pulmonary rehabilitation.

3.2 Aims, research question and objectives

This study aimed to characterise nutritional risk in a sample of outpatients with COPD and examine the impact of undernutrition risk on completion of a programme of pulmonary rehabilitation.

This study set out to answer the following research questions:

What is the prevalence of undernutrition risk in community-dwelling people with stable COPD.

What factors are associated with undernutrition in this population and what are the phenotypic characteristics of patients at risk of undernutrition.

This study set the following objectives:

To analyse the data of 1639 participants following assessment for PR to examine

- i. Prevalence of undernutrition
- ii. The characteristics associated with low, medium and high risk of undernutrition

To assess the rate of completion of PR in groups at low, medium and high risk of undernutrition and compare the characteristics of participants who completed PR to those who did not.

3.3 Methods

This was a cross-sectional study of stable outpatients with COPD recruited without further selection from pulmonary rehabilitation assessment clinics at Harefield Hospital (London, UK) between August 2009 and January 2015. The study had ethical approval (West London (11/H0707/2) and London Camberwell St Giles (11/LO/1780) research ethics committees), and all patients gave informed consent.

Inclusion criteria included a diagnosis of COPD according to the global initiative for chronic obstructive lung disease (GOLD) guidelines (Vestbo et al., 2013), attending pulmonary rehabilitation assessment clinic at Harefield Hospital and stable clinical state (no change in all usual medication in the last 6 weeks). Referral for pulmonary rehabilitation (PR) required a walking ability equivalent to 5 metres or more and a functional deficit due to dyspnoea. It was offered on the condition that no supervised PR had been provided in the past 12 months. The PR programme consisted of sixteen supervised exercise and eight unsupervised sessions (two supervised and one home session per week for eight weeks). Supervised sessions included one hour of exercise and one hour of education. Completion of PR was defined attendance at a minimum of eight supervised sessions.

All assessments were held at Harefield Hospital, organised and conducted by a trained research team. The baseline assessment was conducted following the informed consent procedure and prior to participants commencing PR. Following the completion of PR, participants were invited to attend a follow-up assessment. Follow-up assessments were arranged as close to PR completion as possible, but had no maximum timeframe.

3.3.1 Assessments

All participants were assessed for nutritional risk using the MUST prior to starting a programme of pulmonary rehabilitation (Elia, 2003b) (see section 2.3.1). Height (m) without shoes was measured using a stadiometer and weight (kg) by standardised scales. Body mass index (BMI) was calculated as weight (kg) /height (m). Those patients identified to be at nutritional risk were provided with written dietary information (MUST score ≥ 1) or referred for dietetic support (MUST score ≥ 2). Fat-free mass (FFM), was measured using bioelectrical impedance (Bodystat 1500, Bodystat Ltd., Isle of Man, U.K.) as described elsewhere (Steiner et al., 2002) and fat-free mass index (FFMI) calculated as $\text{FFM}/\text{height}^2$ (VanItallie et al., 1990).

The following baseline demographics were recorded: age, gender, spirometry (FEV1% predicted), smoking status, oxygen use, co-morbidities and number of exacerbations and hospital admissions in 12 months. In addition, exercise performance was measured using the incremental shuttle walk test (ISWT) and the short physical performance battery (SPPB) (Patel et al., 2014). Handgrip strength (HGS) was measured using a handheld hydraulic dynamometer (Jamar), whilst lower limb strength was measured as quadriceps maximal voluntary contraction (QMVC) (Canavan et al., 2015) in a subset of participants ($n=807$), normalised to height squared (m^2) with clinically relevant weakness defined as a QMVC/ht^2 below $5.99\text{kg}/\text{m}^2$ for females and $8.3\text{kg}/\text{m}^2$ for males and compared with gender-specific norms (Canavan et al., 2015). Health related quality of life was measured by St George's Respiratory Disease Questionnaire (SGRQ) (Jones et al., 1991) and COPD Assessment Test (CAT) (Kon et al., 2014), respiratory disability by the Medical Research Council (MRC) dyspnoea scale, and psychological comorbidity by the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983).

3.3.2 Statistical analysis

Descriptive data were presented as mean and standard deviation. Baseline characteristics were compared between the three nutritional risk groups (high, medium, low) using one-way analysis of variance (ANOVA) for continuous variables and Chi-squared for categorical variables. Cohen's f was performed to assess the size of the effect of continuous variables, where $f=0.10$ denotes a small effect, $f=0.25$ medium, and $f=0.40$ large (Cohen, 1988). Cramer's V was used for categorical variables, providing a value for effect size between 0 and 1 (Cramér, 2016).

Due to the anticipated number of at risk participants being relatively small, the dependent variable, nutritional risk status (as defined by MUST), was dichotomised (at risk for undernutrition including high and medium risk and low risk) to describe the phenotypic characteristics associated with undernutrition risk. The process was then repeated using cut points for FFMI (Schols et al., 2005) to explore relationships between normal and low FFMI ranges and several independent variables known to affect individuals with COPD. The continuous variables were assessed for linearity using the Box-Tidwell procedure (Box and Tidwell, 1962). Odds ratios with 95% confidence intervals were calculated for each variable using a univariate logistic regression analysis. Multivariate logistic regression was then performed on variables with $p<0.2$ to explore the independence of associations. Multicollinearity between independent variables was assessed using variance inflation factor (VIF). Results were considered significant if the two-tailed p -value was <0.05 . Analyses were performed using SPSS Version 24 (IBM Corp, 2015).

Univariate logistic regression was also performed to examine the relationships between completion of pulmonary rehabilitation, nutritional risk status (high and medium risk versus low risk) and potential confounders.

3.4 Results

3.4.1 Characteristics of the study population

The participants included in this study were 1,639 outpatients undergoing pulmonary rehabilitation for stable COPD (see figure 3.1). The sample was made up of 57% males (n=935) with a mean (SD) age of 69 (9.7) years and FEV₁% predicted 47.2 (20.5). Of the participants, 18% were current smokers, 75% former smokers and 7% had never smoked.

Prior to commencing pulmonary rehabilitation 13.4% (95% CI: 11.9% to 15.2%) of patients were at nutritional risk (7.7% and 5.7% for high and medium risk status respectively). No significant between-group differences were noted for gender or age but the high and medium nutritional risk groups had significantly higher MRC dyspnoea scores and FEV₁% predicted with a greater proportion of current smokers in the high nutritional risk group. An overview of the characteristics and nutritional status of the participants according to the MUST is included in Table 3.1.

As expected, patients at high or medium nutritional risk had lower weight, BMI, FFM and FFMI than those at low risk. Risk of undernutrition was associated with reduced FEV₁% predicted, worse ISWT, HGS and QMVC (figure 3.2), but not SPPB, CAT, HAD or SGRQ at baseline (table 3.1). Increased rates of self-reported hospital admissions, exacerbations in the past year, current smoking status and higher MRC dyspnoea score were noted in participants at higher risk of undernutrition (table 3.1 and figure 3.2).

Participants with QMVC measurements below the normal cut-off were compared across nutrition risk subgroups. This showed that 42.5% (n=48/113) of at-risk participants had clinically weak quadriceps compared to 17.6% (n=122/694) of low risk individuals, suggesting a relationship between nutritional risk and clinically relevant quadriceps weakness.

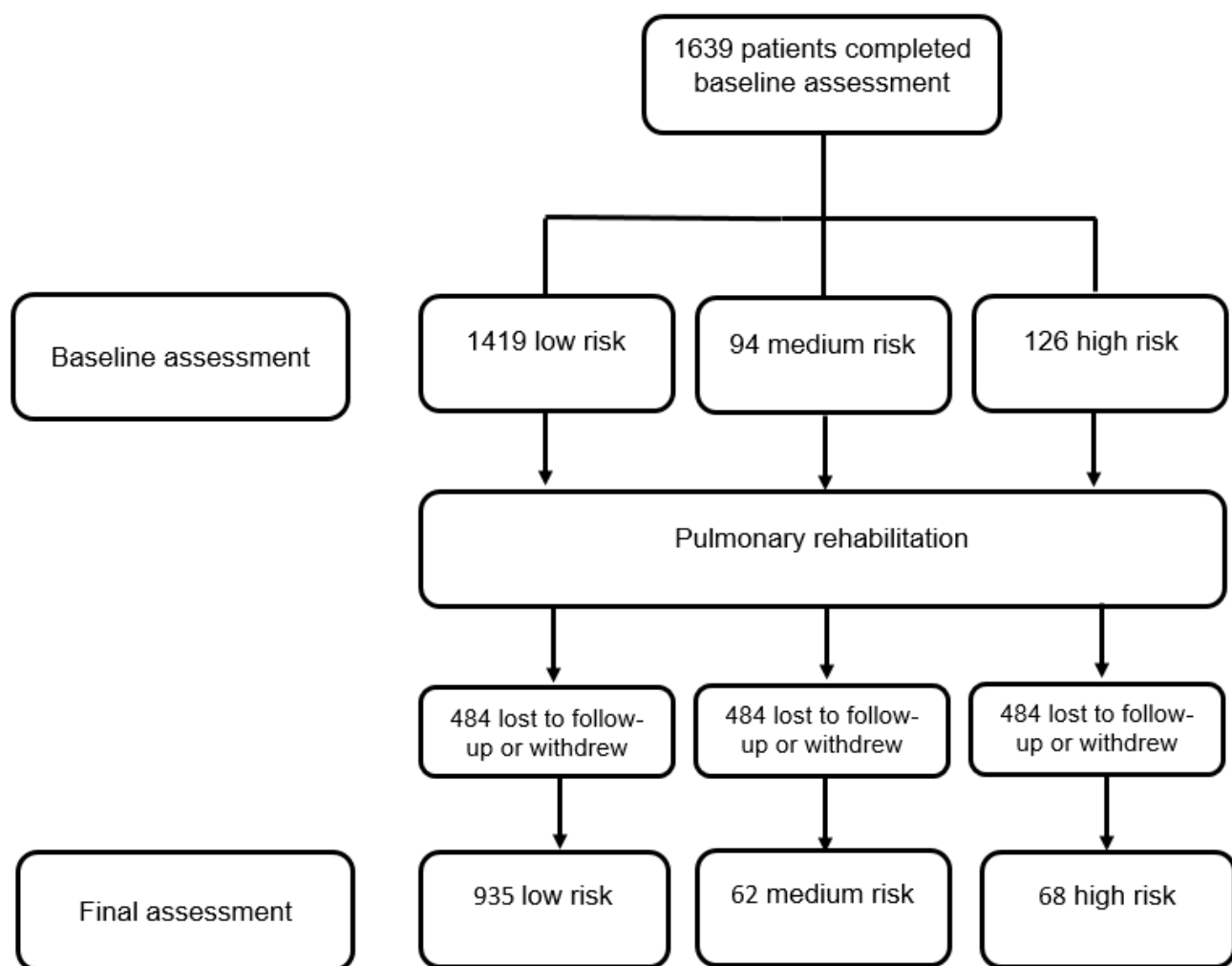


Figure 3.1: Flow diagram showing participant numbers at baseline assessment and follow-up after a programme of pulmonary rehabilitation in community-dwelling adults with stable COPD stratified by nutritional risk

Variable	Total (n=1639)	Nutritional risk category (n=1639)			p-value	Effect size ^e
Mean (SD) unless shown otherwise		Low (n=1419)(87%)	Medium (n=94)(5.7%)	High (n=126)(7.7%)		
Age (years)	70 (10)	70 (10)	71 (11)	69 (10)	0.51	0.98
Males n (%)	935 (57%)	813 (57%)	50 (53%)	72 (57%)	0.74	0.02 ^{c2}
Smoking status (n)	290:1217:108	230:1074:94	21:64:8	39:79:6*	0.001	0.08 ^{c4}
Current:former:never (%)	18%:75%:7%	16%:77%:7%	22%:69%:9%	31%:64%:5%		
Using oxygen n (%)	212 (13%)	181 (13%)	10 (11%)	21 (17%)	0.36	0.04 ^{c2}
MRC dyspnoea score ¹	3 (1)	3 (1)	3 (1)	4 (1)	0.01	0.10
FEV ₁ % predicted ²	47.2 (20.5)	48.6 (20.4)	41.9 (19.3)*	35.7 (19.2)*	<0.001	0.72
Weight (kg)	76.6 (20.9)	80.0 (19.7)	61.8 (16.5)*	49.2 (9)*	<0.001	0.27
BMI (kg/m ²)	27.9 (6.8)	29.1 (6.2)	22.8 (5.6)*	18.2 (2.5)*	<0.001	0.69
FFM (kg)	47.9 (10.6)	49.3 (10.4)	41.6 (7.9)*	37.1 (6.2)*	<0.001	0.69
FFMI (kg/m ²)	17.4 (2.8)	17.9 (2.66)	15.3 (2.03)*	13.7 (1.6)*	<0.001	0.69
SPPB score ³	9 (2.6)	9 (2.6)	9 (2.7)	9 (2.4)	0.23	0.21
Max ISWT (m) ⁴	203.9 (149.8)	208.0 (150.8)	176.0 (147.2)*	178.6 (136.1)*	0.02	0.55
HGS (kg) ⁵	27.1 (10.0)	27.5 (10.2)	23.3 (8.2)*	25.2 (9.2)	0.002	0.70
Peak QMVC (kg) ⁶	26.5 (10.2)	27.5 (10.2)	21.5 (9.07)*	18.4 (7.5)*	<0.001	1.55

Below QMVC cut-point n(%) ⁷	223 (27.7%)	122 (17.6%)	22 (45.8%)*	26 (40.0%)*	<0.001	0.21 ^{c2}
CAT score ⁸	21.7 (8.0)	21.5 (7.9)	21.8 (8.1)	23.1 (8.7)	0.15	0.44
HAD A score ⁹	7.3 (4.6)	7.3 (4.6)	8.0 (4.3)	7.4 (5.1)	0.31	0.76
HAD D score ¹⁰	6.9 (3.9)	6.8 (3.8)	7.6 (4.4)	7.2 (4.4)	0.10	0.72
SGRQ total score ¹¹	52.9 (17.2)	52.4 (17.1)	55.0 (17.5)	56.0 (17.2)	0.12	0.66
Hospital inpatient days over preceding 12 months	4.1 (10.8)	3.8 (10.7)	3.3 (9.4)	6.6 (12.3)*	0.01	0.95
Self-reported exacerbations over preceding 12 months	2.7 (3.5)	2.7 (3.5)	3.1 (2.9)	3.4 (4.6)*	0.03	0.69

*Significant difference compared to 'low risk' reference group (p<0.05). ^{c2}effect size calculated using Cramer's V degrees of freedom=2 (small=0.07, medium=0.21, large=0.35); ^{c4}effect size calculated using Cramer's V degrees of freedom=4 (small=0.05, medium=0.15, large=0.25); ^eCalculated using Cohen's f unless shown otherwise.

1 MRC, Medical Research Council dyspnoea scale. Scores range from 1 (not troubled by breathlessness) to 5 (severe breathlessness)

2 FEV₁%predicted, forced expiratory volume in one second divided by the population average FEV₁%

3 SPPB score, short physical performance battery. This test combines the results of the gait speed, five repetition sit to stand test and balance tests. Scores range from 0 (worst performance) to 12 (best performance) (Guralnik et al, 2000)

4 Maximum ISWT, Incremental Shuttle Walking Test. Participants walk at a gradually increasing speed until they reach a symptom-limited maximum. (Singh et al, 1992)

5 HGS, handgrip strength. Higher scores indicate greater muscle strength

6 QMVC, Quadriceps Maximum Voluntary Contraction. Maximum contraction/force sustained for over one second is used to quantify quadriceps strength with higher scores demonstrating greater strength

7 QMVC, Quadricep Maximum Voluntary Contraction strength below cut-points. NB n=807, low = 694, med= 48, high = 65

8 CAT, COPD Assessment Test. This test assesses the impact of COPD on health. The test consists of eight questions, each rated on a scale of 0-5. The overall score range is 0–40 with higher scores indicating more limitations.

9 Hospital Anxiety and Depression scale – Anxiety domain. Scores range from 0 (normal) to 21 (abnormal) (Zigmond and Snaith,1983)

10 Hospital Anxiety and Depression scale – Depression domain. Scores range from 0 (normal) to 21 (abnormal) (Zigmond and Snaith,1983)

11 SGRQ, St George's Respiratory Questionnaire. Scores range from 0 to 100, with higher scores indicating more limitations

Table 3.1: Baseline clinical characteristics of 1,639 outpatients with COPD prior to starting pulmonary rehabilitation, expressed as n/% (mean (SD))

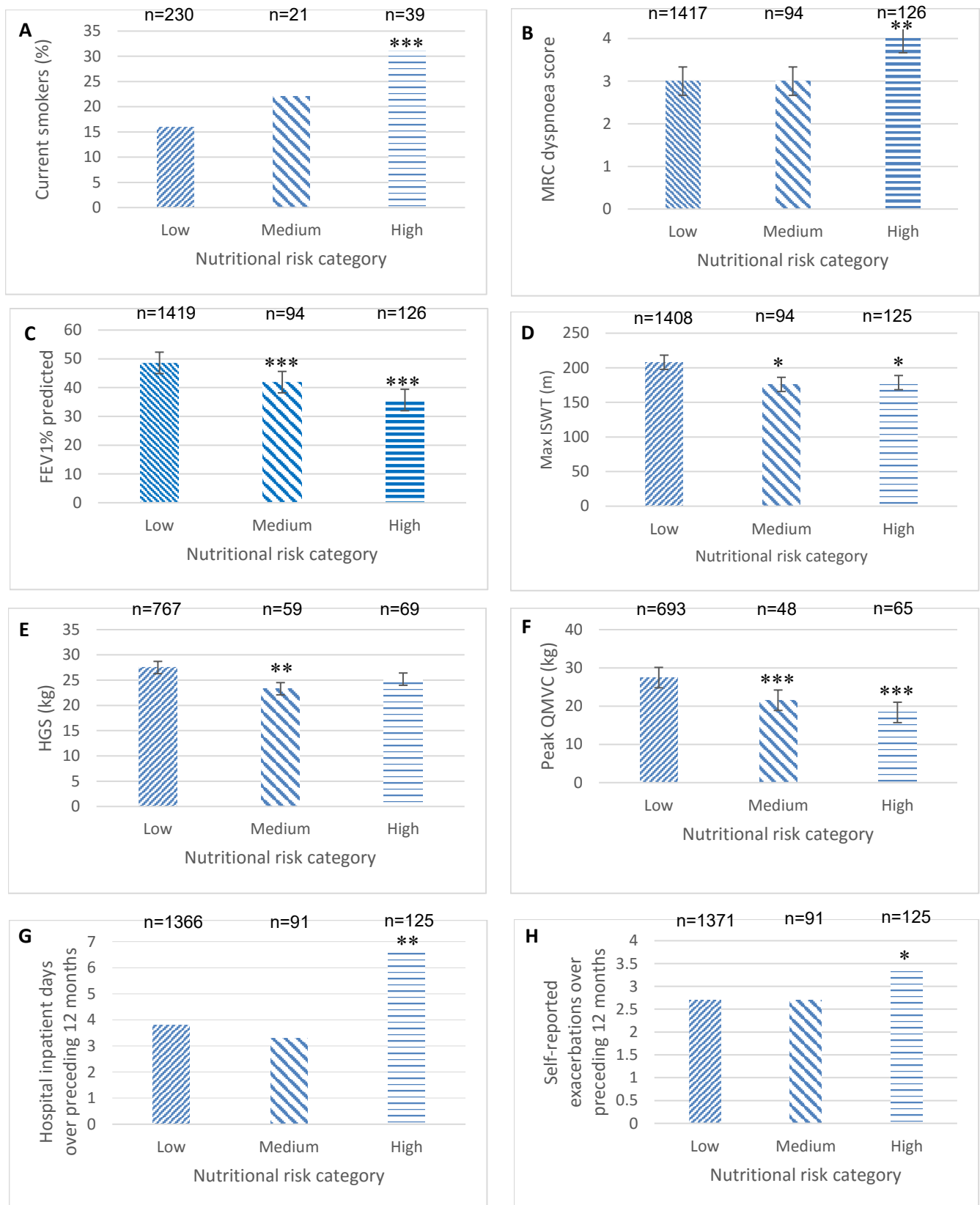


Figure 3.2: Between group differences in COPD outpatients at baseline. Number of current smokers (Aⁱ) (n=1615), MRC dyspnoea score (B) (n=1637), FEV1% predicted (C) (n=1639), performance in ISWT (D) (n=1627), Handgrip strength (E) (n=895) and peak QMVC (F) (n=806) tests according to nutritional risk category. Self-reported exacerbations (G) and hospital inpatient days (H) by nutritional risk category. Between-group differences ($p < 0.05$) compared with base group (far left) denoted by asterisk: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Error bars represent standard errors

ⁱChi-squared test ⁱⁱOne-way Analysis of Variance (ANOVA)

Binomial logistic regression was used to explore the effects of independent variables on the nutritional status of the participants. Table 3.2 shows the univariate logistic model detailing all variables that were entered in to the model. The first multivariate model (Table 3.3) showed that four of the predictor variables were statistically significant in predicting higher risk of undernutrition: Gender, FEV₁% predicted, smoking status and QMVC. The regression model was statistically significant ($X^2 = 7.970$, 8 degrees of freedom, $p < 0.0005$), explaining 22% of the variance and correctly classifying 86.9% of cases. The multivariate model for predicting low FFMI (Table 3.4) showed that five variables were significant: Age, FEV₁% predicted, smoking status, QMVC and maximum ISWT ($X^2 = 6.338$, 8 degrees of freedom, $p < 0.0005$), explaining 30% of the variance and correctly classifying 80.0% of cases.

Univariate	OR (95% CI)	p value
Age	1.00 (0.99 to 1.02)	0.94
Gender ^a	1.08 (0.81 to 1.43)	0.61
Smoking status ^b	0.50 (0.36 to 0.70)	<0.001
Oxygen use ^c	1.12 (0.74 to 1.69)	0.58
MRC dyspnoea score 1	Reference	-
MRC dyspnoea score 2	1.54 (0.45 to 5.27)	0.49
MRC dyspnoea score 3	1.25 (0.37 to 4.26)	0.72
MRC dyspnoea score 4	1.34 (0.40 to 4.51)	0.64
MRC dyspnoea score 5	2.46 (0.73 to 8.32)	0.15
FEV ₁ (% predicted)	0.97 (0.96 to 0.98)	<0.001
SPPB score	0.98 (0.92 to 1.05)	0.54
Max ISWT (m)	1.00 (1.00 to 1.00)	0.01
HGS (kg)	0.97 (0.95 to 0.99)	<0.001
QMVC peak (kg)	0.92 (0.90 to 0.95)	<0.001
CAT score	1.02 (1.00 to 1.04)	0.11
HAD A score	1.02 (0.99 to 1.05)	0.21
HAD D score	1.04 (1.00 to 1.08)	0.04
SGRQ total score (%)	1.01 (1.00 to 1.02)	0.04
Hospital inpatient days over preceding 12 months	1.01 (1.00 to 1.03)	0.01
Self-reported exacerbations	1.04 (1.01 to 1.08)	0.02

CAT, COPD Assessment Test; FEV₁, forced expiratory volume in one second; HGS, hand grip strength; ISWT, incremental shuttle walk test; MRC, Medical Research Council dyspnoea score; QMVC, quadriceps maximum voluntary contraction; SPPB, short physical performance battery; SGRQ, St George's Respiratory Disease Questionnaire.

^aFemales are compared to males

^b Current smokers are compared to former and never smokers

^c Oxygen use is compared to no oxygen use

Table 3.2: Univariate logistic binary regression comparing low and medium/high risk of undernutrition (dependent variable) and associated factors (independent variables)

Multivariate	B	S.E	OR (95% CI)	p-value
Gender ^a	-1.136	0.268	0.32 (0.19 to 0.54)	<0.001
Smoking status ^b	1.2137	0.257	3.312 (1.88 to 5.15)	<0.001
FEV ₁ % predicted	-0.027	0.006	0.97 (0.96 to 0.99)	<0.001
QMVC peak (kg)	-0.119	0.017	0.89 (0.86 to 0.92)	<0.001
Constant	2.430	0.509	11.36	<0.001

FEV₁, forced expiratory volume in one second; ISWT, incremental shuttle walk test; QMVC, quadriceps maximum voluntary contraction. The regression model was statistically significant ($X^2 = 7.970$, 8 degrees of freedom, $p < 0.0005$), explaining 22% of the variance and correctly classifying 86.9% of cases.

^a Females are compared to males

^b Current smokers are compared to former and never smokers

Table 3.3: Multivariate logistic binary regression model comparing low and medium/high risk of undernutrition (dependent variable) and associated factors (independent variables) (n=799)

Multivariate	B	S.E	OR (95% CI)	p-value
Age	-0.036	0.011	0.97 (0.94 to 0.99)	0.001
Smoking status ^b	0.636	0.243	1.89 (1.17 to 3.04)	0.009
FEV ₁ % predicted	-0.040	0.006	0.96 (0.95 to 0.97)	<0.001
QMVC peak (kg)	-0.120	0.014	0.89 (0.86 to 0.91)	<0.001
Max ISWT (m)	0.002	0.001	1.05 (1.00 to 1.10)	0.004
Constant	5.29	0.945	199.23	<0.001

FEV₁, forced expiratory volume in one second; ISWT, incremental shuttle walk test; QMVC, quadriceps maximum voluntary contraction. The multivariate model showed that five variables were significant: Age, FEV₁% predicted, smoking status, QMVC and maximum ISWT ($X^2 = 6.338$, 8 degrees of freedom, $p < 0.0005$), explaining 30% of the variance and correctly classifying 80.0% of cases.

^a Females are compared to males

^b Current smokers are compared to former and never smokers

Table 3.4: Multivariate logistic binary regression model comparing low and adequate fat-free mass index (dependent variable) and associated factors (independent variables) (n=766)

3.4.2 Participation in pulmonary rehabilitation

Completion rates for pulmonary rehabilitation were 64.7% (95% CI: 62.4% to 67.1%) in the cohort as a whole (% referred); the proportion of completers reduced with increasing nutritional risk, however, this was not statistically significant (table 3.5). Non-completers included both patients who did not start rehabilitation at all and those who attended <8/16 sessions. Attendance at rehabilitation was lowest in the highest risk group but again this did not reach significance once type I errors were controlled for using the Bonferroni correction ($p < 0.002$).

Variable	Nutritional risk category				p-value
	Low (n=1419)	Medium (n=94)	High (n=126)	Total (n=1639)	
Completed rehabilitation (%)	65.8 (n=934)	63.8 (n=60)	53.2 (n=67)	64.7 (n=1061)	0.05
Did not complete rehabilitation (%)	15.6 (n=224)	13.8 (n=13)	19 (n=24)	15.8 (n=261)	
Did not start rehabilitation (%)	18.5 (n=261)	22.3 (n=21)	27.8 (n=35)	19.5 (n=317)	
Mean sessions attended (n)	9.24	8.65	7.38	9.1 (5.9)	0.03

Significant difference compared to 'low risk' reference group adjusted for multiple testing using the Bonferroni correction ($p < 0.002$) (Benjamini and Hochberg, 1995).

Table 3.5: Completion rates and sessions of pulmonary rehabilitation attended in a sample of outpatients with COPD (n=1639)

The univariate regression analysis (table 3.6) showed associations between smoking status, MRC dyspnoea score, nutritional risk status and completion of pulmonary rehabilitation. A multivariate regression was performed to consider the relative contribution of each independent variable to the completion of pulmonary rehabilitation; only smoking status and MRC dyspnoea score were included in the final model; undernutrition risk status was not retained suggesting this did not independently predict completion (table 3.6).

Univariate	OR (95% CI)	p-value
Gender (Male)	0.976 (0.795 to 1.198)	0.816
Age	1.015 (1.00 to 1.03)	0.007
Smoking status (current)	2.190 (1.69 to 2.83)	<0.001
MRC dyspnoea score	0.670 (0.61 to 0.74)	<0.001
FEV1% predicted	1.005 (1.0-1.01)	0.076
MUST score	0.786 (0.66 to 0.94)	0.006

Multivariate	OR (95% CI)	p-value
Age	1.009 (0.10 to 1.02)	0.177
Smoking status (current)	2.040 (1.55 to 2.70)	<0.001
MRC dyspnoea score	1.654 (1.24 to 2.21)	<0.001
MUST score	1.270 (0.71 to 2.26)	0.417

MRC, Medical Research Council dyspnoea score; FEV1%predicted, forced expiratory volume in one second divided by the population average FEV₁%; MUST, Malnutrition Universal Screening tool. The multivariate model showed that two variables were significant: smoking status and MRC dyspnoea score. The model was not significant ($X^2 = 1.932$, 5 degrees of freedom, $p=0.858$)

Table 3.6: Univariate and multivariate logistic regression for variables associated with non-completion of pulmonary rehabilitation in patients with COPD (n=1612)

3.4.3 Response to pulmonary rehabilitation

Following rehabilitation there were no significant differences between the nutrition risk groups in the change in weight, BMI or FFM. None of the improvements in CAT score, SGRQ score, HADS anxiety or functional performance outcomes were significantly different between the nutrition risk groups following pulmonary rehabilitation. HADS depression seemed to get slightly worse but again changed to a similar degree in each risk group (table 3.7).

Variable	Nutritional risk category			p-value
	Low (n=935)	Medium (n=62)	High (n=68)	
Mean change (95% CI)				
Age (years)(Mean(SD))	70.01 (9.14)	71.34 (11.18)	70 (9.1)	0.55
Gender (M:F)	541:394	34:28	39:29	0.98
	58%:42%	55%:45%	57%:43%	
Smoking status (current:former:never)	126:718:73	12:44:5	14:48:4	0.37
	14%:78%:8%	20%:72%:8%	21%:72%:6%	
Oxygen use no: yes	824:113	55:7	56:12	0.39
Weight (kg)	0.1 (-0.1 to 0.3)	-0.5 (-1.1 to 0.4)	-0.7 (-1.3 to -0.0)	0.018
BMI (kg/m2)	0.0 (-0.1 to 0.0)	0.2 (-0.0 to 0.4)	-0.2 (-0.0 to 0.5)	0.018
FFM (kg)	-0.0 (-0.2 to 0.1)	0.6 (0.2 to 0.1)	0.5 (0.0 to 0.1)	0.018
FFMI (kg/m2)	-0.0 (-0.1 to 0.0)	0.2 (0.1 to 0.4)	0.2 (0.0 to 0.3)	0.023
MRC dyspnoea score	-1 (-0.7 to -0.5)	-1 (-1.1 to -0.55)	-1 (-0.8 to -0.3)	0.149
CAT	-2.5 (-2.9 to -2.0)	-3.1 (-5.0 to -1.2)	-1.4 (-3.4 to 0.5)	0.393
HADS anxiety	-1.0 (-1.2 to -0.8)	-1.3 (-2.3 to -0.3)	-0.4 (-1.2 to 0.5)	0.223
HADS depression	1.0 (-0.8 to 1.3)	2.6 (1.3 to 3.9)	1.2 (0.2 to 2.2)	0.019
Quads % predicted	4.0 (2.9 to 5.2)	0.3 (-5.7 to 6.4)	4.0 (0.2 to 7.7)	0.342
Max ISWT (m)	58 (53 to 62.3)	55 (40.7 to 70)	49 (27.8 to 70)	0.632
4MGS (m/s)	0.07 (0.07 to 0.09)	0.06 (0.03 to 0.10)	0.09 (0.04 to 1.14)	0.703
SPPB score	1 (0.54 to 0.77)	1 (0.15 to 1.2)	1 (0.37 to 1.4)	0.588
Handgrip (kg)	0.8 (0.5 to 1.1)	1.3 (0.3 to 2.3)	1.5 (0.2 to 2.7)	0.451
SGRQ total score	-5.1 (-6.0 to -4.2)	-2.8 (-6.7 to 1.1)	-5.7 (-7.0 to -2.4)	0.433
Peak QMVC (kg)	1.7 (-1.2 to 2.2)	0.7 (-1.5 to 3.0)	1.5 (0.1 to 2.8)	0.672

Values are mean change (95% CI) pre-to-post rehabilitation

Significant difference compared to 'low risk' reference group adjusted for multiple testing using the Bonferroni correction ($p < 0.002$) (Benjamini and Hochberg, 1995). MRC, Medical Research Council dyspnoea score; FEV₁, forced expiratory volume in one second; BMI, body mass index; FFM, fat-free mass; FFMI, fat free mass index; SPPB, short physical performance battery; 4MGS, 4-metre gait speed; HGS, hand grip strength; ISWT, incremental shuttle walk test; CAT, COPD Assessment Test; SGRQ, St George's Respiratory Disease Questionnaire; QMVC, quadriceps maximum voluntary contraction.

Table 3.7: Comparison of response to pulmonary rehabilitation between COPD patients at low, medium and high risk of undernutrition (n=1065)

3.4 Discussion

This study set out to determine the prevalence of undernutrition risk in community-dwelling people with stable COPD at assessment for pulmonary rehabilitation. In addition, it aimed to examine the factors associated with undernutrition in this population and describe the impact of undernutrition risk on completion of a programme of pulmonary rehabilitation. Results demonstrated a prevalence of 13.4% undernutrition risk in a sample of outpatients with stable COPD. Previous prevalence estimates have found a wide range of rates between 10% to 45% in outpatients (Beck et al., 2013b, Collins et al., 2016, Raguso and Luthy, 2011, Stratton et al., 2003, Vermeeren et al., 2006). However, these studies all defined undernutrition differently and employed different methods of measuring nutritional status, making them difficult to compare. For example a prevalence of 33% was found using the BMI cut-point of $\leq 22\text{kg/m}^2$ (Raguso and Luthy, 2011). The same BMI cut-off in this cohort gave a prevalence of 18.6%, but BMI measurements alone are not regarded as reliable markers of nutritional status, because they can be confounded by shifts in body water commonly seen in respiratory disease. Thus, our estimate of undernutrition prevalence may be more accurate using a validated screening tool. In addition, the overall prevalence of obesity has increased in the last 20-30 years (HSCIC, 2015) and so older studies using BMI alone could be expected to find higher rates of risk of undernutrition in a slimmer population. More recent work has focussed on FFM and FFMI as it provides information beyond that of BMI (Schols et al., 2005, Vermeeren et al., 2006), including mortality (Marquis et al., 2002) and osteoporosis (Bolton et al., 2004). One study used a definition of BMI $< 21\text{kg/m}^2$ and/or FFMI ≤ 15 (females) or ≤ 16 (males) kg/m^2 , which estimated prevalence as 27% (Vermeeren et al., 2006). Examining nutritional risk in the same way in our cohort resulted in a similar prevalence of 27.5%, but body composition alone as a definition of undernutrition is not regarded as optimal because it is important to consider recent unintentional weight loss and food intake or appetite. Looking more closely at those studies employing similar methodology to ours, the UK-based study by Collins et al (2016) also used MUST to uncover a prevalence of 22% participants at risk. However, participants in the study had higher disease severity compared to the current

sample, and as disease severity has frequently been linked to undernutrition rates (Lee et al., 2013, Schols et al., 1993b) this perhaps explains the higher prevalence. Schols et al (Schols et al., 1993b) also explored the prevalence of nutritional depletion in patients with stable disease appropriate for pulmonary rehabilitation using bioelectrical impedance. They showed that fat free mass was a better indicator of physical impairment than body weight and proposed fat free mass measurement as more useful in categorising patients into risk levels. This work shows that the method of nutritional screening or assessment may still need to be refined and the best tool agreed for this patient group. Whilst bioelectrical impedance is useful in research and feasible in clinical practice, there are practical barriers to its use in clinical settings.

We found that increased risk of undernutrition was associated with being male, a current smoking status, lower FEV1% predicted and reduced quadriceps strength. Thus, our sample was exhibiting the expected phenotypic characteristics of undernutrition; weakness and increased morbidity. It is not possible to identify the cause and effect; does weakness predispose the person to undernutrition or does the undernutrition result in weakness? Similarly, is it the current smoking that predisposed to undernutrition and results in greater morbidity or is the undernutrition exacerbating the morbidity in a group that smokes more?

We then observed whether risk of undernutrition could be predicted by the strength, function and disease factors, using logistic binary multivariate regression analysis. The model (table 3.3) included gender, smoking status, FEV1% predicted, and peak quadriceps strength. This suggests that patients who are male, smokers, with worse lung function and weaker quadriceps strength are more likely to be at risk of undernutrition. The model demonstrated an acceptable goodness of fit, however the Nagelkerke R² value was 0.24, indicating that this model is limited in predicting risk of undernutrition. Whilst the contribution of the predictor variables is statistically significant, the effect size is small.

Associations between undernutrition and gender have been identified. In a study of hospitalised patients, logistic regression showed male gender was associated with a higher risk malnutrition (de Aquino and Philippi, 2011). In another study in cohort of medical

inpatients, reduced mid-arm muscular circumference (MAMC) correlated with male gender (Campillo et al., 2004).

Smoking has been linked to lower body weight (Williamson et al., 1991), suppressing appetite (Jo et al., 2002), with heavy smokers showing impairment in both taste and smell (Vennemann et al., 2008). One study in older outpatients with COPD, adjusting for age and gender, found smoking to be one of four factors that independently increased risk of undernutrition (OR 5.5 (95% CI: 1.9-16.4)), alongside multi-morbidity, poor functional status and depression (Lonterman-Monasch et al., 2013).

This analysis shows that FEV1% predicted was lower amongst the most nutritionally at risk. Other groups have shown a similar difference in baseline FEV1% predicted in a stable, outpatient COPD population (Engelen et al., 1994, Schols et al., 1993a) using measures of ideal body weight (IBW) or FFM. Another demonstrated a weak but significant correlation between FEV1%predicted and BMI ($r=0.30$; $p<0.001$) (Soler et al., 2004).

Our study shows that higher quadriceps strength is related to a lower risk of undernutrition (OR 0.89 (95% CI: 0.86 to 0.92), $p<0.001$). Because our data is cross-sectional it is not possible to establish whether this relationship is causative, and whether the association is bidirectional. Other studies have shown 20-30% of individuals with COPD have significant quadriceps muscle weakness, though the exact aetiology of this weakness is not known (Gosselink et al., 1996, Hamilton et al., 1995, Vermeeren et al., 2006).

In this cohort participants classified as having increased undernutrition risk demonstrated reduced incremental shuttle walk test distances, but this was not independently associated with undernutrition risk. Previous work has shown that low weight COPD patients have a lower maximal exercise capacity compared to patients with similar airway obstruction but normal weight (Sahebji et al., 1993). It has been suggested that undernutrition results in greater respiratory and skeletal muscle wastage and consequently reduced diaphragmatic muscle strength and poorer exercise capacity (Arora and Rochester, 1982).

Other work has also highlighted a higher frequency of infective exacerbations in adults at nutritional risk. In a retrospective cohort study patients were screened with Subjective Global Assessment on admission to one of 25 Brazilian hospitals (Correia and Waitzberg, 2003). Multiple logistic regression was used to isolate nutritional status, concluding that undernourished participants experienced more infectious complications than well-nourished subjects, irrespective of diagnosis (27% and 17% respectively) (Correia and Waitzberg, 2003). Higher incidence of nosocomial infection has also been associated with poor nutritional status, including an increased risk of nosocomial pneumonia (Paillaud et al., 2005). This cohort demonstrated slightly higher odds 1.04 (95% CI: 1.01 to 1.08, $p = 0.02$) of nutritional risk in patients with more frequent exacerbations, but the effect was not sustained in multivariable analysis.

This study included a large representative sample of outpatients with stable COPD, including a validated measure of nutritional risk. Nevertheless, there are several limitations to this data analysis to consider. Firstly, HGS was lower in those at risk of undernutrition, but only significantly in those at medium but not high risk. This was unexpected finding, and one that is difficult to account for. The data was cross-sectional and therefore it is not possible to comment on cause and effect. In addition, previous exposure to nutritional interventions was not routinely recorded and so patients may have received nutritional support prior to their involvement in this study affecting functional outcome measures.

Substantial evidence suggests that weight loss is an important adverse event in COPD management and that physical training without nutritional rehabilitation is insufficient to increase weight and muscle mass in underweight COPD patients (Schols et al., 1995). It may be that treating undernutrition before the patient is invited to take part in pulmonary rehabilitation may result in a higher rate of completion with associated benefits for the patients. Indeed the British Thoracic Society guidance notes that enrolment in a rehabilitation programme presents an opportunity for nutritional screening to highlight any patients at risk of undernutrition, with onward support as necessary (Bolton et al., 2014). Thus, even though the

evidence of benefit is not robust there is consensus among experts that identification and treatment of nutrition prior to rehabilitation is important.

Other aetiological factors such as breathlessness, inflammation and medication can impact body composition and dietary intake, adversely affecting nutritional risk status. Baseline characteristics in this study show that breathlessness is highest amongst the most nutritionally at risk, with FEV1%predicted significantly lower in these patients. This could offer a clue as to why those who are undernourished may be less likely to start or complete rehabilitation.

Several studies have explored adherence in respiratory patients undertaking exercise, but few have considered the implications of undernutrition. Sabit et al (2008) performed regression analysis to understand the factors which influenced adherence to an exercise programme noting that BMI appeared to have an impact ($p < 0.05$) but smoking status, dyspnoea score and practical issues such as distance to rehabilitation had the most influence on attendance. This group recently reported that frailty was a strong predictor of non-completion, independent of other factors (Maddocks et al., 2016). Unintentional weight loss is a significant characteristic of frailty and frailty has been closely linked to undernutrition (Espinoza and Fried, 2007).

An existing dataset was used and hence only available data could be included in our analyses. For example, exposure to nutritional interventions was not measured and so patients may have received nutrition support at any point over the course of the rehabilitation programme, but this was not recorded. This could have influence the patients' responses to the rehabilitation. The low prevalence of nutritional risk in our study sample may also affect the other analyses we undertook. The number of patients in the two at-risk groups was much lower than anticipated and may reduce the power of the analysis to detect differences in attendance and completion of rehabilitation, and improvements in performance after rehabilitation.

In summary, the prevalence of nutritional risk in stable COPD patients is approximately 13% in a sample exercising individuals. We have also demonstrated that current smoking, more frequent infective exacerbations, worse lung function and weaker quadriceps strength are

associated with risk of undernutrition. Therefore, it is important to identify, monitor and treat undernutrition in stable COPD outpatients and these factors may help clinicians target effective assessment. Our analysis also showed that nutritional risk did not appear to impact on the response to rehabilitation, suggesting that stable COPD patients at risk of undernutrition, who attended the majority of the programme of rehabilitation, experience the same benefits as their counterparts at low risk of undernutrition, albeit from a lower baseline. These results contrast with some previous work showing nutritional depletion did affect performance in a 12-minute walking test in a rehabilitation setting (Beck et al., 2013b). A second study that included a nutritional support intervention (Redelmeier et al., 1997) found greater improvements in 6-minute walk time in patients not at nutritional risk, although there was debate around whether the difference in the improvement was clinically important. Additionally, low weight COPD patients have been shown to have a lower exercise capacity compared to patients with equal bronchial obstruction but normal weight (Sahebji et al., 1993). Others have speculated that undernutrition results in greater respiratory muscle and skeletal muscle wastage and consequently worse exercise capacity (Arora and Rochester, 1982). We did find, as others have previously reported, that risk of undernutrition is associated with lower weight, BMI and FFM, a reduced FEV1%predicted and higher perceived breathlessness, a reduced functional performance and a reduced quality of life score measured by St George's respiratory questionnaire (Gray-Donald et al., 1989, Kyle et al., 2003, Sahebji et al., 1993). Thus, our sample was exhibiting the expected consequences of undernutrition, but this did not seem to influence response to rehabilitation.

Chapter 4: Undernutrition at the hospital-community interface: an investigation in to the relationships between undernutrition risk, sarcopenia risk, functional status, quality of life and satisfaction with food-related life

4.1 Introduction

It is widely acknowledged that admission to hospital is a stressful event for people, with changes in the physical environment and distance from usual support networks (Volicer and Bohannon, 1975). Hospitalisation has the potential to affect physical and psychological health and alter the trajectory of recovery (Gillick et al., 1982). Maintaining good physical function is an important aspect of recovery following illness, and as discussed in section 1.7, functional status shares close relationships with level of dependence and quality of life. Psychological health too is important, and quality of life is an outcome measure that is increasingly recognised and utilised. As detailed in section 1.7, measuring health-related quality of life allows us to capture individual perspectives on the impact of illness and recovery following a period of illness, providing data which compliments measures of sarcopenia risk and physical function.

There has been little work to examine the effects of undernutrition risk following a hospital admission, so this cohort study in community-dwelling older adults post-discharge aims to increase our understanding of the influence of undernutrition risk on recovery post hospital.

4.2 Aims, Research questions and objectives

The aim of this study was to examine person-centred characteristics within a group of older people following discharge from hospital.

This study set out to answer the following question:

What are the nutritional, quality of life and functional characteristics of older people leaving hospital, and how do these characteristics change during 1 year follow-up.

This study set the following objectives:

- i. to examine sarcopenia risk using a validated scale and muscle strength using handgrip dynamometry, in a sample of older adults at discharge from hospital, then at 3, 6 and 12 months, comparing a group of participants over the age of 60 and at medium or high risk of undernutrition at discharge from hospital to a group of participants at low risk.
- ii. to explore ability to perform activities of daily living using a validated tool in a sample of older adults, at discharge from hospital, then at 3, 6 and 12 months, comparing a group of participants over the age of 60 and at medium or high risk of undernutrition at discharge from hospital to a group of participants at low risk.
- iii. to examine quality of life and satisfaction with food-related life using validated scales, in a sample of older adults at discharge from hospital, then at 3, 6 and 12 months, comparing a group of participants over the age of 60 and at medium or high risk of undernutrition at discharge from hospital to a group of participants at low risk.

4.3 Methods

This study was an observational, cohort study. Chapter 2 includes details of patient selection and consent procedures (section 2.1), the training of research assistants (section 2.2), and questionnaire design (section 2.4). Patients who met the inclusion criteria were identified and asked if they would be interested in taking part in the study by the ward staff. Those indicating they did want to participate were then referred to the research team who approached them and invited them to take part. Potential participants were provided with all the relevant information required for them to make an informed decision about participation, including written information and the opportunity to ask questions. Each was given time to consider the information prior to making a decision and it was made clear that declining participation would have no effect on the care they received. Each was informed that they could withdraw at any point, without giving a reason.

To assist patients with visual impairment a large print information booklet was available, and care was taken when explaining the study purpose and procedures to ensure all the information was heard and understood. Examples of the consent form, declaration form for consultees and the patient and consultee information booklets have been included in appendix 9.2.

Study visits took place at hospital discharge, 3 months, 6 months and 12 months. Participants were contacted by telephone 3-4 weeks prior to the next study visit to arrange a suitable time and date for the visit. Visits took place on the hospital site or at the participant's home depending on their preference. Where there was concern around a change in cognition, the Abbreviated mental test 4 (AMT-4) was used with the participant (Hodkinson, 1972). A score <4 indicated abnormal cognition and the participant was withdrawn from the study or a consultee sought. Where participants were uncontactable within 14 days from the planned assessment date, they were considered lost to follow-up and withdrawn from the study.

4.3.1 Measures

For this study we needed to measure nutritional intake, functional status and quality of life assessment. The measurements employed for the study are discussed in chapter 2, section 2.4 and 2.5. In addition, the demographic variables age, gender, ethnic group, marital status and household relationships were collected as potential confounders (see table 4.1).

Variable	Methods	Rationale
Date of birth	Health records	To characterise the study population according to age
Gender	Health records	To characterise the study population according to gender
Ethnicity	Patient interview using the Self-defined ethnicity codes (UK Home Office)*	To characterise the study population according to ethnicity
Marital status	Patient interview*	To characterise the study population according to marital status at baseline and to record any changes over the study period e.g. divorce or widowhood which may affect outcomes
Household relationships	Patient interview using data collected on the Client Service Receipt Inventory (CSRI) including if participant is living alone, living with a spouse, living with other family members; receiving informal support with shopping or cooking*	To characterise the study population according to living conditions at baseline and to record any changes over the study period e.g. move from own home to sheltered housing or residential care home
Co-morbidities	Patient interview and health records using the Charlson Co-morbidity Index* (Charlson et al., 1987)	To characterise the study population according to the number of comorbidities at baseline and to record changes at 12 months
Frailty score	Patient interview using the Clinical Frailty Scale* (Rockwood et al., 2005)	To characterise the study population according to a 7-point frailty scale at baseline and to record changes at 12 months
Sarcopenia score	Patient interview using the SARC-F* (Malmstrom and Morley, 2013)	To characterise the study population according to a 10 point sarcopenia scale at baseline and to record changes at 12 months
Height (m)	Measured using a stadiometer, or by review of health records or patient interview*	To calculate body mass index (BMI) and to characterise participants according to nutrition risk status at baseline
Current weight (kg)	Measured using portable weighing scales	To calculate percentage weight change and current BMI, to characterise participants according to nutrition risk status at baseline and to record changes over the study period
Usual weight (kg)	Patient interview or by review of health records i.e. patient's reported or recorded usual weight*	To calculate percentage weight change and usual BMI, and to characterise participants according to nutrition risk status at baseline
Nutritional screening questions	Patient interview using MUST (Elia, 2003a) Information required includes reported changes in weight, dietary intake and clinical status*	To characterise the study population according to nutrition risk status at baseline and to record changes over the study period

Activities of daily living	Patient interview using the Adapted Townsend Scale (Bowling and Grundy, 1997). This scale assesses ability to perform 19 activities in three domains: mobility, personal care and domestic activity*	To determine the impact of nutrition risk status on activities of daily living
Hand grip strength	Measured using a handgrip dynamometer (Fried et al., 2001c)	To characterise the study population according to skeletal muscle strength at baseline and to record changes at 3, 6 and 12 months
Health-related quality of life	Patient interview using the EQ-5D quality of life questionnaire (Rabin and Charro, 2001). The EQ-5D-5L has mobility; self-care; usual activities; pain/discomfort; and anxiety/depression*	To determine the impact of nutrition risk status on health related quality of life including physical, mental and social functioning.
Satisfaction with food related life	Patient interview using the Satisfaction with food-related life questionnaire (SWFL)* (Grunert et al., 2007)	To characterise the study population according to satisfaction with food-related life at baseline and to record changes over the study period
Oral nutritional supplement use	Patient interview*	To quantify the use of ONS within the study population including volume and treatment period
Support from dietetic services	Patient interview*	To quantify the type and duration of support from a dietitian in the 12 months preceding the study and during the study

* Where the participant is unable to provide this information, their carer or consultee was approached.

Table 4.1: Descriptors and outcome measures collected for study 2

4.3.2 Descriptive Analysis

In order to answer the research question, I needed to be able to describe the cohort at four time points; baseline, 3 months, 6 months and 12 months. This was done using descriptive analysis of the outcomes functional status, muscle strength, quality of life and satisfaction with food-related life. The Shapiro-Wilk test plus visual inspection of histograms and boxplots were used to assess the distribution of all variables, observing skewness and kurtosis and calculating z-scores where appropriate (Field, 2013).

Baseline demographic characteristics were described using percentage, mean and standard deviation (SD) or median and interquartile range (IQR) as appropriate according to data distribution. A p-value of less than 0.05 was considered statistically significant.

Two groups were created based on nutritional risk status at baseline; low risk of malnutrition and medium or high risk of malnutrition according to the malnutrition universal screening tool (MUST) (see section 2.3.1).

4.3.3 Comparative Analysis

In order to compare the means of two independent nutritional risk groups (low risk and medium/high risk), the parametric independent t-test was used for normally distributed data. The non-parametric Mann-Whitney U test was used to compare differences between the two groups when the dependent variable was continuous, but not normally distributed. The Chi-square test was used to examine associations between the two independent groups for categorical data.

The effect of time between baseline and 3 months, baseline and 6 months and baseline and 12 months was analysed using paired t-tests where data was normally distributed, or the non-parametric alternative, Wilcoxon signed-rank test, where data were not normally distributed. Change scores were calculated and mixed modelling was used to examine the effect of nutritional risk on our dependent variables HGS, function and quality of life over time adjusting for key confounders reported in the literature.

For EQ-5D national population norms have been published (Kind et al, 1999). This data is categorised by age, with data from the older population split into three groups, 60-64years, 65-74 years and 75 years and older. The data is presented as a mean and standard deviation. The independent t-test was employed to assess differences between the study cohort and UK population norms.

4.3.4 Missing data

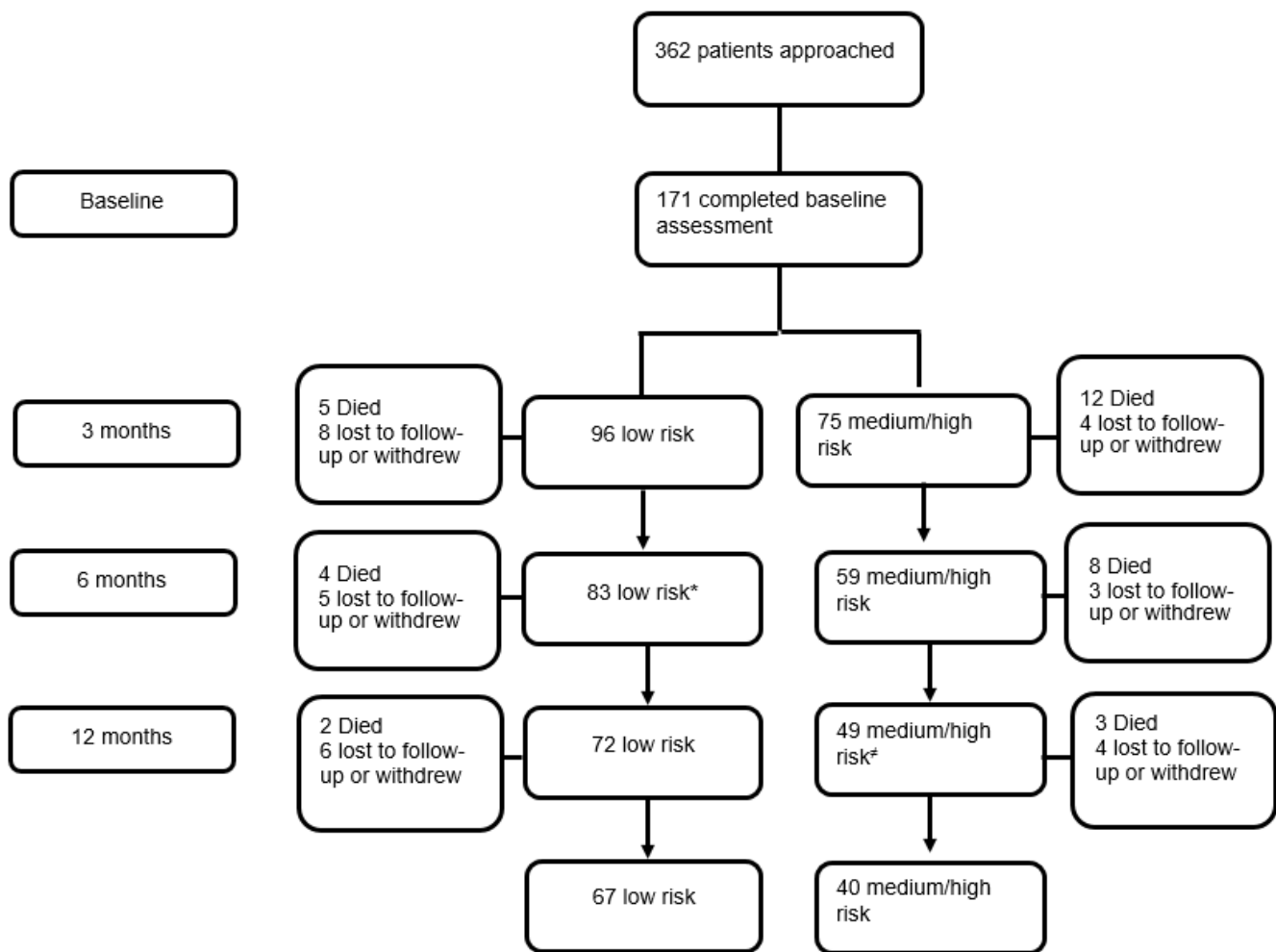
Repeated measures over time may cause missing data due to participants not being contactable, not being well enough to participate or withdrawing from the study. Missing data leads to a loss of information and have the potential to introduce bias in to the results. For the analysis contained within this chapter, participant numbers in the tables presented vary due to missing data; this is problematic when cross-tabulating the same variables against each other over time (e.g. HGS). Complete case analysis was chosen to deal with missing data, excluding participant data for follow-up waves where outcome data were missing from our analysis. In prospective cohort studies where participants are followed up over time, complete case analysis has been widely used and should not introduce bias (Karahalios et al., 2012).

4.4 Results

4.4.1 Recruitment and Preliminary Analyses

Participants were recruited from Imperial College Healthcare NHS Trust. One-hundred and seventy-one participants completed the baseline assessment. At the 3 month follow up 142 were retained (83%) but only 139 could be assessed (81%). Three participants could not be seen in the timeframe required (due to holidays and other commitments), but were retained in the study up to 12 months. Details are presented in Figure 4.1.

A total of 13 participants did not have the capacity to consent to the study (assessed by hospital staff as part of usual care) and were therefore recruited with the support of a consultee.



*assessment not completed for 3 participants due to unavailability

Figure 4.1: Flow diagram showing recruitment and dropout from baseline to 12 month follow-up

4.4.2 Characteristics of the study cohort

The baseline characteristics of all 171 participants are summarised in table 4.2. This shows that the study sample was predominantly white females, aged over 79 years, and mostly living alone. Categorisation by nutrition risk revealed that the medium/high risk group were older, frailer, had lower BMI, were less able to perform activities of daily living, were more likely to be at risk of sarcopenia, had a lower food related quality of life, and had a weaker hand grip strength. Gender and number of comorbidities were statistically similar.

Variable	All participants	Nutritional risk category		p-value (n=171)
Mean (SD) or median (IQR)				
		Low (n=96)	Medium/High (n=75)	
Gender % Male (n)	35 (59)	38.5 (36)	30.6 (23)	0.353
Female (n)	65 (112)	62.5 (60)	69.3 (52)	0.761
Age (years)	79.2 (9.9)	77.3 (9.1)	81.6 (10.5)	0.004*
Marital status % (n)				
-Single	26.9 (46)	32.3 (31)	20.0 (15)	0.091
-Married or cohabiting	24.6 (42)	22.9 (22)	26.7 (20)	0.733
-Separated or divorced	17.0 (29)	16.7 (16)	17.3 (13)	0.985
-Widowed	31.6 (54)	28.1 (27)	36.0 (27)	0.545
Household relationships % (n)				
-Live with someone	40.9 (70)	37.5 (36)	45.3 (34)	0.548
-Live alone	59.1 (101)	62.5 (60)	54.7 (41)	0.373
Ethnic group % (n)				
- White	79.5 (136)	76.6 (72)	83.1 (64)	0.629
- Non-white	20.5 (35)	23.4 (24)	16.9 (11)	0.107
Reason for admission % (n)				
- Orthopaedic	29.2 (50)	21.9 (21)	38.7 (29)	0.017*
- Respiratory	22.8 (39)	19.8 (19)	26.7 (20)	0.289
- Cardiology	13.5 (23)	19.8 (19)	5.3 (4)	0.006*
- Infection	9.4 (16)	10.4 (10)	8.0 (6)	0.591
- Generally unwell or unspecified	7.6 (13)	7.3 (7)	8.0 (6)	0.863
- Gastroenterological	6.4 (11)	8.3 (8)	4.0 (3)	0.253
- Skin or eye problems	4.7 (8)	6.3 (6)	2.7 (2)	0.272
- Elective surgery	2.9 (5)	3.1 (3)	2.7 (2)	0.860
- Pain or mobility issues	2.3 (4)	3.1 (3)	1.3 (1)	0.443
- CVA	0.6 (1)	0.0 (0)	1.3 (1)	0.258
- Other	0.6 (1)	0.0 (0)	1.3 (1)	0.258
Significant cognitive impairment % (n)	8.8 (15)	5.0 (5)	13.3 (10)	0.063
Comorbidity score	5 (4, 6)	5 (4, 6)	5 (4, 6)	0.640
Frailty score	5 (3, 6)	4 (2, 6)	5 (4, 6)	0.001*
Weight (kg)	65.2 (17.8)	73.3 (15.8)	55.0 (14.8)	<0.001*
BMI (kg/m2)	24.8 (6.2)	27.7 (5.2)	21.23 (5.3)	<0.001*
ADL score ^a	32 (10, 54)	23.5 (5, 48)	37.0 (21, 58)	0.004*

SARC-F^b score	4 (2, 7)	3 (1, 6)	5 (2, 7)	0.002*
HGS^c (kg)	18.7 (8.2)	20.8 (8.6)	15.8 (6.8)	<0.001*
EQ-5D-5L UI^d	0.74 (0.45, 0.90)	0.79 (0.49, 0.94)	0.67 (0.37, 0.87)	0.097
EQ-5D VAS^e	59.32 (25.60)	60.82 (25.79)	57.31 (25.43)	0.118
Satisfaction with food-related life^f	20 (15, 21)	20 (16, 22)	18 (14, 20)	0.003*

ADL score, modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0-40 (low), 41-70 medium and >71 (high).

^b SARC-F score, sarcopenia risk score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3=Healthy, 4+=symptomatic

^c HGS, handgrip strength (kg). Higher scores indicate greater muscle strength

^d EQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^e EQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

^f Satisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

Association analysis was adjusted for age, gender, comorbidities and readmission

Table 4.2: Baseline characteristics of a sample of community-dwelling older adults at hospital discharge comparing participants at low and medium/high undernutrition risk

Variable	Nutritional risk category							
	Baseline		3 month follow-up		Change over time		p-value	
	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk
Median (IQR)								
SARC-F score ^a	3 (1, 6)	5 (2, 7)	4 (2, 7) [‡]	6 (4, 8) [‡]	1 (0, 2)	1 (-1, 2)	0.001	0.037
ADL score ^b	21 (5, 46)	36 (22, 56)	35 (11, 57) [‡]	48 (27, 70) [‡]	8.5 (-1, 14.5)	9.4 (-1, 16)	<0.001	<0.001
Mean (SD)								
HGS ^c	21.0 (8.7)	15.5 (6.8)	20.9 (8.9) [*]	15.1 (6.9) [*]	-0.5 (4.6)	-0.3 (3.6)	0.409	0.524

[‡]p=0.003, between group comparison low risk versus medium/high risk of undernutrition

[‡]p=0.003, between group comparison low risk versus medium/high risk of undernutrition

^{*}p<0.001, between group comparison low risk versus medium/high risk of undernutrition

^aSARC-F score, sarcopenia risk score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3=Healthy, 4+=symptomatic

^bADL score, modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0-40 (low), 41-70 medium and >71 (high).

^cHGS, handgrip strength (kg). Higher scores indicate greater muscle strength

Table 4.3: Change in sarcopenia risk, activities of daily living and handgrip strength from baseline to 3 months in a sample of community-dwelling older adults categorised by nutritional risk (n=139)

Variable	Nutritional risk category							
	Baseline		6 month follow-up		Change over time		p-value	
	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk
Median (IQR)								
SARC-F score ^a	3 (1, 6)	4 (2, 7)	4 (1, 7) [#]	6 (4, 8) [#]	0 (0, 2)	0 (-1, 3)	0.003	0.010
ADL score ^b	20 (5, 45)	33 (21, 57)	24 (8, 60) [‡]	55 (27, 70) [‡]	4 (-1, 2)	8 (-1.5, 17.5)	<0.001	<0.001
Mean (SD)								
HGS ^c	21.4 (8.9)	15.3 (6.4)	18.5 (8.9) *	14.5 (6.8) *	-0.4 (5.4)	-0.0 (3.6)	0.501	0.976

[#]p=0.005, between group comparison low risk versus medium/high risk of undernutrition

[‡]p=0.002, between group comparison low risk versus medium/high risk of undernutrition

*p=0.182, between group comparison low risk versus medium/high risk of undernutrition

^aSARC-F score, sarcopenia risk score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3=Healthy, 4+=symptomatic

^bADL score, modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0-40 (low), 41-70 medium and >71 (high).

^cHGS, handgrip strength (kg). Higher scores indicate greater muscle strength

Table 4.4: Change in sarcopenia risk, activities of daily living and handgrip strength from baseline to 6 months in a sample of community-dwelling older adults categorised by nutritional risk (n=121)

Variable	Nutritional risk category							
	Baseline		12 month follow-up		Change over time		p-value	
	Low risk	Med/high risk	Low risk	Med/high risk	Low risk	Med/high risk	Low risk	Med/high risk
Median (IQR)								
SARC-F score ^a	3 (1, 6)	4 (2, 7)	4 (1, 7) [#]	6 (4, 8) [#]	0 (0, 2)	0 (-1, 3)	0.002	0.009
ADL score ^b	20 (3, 46)	35 (19, 61)	24 (9, 57) [‡]	53 (26, 74) [‡]	4 (-1, 17)	8 (0, 22)	<0.001	<0.001
Mean (SD)								
HGS ^c	21.6 (9.1)	15.2 (6.7)	21.0 (9.8) [*]	13.9 (8.3) [*]	-0.7 (5.4)	-1.2 (4.4)	0.284	0.106

[#]p=0.004, between group comparison low risk versus medium/high risk of undernutrition

[‡]p=0.003, between group comparison low risk versus medium/high risk of undernutrition

^{*}p=0.001, between group comparison low risk versus medium/high risk of undernutrition

^aSARC-F score, sarcopenia risk score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3=Healthy, 4+=symptomatic

^bADL score, modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0-40 (low), 41-70 medium and >71 (high).

^cHGS, handgrip strength (kg). Higher scores indicate greater muscle strength

Table 4.5: Change in sarcopenia risk, activities of daily living and handgrip strength from baseline to 12 months in a sample of community-dwelling older adults categorised by nutritional risk (n=107)

Outcome variable	Group effect		Time effect		Group x time effect	
	<i>F</i> (df 1, df 2)	p-value	<i>F</i> (df 1, df 2)	p-value	<i>F</i> (df 1, df 2)	p-value
ADL score ^b	8.2 (1, 159)	0.005	15.2 (3, 116)	<0.001	0.87 (3, 116)	0.967
HGS ^c	16.1 (1, 160)	<0.001	1.7 (3, 112)	0.190	0.17 (3, 129)	0.914

F, *F*-distribution; *df*, degrees of freedom

^aSARC-F score, sarcopenia risk score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3=Healthy, 4+=symptomatic

^bADL score, modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0-40 (low), 41-70 medium and >71 (high).

^cHGS, handgrip strength (kg). Higher scores indicate greater muscle strength

Table 4.6: Comparison of sarcopenia risk, activities of daily living and handgrip using mixed modelling to show within- and between-subjects effects (n=171)

Tables 4.3, 4.4 and 4.5 describe changes in function (ADL score), sarcopenia score and handgrip strength over the 3 month immediate post-discharge period, 6 month and 12 month assessments. Both groups got worse in terms of activities of daily living, risk of sarcopenia and handgrip strength, although the magnitude of change differed at each time point. The data is described in more detail below for each outcome.

4.4.3 Sarcopenia risk (SARC-F)

At baseline sarcopenia risk was higher in the medium/high nutritional risk group compared to low risk (table 4.2). The scores indicated that the low risk group was 'healthy' (median 3 (IQR: 1,6)) and the medium/high risk group was 'symptomatic' (5 (2,7)). Over time both groups SARC-F scores got worse, as indicated by the significant increase in group scores. This change triggered a switch from the healthy category (score 0–3) to symptomatic (score ≥ 4) in many of the patients in the low risk group. At baseline 56% were symptomatic compared to 65% at 3 and 12 months. By 3 months both risk groups were on average categorised as 'symptomatic' of sarcopenia and this was maintained at 12 months.

4.4.4 Muscle strength (Hand grip strength)

At baseline, 79.5% of participants were right-handed and 12.9% were left-handed. A total of 7.0% were unable to perform HGS at baseline, and therefore data were recorded as missing.

A significantly higher HGS was seen in the low risk group compared to the medium/high nutritional risk group at baseline (see table 4.2). This difference was maintained at 3, 6 and 12 months (table 4.3, 4.4 and 4.5). In the mixed model analysis, neither group exhibited any effect of time (table 4.6). These effects persisted when the model was adjusted for age, gender, comorbidity and readmission.

It is well cited in the literature that gender impacts HGS significantly (Peebles and Norris, 2003) and the results of this study support this view with male participants exhibiting significantly higher HGS compared to their female counterparts at each study time point. For example, at baseline males at low risk and medium/high risk of undernutrition exhibited mean (SD) grip strengths of 26.1 (9.2) kg and 20.1 (7.7) kg respectively, compared to females at low risk and

medium/high risk with grip strengths of 17.5 (6.2) kg and 14.1 (5.6) kg. In line with published literature (Newman et al., 2016), age too had a clear effect on HGS in our sample, strength reducing with age. For example, in the age categories 60-69 years and ≥ 70 years, mean (SD) grip strengths of 23.4 (8.7) kg and 20.0 (8.3) kg for those at low risk and 21.7 (7.5) kg and 14.5 (6.0) kg at medium/high risk respectively. As a result, population reference values have been developed to provide age and gender specific norms (Dodds et al., 2014). The study data was stratified by gender, and reclassified into six separate age categories (60-69, 70-74, 75-79, 80-84, 85-89 ≥ 90 years) for comparison to reference data by Dodds et al (table 4.7). The higher risk group demonstrated lower HGS compared to the low risk group in 9/10 age categories (in 1/10 the values were higher; male 70-74, but the difference minimal). However, both groups were consistently lower than age and gender matched reference values.

		Grip strength values (kg)		Grip strength normative values (kg)
Age (years)	Observations	Mean (SD) (low risk)	Mean (SD) (medium/high risk)	Mean (SD) (Reference)
Male				
60-69	11	30.0 (10.6)	28.5 (6.9)	42.3 (8.6)
70-74	6	21.3 (10.3)	22.0 (5.3)	39.1 (8.1)
75-79	12	29.7 (7.9)	22.0 (8.7)	35.6 (7.6)
80-84	11	24.5 (8.7)	12.0 (0.0)	32.2 (7.3)
85-89	7	22.5 (9.7)	16.0 (5.3)	28.5 (7.0)
90+	8	24.5 (7.8)	12.7 (6.1)	24.7 (6.8)
Female				
60-69	24	20.4 (6.1)	18.3 (5.2)	25.3 (6.0)
70-74	8	19.4 (8.3)	18.3 (10.4)	23.5 (5.7)
75-79	19	19.3 (6.4)	14.2 (6.8)	21.4 (5.4)
80-84	16	13.8 (4.5)	14.3 (5.0)	19.1 (5.1)
85-89	13	12.3 (1.3)	13.2 (4.1)	16.6 ± 4.7
90+	23	14.4 (3.8)	11.1 (4.1)	14.2 ± 4.4

Table 4.7: Comparison of handgrip strength within a sample of older adults at hospital discharge and normative values for hand grip strength, (Dodds et al., 2014) stratified by gender (n=159)

4.4.5 Functional status – activities of daily living (The modified Townsend activities of daily living scale)

A significantly higher total activities of daily living (ADL) score was seen in the medium/high risk group compared to the low risk group, demonstrating a worse functional status at study baseline (table 4.2). This significant difference was maintained at 3 month, 6 month and 12 month assessments. Within each of the two nutritional risk groups, at least 45% of participants reported one or more difficulties performing activities of daily living in all domains at baseline, and domestic activities presented the most difficulties.

Whilst the between-group differences persisted, there was also a significant worsening in ability to perform ADLs over the first 3 months in each group (table 4.3). However, at 12 month follow-up, there was a clear difference in each group's recovery: For the low risk group, ADL score had reduced back towards baseline levels by 6 month follow-up, showing improvement in functional status. On the other hand, the medium/high risk group saw a further increase in ADL score at 6 months indicative of worsening functional status (table 4.4). This remained true when the model was adjusted for age, gender, comorbidities and readmission.

Figures 4.2 and 4.3 show the number of participants experiencing one or more problems in food preparation and shopping activities. Mirroring the overall trend, ability to prepare food showed a significant between-group difference with 39.7% of low risk participants experiencing difficulties at baseline compared to 56.0% of participants at medium/high risk ($F(1, 159) = 7.1, p = 0.009$). In addition, problems appeared to resolve between 3 and 12 months for the participants at low risk, where those at medium/high risk experienced ongoing worsening showing an effect of time ($F(3, 121) = 8.9, p < 0.001$). The group by time interaction was not significant ($p = 0.055$). Again shopping ability showed clear between group differences ($F(1, 164) = 12.8, p < 0.001$), with a worsening at 3 months which did not improve or deteriorate significantly by 12 month assessment ($F(3, 123) = 10.3, p < 0.001$).

Table 4.8 shows how ADL score changed over three months, with 29 participants experiencing a deterioration over time, and no participants reporting an improvement. Similarly, from

baseline to 12 month assessment, only one participant demonstrated improvement, whilst 18 participants experienced functional deterioration. On both occasions a higher proportion of participants at medium/high risk reported deterioration.

Nutritional risk	ADL score									
	Low (good) ^a (0-40*)		Medium/high (poor) ^b (41+*)		Deteriorated ^c		Improved ^d		Remained stable	
	n	%	n	%	n	%	N	%	n	%
Baseline to 3 month change (n=139)										
Low risk	46	57.5	34	42.5	18	22.5	0	0	62	77.5
Medium/high risk	23	39.0	36	61.0	11	18.6	0	0	48	81.4
Baseline to 12 month change (n=107)										
Low risk	40	58.8	27	41.2	10	14.7	0	0	57	85.3
Medium/high risk	14	35.0	26	65.0	8	20.0	1	2.5	31	77.5

Low, 0-40; medium, 41-70; high, >71

^a Low at baseline and follow-up

^b Medium/high at baseline at follow-up

^c Low at baseline; medium/high at follow-up

^d Medium/high at baseline; low at follow-up

Table 4.8: Change in activities of daily living scores dichotomised to show deterioration versus improvement at 3 and 12 months

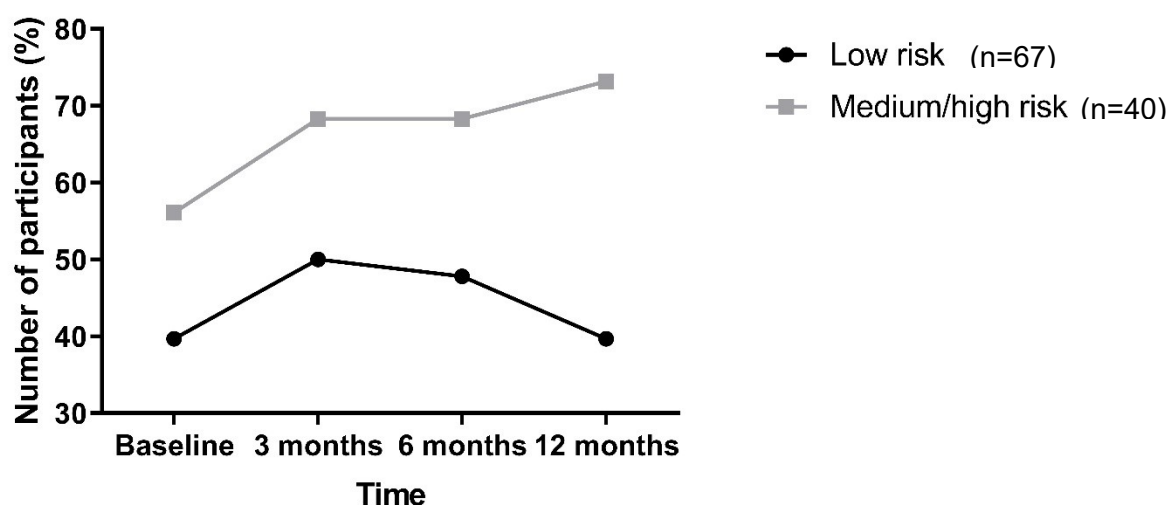


Figure 4.2: Percentage of community-dwelling older adults reporting a problem with food preparation following a hospital admission compared to those reporting no problem and stratified by nutritional risk status (n=107)

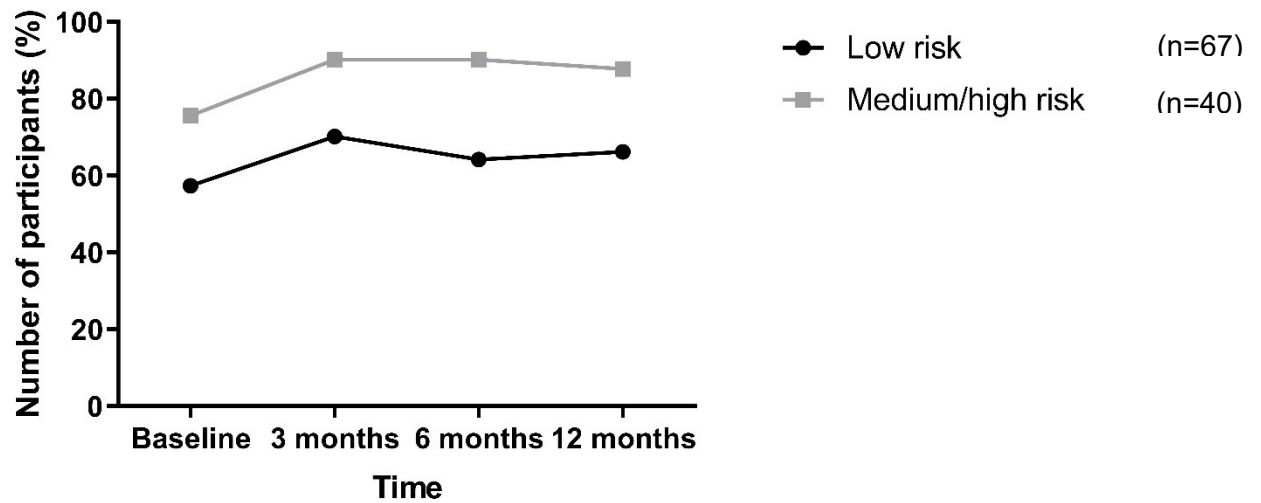


Figure 4.3: Percentage of participants reporting a problem with shopping following a hospital admission compared to those reporting no problem and stratified by nutritional risk status (n=107)

4.4.6 Quality of life

The next data tables, table 4.9, 4.10 and 4.11, describe changes in quality of life and satisfaction with food-related life over the 3 month immediate post-discharge period, 6 and 12 month follow-up. There are significant differences between the groups and over time.

At baseline, EQ-5D utility index scores did not differ between the group at medium/high risk of undernutrition compared to the group at low risk, and no difference in score was seen at 3 month follow-up (table 4.9). No significant change was experienced from 0 to 3 months in either group (table 4.9). However, at 12 month follow-up, there was a significant between-group difference ($p=0.032$), with the utility index score in the low risk group increasing (table 4.10). This equates to a significant improvement in EQ-5D utility index score in the low risk group over time (table 4.12).

In addition, the total cohort had significantly lower scores in the EQ-5D-5L compared to a national sample (table 4.13) and experienced more problems overall compared to population norms (figure 4.4). Of those participants reporting a problem, self-care showed the biggest difference compared to the normative data (figure 4.5). This effect was also seen when EQ-5D VAS data was compared to UK population norms (figure 4.6).

There was no significant difference in EQ-5D VAS scores between the two groups at baseline (table 4.10). At 3 month follow-up there was a significant between-group difference ($p=0.046$), but this did not persist at 12 months. However, at 12 month follow-up, EQ-5D VAS score had improved significantly in the low risk group ($p=0.044$), compared to the medium/high risk group which showed no improvement (table 4.11). This result along with that for EQ-5D utility index suggests the trajectory of recovery was different for the low risk compared to the medium/high risk group. Mixed modelling confirms a between group difference (table 4.12), but no effect of time and no significant interaction between group and time.

Adjusting both utility index and VAS models for age, gender and comorbidities had no effect on the data, however introducing hospital admission (dichotomous – yes or no) as a covariate

reduced the effect of the group, so that nutritional risk no longer had a significant effect on quality of life ($F(1, 99) = 2.2, p = 0.138$). This suggests that hospital admission may contribute to the lower quality of life seen in the participants at higher nutritional risk.

Variable	Nutritional risk category							
	Baseline		3 month follow-up		Change over time		p-value	
	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk
Median (IQR)								
EQ-5D-5L UI ^a	0.79 (0.49, 0.94)	0.69 (0.45, 0.88)	0.87 (0.62, 0.94) [#]	0.74 (0.41, 0.90) [#]	0.01 (-0.08, 0.23)	0.04 (-0.11, 0.16)	0.062	0.187
SWFL ^b	20 (16, 22)	19 (15, 20)	18 (13, 20) [*]	17 (14, 20) [*]	-1 (-3, 2)	0 (-3, 2)	0.001	0.101
Mean (SD)								
EQ-VAS ^c	60.82 (25.79)	59.02 (25.43)	67.45 (23.94) *	59.02 (23.32) *	5.68 (27.1)	-0.59 (19.6)	0.070	0.825

[#]p=0.053, between group comparison low risk versus medium/high risk of undernutrition

^{*}p=0.285, between group comparison low risk versus medium/high risk of undernutrition

^{*}p=0.046, between group comparison low risk versus medium/high risk of undernutrition

^aEQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^bSatisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

^cEQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Table 4.9: Change in quality of life and satisfaction with food-related life measures from baseline to 3 months categorised by nutritional risk (n=139)

Variable	Nutritional risk category							
	Baseline		6 month follow-up		Change over time		p-value	
	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk
Median (IQR)								
EQ-5D-5L UI ^a	0.79 (0.46, 0.94)	0.69 (0.46, 0.87)	0.87 (0.65, 0.94) [‡]	0.75 (0.43, 0.90) [‡]	0.02 (-0.06, 0.21)	0.04 (-0.16, 0.23)	0.035	0.328
SWFL ^b	20 (16, 22)	19 (15, 21)	19 (15, 20) [‡]	16 (14, 20) [‡]	-1 (-4, 0)	0 (-4, 2)	0.004	0.90
Mean (SD)								
EQ-VAS ^c	61.11 (26.13)	60.40 (25.54)	68.83 (21.83) *	63.00 (25.14) *	8.18 (27.4)	1.66 (20.2)	0.015	0.576

[‡]p=0.063, between group comparison low risk versus medium/high risk of undernutrition

[‡]p=0.072, between group comparison low risk versus medium/high risk of undernutrition

^{*}p=0.182, between group comparison low risk versus medium/high risk of undernutrition

^aEQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^bSatisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

^cEQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Table 4.10: Change in quality of life and satisfaction with food-related life measures from baseline to 6 months categorised by nutritional risk (n=121)

Variable	Nutritional risk category							
	Baseline		12 month follow-up		Change over time		p-value	
	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk	Low risk	Medium/high risk
Median (IQR)								
EQ-5D-5L UI ^a	0.79 (0.46, 0.95)	0.69 (0.46, 0.87)	0.89 (0.61, 1.00) [#]	0.69 (0.41, 0.69) [#]	0.05 (-0.06, 0.28)	0.04 (-0.08, 0.21)	<0.001	0.293
SWFL ^b	20 (16, 22)	19 (15, 21)	19 (13, 20) [*]	16 (12, 20) [*]	-1 (-4, 1)	-1 (-5, 1)	0.001	0.029
Mean (SD)								
EQ-VAS ^c	61.3 (26.7)	60.5 (24.6)	68.5 (26.0) [*]	60.4 (27.6) [*]	7.50 (29.7)	0.15 (28.6)	0.044	0.974

[#]p=0.032, between group comparison

^{*}p=0.181, between group comparison

^{*}p=0.118, between group comparison

^aEQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^bSatisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

^cEQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Table 4.11: Change from baseline to 12 months categorised by nutritional risk (n=107)

Outcome variable	Group effect		Time effect		Group x time effect	
	<i>F</i> (df 1, df 2)	p-value	<i>F</i> (df 1, df 2)	p-value	<i>F</i> (df 1, df 2)	p-value
EQ-5D-5L UI ^a	6.624 (1, 161.2)	0.013	2.702 (3, 129.3)	0.048	0.194 (3, 129.3)	0.900
SWFL ^b	6.416 (1, 156.0)	0.012	7.559 (3, 124.2)	<0.001	0.692 (3, 124.2)	0.559
EQ-VAS ^c	6.930 (1, 149.0)	0.009	2.197 (3, 120.3)	0.092	0.396 (3, 120.3)	0.756

F, F-distribution; df, degrees of freedom

^aEQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^bSatisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

^cEQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Table 4.12 Comparison of outcome variables using mixed modelling (n=171)

Age group	This sample EQ-5D UI (n=170*)	England normative values (n=996)	p-value
		Mean(SE)	
55-64	0.57 (0.098)	0.80 (0.010)	<0.001
65-74	0.45 (0.587)	0.79 (0.010)	<0.001
75+	0.55 (0.648)	0.73 (0.013)	<0.001
	EQ-5D VAS (n=167)	UK normative values (n=3395)	p-value
		Mean(SD)	
55-64	53.56 (22.67)	81.6 (2.1)	<0.001
65-74	53.32 (28.42)	77.3 (0.8)	<0.001
75+	60.68 (26.22)	73.8 (1.1)	<0.001

*1 participant failed to provide data for quality of life utility index at baseline

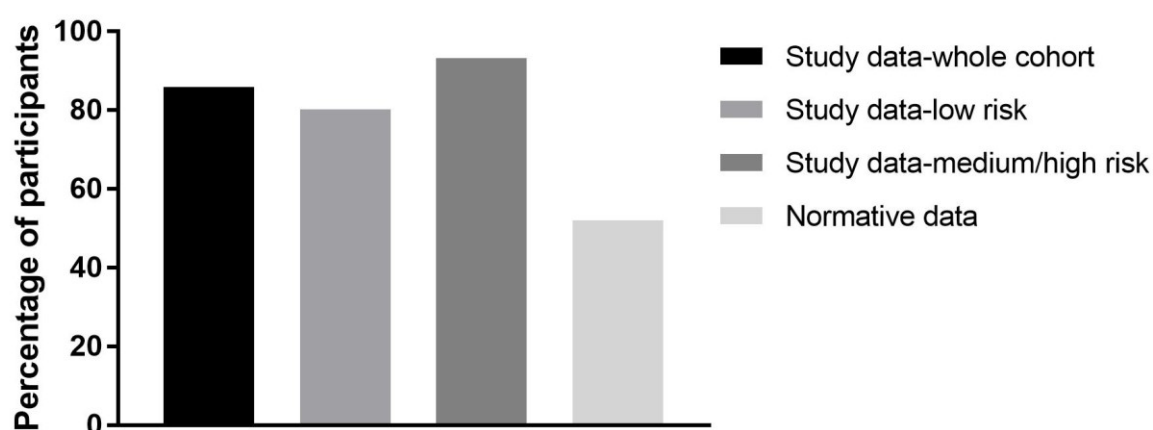
**4 participants failed to provide data for quality of life VAS at baseline

^aEQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = worst to 1 = best)

^bSatisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

^cEQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Table 4.13 Comparison of study cohort scores at baseline and population norms for EQ-5D-5L Utility Index (UI) and EQ-5D VAS for a normative sample (Devlin et al., 2018, Kind et al., 1998)



*1 participant failed to provide data for quality of life outcomes as baseline

Figure 4.4: Reported health status of a sample of older adults at hospital discharge (n=170) compared to normative data from England (Kind et al., 1998) (n=996). Data includes participants reporting any problem compared to no problems

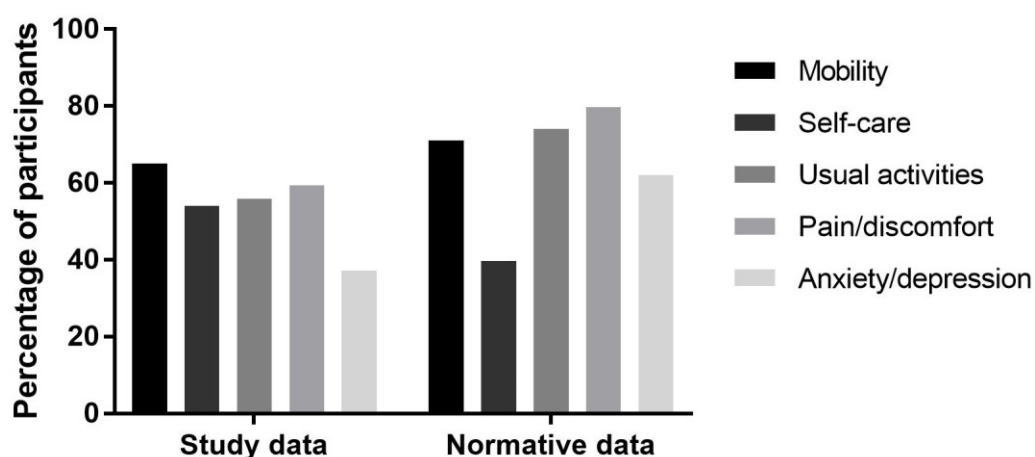
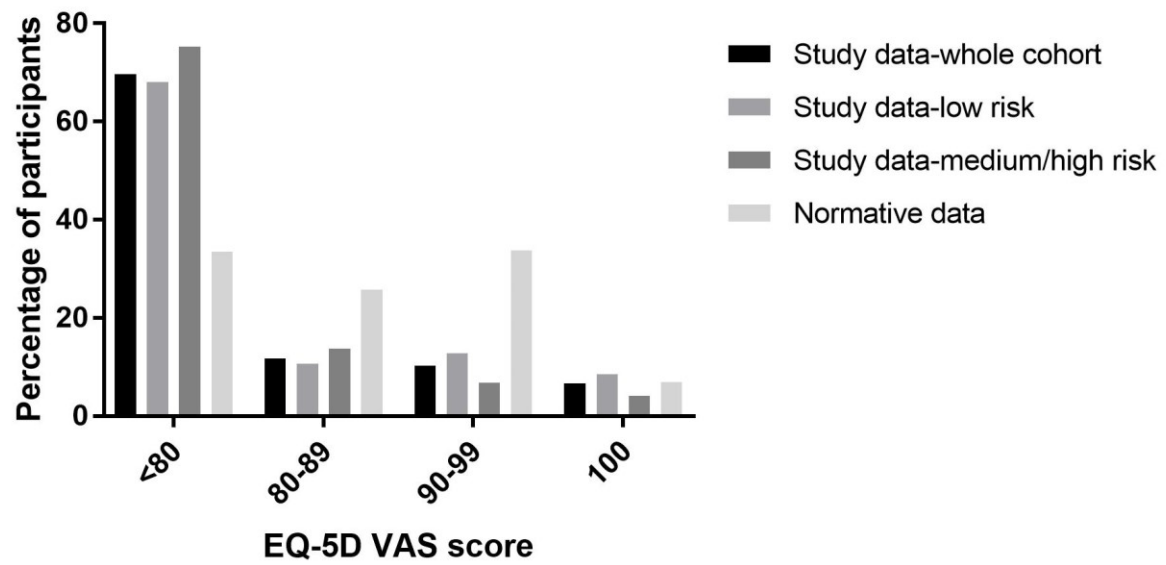


Figure 4.5: Type of problem experienced by a sample of older adults at hospital discharge (n=146) compared to normative data from England (Kind et al., 1998) (n=522)



EQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

Figure 4.6: Reported EQ5D VAS score by a sample of older adults at hospital discharge (n=167) compared to normative UK data (Devlin et al., 2018)

4.4.7 Satisfaction with food-related life

Satisfaction with food-related life was measured as an adjunct to quality of life, see table 4.9, 4.10 and 4.11. As table 4.12 shows, there were between-group and within group differences ($p=0.012$ and $p<0.001$ respectively). The change in satisfaction with food-related life score reduced at 3 month follow-up for those at low risk of undernutrition ($p=0.001$) then remained stable at 3, 6 and 12 month follow up. On the other hand, in the medium/high risk group scores reduced slowly with scores at 12 months significantly lower than at baseline ($p=0.029$). At 12 month follow-up both groups demonstrated significant reductions in satisfaction with food-related life compared to baseline (table 4.11). This significant interaction suggests that individuals at nutritional risk are less satisfied with their food-related life and that the trajectory of recovery post-hospitalisation may differ.

4.4.8 Readmission and mortality

Hospital readmission was assessed at 3, 6 and 12 month time points. Readmission rate was high in both groups, but there was no statistical difference between groups ($p=0.195$) or within groups over time ($p=0.082$) (table 4.14). Of those at medium or high nutritional risk 56.1% had a readmission, compared to 38.2% of those at low risk.

To determine any differences in mortality between the two groups at 12 months a chi-square test for association was performed between mortality and nutritional risk group. Of 139 participants not lost to follow-up, a total of 23.0% ($n=32/139$) had died at 1 year. Of those participants at medium or high nutritional risk 36.5% ($23/63$) had died, compared to 11.8% ($9/76$) of those at low risk. A statistically significant association was present between mortality and nutritional risk category low versus medium/high, $\chi^2(1) = 13.2$, $p < 0.001$ (see table 4.14). The relative risk of death was 3.241 (95% confidence interval 1.622 to 6.476). As the relative risk value is greater than 1, participants at medium and high risk of undernutrition were shown to be at increased risk of death compared to participants at low risk.

A binomial logistic regression was then undertaken to explore the effects of undernutrition risk, age, gender, comorbidity, living alone and frailty on the risk of mortality. The logistic regression

model was statistically significant, $\chi^2(16)=37.211$, $p=0.002$. The variation in mortality (dependent variable) was 35% using Nagelkerke R² to calculate explained variation and accurately classified 79.9% of cases. Statistical measures of performance showed that the sensitivity of the test was 33%, i.e. that 33% of participants were correctly identified by the regression as dead; the specificity showed that 94% of participants who remained in the study were correctly identified. The model displayed high specificity but low sensitivity, signifying that a positive test result is more reliable than a negative one. Positive predictive value was 61.1% and negative predictive value 82.5%. Of the six independent variables in the model, two were statistically significant: Nutritional risk and gender. The odds of mortality were 5.7 times higher for those at medium or high risk of undernutrition compared to their counterparts at low risk. Risk of mortality was 3 times higher for males compared to females. Increasing age, a higher number of comorbidities, living alone, and frailty were not associated with mortality.

	All participants (n=139)	Low risk (n=76)	High/medium risk (n=63)	p-value
Mortality % (n)	22.4 (32)	27.3 (9)	72.7 (23)	<0.001
Readmission ≥1 % (n)	43.9 (47)	37.3 (25)	55.0 (22)	0.107
Total readmissions at 1 year Median (IQR)	0 (0, 2)	0 (0, 2)	1 (0, 2)	0.195

Table 4.14: Mortality and readmission at 12 months stratified by nutritional risk

4.5 Discussion

This chapter set out to examine the impact of nutritional risk in a cohort of older adults, following a hospital admission. The key results are summarised in the points below, I will then go on to consider the findings in the context of existing literature and to draw conclusions.

- Individuals at medium and high risk of undernutrition at hospital discharge had a higher sarcopenia risk, worse functional status and lower muscle strength than individuals at low risk of undernutrition.
- Whilst both groups appeared to deteriorate following a hospital admission, the trajectory of recovery differed, with improvements seen more readily in participants at low nutritional risk.
- Strikingly, mortality at 1 year was significantly higher in community-dwelling older adults at nutritional risk compared to those at low risk, with logistic regression indicating that nutritional risk was a significant predictor.
- Health-related quality of life and satisfaction with food related life showed between-group differences at varying time points, with improvements in quality of life seen in those at low risk of undernutrition over time compared to their medium and high risk counterparts, and a deterioration in satisfaction with food-related life observed in medium and high risk participants compared to participants at low risk.

This study found that older adults at medium and high risk of undernutrition at discharge from hospital were at increased the risk of mortality at 12 months. Despite its relatively small sample size, there was a stark difference in mortality between those at low risk of undernutrition compared to those at medium or high risk. As there are several variables that may impact mortality, regression was used to examine the role of undernutrition risk as a predictor. As discussed in the thesis introduction in section 1.8, this finding has been shown elsewhere in the literature, however these studies are primarily limited to in-hospital or community-dwelling populations (Friedmann et al., 1997, Isabel T. D. Correia and Waitzberg, 2003). One American study has examined older people in the transition period from hospital to home (Liu et al.,

2002) finding that both BMI ≤ 20 kg/m² and recent weight loss increased mortality risk with a relative risk (95% CI) 1.83 (1.17–2.85) and 2.31 (1.35–3.94) respectively.

Our results show that 56% of the study population were symptomatic for sarcopenia at baseline. To my knowledge, no studies have used SARC-F to measure prevalence in a population of older adults at hospital discharge and again at follow-up, thus no comparison exists. However, as both sarcopenia measured using the European Working Group on Sarcopenia in Older People (EWGSOP) criteria and SARC-F score ≥ 4 , indicative of symptomatic sarcopenia, have been associated with a hospital admission in retrospective and prospective research (Cao et al., 2014, Wu et al., 2016, Zhao et al., 2018), I would anticipate greater prevalence of sarcopenia in hospital populations compared to community cohorts, thus higher SARC-F scores. There are three available studies using SARC-F to explore sarcopenia in community-dwelling older adults (Malmstrom et al., 2016, Woo et al., 2014, Wu et al., 2016), one of which explores a cohort whilst in hospital (Wu et al., 2016). These all show much lower rates of sarcopenia risk; from 2.6% and 6.1% (Woo et al., 2014, Wu et al., 2016) in the first two studies, and 18.4%, 6.3% and 15.4% in three cohorts (Malmstrom et al., 2016). This may be due to a number of reasons. The first two studies took place in Asia and recruited community-dwelling older adults. Despite differences in ethnicity between this cohort and our sample, the lower prevalence of sarcopenia is surprising. This difference in prevalence may have occurred for three reasons: The first, that participants recruited in two of the studies were middle-older aged, and therefore somewhat younger than our study population (Malmstrom et al., 2016, Wu et al., 2016). Secondly, our study specifically set out to recruit 50% individuals with nutritional risk who are likely to have a lower body mass and potentially strength too, this was not a criteria for these studies and nutritional risk was not measured. Thirdly, the study by Woo et al. may be biased toward those without sarcopenia, as participants had to visit a study centre for inclusion in the study, where the participants of our study were predominantly visited at home. In the study Malmstrom et al (2016), participants were visited at home perhaps explaining the higher prevalence. Additionally, in all of the studies whilst follow-up was

completed, SARC-F was not measured again, so it was not clear if or how it changed over time. From this point of view, our study adds to the limited longitudinal data on changes in sarcopenia over time.

Other studies using the EWGSOP criteria for sarcopenia have shown prevalence of 40% in older adults (Joglekar et al., 2015, Marzetti et al., 2016, Pérez-Zepeda et al., 2017, Zhuang et al., 2016). A further two studies provide information on sarcopenia and nutritional status. The first, a Spanish study (n=88) showed a prevalence of 45% in older adults at risk of undernutrition admitted to a post-acute geriatric care unit (Sánchez-Rodríguez et al., 2017); the second in a sample of independent, community-dwelling adults in Singapore aged ≥ 50 years (n=200), demonstrated prevalence of 25% with those at risk of sarcopenia threefold more likely to be undernourished ($p=0.025$) (Tay et al., 2015).

A key component of sarcopenia diagnosis is hand grip strength, and with a high proportion of participants symptomatic for sarcopenia, it is perhaps unsurprising that hand grip strength was consistently lower than age and gender matched reference values. Baseline data showed lower grip strengths in the group at higher risk of undernutrition compared to participants at low risk in 7/10 age categories, a pattern which persisted at follow-up assessments. Our cohort exhibited mean (SD) grip strengths of 24.0 (9.1) kg and 15.9 (6.1) kg for male and female participants respectively. Existing data in community-dwelling individuals have shown mean grip strength values in the range of 31-36 kg and 10-21 kg for males and females respectively (Ehlenbach et al., 2015, Phillips, 1986, Roberts et al., 2013). This suggests the male participants were exhibiting lower strength compared to their counterparts in other studies.

Several studies have explored the relationship between undernutrition and grip strength in hospital (Jacobsen et al., 2016, McWhirter and Pennington, 1994, Pierik et al., 2017, Steihaug et al., 2017), a few studies have worked with community-dwelling populations, and fewer still have followed participants over time. In the seminal study by McWhirter and Pennington (1994) grip strength was undertaken in 420 hospital inpatients. Whilst mean grip strength values were not provided, the data showed grip strengths of <85% of normative values for

67% of participants, 47% of whom were at risk of undernutrition. Of the remaining 33% of participants achieving grip strength $\geq 85\%$ of normative values, 14% were undernourished. In our study, 57% of participants had a grip strength $< 85\%$ of normative values, 48% of whom were at risk of undernutrition and 43% achieving grip strength $\geq 85\%$ of normative values, 37% were undernourished. One study (n=75) with a sample similar to ours, measured median maximum grip strength on discharge from hospital (Jones et al., 2017). The study found a median (IQR) HGS of 11.8 (9.0, 17.0) kg, but did not follow up post-discharge. Other studies conducted follow-up, but either did not include grip strength at the visit or conducted follow-up using telephone or written questionnaires (Buscemi et al., 2016, Di Monaco et al., 2015, Goto et al., 2017). Our results show that grip strength of the total cohort remained relatively stable at each time point over 12 months. A similar result was seen in both the English Longitudinal Study of Aging (n=3703) and the Hertfordshire Cohort Study (n=441) (Syddall et al., 2018) where annual changes in grip strength ranged from -0.38 (0.60) kg to -0.74 (0.48) kg. Another prospective, longitudinal cohort study of community-dwelling older people (n=2926) collected data over a 14-year period to explore the relationship between hospitalisation and grip strength (Ehlenbach et al., 2015). The authors analysed their data using multiple linear regression, showing grip strength significantly reduced following a hospital admission (-0.8 kg, 95% CI = 1.0, 0.5; $p < 0.001$) compared to no hospital admission. The study raises an important question regarding minimum clinically important difference. Whilst a significant difference in grip strength was visible from the analysis (unlike in our data), the reduction was below the minimum clinically important difference and therefore unlikely to be clinically significant. In addition, the methods used, including the long periods between study visits, mean other confounding variables may influence the result. For example, functional status may have deteriorated prior to the admission or participants may have recovered functional status between hospital discharge and study follow-up.

In addition to differences in grip strength, our study showed a clear difference in self-reported activities of daily living between those at low risk of undernutrition and those at medium or

high risk at baseline. After exploring the literature in older adults I expected that recovery may not be rapid following a hospital admission, as discharge from hospital marks an improving situation in the recovery pathway but does not indicate full recovery. Our data demonstrates a reduction in self-reported functional abilities in the whole cohort. Many studies report a relationship between hospitalisation and changes in the functional status of older adults, in the period after an admission. Recovery of ADL and IADL in older adults is thought to happen in the 4 weeks immediately following discharge (Boyd et al., 2008), although other studies have suggested deficits may persist up to 12 months after discharge (Landefeld et al., 1995, Sager et al., 1996, Wu et al., 2000). We found that even at 12 months, functional status was significantly different to baseline values in both the low risk and medium/high risk group.

A review of functional status in older adults found that 33% of patients aged over 70 years, are discharged with additional functional issues (Covinsky et al., 2011). In one study, 67% percent of individuals with good ADL scores at baseline assessment maintained the same level 12 months post discharge, whereas only 30% of the participants with reduced ADLs were able to improve back to their pre-hospital ADL level (Boyd et al., 2008). Our data showed that 16.5% of participants experienced a sustained reduction in function at 12 months, 74% of participants with 'good' ADL scores remained 'good' at 12 months, where only 1 participant (2%) was able to improve from 'poor or moderate' functional status to 'good'. A study found that functional limitations reduced significantly more in a group without nutritional support 3 months post-hospitalisation compared to a group with nutritional care (Neelemaat et al., 2011a). Two studies examined functional status following admission to a rehabilitation unit (Marshall et al., 2015, Neumann et al., 2005). Both studies showed a decline in physical function measured using the Modified Barthel Index (Marshall et al., 2015, Neumann et al., 2005). The first showed that participants at medium and high risk of undernutrition had reduced function at baseline ($p<0.001$), which had worsened at 3 month follow-up ($p=0.002$). The second study showed improvement in a minority of participants only at 3 month follow-up compared to point of discharge. The majority of participants experienced no significant change

or deterioration (Marshall et al., 2015). The authors noted that the increase in Barthel index score was adversely affected by attrition, where by participants with the worst scores (and hence worst function) were unable to attend for follow up due to functional limitation. It is also worth considering the participants frame of mind. At the point of discharge, the individual may just be happy to be returning home; compared to their situation at 3 month follow-up where they will have experienced the challenges of life after illness.

In addition, in the study by Boyd et al., (2008), ADL data measured by Barthel index showed significant differences between malnourished and well-nourished participants at 12 months post-discharge, as ours did. In the study (Boyd et al., 2008), participants classed as 'at risk' of undernutrition rather than undernourished displayed characteristics more comparable to the well-nourished group. This suggests that by including undernourished and 'at risk' participants within one group, our results may not be as clear.

Our analysis highlighted the two nutrition-related activities because of their potential influence on dietary intake in an older population (Gray-Donald et al., 1995). In our study, 46% of participants reported difficulties with food preparation and 64% with shopping at baseline (56% and 76% of medium/high risk participants; 40% and 57% low risk participants. At 3 month assessment this had increased to 57% and 79%, with 90% of participants at medium/high undernutrition risk reporting difficulty with shopping compared to 70% of those at low risk. Other studies have reported difficulties with meal preparation and food shopping in 80% of participants immediately following hospital discharge; 57% and 56% in food preparation and shopping respectively 6-months post stroke (Anyanwu et al., 2011, Westergren, 2008).

Functional change, and specifically loss of function in older adults is an important issue which may adversely impact health-related quality of life (Covinsky et al., 2011, Davydow et al., 2013, Gill et al., 2010). A study exploring life satisfaction in older people in England showed that a deterioration in health and function was a significant predictor of low life-satisfaction (Bowling and Grundy, 1997) and data from survivors of critical illness has demonstrated an association between functional impairment and health-related quality of life. A large longitudinal study in

the United States (n=11,243) showed that hospital admission was associated with worse health-related quality of life after discharge (Feemster et al., 2015). Our data on quality of life show a significant difference in quality of life between participants at low nutritional risk and those at medium and high nutritional risk, with each demonstrating a different trajectory of recovery following a hospital admission. Participants at medium and high nutritional risk showed no improvement in quality of life following hospital admission using both EQ-5D-5L and VAS scales, with quality of life remaining stable at 3 and 12 month assessments. On the other hand, participants at low risk of undernutrition showed improvements in quality of life measured by the EQ-5D-5L at 12 month follow up. Similarly in a study of participants in a rehabilitation unit, quality of life measured by the 'assessment of quality of life instrument' did not differ by nutritional status (malnourished or at risk of malnutrition versus normal nutritional status) at baseline (Neumann et al., 2005). Again sharing similarities to our data, follow-up post-discharge revealed a significant difference between groups, suggesting each group experienced a different trajectory of recovery (Neumann et al., 2005). This differed to a study in residents of sheltered housing which showed clear differences in health index score between undernourished and well-nourished participants both at baseline and again at one year (Odlund Olin et al., 2005). Interestingly, this study separated the effects of malnutrition and 'risk of' malnutrition, finding any differences were exclusive to malnourished individuals rather than individuals at nutritional risk and those with a normal nutritional status.

National data was used to allow comparison of both utility index and visual analogue scale scores (Kind et al., 1998). Our cohort demonstrated significantly lower EQ-5D scores when compared to UK norms split by age. This is an expected result as, although some individuals within the normative sample will have had a hospital admission, recent hospital stay was not a definite 'stressor' in the community-dwelling sample used for the normative data. Nonetheless, our study data show the effect of hospital admission on quality of life. A study comparing EQ-5D-5L scores across different medical conditions showed mean (SD) of 0.487 (0.36) in Parkinson's disease, 0.688 (0.22) in individuals with breathing problems, to 0.773

(0.22) in diabetes, demonstrating the impact of disease on quality of life (Mulhern et al., 2018). Whilst it is not possible to draw conclusions from this data, the results offer insight into why mean (SD) EQ-5D-5L utility index in our study ranged from 0.45 (0.587) to 0.57 (0.098), reflecting the disease status of the participants.

Analysing our data across the five dimensions of quality of life, shows that overall prevalence of any problem was higher within our study cohort compared to normative data. Interestingly, self-care was the dimension where differences between our study and national data was largest, with the study sample exhibiting more problems in this area compared to the normative data. Otherwise the spread appeared similar, with anxiety and depression contributing the smallest impact. This suggests that there is one dimension causing the difference in EQ-5D-5L problems post discharge. This fits with the larger picture, tying in with the high incidence of ADL problems post-hospital admission.

The spread of EQ-5D VAS mirrored utility index, with more than twice as many study participants demonstrating a VAS score <80% compared to the normative data. The percentage of individuals achieving a VAS score of 100% was relatively small, but similar in both data sets.

It would have been useful to measure participants' quality of life pre-admission for comparison, however this would require a different study design with greater resource which was not feasible. In addition, proxy measures can underestimate, and retrospective recall may overestimate pre-admission health-related quality of life (Scales et al., 2006).

Disease is associated with a worse quality of life, and as undernutrition is a common consequence of disease, it therefore makes sense that a relationship exists between these two factors, however very little has been done to explore this in older adults. This is in part due to a lack of valid instruments to measure food-related quality of life. Research has tended to focus on standard aspects of nutritional risk such as weight loss and reduced intake, but few tools have been designed to capture the wider psychosocial elements of food consumption.

Satisfaction with food-related life is not included in generic quality of life instruments, and has minimal representation in the literature, so our study provides novel data and helps move forward our understanding of food-related quality of life. Our data shows clear between-group differences in satisfaction with food-related life at baseline, with participants at low risk of undernutrition exhibiting higher satisfaction levels compared to their counterparts at medium and high nutritional risk. This is an expected result, tying in with our hypothesis that both quality of life and food-related quality of life would be significantly lower in participants at medium and high risk of undernutrition.

Both groups then experienced a reduction in satisfaction with food-related life at 12 month follow-up, which was not anticipated. I hypothesised that satisfaction with food-related life would mirror quality of life over time, increasing after discharge from hospital, but with the low risk group showing more rapid improvement. Instead, whilst the group at low risk saw a significant drop in satisfaction level at 3 months, levels then remained stable, whilst the group at medium/high risk experienced reducing satisfaction with food-related life at 12 months.

A UK study (Dean et al., 2008a) demonstrated that an association existed between good health status, functional status and satisfaction with food-related life. In this study, 91% of participants reported moderate to high satisfaction with their life and with their food-related life, leaving 9% who were moderately satisfied with their life, but unsatisfied with their food-related life. This result was replicated in two later studies by the same group (Lobos et al., 2016, Schnettler Morales et al., 2014). Mean (SD) satisfaction with food-related life scores were 18.7 (SD not provided) (Dean et al., 2008b), 22.9 (4.5) (Schnettler Morales et al., 2014) and 24.1 (3.8) (Schnettler et al., 2013). The first, an observational study in community-dwelling older adults (n=3291), shows a similar result to the scores in our study. The latter studies however, show somewhat higher results. To compare, the study sample used by Dean et al is similar to ours, collected in European countries including the UK and with older people. The second two are very different, performed in Chile, a country with many differences to the UK, and focussing on a younger population. Whilst Schnettler et al. suggest that further research

should focus on individuals at high nutritional risk, none of the studies explored nutritional risk status and satisfaction with food-related life.

There were some limitations to the study, including within the tools used to measure outcomes. Whilst specificity of the SARC-F tool is high (84-99.0%), sensitivity was low (4.2-33.3%) (Barbosa-Silva et al., 2016, Woo et al., 2014) suggesting the tool lacks accuracy and therefore sarcopenia could be missed in patients. Predictive validity has compared well to other tools which use a measure of muscle mass such as the EWGSOP, IWGS and AWGS tools (Cao et al., 2014, Woo et al., 2014). In addition, self-reported measures have received criticism in the past due to potential differences in perception, particularly between different socioeconomic groups (Dowd and Zajacova, 2007; Singh-Manoux et al., 2007). To illustrate this point, Ferdous et al., (2009) examined self-reported function in comparison to performance measures in a cross-sectional study of undernourished older adults (n=457). A total of 8% reported limitations in ADL. However, over 50% experienced problems in the performance tests (Ferdous et al., 2009). Conversely, other studies have countered this argument, suggesting that participant-reported measures correlate well with performance measures (Schou et al., 2006; van and Gerdtham, 2003). The subjective element of self-reporting is likely to have an effect on functional status using the modified Townsend index and quality of life using the EQ-5D in our study, and may lead to underestimation of functional difficulties.

4.6 Conclusion

There were clear differences between those at medium/high nutritional risk and those at low risk following a hospital admission. Many of these differences persisted with repeated measures suggesting a different trajectory of physical recovery and quality of life between the two groups. Clear between-group differences existed at baseline which was unsurprising, we know from the literature that older adults at risk of undernutrition are likely to suffer adversely. However, what this study has highlighted is that regardless of nutritional status, at hospital discharge older individuals are on a downward trajectory initially. Whilst for low risk

participants this appears to ease over time, those at medium and high risk of undernutrition continue to deteriorate.

Older adults are at risk of declines in various aspects of health status following hospital discharge. This study suggests that older adults may endure specific challenges based on functional issues, with more than a third of participants unable to shop and prepare meals. In our analysis we chose to examine these two activities in greater depth because of the fundamental role they play in ensuring adequate dietary intake with the potential to influence all aspects of functional status in community-dwelling older adults.

Where this study has identified issues with the functional status of older adults, including difficulties with food shopping and food preparation, chapter 6 will go on to look at changes in nutritional status of these participants and consider the dietary data collected within the study and how this changes in parallel.

Chapter 5: Nutritional status, energy and protein intakes in community-dwelling older adults

5.1 Introduction

Longitudinal studies examining changes in nutritional status and nutritional intake with age are rare due to the cost, time and burden on participants involved. Most studies are cross-sectional, whereby participants are stratified by age group and compared to one another. Whilst this provides some insight, it is difficult to separate between-group differences from the physiological changes of aging (Wakimoto and Block, 2001). Nonetheless, results from cross-sectional studies, such as the National Health and Nutrition Examination Survey (NHANES) and longitudinal studies, such as the Baltimore Longitudinal Study of Aging, demonstrate an age-associated reduction in food intake. Energy intakes between ages 25 and 70 years can decline by as much as 1000 to 1200 kcal/day for men and 600 to 800 kcal/day for women (Briefel et al., 1995). By the age of 80 years, 1 in 10 men consumed less than 890 kcal/day whereas 1 in 10 women consumed less than 750 kcal/day (Wakimoto and Block, 2001). Reduced energy intakes can lead to inadequate intakes of protein, vitamins and minerals. NHANES III data show potentially important decreases with age in protein, zinc and other nutrients (Briefel et al., 1995). In one study, 10% of older men consumed 20-30% of the recommended quantities of protein, zinc, calcium, vitamin E, thiamin, riboflavin, vitamin B6, and vitamin B12. The National Diet and Nutrition Study in the UK showed that intakes of vitamin D were suboptimal, failing to meet the RNI for people aged 65 years and over. Intake of the minerals magnesium and copper were also low (Bates et al., 1999). In contrast to the general decline in micronutrient intakes, estimated intakes of carotene, vitamin A, and vitamin C tended to increase with age, especially for women (Wakimoto and Block, 2001). Nutrient density (i.e., consumption of a given nutrient expressed per 1000 kcal) has been shown to decrease significantly with age. In addition, some evidence suggests that reduced metabolic efficiency and bioavailability with advancing age, mean that requirements for specific nutrients may be greater for older adults than their younger counterparts (Bullamore et al., 1970, Lindenbaum et al., 1994). Although clinical studies revealed few explicit nutrient deficiencies

among elderly adults (Palacios et al., 2013), subclinical deficiencies can adversely affect health and physical functioning, and are more difficult to identify (Conzade et al., 2017).

It is important that we learn the most effective way to structure nutritional care across the interface from hospital to community settings in order to ensure efficient nutritional care, and in order to do so more research is required to fully understand the nutritional risk of people following a hospital admission. This study aimed to characterise nutritional risk in a cohort of older adults, comparing a group at low risk of undernutrition with a group at medium or high risk over a 12 month period, examining weight, BMI, energy intake and protein intake.

5.2 Aim, research question and objectives

The aim of the study was to examine nutritional risk in the context of dietary adequacy within a group of older people following discharge from hospital

This study set out to answer the following question:

How do food intake and nutritional status [and factors influencing nutritional status] change over a 12 month period, in older adults after a hospital admission?

This study set the following objectives:

- i. To examine nutritional risk, weight and body mass index group of older adults at discharge from hospital, then at 3, 6 and 12 months, comparing a group of participants over the age of 60 and at medium or high risk of undernutrition at discharge from hospital to a group of participants at low risk.
- ii. To examine the adequacy of energy and protein intakes compared to estimated requirements in a sub-group of older adults at discharge from hospital, then at 3, 6 and 12 months, comparing a group of participants over the age of 60 and at medium or high risk of undernutrition at discharge from hospital to a group of participants at low risk.

5.3 Methods

Recruitment and data collection methodologies have been discussed previously in the methods chapter in chapter 2. However, this chapter will provide more detail on the data included in the analysis, and discuss the measurement of nutritional status and dietary intake.

5.3.1 Nutritional risk status, weight and body mass index

Risk of undernutrition was assessed by the Malnutrition Universal Screening Tool (MUST) at discharge from hospital, 3 months, 6 months and 12 months following discharge to the community. The specific methods used to collect weight and calculate body mass index (BMI) are included in section 2.2.1 and a detailed overview of the MUST, its' reliability and uses is provided in section 2.3.1. The MUST is composed of a numerical score for recent weight loss, dietary intake and acute disease, based on a scale of 0-6. A score of 0 indicates low risk of undernutrition, a score of 1 indicates medium risk, and a score of 2 or more indicates high risk of undernutrition. A decrease in MUST score at repeat assessments signals a reduction in nutritional risk. For this study, MUST score was dichotomised to 'low risk' and 'medium/high risk'. Three participants were excluded as they were missing data for one of the assessments at either 3 or 6 months.

Nutritional risk (as defined by MUST) was dichotomised (medium and high risk of undernutrition compared to low risk of undernutrition) to describe the characteristics associated with improvement in nutritional risk over time. The continuous variables were assessed for linearity using the Box-Tidwell procedure (Box and Tidwell, 1962). Odds ratios with 95% confidence intervals were calculated for each variable using a univariate logistic regression analysis. Multivariate logistic regression was then performed on variables with $p < 0.2$ to explore the independence of associations. Multi-collinearity between independent variables was assessed using variance inflation factor (VIF). Results were considered significant if the two-tailed p-value was < 0.05 . Analyses were performed using SPSS Version 24 (IBM Corp, 2015).

5.3.2 24-hour-recall

A subset of participants were selected to provide data on their current dietary intake using the multiple pass 24 hour recall method (see section 2.9.1). Following data collection, data was coded by three researchers at University of Plymouth, over an eight-week period in June and July 2017 using Dietplan 7 software (Forrestfield Software Limited, Horsham, UK). To ensure a consistent approach across the coding team, training on the coding protocol was provided and inter- and intra-rater reliability tested. A codebook was created to provide detailed instructions on the coding protocols (appendix 9.4.2). This was continually reviewed during coding and new queries were discussed, agreed between coders and added to the protocol. Training was designed to ensure excellent agreement within and between coders. As part of the training, the coders completed ten example 24-hour recalls using the protocol and codebook before moving to code the study data. Each recall was analysed for coding errors, and where total energy or protein showed differences over 10%, coders received feedback and were asked to complete further 24-hour recalls until errors were less than 10%. In addition, inter-rater reliability was calculated following the training period to ensure excellent agreement between coders, then for a second time two weeks in to study data coding to ensure good practice was maintained and highlight any training needs. Intra-rater reliability was also checked to establish the degree of agreement between coded 24HRs completed by a single coder. As data were continuous and there were three coders each completing reliability testing at two time points, both inter- and intra-rater reliability were assessed using a two-way mixed, consistency, average-measures intraclass correlation for multiple raters and then a single rater respectively (McGraw and Wong, 1996). Inter and intra-rater reliability testing was performed on the data of ten participants chosen at random by a team member outside the coding team. To reduce bias, coders were blinded to participant details, including age, gender, diagnosis, comorbidities and nutritional risk status.

Intraclass correlation coefficients were calculated for both inter- and intra-rater reliability using a scale of 0 to 1. Each of ten recalls was assessed by each rater (n=3). Higher intraclass correlation coefficient values were indicative of greater reliability, with a value of 1 showing

perfect agreement and a value of 0 indicating random agreement only. Thresholds for ratings of agreement have been published, with poor intraclass correlation coefficient value considered to be less than 0.40; fair agreement 0.40-0.59; good agreement 0.60-0.74 and excellent agreement 0.75-1.0 (Cicchetti 1994).

Participants' individual energy requirements were calculated at each assessment from age and weight (Henry, 2005) and an overall physical activity level (PAL) value was assigned to each participant. All participants were attributed a value of 1.4 based on published Department of Health guidance representing a low activity level (both occupational and non-occupational) (Department of health, 1991). As there is speculation regarding the optimal protein intake for older adults, protein requirements were calculated at each assessment using two different equations to allow comparison. The first; 0.75g protein per kilogram of bodyweight per day based on current Department of Health guidance (1991). The second, 1g protein per kilogram of bodyweight per day based on recent guidance for older adults (Bauer et al., 2013) (table 5.1).

Mean energy and protein intakes were calculated from 24-hour recalls collected in a subsection of the cohort. Participants were included in the analysis where data were available for four 24-hour recalls including one at baseline, 3, 6 and 12 months. Assumptions regarding normality and variance homogeneity were assessed using the Shapiro-Wilk test and by visual inspection of normality plots and histograms. Results were analysed by group (low nutritional risk versus medium/high nutritional risk) using SPSS Version 24 (IBM Corp, 2015) and employing the statistical tests detailed in table 5.2. For all studies, $p < 0.05$ was regarded as significant.

Previous studies have documented that food consumption is underreported by as much as 25%. In order to validate dietary intake without the use of expensive methods such as the doubly-labelled water technique (Schoeller and Van Santen, 1982), the ratio between reported energy intake (EI) and estimates of basal metabolic rate (BMR_{rest}) was examined (Black et al., 1991, Goldberg et al., 1991).

5.3.3 Missing data

Repeated measures over time may cause missing data due to participants not being contactable, not being well enough to participate or withdrawing from the study. Missing data lead to a loss of information and have the potential to introduce bias in to the results. For this analysis complete case analysis was chosen to deal with missing data, excluding participant data for follow-up waves where outcome data were missing from our analysis. In prospective cohort studies where participants are followed up over time, complete case analysis has been widely used and should not introduce bias (Karahalios et al., 2012). Throughout this chapter results will be presented for the participants who had data at all four time points.

Requirement	Equation for estimating older (>60 years) adult requirements	
Energy (kcal/d) ^a	Males	$[(11.4 \times BW) + (541 \times H) - 256] \times PAL^b (1.4)$
	Females	$[(8.52 \times BW) + (421 \times H) + 10.7] \times PAL^b (1.4)$
Protein (g/d) ^{b, c}	Males	i) $0.75 \times BW^b$ ii) $1.0 \times BW^c$
	Females	i) $0.75 \times BW^b$ ii) $1.0 \times BW^c$

BW, body weight; H, height; PAL, physical activity level

Table 5.1: Equations for calculating dietary requirements in sample

Analysis	Corresponding statistical test
Descriptive	Percentage, mean, standard deviation, median, interquartile range
Exploring differences between nutritional risk groups and over time	Independent t-test ^d (weight, BMI, measured weight loss, self-reported weight loss, energy intake, and protein intake) McNemar's test ^e (Nutritional risk score) Linear mixed modelling ^f (weight, BMI, measured weight loss, self-reported weight loss, energy intake, and protein intake)
Inter-rater/Intra-rater reliability	Intraclass correlation coefficient

Table 5.2: Descriptive and inferential statistical tests for data analysis

^a HENRY, C. 2005. Basal metabolic rate studies in humans: measurement and development of new equations. *Public health nutrition*, 8, 1133-1152.

^b DEPARTMENT OF HEALTH 1991. *Dietary reference values for food energy and nutrients for the United Kingdom*, HM Stationery Office.

^c BAUER, J., BIOLO, G., CEDERHOLM, T., CESARI, M., CRUZ-JENTOFT, A. J., MORLEY, J. E., PHILLIPS, S., SIEBER, C., STEHLE, P. & TETA, D. 2013. Evidence-based recommendations for optimal dietary protein intake in older people: a position paper from the PROT-AGE Study Group. *Journal of the American Medical Directors association*, 14, 542-559.

^d STUDENT 1908. The probable error of a mean. *Biometrika*, 1-25.

^e COCHRAN, W. G. 1950. The comparison of percentages in matched samples. *Ibid.* 37, 256-266.

^f BRESLOW, N. E. & CLAYTON, D. G. 1993. Approximate inference in generalized linear mixed models. *Journal of the American statistical Association*, 88, 9-25.

5.4 Results

5.4.1 Reliability

Reliability results are shown in table 5.3. Reliability within and between coders is in order to gain confidence in our measurements, and to draw reliable conclusions.

Three coders were entered in to the analysis. As discussed in section 5.1, intraclass correlation (ICC) is measured on a scale of 0 to 1, with higher ICC values indicative of greater interrater reliability. Data was indicative of excellent consistency between coders, with ICC values between 0.75-1.0 (Cicchetti 1994). The high ICC value suggests that measurement error caused by the individual coders was minimal and that the training programme was successful. This means that variation between participants' intake data is only minimally attributable to differences in coding and data entry between coders. This level of reliability was maintained at two weeks post training.

The intra-rater reliability is also shown in table 5.3. ICC values above 0.9 for each individual coder represent excellent agreement between measurements made by each coder. This shows that coders kept variance to a minimum over time.

		Energy	Protein	p-value^c
		ICC (95% CI)	ICC (95% CI)	
Inter-rater Reliability:	Test 1:	0.984 (0.954-0.996)	0.948 (0.857-0.986)	<0.001
	Test 2:	0.997 (0.991-0.999)	0.974 (0.926-0.993)	<0.001
Intra-rater Reliability:	Coder 1:	0.966 (0.869-0.991)	0.923 (0.723-0.980)	<0.001
	Coder 2:	0.993 (0.973-0.998)	0.990 (0.961-0.998)	<0.001
	Coder 3:	0.988 (0.954-0.997)	0.960 (0.848-0.990)	<0.001

ICC, Intraclass correlation coefficient, ICC <0.40 = poor; 0.40-0.59 = fair agreement; 0.60-0.74 = good agreement; 0.75-1.0 = excellent agreement (Cicchetti, 1994)

^a Completed prior to analyses

^b Completed two weeks in to analysis period

^c p-value derived from Pearson's r

Table 5.3: Intraclass correlation results of ten 24-hour recalls completed by three coders at time points 1^a and 2^b

5.4.1 Malnutrition Universal Screening Tool score

MUST scores at each assessment time point are presented in table 5.4, participants who completed all four study visits (n=104) were included in the analysis. At baseline, on discharge from hospital, 61.5% (64/104) of participants were at low nutritional risk and 38.5% (40/104) were at medium or high risk. At 12 months, the number of participants at low nutritional risk had increased to 63.4% (66/104) and those at medium/high risk reduced to 36.6% (38/104) (see table 5.4). This change was a result of an increase in nutritional risk in 12 participants and a concomitant decrease in risk in 12 participants at 3 months; an increase in nutritional risk in 11 participants and a concomitant decrease in risk in 14 participants at 6 months, and an increase in nutritional risk in 15 participants and a corresponding reduction in risk for 14 participants at 12 months. Cochrane's Q test was used to determine whether these changes in nutritional risk at the four assessment points were significant. The results indicate that there was no statistically significant difference in the proportion of participants at low and medium/high nutritional risk ($\chi^2(3)=0.468$, $p=0.926$). This shows that changes in nutritional risk within the study cohort at the different time points were not significant indicating that, on average, there was no improvement or deterioration in nutrition risk status in the 12 months post-discharge.

MUST score	Frequency % (n)			
	Baseline	3 months	6 months	12 months
Low Risk	61.5 (64)	61.5 (64)	64.4 (67)	63.5 (66)
Medium Risk	18.3 (19)	22.1 (23)	22.0 (23)	19.2 (20)
High Risk	20.2 (21)	16.3 (17)	13.5 (14)	17.3 (18)

Table 5.4: Change in nutritional status as measured by MUST at 3, 6 and 12 months following discharge

In order to understand which, if any, of the independent variables were related to an improvement in nutritional risk score, logistic regression was performed. Univariate analysis showed that satisfaction with food-related life, energy intake at 12 months, dietitian input within the study period, and having an oral nutritional supplement prescription were significant (table 5.5). The multivariate model (table 5.6) showed that none of the predictor variables was statistically significant in predicting improvement in nutritional status. However, the regression model was not statistically significant suggesting limited accuracy ($X^2 = 6.469$, 8 degrees of freedom, $p=0.486$).

Univariate	OR (95% CI)	p-value
Age at 12 months	0.98 (0.92 to 1.03)	0.40
Gender^a	1.17 (0.26 to 5.20)	0.84
Living alone^b	1.02 (0.29 to 3.60)	0.98
Rockwood Frailty score at 12 months	0.71 (0.46 to 1.10)	0.12
Charlson comorbidity score at 12 months	1.26 (0.79 to 1.99)	0.32
Readmission at one year	0.81 (0.54 to 4.23)	0.32
Activities of daily living score at 12 months	0.98 (0.96 to 1.00)	0.11
Satisfaction with food-related life at 12 months	1.25 (1.06 to 1.48)	0.01
Quality of life (EQ-5D VAS) at 12 months	1.02 (0.99 to 1.04)	0.18
Energy intake at 12 months (kcal)	1.00 (0.99 to 1.00)	0.09
Dietitian input over the 12 month study period^c	0.07 (0.01 to 0.65)	0.02
Oral nutritional supplement prescription^d	3.33 (0.75 to 14.75)	0.07

^a Males are compared to females

^b Living alone is compared to living with others

^c No dietitian support was compared to dietitian support

^d No oral supplement prescription was compared to oral supplement prescription

Table 5.5: Univariate logistic binary regression with nutritional risk status (dependent variable) and associated factors (independent variables)

Multivariate	B	S.E	OR (95% CI)	p-value
Rockwood frailty score at 12 months	-2.02	0.419	0.82 (0.36 to 1.85)	0.359
Activities of daily living score at 12 months	0.032	0.026	1.03 (0.98 to 1.32)	0.266
Satisfaction with food-related life at 12 months	0.10	0.091	1.11 (0.93 to 1.32)	0.266
Quality of life (EQ-5D VAS) at 12 months	0.013	0.015	1.01(0.98 to 1.04)	0.390
Energy intake at 12 months (kcal)	-0.001	0.001	1.00 (0.99 to 1.00)	0.841
Dietitian input over the 12 month study period	0.434	0.991	1.54 (0.22 to 10.76)	0.444
Oral nutritional supplement prescription	-1.173	1.022	0.841(0.11 to 6.23)	0.459
Constant	-0.489	2.503	0.61	0.845

The regression model was not statistically significant ($X^2 = 6.469$, 8 degrees of freedom, $p=0.486$)

Table 5.6: Multivariate logistic binary regression final model with nutritional risk status (dependent variable) and associated factors (independent variables)

Variable	Low risk				Medium/high risk				Group time effect p-value	x Group effect p-value	Time effect p-value
	Baseline	3 months	6 months	12 months	Baseline	3 months	6 months	12 months			
% (n)											
Nutritional risk	61.3 (65)	61.3 (65)	64.2 (65)	63.2 (65)	38.7 (39)	38.7 (39)	35.8 (39)	36.8 (39)	-	-	-
Mean (SD)											
Weight (kg)	73.3 (5.0) [#]	72.0 (5.0) [#]	72.4 (15.5) [#]	73.6 (17.3) [#]	55.4 (15.8) [#]	55.8 (15.5) [#]	55.8 (15.5) [#]	57.8 (16.8) [#]	0.545	0.363	0.671
BMI (kg/m ²)	28.0 (4.9) [#]	27.5 (5.2) [#]	27.7 (5.3) [#]	27.9 (5.5) [#]	21.6 (5.7) [#]	21.7 (5.6) [#]	21.7 (5.6) [#]	22.6 (5.7) [#]	0.056	<0.001	0.857
Measured weight change (kg)	-	-0.75 (4.5)	-0.53 (3.7)	0.05 (5.3)	-	1.9 (7.7)	0.87 (3.3)	-0.65 (6.0)	0.148	<0.001	0.955
Self-reported unintentional weight loss (kg)	-0.48 (1.1) [‡]	-1.67 (2.9)	-1.82 (3.5)	-0.91 (1.9)	-4.52 (3.8) [‡]	-2.81 (3.7)	-1.06 (2.6)	-1.19 (1.8)	<0.001	<0.001	<0.001

[#]p<0.001, between group comparison comparing low risk to medium/high risk of undernutrition

[‡]p<0.001, between group comparison comparing low risk to medium/high risk of undernutrition

Table 5.7: Comparisons of outcome variables between the nutritional risk groups at baseline, 3, 6 and 12 months (n=104)

5.4.2 Weight and body mass index

Table 5.7 shows the changes in weight, self-reported weight, BMI, energy and protein intake over the 12 month follow up period. Participants who completed all four study visits (n=104) were included in the analysis as two groups: those at low risk of undernutrition at baseline were compared to those at medium or high risk of undernutrition.

Weight and body mass index (BMI) showed significant between-group differences at baseline, which persisted at 3, 6 and 12 month follow up ($p < 0.001$). There was no change in BMI or body weight throughout the study period and the mean BMI remained “overweight” (BMI 25-29.9 kg/m²) in the low risk group and “normal” (BMI <25 kg/m²) in the medium/high risk group at all time-points (table 5.4). Mixed model analysis confirmed that time had no effect and that there was no interaction between group and time (table 5.4). A clinically significant measured unintentional weight loss $\geq 5\%$ was seen in 26.9% of participants (28/104) between 3 month and 12 month assessments

Examining self-reported weight loss showed significant main effects of both group and time, plus an interaction effect between group and time (table 5.7). This significant interaction effect means that the differences in self-reported weight loss over time were dependent on nutritional risk group. Post-hoc tests show that these changes in self-reported weight loss were different only at baseline, where reported weight loss in the group at medium/high risk of undernutrition was significantly higher than that reported by participants at low risk. As self-reported weight loss was a component of nutritional status classification it is unsurprising that there is a significant difference between groups at baseline. What we didn't know was how the groups would differ over time, and that actually at 3, 6 and 12 month assessments, reported weight loss remains similar between both groups.

To determine whether self-reported, unintentional weight loss (the dependent variable) was different for the different risk groups over time mixed model analysis was used. So, whether there was an interaction between undernutrition risk status (low compared to medium/high) and "time" (the "within-subjects" factor, time post-discharge).

There was statistical significance in self-reported unintentional weight loss between groups ($F(1, 72.7) = 27.8, p < 0.001$) and over time with and without adjustment for baseline weight. Self-reported weight loss appeared to increase in the low risk group and reduce in the medium/high risk group, minimising the between group difference. A significant difference was seen for the interaction effect group by time (table 5.7). Post hoc tests showed that for the low risk group this was present between baseline and 3 months, 3 and 6 months and 6 and 12 months, and for the medium/high risk group at all time points.

5.4.3 Energy intake

Energy intake is recorded in table 5.7. Participants who completed a 24-hour recall at all four study visits (n=69) were included in the analysis stratified in to two groups: group 1 at low risk of undernutrition and group 2 at medium or high risk of undernutrition. Of the potential 104 participants with all four assessments, 24-hour recall was not performed in 34 participants due to lack of participant time, refusal, communication difficulties or cognitive impairment.

Linear mixed models were used to analyse energy intake between groups and over time (see table 5.7). There was no statistically significant interaction between nutrition risk and time on energy intake, ($F(3, 89) = 0.82$, $p = 0.487$). Neither the main effect of time or the main effect of the group showed a statistically significant difference ($F(3, 89) = 2.40$, $p = 0.073$ and $F(1, 102) = 0.049$, $p = 0.826$ respectively). This suggests that energy intake remained stable in both groups in the 12 months following discharge and was similar between the low and medium/high risk groups.

The energy intake was also examined for adequacy and data showed that only a tenth to a third of participants in each nutritional risk group fulfilled their energy requirements (see figure 5.1). This did not change substantially over time. This suggests that the energy intake was insufficient in most participants. To achieve nutritional recovery, increased, not stable (as indicated by the data shown above), energy intake was required post discharge, but reported energy intake for the sample as a whole was 20.5% lower than requirements.

Since energy requirements are estimates based on imprecise formulae the data was also analysed by weight loss. Weight loss indicates that energy intake is insufficient and thus is a more certain measure of energy inadequacy than estimated requirements. In order to validate dietary intake without the use of expensive methods such as the doubly-labelled water technique (Schoeller and Van Santen, 1982), I chose to examine the ratio between reported energy intake (EI) and estimates of basal metabolic rate (BMR_{est}) (Black et al., 1991, Goldberg et al., 1991). Of the 69 participants who completed the full four 24-hour recalls over the 12 month study period, 42 participants were weight stable (weight change <5%). To examine the

effect of underreporting energy in our cohort, a ratio of energy intake (EI) to estimated basal metabolic rate (BMR_{rest}) calculated. The mean EI/BMR_{rest} was 1.14 in this weight stable sample compared to 1.16 in the sample as a whole. This suggests that either participants had energy requirements different to those estimated (since we would expect weight stable and gainers to meet their requirements and weight losers not to) and/or that the 24-hour recall data contained non-systematic errors resulting in both over and underestimation of energy intake. In addition, it was important to examine variables within our data that are known to impact accuracy of reporting. As both high BMI and female gender have been cited in the literature as potential influences, energy intake was stratified by BMI and then by gender to allow comparison (table 5.8). Independent t-tests showed a clear difference between overweight/obese participants and their normal/underweight counterparts, with the first group meeting 68% and the second 91% of their energy requirements on average ($p < 0.001$). On the other hand, gender did not appear to influence reporting with no significant difference between male and female participants (mean 77% versus 78% in males and females respectively ($p = 0.771$)).

Nevertheless, 48.5% of participants lost weight following hospital discharge and data indicates intakes lower than average requirements overall so there does appear to be a tendency for an inadequate intake following hospital stay, which may impact on recovery.

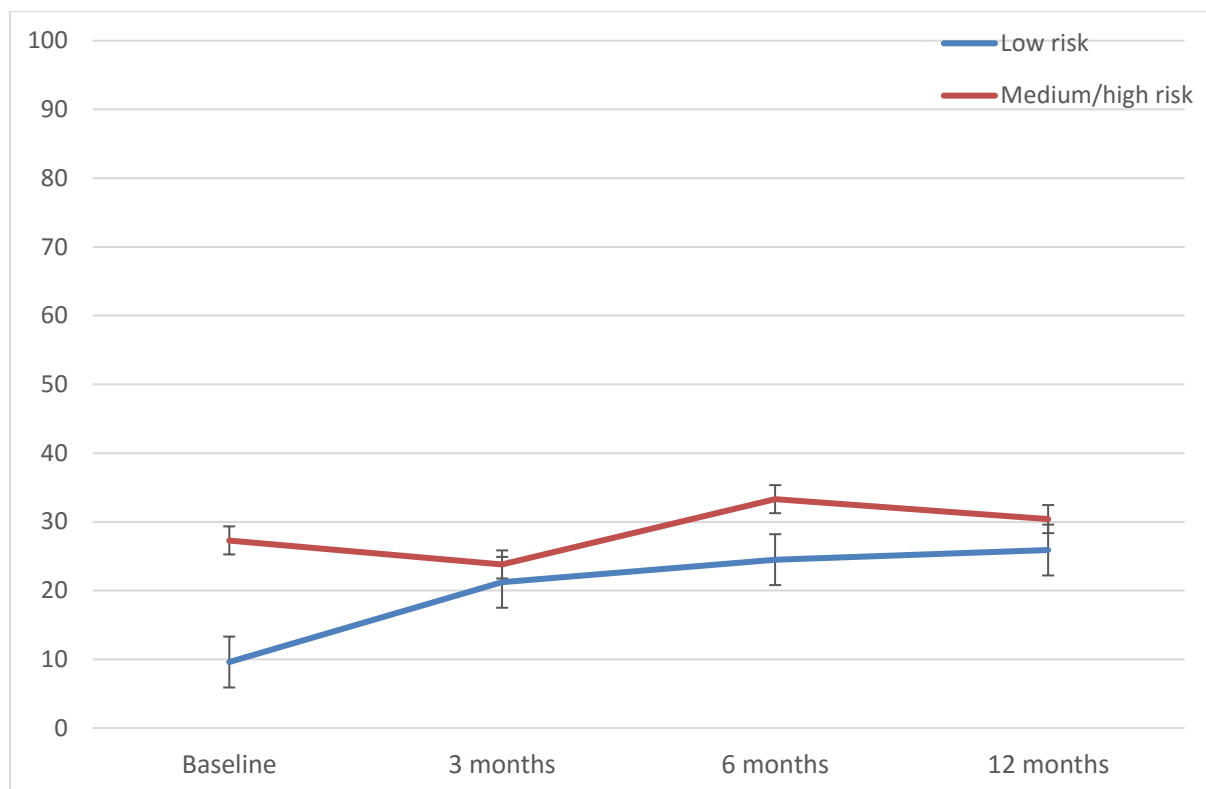


Figure 5.1: Mean percentage of energy requirements achieved^a from baseline to 12 months in a sample of community-dwelling older adults categorised by nutritional risk

^a Energy requirements calculated using the Henry equations for males and females (Henry, 2005) and physical activity level (PAL) using Department of Health guidelines (Department of health, 1991)

Participant group	Percentage Energy requirement met		12 months	p-value	Mean	p-value
	Baseline					
		p-value				
BMI category						
- Overweight/obese ^b (38/69)	58.2	<0.001*	74.0	0.005*	68.2	<0.001*
- Normal weight/underweight ^c (29/69)	86.8		96.8		90.6	
Gender						
- Male (23/69)	66.3	0.363	81.9	0.762	76.6	0.771
- Female (46/69)	72.3		84.6		78.4	

BMI, body mass index

^a Energy requirements calculated using the Henry equations for males and females (Henry, 2005) and physical activity level (PAL) using Department of Health guidelines (Department of health, 1991)

^b BMI ≥ 30.0

^c BMI < 29.9

* p < 0.05 denotes a significant difference between categories

Table 5.8: Mean percentage of energy requirement achieved in overweight/obese versus normal/underweight participants and male versus female participants^a in a sample of community-dwelling older adults at hospital discharge and 12 months

5.4.4 Protein intake

Protein intake is shown in table 5.4. Participants who completed a 24-hour recall at all 4 study visits (n=69) were included in the analysis stratified in to two groups: group 1 at low risk of undernutrition and group 2 at medium or high risk of undernutrition.

Linear mixed models were used to analyse protein intake between groups and over time. There was no statistically significant interaction between nutrition risk and time on protein intake ($F(3, 89) = 0.866, p = 0.462$). However, the main effect of time was statistically significant with mean protein intake increasing over time, showing differences between baseline and 3 months, baseline and 6 months and baseline and 12 months ($F(3, 89) = 6.40, p < 0.001$). The main effect of nutritional risk status however, was not statistically significant ($F(1, 102) = 3.09, p = 0.580$) (table 5.7). This suggests that both low and medium/high risk groups consumed similar amounts of protein and this increased over the 12 months following hospital discharge.

Protein intake was also compared to theoretical requirements (Bauer et al., 2013). Data showed that between 33.3% and 59.3% of participants at low nutritional risk and 43.5% to 69.6% of participants at medium/high nutritional risk met their protein requirements at 0.75g/kg (see figure 5.2) and between 12.5% and 37.7% of participants at low nutritional risk and 28.0% to 59.1% of participants at medium/high nutritional risk met their protein requirements at 1g/kg (see figure 5.3). In those participants who failed to meet requirements, protein intake was underreported by an average of 5.2% when requirements were calculated at 0.75g/kg and an average of 32.1% when requirement was calculated at 1g/kg. This suggests that protein intake was inadequate in a large majority of participants at discharge from hospital, and that despite improved intakes following discharge, there remained a large difference between protein requirements and intakes 12 months after a hospital admission.

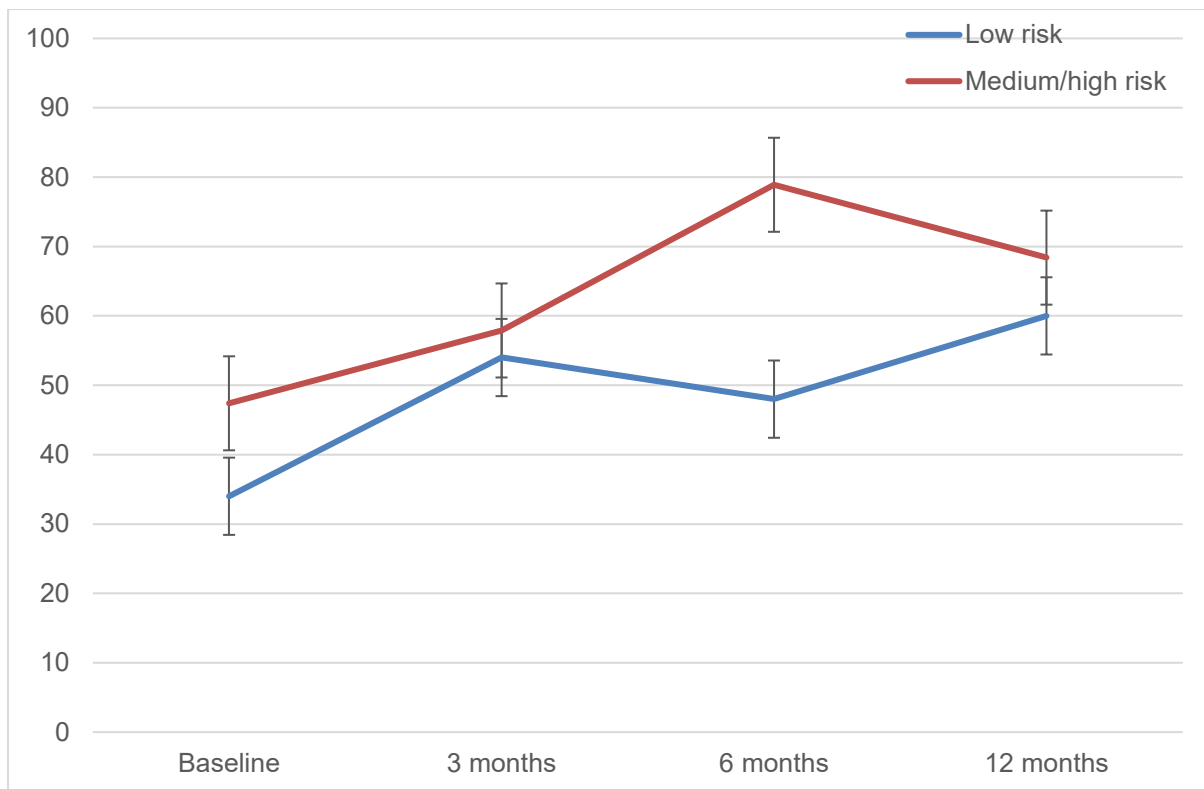


Figure 5.2: Mean percentage of protein requirements achieved at 0.75g/kg^a (Department of health) of a sample of community-dwelling older adults at hospital discharge comparing participants at low and medium/high undernutrition risk

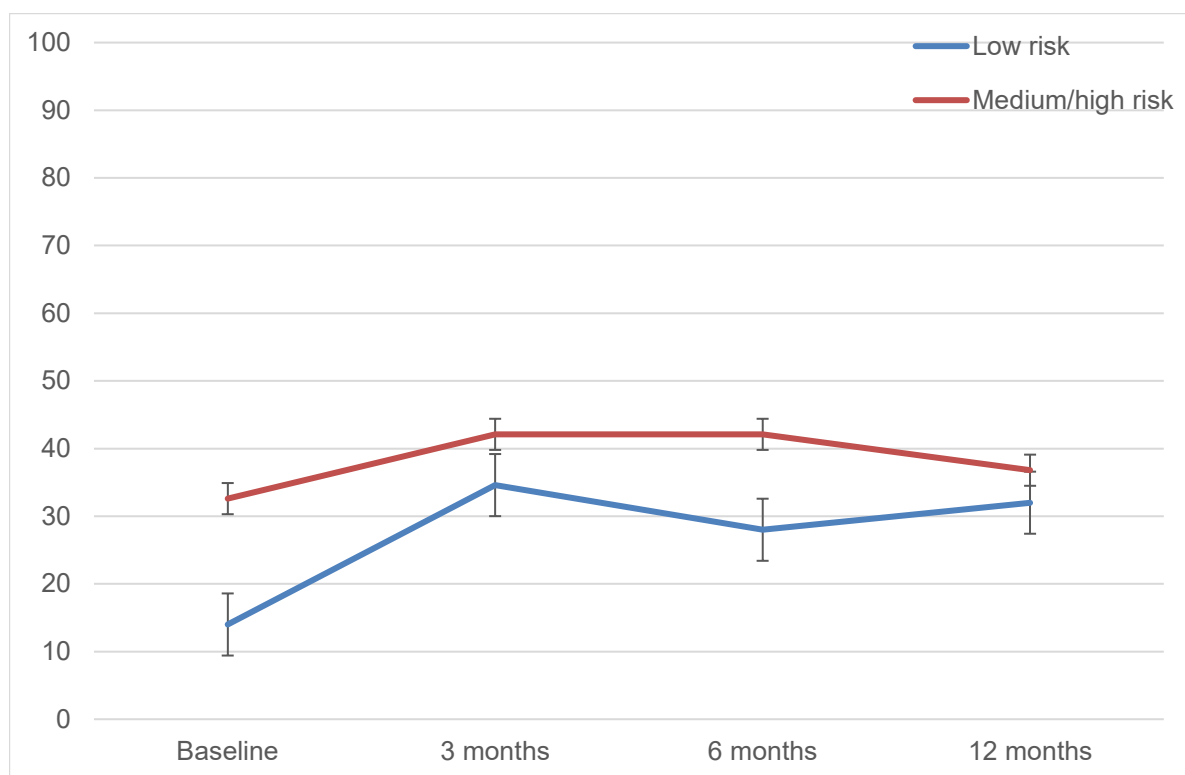


Figure 5.3: Mean percentage of protein requirements achieved at 1g/kg (Bauer et al., 2013) from baseline to 12 months in a sample of community-dwelling older adults categorised by nutritional risk

5.5 Discussion

This chapter set out to characterise nutritional risk in a cohort of older adults, comparing a group at low risk of undernutrition with a group at medium or high risk over a 12 month period, examining weight, BMI, energy intake and protein intake.

Our findings over the 12 month study period are summarised in the points below. Through the discussion that follows, I aim to address the factors which have led to these results, to compare the results of this chapter with existing evidence and to draw conclusions.

- Nutritional risk remained stable across the cohort over time, but improvement was associated with dietetic input and higher levels of satisfaction with food-related life.
- Weight and body mass index were significantly different between the two risk groups, but changed minimally in the cohort as a whole over time. Almost one third of individuals experienced significant, unintentional weight loss during the study period.
- Dietary energy intake was similar between low and medium/high risk groups and did not change significantly over time. When compared to age and gender matched requirements, energy intakes were low, with only 10 to 33% of participants meeting their energy needs through the 12 month study period and an average energy deficit of 21%. Whilst inadequate intake is common following hospital stay, underreporting is also likely to have impacted results in this study.
- Dietary protein intake was similar between low and medium/high risk groups and this increased over the 12 months following hospital discharge. When intake was compared to protein requirements at 0.75g/kg and 1.0g/kg respectively, 33-70% and 13-59% of participants met their requirements, with fewer participants in the low risk category achieving their daily protein requirement.

Despite being a vulnerable group experiencing deterioration in nutritional health in hospital, there has been little examination of post-hospital nutritional status in older adults. Following hospitalisation, older people are at risk of decline and readmission, which provides a challenge to prevent (Abbasi et al. 1992). Comparing the results of our study to the literature on energy and protein intake is challenging for a number of reasons. Firstly, there is a lack of studies in community dwelling populations with much of the current literature focused on inpatient and care home settings. Secondly, the few studies in community-dwelling populations including different definitions of older age, from aged ≥ 60 , through ≥ 65 (Chen et al., 2009, Young et al., 2018) to ≥ 79 and collect data over different time periods, with many cross-sectional rather than longitudinal. Many collecting dietary data by telephone. In addition, differences in the methods used to calculate energy and protein requirements and differences in the definition of adequate intake make comparisons difficult.

Our data showed a significant difference in energy and protein intake compared to requirements, indicating inadequate average dietary intake throughout the study period. A low intake of energy or protein can be attributed to two things; either discrepancy in the calculation of requirements or underreporting of dietary information. First to consider nutritional requirements. From the NHANES III data we know that mean energy intake peaked age 16-19 years and then declined with age (Briefel et al., 1995). Requirements were calculated using standard formulae based on gender and age over 60, plus a physical activity (PAL) factor of 1.4 due to modest levels of activity across the sample. The most appropriate PAL value for this population is debatable. In a review of data ascertained using doubly-labelled water technique, Black (1996) suggests that PAL values for free-living, undertaking 'normal' levels of activity may be >1.55 in all age groups except those over 75 years. As mean age was 80 years and the rate of physical problems high, a PAL of 1.4 may have been an overestimation. Studies have varied considerably in their calculation of energy requirement, for example in their systematic review, Ter Borg et al (2015) set energy requirements at 2450 kcal and 2000

kcal for males and females respectively, incorporating a PAL of 1.6 for their free-living population, although mean age was considerably younger at 65 years.

The second factor to consider is the underreporting of dietary information. As discussed in section 2.6 of the methods chapter, several studies comparing reported intake to gold standard biomarker methods demonstrate under-reporting of energy and over-reporting of protein intake in lean, overweight, obese and normal-weight populations. A difference in energy between the 24-hour recall and total energy expenditure estimated using the doubly-labelled water method highlighted under-reporting of energy intake in 27/28 participants in the European Prospective Investigation into Cancer and Nutrition (EPIC) with participants under-reporting by an average of 22% (Kroke et al., 1999). To examine the effect of underreporting energy in our cohort, weight stable participants were examined (n=42) and a ratio of energy intake (EI) to estimated basal metabolic rate (BMRest) calculated. This ratio (EI/BMRest) was 1.14 compared to 1.16 in the weight stable sample compared to the cohort as a whole. This was considerably lower than a ratio of 1.32 for males and 1.18 for females (average 1.24) aged ≥ 60 in the NHANES cohort (Briefel et al., 1995) and compared to a predicted ratio of 1.5 in sedentary populations (Black et al., 1991, Black et al., 1993). Mean energy underreporting was 23.8% in our weight stable sub-group which is similar to the findings of EPIC at 22% (Kroke et al., 1999).

Large scale, studies such as NHANES have shown that two factors significantly influence underreporting; BMI and gender. Studies have shown that under-reporting in overweight and weight-conscious individuals is to be expected (Briefel et al., 1995, Ma et al., 2009) and that gender differences in reporting have been shown in previous studies, supporting a higher prevalence of underreporting in women compared to men. In order to investigate this further, the current cohort data were first stratified by BMI and then by gender. Examining the data by BMI group (overweight or obese versus normal weight or low weight) revealed a significantly higher reported energy intake in those classified as overweight or obese compared to participants of normal weight or low bodyweight. However, when the current data was stratified

by gender no difference was seen. These results suggest that our data was not influenced by a gender reporting bias, but as 56% of our dietary data came from overweight participants, the effect of underreporting may be significant.

The fact that energy and protein intakes were not significantly different between nutritional risk groups is surprising, since it would be expected that the medium/high risk group would have a lower intake, reflecting their worse nutritional status. Increases in energy intake over time were present, but they were small and non-significant. This compares with a study of free-living older people (Toffanello et al., 2010) where no significant change in total energy intake was observed after 10 year follow-up. Protein intakes on the other hand, increased to a significant degree over the follow-up period. This increase in protein may be due to nutritional recovery in these participants over time. However, changes in reported intake may also be due to differences in participants reporting at the different assessment time points. As discussed in section 2.6.1, self-reporting dietary data is an imperfect method, and this notion may be worse with repeated measures data. For example, in a study exploring the optimal number of 24-hour recalls that should be employed in dietary assessment (Ma et al., 2009), under-reporting was most prominent in the first 24-hour recall, with subsequent data shown to be more accurate. Although these recalls took place within 1-2 days of one another, the conclusions drawn by the authors, that participants' trust in the researcher improved with later 24-hour recalls, may be relevant to our study population. In the current study, as participants generally saw the same researcher for each assessment, they may have found dietary recall easier with a more familiar person at 3, 6 and 12 month assessments.

Drop-out analysis showed that the sub-group used for dietary assessment were younger, less frail and with less comorbidity than those who were unable to perform recalls at each time point. However, the group also had a higher BMI. This suggests that whilst they were more able, they may have been at higher risk of underreporting.

In the 10-year longitudinal study by Toffanello (2010), mean total protein intake met or exceeded the recommended dietary intake, and notably this value was set at 40g/day for both

males and females. The range of intakes from 49-60g over the study period, was similar to protein intake in our study, even without the impact of hospital admission as a stressor (Toffanello et al., 2010). Comparing our results with those of a systematic review of studies in community-dwelling populations with a mean age ≥ 65 years (Ter Borg et al., 2015), the review showed that on average 10-12% failed to meet the estimated average requirement set at 0.66g/kg. In our study 29% of participants would fail to achieve the same threshold.

Baseline dietary intake data collected at hospital discharge, are in line with previous literature showing that poor energy and protein intakes are prevalent in hospitalised older adults (Munk et al, 2016). Previous studies have reported that only 30% of hospitalised patients met energy needs (Starke et al., 2011), and that 21% of hospitalised older adults consumed less than 50% of their energy requirements (Sullivan 1999). The factors leading to suboptimal intake in these studies included poor dentition and isolation; increased nutritional requirements due to illness; and amplified losses through malabsorption and wounds. Many of these factors are not limited to the hospital but persist upon discharge, prolonging suboptimal intakes. Studies have then gone on to demonstrate low dietary intakes at six and twelve months post-discharge (Chen et al., 2009, Locher et al., 2007).

Our study showed that protein requirements were more commonly met compared to energy requirements, which differs to other literature. In their respective hospital-based studies, Dupertuis et al (2003) and Mudge et al (2011) found that fewer participants met protein requirements (41% and 14%) when compared to energy requirements (69% and 41%). Under-reporting was shown to be less common in the reporting of protein foods compared to foods high in energy and fat when comparing food intake via 24-hour recall and 24-hour urinary nitrogen collection (Heitmann and Lissner, 1995). So it is difficult to determine whether our results reflect underreporting or a genuinely increased protein intake. In addition where protein intakes met lower protein requirements more frequently, the current literature suggests that this is inadequate (Bauer et al., 2013).

In the current study, nutritional risk status in the cohort as a whole remained stable over the course of the 12 months. This differed from other studies. The first, a longitudinal study in older adults following a hospital admission (Chen et al., 2009), reported a 59% prevalence of undernutrition at discharge, then at 3 months post-discharge 27% of participants remained undernourished, and at 6 months 21% remained undernourished using MNA. An additional six months follow-up would have been useful to help understand whether these remaining participants would improve without intervention. In another study of 319 community-dwelling older adults at low risk of undernutrition, nutritional risk increased in 38.2% of participants during 12 month follow-up (Roberts et al., 2007). In this second study, participants were recruited randomly so were not specifically subjected to a stressor such as hospital admission. Whilst many potential determinants of nutritional health were considered, including chronic disease, however the impact of hospitalisation was not and nutritional intervention was not specified in either study. The results of our logistic regression suggested that dietetic intervention, oral nutritional supplementation, higher satisfaction with food-related life and higher energy intakes were all associated with improvement in nutritional status, however when they were added to the model, these effects did not persist. One of the limitations of logistic regression is the exclusion of missing data which meant the sample analysed was small. A larger sample is required to accurately assess the influence of these factors on nutritional risk status.

The small size of the 'at risk' component of our cohort is a limitation, and it is likely that the two risk groups are not dramatically different. Self-reported weight, which forms a large component of the MUST score, showed the biggest between-group difference at baseline, showing a significantly higher weight loss for participants at medium and high nutritional risk. This 3-6 month period covers the pre-admission period and therefore the period of acute illness for the majority of participants. In addition, this was the time period which could not be verified by study data, so we were reliant of self-reported data at this point in time, whereas at 3, 6 and 12 month assessment study data included actual weights for comparison. A

comparison of self-reported weight and actual weight showed significant differences at each time point and between each group, though these are not clinically significantly different (Sullivan et al., 2004). This differed to a study of older males (n=4716) which was able to demonstrate agreement between self-reported weight change and measured weight change (Wannamethee et al., 2000).

A strength of the study was the use of the malnutrition universal screening tool, a tool suggested for use in community-dwelling older individuals (Kondrup, 2003a). This tool allowed the identification of unintentional and intentional weight loss to classify undernutrition risk. This is important, because individuals with involuntary weight loss have different characteristics and health outcomes compared with individuals with voluntary weight loss (Wannamethee et al., 2000). There are several limitations with our study. Firstly, whilst assessments were performed at four time points over a 12 month period of observation, it was not possible to isolate exactly where a change in nutritional status occurred between observation points, and whether this was linked to an event such as acute illness (McCormack, 1997). Undernutrition risk may have been higher as there is the possibility that participants experienced a worsening in their nutritional status in between assessments, and were unable to remain in the study or died preventing the data from being collected. This limitation had the potential to reduce the number of participants at risk of undernutrition. Also, whilst analyses were adjusted for known confounders, additional confounders may not have been considered. Participants were recruited from one hospital potentially reducing the generalisability of our results.

5.6 Conclusion

I found that nutritional risk status, measured by MUST, did not change in the 12 months following discharge from hospital. I expected that nutrition risk would improve on discharge from hospital, because many of the factors that are known to contribute to undernutrition occur in the hospital setting. For example, recovery from acute disease, freedom from the hospital routines and environment, and a return to habitual foods and intakes. However, nutritional risk was stable overall and thus, suggests that interventions may be required post hospital stay to

improve nutritional status. Simply assuming it will improve in the home environment may not be a reasonable assumption.

I also found that energy intake remained stable and protein intake increased, although the majority of participants were not meeting their requirements for either energy or protein with an average energy deficit of 21% and protein deficit of 0-15% (no deficit was seen using the lower protein requirement, but an average deficit of 15% was present when the higher requirement was used) across the cohort. This is at odds with the previous finding that nutritional status was stable. If most participants were not meeting energy and protein requirements one would expect the nutritional status to worsen.

It is fundamental that we learn the most effective way to structure nutritional care across the interface from hospital to community settings to ensure monitoring is in place. Section 7 will go on to explore the pathways of nutritional care over the year following hospital admission to identify any gaps in the nutritional care pathway which may support future interventions.

Chapter 6: Pathways of nutritional care in a sub group of community-dwelling older adults

6.1 Introduction

The management of undernutrition tends to focus on acute hospital care, however data suggest that people come into hospital poorly nourished and are discharged back to the community at greater nutritional risk (Krumholz, 2013, McWhirter and Pennington, 1994). As discussed in the introduction section 1.8, hospital admission is a stressor, with the potential to cause secondary problems such as undernutrition, thus increasing length of stay and predicted readmission (Friedmann et al., 1997). Whilst care pathways have been designed to manage undernutrition (Kyle et al., 2002), we do not know how they perform in practice and there is concern that gaps exist (Elia and Russell, 2011). There is therefore a need to explore the practical impact of undernutrition on older people and map the nutritional care pathways for individuals at risk of undernutrition.

Risk of undernutrition is commonly picked up in the hospital setting through screening; NICE recommends that all patients are screened for nutritional risk on admission and weekly thereafter (NICE, 2012). As undernutrition takes significant time to treat (Miller and Wolfe, 2008), interventions commenced in hospital are a starting point only. However, few studies have explored nutritional status at hospital discharge, and the onward process of nutritional care to understand how nutritional status changes post hospital stay and what measures are used to treat or prevent it. It is important that we understand firstly what happens to those individuals who are identified at high nutritional risk in hospital to examine whether there is a clear pathway of nutritional care. It is perhaps even more pertinent to examine what happens to those individuals who are either not identified during their hospital stay or are considered at 'medium' risk. We wanted to explore the 'trajectory of nutritional care' characterised by care processes for a particular condition (in this case undernutrition) including strategies to improve care, facilitate interventions and promote prevention (Pinaire et al., 2017)

The Process for Nutrition and Dietetic Practice is a systematic process designed to guide the in the documentation of dietetic assessment, treatment and monitoring. Assessment is the first

stage in the process and confirms a need for dietetic input highlighted, for example, by nutritional screening or referral by a health professional. The second stage in the process is the formation of a nutrition and dietetic diagnosis to identify the nutritional risk and its aetiology. Stages three and four include the nutrition and dietetic plan, detailing and actioning an intervention or interventions to treat the identified diagnosis. Interventions may include strategies to improve diet quality, the implementation of services, or nutrition support for example. Stage five, monitoring and review, refers to the measurement of intervention outcomes such as nutritional status or dietary intake at pre-determined intervals. Finally, evaluation makes up the final stage of the process. The evaluation presents the final outcomes of an intervention alongside baseline nutritional status to demonstrate the success of dietetic intervention,

In addition, older adults with multiple health problems transition across multiple care settings and are at high risk of receiving fragmented care. Other than the BAPEN Nutrition Screening Week data exploring nutrition information at hospital discharge, research during this period is limited. This study aims to quantify the nutritional information provided within written communications at hospital discharge.

6.2 Aim, research questions and objectives

The aim of this sub-study was to examine the communication of nutritional risk between hospital and community settings, and explore the type and extent of nutritional interventions experienced by at-risk older adults following a hospital admission.

This study set out to answer the following questions:

What is the process of discharge from the acute to the community sector in the context of nutritional care?

What is the trajectory of the care process from discharge to 12 months post-discharge in terms of nutritional care for older people?

This study set the following objectives:

- i. To examine the proportion of participants at nutritional risk and receiving nutritional care through self-reported interview data at hospital discharge, 3, 6 and 12 months.
- ii. To examine the staff groups involved in the nutritional care of a sample of older adults following hospital discharge through self-reported interview data at hospital discharge, 3, 6 and 12 months.
- iii. To examine discharge communications from hospital to primary care settings in a sub-group of participants at nutritional risk using electronic patient records.
- iv. To explore the nature of community-based interventions in a sub-group of participants receiving care in the community using electronic patient records and comparing documented care against the BDA Nutrition and Dietetic Process.

6.3 Methods

6.3.1 Pathways of nutritional care

Descriptive statistics were carried out to describe the nature and extent of community-based nutritional interventions received by study participants including the following.

- a. The proportion of the study population receiving nutritional interventions in the community (according to nutrition risk status)

- b. Which staff groups provided nutritional interventions e.g. GP, district nurse
- c. The types of intervention received e.g. oral nutritional supplements, food-based interventions or home meal delivery and how long the interventions lasted
- d. Whether or not there was a documented change in nutritional status and other outcomes in those who received nutritional intervention
- e. The numbers of patients where their pathway of care was ideal (i.e. included all aspects of good quality nutritional care outlined by the British Dietetic Association (BDA 2012) as essential for the provision of good quality nutritional care (see figure 6.1).

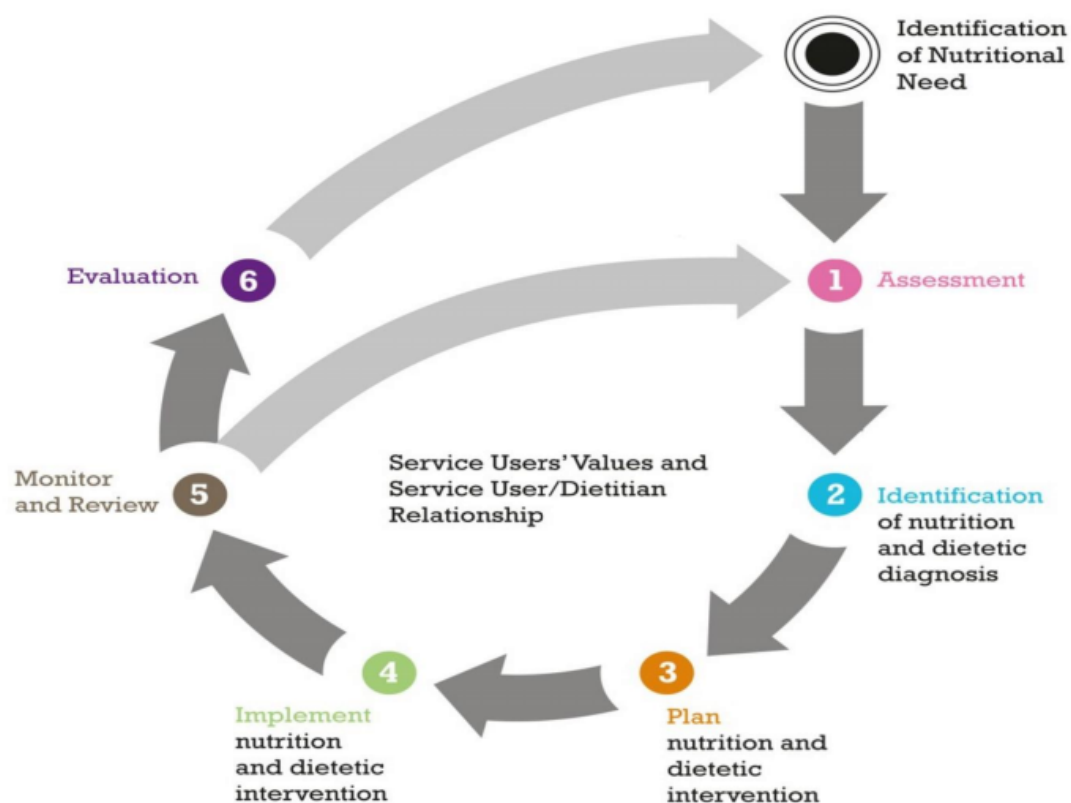


Figure 6.1: BDA Nutrition and Dietetic Process

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6.3.2 Dietetic intervention

The dietetic pathway data was collected in two ways:

1. Self-reported data was provided by participants at interview to examine overall dietetic input. This was facilitated by asking participants to keep diaries of any interaction with healthcare professionals and careful interviewing at each time point to establish as far as possible the components which form the dietetic care process (factors a-e as listed above).
2. Dietetic notes were examined within hospital and community settings to explore referral and intervention during the study period. All participants' hospital records were checked for referral to dietetic services at discharge from hospital. Participants were distributed across two community dietetic trusts (both separate from the acute trust), thus permission was sought from each community dietetic service. Local dietetic services were then provided with a list of participants so see if they had been referred and seen post discharge, and if so whether the components of the dietetic care process outlined above were met. A copy of the information requested is included in appendix 9.5.1. In addition, GPs were contacted and asked to provide information relating to the nutritional care of study participants, including oral nutritional supplement prescriptions. A copy of the information requested is included in appendix 9.5.2.

6.3.3 Missing data

Due to the subsets of participants used within this chapter, participant numbers vary significantly. This was due to the difference in numbers of participants who a) self-reported dietetic support and b) had support through local community dietetic services and could therefore be verified. Data was collected for and analyses were completed on participants who were either retained in the study, or who died during the study (n=139).

6.4 Results

6.4.1 The proportion of the study population receiving nutritional interventions

The hospital policy where the participants were recruited was that all patients must be nutritionally screened on the day of admission and weekly thereafter. The tool in use was the NRS-2002. A score of 4 or more indicated a referral to the dietetic service was required, and as common to many hospitals, only those at greater risk were referred to dietetic services. The nursing staff used ward-based interventions to treat patients at medium risk and monitored status weekly, referring if and when nutritional status deteriorated further. Table 6.1 shows the patients at nutritional risk at baseline (using the NRS score recorded) and the numbers referred to dietetic services according to the hospital policy. The table shows that in most cases where a dietetic referral was not indicated it was not made, but where patients should have been referred, 18/28 (64.3%) were correctly referred, indicating that 10/28 (35.7%) of patients were not referred. Table 6.2 shows patients at nutritional risk at baseline (using the MUST score calculated by the researcher) and compares the numbers referred to dietetic services. The MUST is used to categorise participants' nutritional risk and is used throughout the thesis.

	NRS score ≥4 (referral indicated)	NRS score 3 (referral not indicated)	NRS score <3 (referral not indicated)	Totals
Participants referred to the dietetic service	18 (64.3%)	8 (21.6%)	1 (1.4%)	27
Participants not referred to the dietetic service	10 (35.7%)	29 (78.4%)	73 (98.6%)	112
Totals	28	37	74	139

NRS, Nutrition risk screening 2002

Table 6.1: Nutritional risk category in a sample of community-dwelling older adults (n=139) as assessed by NRS-2002 at hospital discharge and onward referral to dietetic services at hospital discharge.

	MUST score ≥2 (referral indicated)	MUST score <2 (referral not indicated)	Totals
Participants referred to the dietetic service	20 (50.0%)	6 (6.5%)	26
Participants not referred to the dietetic service	20 (50.0%)	93 (93.5%)	113
Totals	40	99	139

MUST, Malnutrition Universal Screening Tool

Table 6.2: Nutritional risk category in a sample of community-dwelling older adults (n=139) as assessed by MUST at hospital discharge and onward referral to dietetic services at hospital discharge.

At hospital discharge, nutritional status should be communicated, as part of a medical discharge letter, to the GP. For the patients who were not referred to the dietitian (n=39), but were either at high (10/39) or medium risk (29/39), no information about nutrition risk was included in the GP letter.

The data once patients were followed up in the community are shown in table 6.3. Of those referred 79% (15/19) were at risk at baseline and 21% (4/19) were not, but risk increased over the course of the study period triggering referral. A total of 37% (7/19) participants had an open community referral prior to admission, 5/7 of which had been requested by the GP and 2/7 from hospital dietitians during previous admissions. An additional 3/19 participants were referred as a direct result of dietitian-dietitian communication from hospital to community services during the baseline admission. The remaining nine participants were referred by dietitians in hospital or rehabilitation units following further hospital admission (3/12), GPs (3/12), district nurses (2/12), and physiotherapists (1/12).

As part of the study protocol, following each study assessment GPs were alerted to the nutritional risk status of any high risk participants so that appropriate action could be taken. Therefore all GP practices would have received an alert from the study. Comparing referral dates, 3 participants were referred on to community dietetic services shortly after the alert letter was sent, therefore it is possible that this safeguarding process triggered the community dietetic referral.

Of the 19 participants referred to community dietetics, 95% (18/19) were referred with a diagnosis of undernutrition. The other participant was referred for artificial nutrition support secondary to gastroparesis.

	MUST score = >2 (a referral indicated)	MUST score <2 (a referral not indicated)	Totals
Participants referred to the dietetic service	18 (18.4%)	1 (2.4%)	19
Participants not referred to the dietetic service	80 (81.6%)	40 (97.6%)	120
Totals	98	41	139

MUST, Malnutrition Universal Screening Tool

Table 6.3: Participants within a sample of older adults categorised at nutritional risk using MUST (medium or high) during a 12-month follow up period post-hospital admission and their referral to dietetic services (n=139).

7.4.2 Staff groups involved in nutritional care

Whilst 19 patients were seen by a dietitian, four other professional groups were involved in 13 other participants' nutritional care; general practitioners (GPs), hospital consultants, nurses and speech and language therapists.

Seven (7/13) participants reported obtaining their oral nutrition supplement prescription from the GP without any other dietetic monitoring. In addition, two (2/13) participants reported receiving nutritional advice from their GP without oral nutritional supplements.

Two (2/13) participants received nutritional care from practice or district nurses in the form of weight monitoring.

One (1/13) participant received nutritional care from a hospital consultant who discussed their nutritional status and one (1/13) participant discussed the importance of good nutrition with their speech and language therapist.

6.4.3 The types and duration of interventions received

From self-reported data of 98 participants at risk of undernutrition over the study period, the mean (SD) number of dietetic consultations was 1.8 (1.1). From our subgroup of patients under the care of community dietetic services, the mean number of consultations with a community dietitian was 3.1 (SD=1.77). Table 6.4 describes these interventions.

Of the 98 participants at high nutritional risk and thus having the potential for referral to dietetic services, almost half received food-based interventions. In addition, one third of participants reported using oral nutritional supplements in the year prior to or during the study period. Unfortunately it was not possible to ascertain length of supplement prescription for the cohort as a whole as insufficient data was returned by GPs. Of the questionnaires sent to GPs, 24% were returned (33/139). Of these, two participants were confirmed as having oral nutritional supplement prescriptions.

Within the subgroup receiving care from local community dietetic services, all but one participant received food-based interventions. Two-thirds of the sample received oral nutritional supplements as a source of nutrition support, with supplements initiated either as first or second line treatment and used for an average duration of 30 weeks. One participant required enteral tube feeding during the study period.

	All participants at nutritional risk (n=98^A)	Duration of intervention Mean (SD) visits	Participants under care of community dietetics	Duration of intervention Mean (SD) visits
Food-based intervention	46 (46.9%)	1.8 (1.1)	21/22 (95.5%)	3.1 (1.77)
		Duration of dietetic support (weeks) Mean (SD)		Duration of dietetic support (weeks) Mean (SD)
Meal delivery service	10 (10.2%)	9.9 (7.1)	1/22 (4.6%)	24.0 (0.0)
Oral nutritional supplements	35 (35.7%)	Insufficient data	13/22 (59.1%)	29.9 (19.9)
Enteral tube feeding	1 (1.0%)	8.0 (0.0)	1/22 (4.6%)	8.0 (0.0)

^An=98 based on all participants reporting dietetic support during the study and who either remained in the study at 12 months or died, but not those who were not lost to follow-up

Table 6.4: Dietetic interventions experienced by a sample of older adults by type and duration during a 12-month follow up period post-hospital admission (n=98).

The interventions in the subgroup receiving community dietetic input, 100% received dietetic assessment, with identification of nutritional diagnosis and goal setting. In terms of monitoring, 95.5% (18/19) received a progress review by the dietitian, with the exception of one participant where they had died. Evaluation was clear and rationale provided for all participants where duty of care was closed (12/19). This shows that the ideal process as outlined in figure 6.1 was being met.

6.4.4 Changes in nutritional status and patient-centred outcomes

To examine the success of dietetic input, participants at high nutritional risk (and therefore warranting dietetic input) during the 12 month study period and who had data from baseline and 12 month assessments (n=56) were categorised in to two groups; group 1 represented those who had dietetic input during the study period (17/56) were compared to those who did not (39/56). Results are displayed in table 6.5.

There were no significant between-group differences in weight or MUST score. Whilst neither group showed significant improvement in any outcome, SARC-F score worsened significantly over time in the group without dietetic intervention, suggesting a higher rate of deterioration in participants without intervention compared to those with dietetic support. In addition, activities of daily living (ADL) score worsened significantly for participants without intervention compared to those who received dietetic support. Satisfaction with food-related life also appeared to decline over time to a significant degree in the group without intervention.

To better understand the change in nutritional status in participants, those participants who were categorised at medium or high risk using MUST at study baseline and who improved over the study period were examined at 12 months. Almost half of participants had improved over 12 months (17/40), reducing their risk from medium or high to low risk. Of those, the majority, 58.8%, improved within 3 months (10/17) a further 23.5% (4/17) at 6 months and the remaining 17.6% (3/17) at 12 months. Of these participants, 23.5% (4/17) did so with support from a dietitian and 17.6% (3/17) with oral nutritional supplements alone.

Variable	Dietetic intervention							
	Baseline No intervention (n=39)	Intervention (n=17)	12 month follow-up No intervention (n=39)	Intervention (n=17)	Change over time No intervention (n=39)	Intervention (n=17)	p-value No intervention (n=39)	Intervention (n=17)
Median (IQR)								
MUST ¹	1 (0, 1)	1.5 (0, 2)	0 (0, 1)	1 (0, 2)	0 (-1, 1)	0 (-1, 0.3)	0.761	0.490
SARC-F score ²	4 (2, 7)	6 (4, 7)	5 (4, 6)	7 (4, 9)	1 (0, 3)	0 (0, 3)	0.021*	0.158
ADL score ³	32 (11, 58)	50 (33, 64)	52 (24, 72)	58 (25, 85)	8 (2, 19)	8 (-6, 24)	<0.001*	0.127
EQ-5D-5L UI ⁴	0.75 (0.48, 0.89)	0.65 (0.40, 0.85)	0.83 (0.55, 0.98)	0.70 (0.36, 0.89)	0.06 (-0.06, 0.21)	0.15 (-0.35, 0.25)	0.069	0.981
SWFL ⁵	20 (17, 21)	20 (13, 21)	18 (11, 20)	15 (11, 20)	-1 (-4, 1)	-1 (-5, 1)	0.041*	0.206
Mean (SD)								
Weight	63.9 (16.1)	59.1 (15.9)	62.7 (14.5)	60.1 (16.6)	-1.1 (-5.0, 3.8)	2.8 (-4.1, 10.6)	0.313 ^u	0.356 ^u
HGS ⁶	17.5 (6.9)	14.2 (5.2)	17.6 (7.2)	12.1 (6.5)	0.0 (-3, 3)	-1.0 (-6.5, 1.8)	0.970 ^u	0.205 ^u
EQ-VAS ⁷	59.3 (25.8)	64.4 (23.7)	65.6 (24.8)	63.1 (29.2)	5.0 (-10, 30)	0.5 (-6, 15)	0.204*	0.729 ^u

¹ Malnutrition Universal Screening tool (Elia et al., 2000). Scores 0 to 6, 0 = low risk, 1 = medium risk, 2+ = high risk

² SARC-F score (Malmstrom and Morley, 2013). Scores 0 to 10 (0 = best to 10 = worst), 0-3 = Healthy, 4+ = symptomatic.

³ Modified Townsend activities of daily living scale (Bowling & Grundy, 1997), score 0 (no incapacity) to 11+ (severe incapacity).

⁴ EQ-5D-5L utility index score (The EuroQol Group, 1990). Score 0 to 1 (0 = best to 1 = worst)

⁵ Satisfaction with food-related life (Grunert, 2007). Scores 0 to 25 (0 = worst to 5 = best)

⁶ Handgrip strength (kg)

⁷ EQ-5D VAS (The EuroQol Group, 1990). Scores range from 0 to 100 (0 = worst to 100 = best)

^An=56 and includes all participants at risk at any time point during the study and who have both baseline and 12 month data for comparison

^uChange scores did not follow a normal distribution therefore Wilcoxon signed rank tests were used

Table 6.5: Change from baseline to 12 months categorised by dietetic intervention in a sample of older adults at hospital discharge (n=56^A)

6.5 Discussion

This chapter set out to explore the level of communication around nutritional care from the acute to the community sector and to map the care process from discharge to 12 months post-discharge in a cohort of community-dwelling older adults.

Our findings over the 12 month study period are summarised in the points below. Through the discussion that follows, I aim to address the factors which have led to these results, to compare the results of this chapter with existing evidence and to draw conclusions.

- Worsening sarcopenia risk, reduced ability to perform activities of daily living and decreasing satisfaction with food-related life were associated with a lack of dietetic intervention.
- Less than half of participants at risk of undernutrition at baseline improved over 12 months, reducing their nutritional risk from medium or high to low risk.
- Two-thirds of participants identified as high nutritional risk at baseline had been referred to dietetic services during hospital admission as per protocol.
- Discharge communications highlighted nutritional risk in cases where dietitians were already involved in patient care. However, discharge letters failed to communicate a nutritional care plan in participants with medium or high nutritional risk, but without dietetic involvement, despite a nutritional plan being indicated in local guidelines.
- GPs, hospital consultants, nurses and speech and language therapists were actively involved in participants' nutritional care, through prescribing of oral nutritional supplements, weight monitoring and nutrition-related discussion. Referral to community dietetic services were made primarily by hospital dietitians and GPs, but were also generated by other allied health professionals and district nurses in small numbers.
- Food based interventions delivered by a dietitian were the most common nutritional treatments for undernutrition, followed by oral nutritional supplement prescription.

Several key documents have suggested that gaps in the nutritional care of older adults exist, with the transition of patients from hospital back to the community highlighted as an area of concern (NICE, 2012). However, few studies have investigated the pathways of nutritional care at the hospital-community interface.

Of those participants at high risk of undernutrition in our study two-thirds were seen by a dietitian in hospital as per policy. This compared well with a study by (Marshall et al., 2015) who found a 67% of participants were seen by a dietitian as part of standard care. However, it shows that there remains a gap in nutritional care at the first step of the pathway: screening. Whilst this is not unusual, several observational studies have identified that hospital screening only identifies 60% of at risk patients, and that fewer still had a nutritional care plan in place (Braunschweig et al., 2000), it is a significant gap at the top level of the pathway. An efficient nutritional care pathway requires a coordinated, multidisciplinary approach in which the health professional or service who has initial contact with the patient activates the pathway by performing nutritional screening.

The study results showed that the majority of participants who improved did so within 3 months of hospital discharge, less than half of participants at medium or high nutritional risk at baseline, improved by 12 months. The longitudinal study of older adults by Chen et al (2009) also found that recovery in nutritional status took up to three months following a hospital admission, but within their cohort a smaller 21% of participants failed to improve at all (Chen et al., 2009).

In the self-reported data, a lack of dietetic support was associated with sarcopenia risk, reduced ability to perform activities of daily living and decreasing satisfaction with food-related life. Weight did not change significantly. Reduced muscle function in the context of weight stability has been demonstrated in the literature before as a result of sarcopenia (Gallagher et al., 2000). Sarcopenia is a result of aging, incorporating loss of muscle function or performance, and mass. However, weight losses are not always seen, concealed by a corresponding increase in fat mass (Gallagher et al., 2000). This data is observational in a

small, subset of participants with dietetic support of varying type and duration, but suggests that further studies of dietetic support at the hospital-community interface are warranted to determine the most appropriate interventions.

Data from the sub analysis of participants receiving community dietetic support shows that 22 participants went on to receive dietetic care during the 12 month follow-up period. The majority of referrals to community services were as a direct result of dietitian-dietitian from hospital-community. In another study of nutritional care following a hospital admission, 11% (61/544) of participants went on to receive dietetic support, which was strongly associated with a dietetic consultation during hospital admission (OR 3.4, 95% CI:1.95–5.97).

There is currently no simple, standardised approach to nutritional care. Where sections of pathway exists, they are not consistently implemented and processes are not standardised and not part of routine care. Effective, validated pathways for nutritional care are not routinely available in hospital settings (Kondrup, 2002), and existing recommendations guiding referral on to a nutritional care pathway are often generic with a lack of evidence-based protocols for nutritional care. As a worse nutritional status is associated with suboptimal treatment outcomes (Correia et al., 2014), addressing the nutritional status of hospital patients makes sense and the strength of evidence provided in nutritional care guidelines validates the use of pathways (Agarwal et al., 2012). For example, organisations including The U.K. Joint Commission and local NHS organisations have set standards for nutritional care, such as nutritional screening within 24 hours of hospital admission (Joint Commission on Accreditation of Healthcare Organizations, 2007), however these timelines do not extend to hospital discharge, outpatient and community settings where screening and onward interventions are more opportunistic. The management of chronic conditions has evolved over time, with outpatient care far more common. This change in management requires a shift not only in treatment, but in the supportive care, to include nutritional care.

Our study considered hospital discharge as step one in the pathway of nutritional care. Effective discharge planning aims to facilitate a successful transition between hospital and

community settings, with support to ensure function and quality of life are optimised ((Hunter et al., 2011, Mukotekwa and Carson, 2007). Discharge planning should be led by health professionals and patient-centres, based on a set of protocols tailored to the patient's medical condition, future objectives and preferences (Coleman and Boulton, 2003).

There are several barriers that prevent effective nutritional care at the hospital-community interface. The average length of hospital stay for older patients in the UK (based on data from emergency admissions in 2014-15) is 11.9 days (Department of health, 2016). This timeframe limits the scope of inpatient interventions for individuals with undernutrition. In addition, evidence suggests that nutritional status worsens during a hospital admission (McWhirter and Pennington, 1994) and thus patients may return home to the community undernourished. This is of particular importance as undernutrition increases the risk of readmission (Friedmann et al., 1997), and therefore has the potential to cause a situation whereby patients are repeatedly admitted to hospital with worsening undernutrition, returning to the community each time, with reduced capacity for recovery. It is imperative that there is systematic follow-up to monitor nutritional risk and provide ongoing nutritional treatment for older individuals following a hospital admission.

Our results in chapter 5 showed that the majority of participants had functional problems, with up to 50% of participants at low risk and up to 73% of those at medium and high risk of undernutrition reporting problems with food preparation. The incidence of reported problems was even higher with respect to shopping ability; up to 70% and 90% in low risk and medium/high risk participants respectively. In a hospital environment where the focus is on medical care, the nutritional care of patients is not prioritised. These functional issues are important to a patient's ability to manage at home, but an Australian study in older people demonstrated that discharge planning failed to consider the typical routine of patients and support adaptations to support care at discharge (Grimmer et al., 2006).

Whilst at nutritional risk, it is clear from the results that a significant proportion of the study participants were not under the care of a dietitian, but are nutritionally vulnerable with the

potential to develop problems post-hospital. Discharge planning should be multifaceted and include all relevant members of the multidisciplinary team in order to support older individuals across the hospital-community interface. Continuity in information sharing is paramount, including patients and carers, health professionals from acute and community settings, and general practitioners (Holst and Rasmussen, 2013, Locher and Wellman, 2011, Mudge et al., 2012, Westergren, 2008, Young et al., 2018). Protocols used to identify and address challenges prior to discharge should incorporate components of nutritional care within this. Continuity in information sharing is fundamental, with inadequate verbal and written communication one of the top issues contributing to inefficient discharge processes. Exploring documentation in our study showed clear gaps in the communication of nutritional care. When participants were under the care of dietetic services, dietitians contributed to discharge communications back to the general practitioner. However, I found that for those participants at risk of undernutrition without dietitian input, nutritional status was not communicated. Discharge letters focussed on the medical and pharmacological aspects of care, without discussing nutrition. Stroke is an area where nutritional problems are prominent and as a result this patient group has been more commonly examined. A study of 59 patient records (Carlsson et al., 2010) found discharge summaries vague with regards to eating ability and nutritional status, with ambiguous terminology and few clear management plans. Priority is given to the sharing of medical information, and other important information neglected.

With developments in technology and corresponding increase in the methods and speed of communication, the use of electronic patient records should allow greater information sharing (Holst and Rasmussen, 2013, Locher and Wellman, 2011, Mudge et al., 2012, Westergren, 2008, Young et al., 2018). However, as Locher et al report (2011), this is often not the case with systems failing to talk to one another.

Studies exploring the nutritional care process have shown that team working and support from hospital through discharge was key for effective outcome. However, very few studies have explored the role of health professionals, other than dietitians, systematically supporting a

pathway of nutritional care. One study used GPs to support community-dwelling patients at nutritional risk following hospital discharge. The primary outcome was hospital readmission, with the hypothesis that health professional involvement would be preventative. However, the study did not work because only 10% of study visits were carried out despite prior agreement and funding for the GPs to do so (Beck et al., 2013a). Difficulties in setting up studies and recruiting participants to coordinated services has also been a challenge (Locher and Wellman, 2011). Weight loss is seen as desirable by many patients and this view echoed by carers and potentially misinformed health professionals who fail to realise the risks associated with such losses in advancing age (see section 1.7). Education for staff working with older adults as well as the older people themselves, may help individuals to be more aware of the symptoms associated with undernutrition and take appropriate action to minimise its consequences. In addition, exploration of the issues which prevent older adults from participating in nutritional interventions are required so better studies can be designed. (Kamp et al., 2010).

Nutritional interventions that focus on pathways through the hospital-community interface are required to ensure continuity. There is no room for individual processes, when care should be streamlined and systematic. One trial protocol introduced a structured approach to nutritional care including nutritional assessment and intervention based on a decision algorithm (Starke et al., 2011). The intervention included an individualised food supply, fortification of meals, additional snacks and oral nutritional supplements to meet individually calculated nutritional requirements and support from a physician to minimise medical barriers to good nutrition (for example antiemetic prescription for nausea). Results were positive, with the intervention group demonstrating higher macronutrient intakes, maintaining their weight, experiencing fewer complications, requiring fewer antibiotics and fewer repeat admissions (Starke et al., 2011).

Examples of effective pathways can be drawn from research in other healthcare specialties. Working with nursing staff, Anthony and Hudson-Barr (1998) used thematic analysis to identify core components in effective hospital discharge. Communication and multidisciplinary

involvement, including the patient's family, were key, whilst a lack of continuity was highlighted as the main barrier to successful patient discharge. In addition, a systematic review examining organised transitional care services in 68 trials in older adults with chronic disease, demonstrated reduced mortality up to 18 months post-discharge and fewer readmissions when pro-active follow-up was present (Le Berre et al., 2017). Successful interventions included rapid contact within the week post-hospital, multidisciplinary coordination and follow-up (Le Berre et al., 2017). Existing models provide good examples of transitional care for older adults and have demonstrated good outcomes including reduced costs and increased patient satisfaction with the transition from hospital to home (Coleman and Boulton, 2003).

However, when interventional studies in nutrition have attempted to replicate these positive outcomes, they have been less successful. Regular face-to-face support post-hospital did not (Beck et al., 2013c, Deutz et al., 2016, Feldblum et al., 2011), and several using telehealth, (Neelemaat et al., 2011a, Sharma et al., 2017, Young et al., 2018) varying in length from 6 to 12 weeks, have failed to influence functional status. Young et al., found nutritional intervention for 6-weeks post hospital improved gait speed in a cohort of undernourished older people, when compared to usual care, however change was minimal and the intervention did not improve other functional measures or quality of life.

There were some limitations to this analysis, which were common to the study as a whole and are therefore explored in a final discussion in chapter 7. As mentioned earlier in the chapter, an alert was sent to the participant's GP when a participant was identified as high nutritional risk, to ensure appropriate action was taken. This makes it difficult to determine whether referrals would have been made without study interference. Also pertinent to this chapter, is the difficulty associated with accurate process mapping. For example, patients may be admitted to hospital and referred following local protocol, but have an open episode of care with a community dietetic team. A judgement may be made not to see the patient as a care pathway already exists. On the other hand, a patient may be under the care of several dietetic teams at once and valuable dietetic resources wasted if pathways are not clear.

Research is warranted related to standardised processes for undernutrition from screening through the pathway of nutritional care. Many conditions have clear management plans based on stage of disease and patient comorbidities. That same systematic approach should be utilised for undernutrition. Protocols should be modelled, nutritional care pathways designed, implemented, and then evaluated.

A review of the literature shows that the presence of a pathway incorporating nutritional care in to discharge planning and ensuring post-discharge dietetic follow up may lessen the weight loss experienced by community-dwelling older adults at risk of undernutrition. However, it highlights that current interventions are short (generally 6 to 12 weeks).

6.6 Conclusion

Older adults at risk of undernutrition at hospital discharge remain at risk in the community for at least 12 months. This analysis showed that they are not likely to improve and may be at heightened risk of sarcopenia and of further functional deterioration without nutritional intervention. Collaboration between health services across the hospital-community interface is lacking, but is fundamental in order to identify and monitor older adults at nutritional risk. In addition, strategies to support patients and their carers to maximise awareness and self-management of undernutrition post-discharge are needed.

In chapter 4 we identified that a significant number of patients, no matter their nutritional status, are on a downward trajectory in this first 12 weeks post-hospital. From our analyses in this chapter, there is clearly work to be done involving referring to dietetic services when appropriate, but also in recognising the important role of other health professionals in nutritional care for those at medium nutritional risk at discharge who are at increased risk of decline.

There is a dearth of evidence exploring nutritional care pathways, and both observational and interventional studies are required. Chapter 7 aims to draw together the work presented in this thesis and make recommendations for future research.

Chapter 7: Discussion and future research

Through the work described in this thesis, I set out to examine the effects of undernutrition risk in community-dwelling older adults accessing medical care. An in-depth discussion of results is included within each chapter, the purpose of this final chapter is to consolidate the ideas presented and to consider areas for future research.

Study 1 (chapter 3) explored the impact of low, medium and high nutritional risk in a large cohort attending outpatient pulmonary rehabilitation as treatment for COPD. The study demonstrated that higher nutritional risk prior to pulmonary rehabilitation was associated with male gender, current smoking status, worse lung function and weaker quadriceps strength. However, being at medium or high nutritional risk did not significantly affect response to rehabilitation. Whilst univariate analyses showed nutritional risk was associated with non-completion of pulmonary rehabilitation, once the model was adjusted for potential confounders, only current smoking status and higher levels of dyspnoea predicted non-completion of pulmonary rehabilitation.

The finding that no significant between-group differences were present following pulmonary rehabilitation adds to the existing evidence base. Whilst the impact of nutritional risk status on pulmonary rehabilitation has not been explored before, a previous study examined the influence of frailty on outcomes following pulmonary rehabilitation (Maddocks et al., 2016). The study showed that frailty did not hinder performance in the programme, and that frail individuals showed greater improvement in some performance measures. As the relationship between frailty and undernutrition has been well documented, it is unsurprising that the response of participants at nutritional risk showed similar trends. This information is useful when considering the timing of interventions to treat undernutrition, supporting the use of nutrition support alongside a programme of exercise. More evidence is required to examine interventions such as 'prehabilitation', where nutritional support is provided prior to interventions to maximise their effect, and whether this would offer any additional benefit (Puts et al., 2017).

Similarly, in a group of community-dwelling older adults post-hospital admission, risk of undernutrition adversely influenced functional status, quality of life and satisfaction with food-related life (study 2 within chapter 4). The results showed that all patients, regardless of nutritional risk, deteriorated following a hospital admission, indicating that all patients are at risk of decline post-hospital. It was interesting too that this effect was not seen at the point of discharge (baseline assessment), but became clear at 3 month follow-up. The reasons for this are unknown, but it may be that results were coloured by participants' positivity at being discharged from hospital; that the realities of managing activities of daily living at home following a period of illness (which may not be fully better) and after a hospital stay were not yet clear.

Exploring the impact of nutritional risk at three time points following hospital discharge showed that time too influenced the recovery of functional and quality of life measures in community-dwelling older people, with recovery of functional status (demonstrated by self-reported activities of daily living), quality of life (measured by the EQ-5D-5L tool) and satisfaction with food-related life significantly different between those at low risk and those at medium and high risk of undernutrition.

The movement of patients from hospital to home can be complex, particularly for older patients and those with chronic conditions. As the length of a hospital admission has reduced in recent years, this presents a challenge for care at the hospital-community interface. This study was novel both in the community-dwelling population studied and with regards to the length of follow-up. As a result the observational data produced serves several purposes for future research. Firstly, future research could use measures of body composition such as bioelectrical impedance to confirm self-reported data on sarcopenia and provide more in-depth information to support nutritional risk status. This additional data would help to consolidate the findings of this study.

Secondly, despite a reduction in function and quality of life associated with undernutrition, there is little research in to older peoples' understanding of nutritional status. Whilst I have

chosen to measure outcomes deemed to be important to patients, there is little research investigating older peoples' expectations of aging in the context of nutrition. Numerous studies have shown an adverse relationship between weight loss and mortality, even in overweight individuals. Increasing our understanding of community-dwelling older adults' attitude towards weight loss and undernutrition through qualitative research would help to inform the design of treatment pathways. The barriers to adequate nutrition in older age have been well documented and it is known that adherence to dietary intervention can be poor. However, there has been little research in to the reasons behind this and the importance placed on good nutritional care. More research is required to design and evaluate educational interventions raising awareness of the consequences of undernutrition using outcomes that matter most to community-dwelling older people.

Chapter 5 investigated energy and protein intakes of community-dwelling older adults at hospital discharge, 3, 6 and 12-months post-admission using data from study 2. A significant proportion of participants demonstrated intakes of energy and protein well-below their requirements at hospital discharge, with no significant improvement in energy intake at follow-up. Protein intake showed a significant increase over time, however the cause for this was unclear. Underreporting of both energy and protein intake is common in overweight individuals and women (Briefel et al., 1995) – two groups which made up a significant proportion of the current cohort. In addition, some authors have suggested a relationship between age and underreporting of dietary intake (Johansson et al., 2001, Sawaya et al., 1996). However, the significant difference appears to be between younger adults and middle-older age adults, so it is unlikely that the age of participants lead to underreporting in this case (Tomoyasu et al., 1999). One outcome that was not measured was depression. As discussed in the introduction chapter, section 1.8.6, the relationships between undernutrition and mood are complex and may be reciprocal, however it is clear that older people suffering from depression may struggle to meet their energy and protein requirements (Sharkey et al., 2002). Individuals suffering with

depression may be less likely to engage in nutritional care and they may have been more likely to drop out.

In the final chapter, chapter 6, a sub analysis was undertaken to investigate the pathways of nutritional care in older adults at discharge from hospital. The results showed that nutritional risk did not improve on its own, with less than half of participants at risk of undernutrition at baseline improving over 12 months to reduce their nutritional risk to low. However, exploratory sub group analysis indicated differences between those participants who received dietetic support compared those who had not. While weight did not change significantly, participants without dietetic support experienced a worsening sarcopenia risk and reduction in ability to perform activities of daily living. These self-reported functional changes may indicate loss of muscle mass and muscle function in the absence of weight loss due to a reduction in activity level and an age-associated increase in fat (Gallagher et al., 2000).

Despite a number of recommendations, communication of nutritional risk at the hospital-community interface was poor. Investigation of the barriers preventing both primary and secondary care professionals from communicating nutritional status more effectively would be beneficial. In an NHS where dietetic resource is limited, it is important to find effective ways to monitor nutritional risk. GPs, consultants, nurses and allied health professionals all have the potential to contribute to the nutritional care of patients, but there is a need for nutritional health to be prioritised by all health professionals working in acute and community settings. Significant work has taken place in hospital settings to facilitate routine nutritional screening and assessment at regular intervals during an admission. However, recognising older adults with characteristics known to be associated with nutritional deficits is no use if that information is not communicated along the pathway. This presents an opportunity for collaboration between services to co-design interventions where gaps in nutritional care have been identified by this work and by others (Elia et al., 2005, NICE, 2012). Improved communication of information from secondary care to community settings will enable nutritional risk to be

monitored and nutritional intervention commenced quickly in those individuals who go on to require it.

The chronic care model is a management pathway for organising chronic disease in primary care, centred on effective organisation of health care resources in primary and secondary care, a clinical information system, and decision support tools for patients to aid self-management (Bodenheimer et al., 2002). It has been shown to be effective in chronic conditions and may be a useful tool in the development of nutritional care pathways. Self-management interventions have been shown to improve health related quality of life and reduce readmission for patients with COPD (Zwerink et al., 2014). Previous work has shown that barriers to self-management include functional difficulties, comorbidity and a poor knowledge of medical conditions (Bayliss et al., 2007), but little research has been performed in relation to nutrition and nutritional care.

Very few studies have explored the characteristics associated with nutritional risk in a community dwelling older population, and fewer still have examined the recovery of nutritional health following a hospital admission. Longitudinal studies exploring undernutrition and undernutrition risk are few, and to my knowledge none have used interview at 4 separate time points to explore the trajectory of recovery 3, 6 and 12 months post-discharge. In addition, the inclusion of a cohort at low nutritional risk allows comparisons to be drawn. However, a limitation of the study is the reliance on self-reported measures, without actual measurement of fat-free mass to support diagnoses of frailty and sarcopenia which some research has indicated may be more definitive than nutritional risk, BMI and weight change in predicting mortality and functional decline (Beck et al., 2016).

Together the analyses from study 2 show us that at the basic level the definitions and routine approach to measuring undernutrition are not clear. At step one, nutritional screening is not always performed and when it is, the next steps are not performed consistently. Pathways leading on from this point are far from standardised and communication limited.

Whilst a precise definition of undernutrition is lacking, there is clear evidence of suboptimal nutritional health on admission to hospital which continues to worsen during hospital stay. Our work leads on from this to suggest that patient outcome is adversely affected as a result, with at risk individuals starting from a lower base and experiencing a different trajectory of recovery in the 12 months after hospital discharge. This disadvantage is reflected in recovery of functional ability and visible in reduced quality of life. As the results of our observations show, nutritional risk is unlikely to improve on its own, but has the potential with support of health professions.

Going forward, definitions of undernutrition and risk of undernutrition must be clear and distinct to prevent confusion of terms, with clear guidance on the identification and treatment of each so that health care professionals are clear on the protocol to follow. Unless a consensus is reached, it will not be possible to accurately monitor improvement or deterioration in nutritional care in the older population using over time.

Conclusion

This thesis suggests that irrespective of nutritional status, older adults recently discharged from hospital or attending outpatient rehabilitation programmes exhibited reduced function, and that individuals at nutritional risk experience a reduced rate of recovery following hospital admission and that worse nutritional status may compound adverse effects on physical function and quality of life following hospital admission. However, preliminary findings suggest that in outpatients with chronic disease, higher nutritional risk may not prevent them from improving during exercise-based rehabilitation interventions, and that nutritional intervention has the potential to reduce further deterioration in participants at risk of undernutrition. There was a high prevalence of chronic disease, and often multiple diseases in our study population which is comparable to other studies in older adult cohorts. Nutritional status is a modifiable factor which impacts on mortality, morbidity and health care costs in the context of chronic illness. Pathways of nutritional care which include processes to identify and address nutritional determinants can help to optimise the management of long-term conditions and have the potential to decrease hospital readmissions and save costs.

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Chapter 9: Appendices

Appendix 9.1 Ethical approval letters

9.1.1 JRCO site approval letter, study 2: An observational study to investigate the impact of nutrition risk status on utilisation of health and social care resources and patient-centred outcomes in older people living in the community

**Imperial College
London**

Imperial College Healthcare NHS Trust

Joint Research Compliance Office
Academic Health Science Centre
Imperial College London and
Imperial College Healthcare NHS Trust
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Ruth Nicholson
Research Governance Manager

05/08/2015

Dr Mary Hickson
Post Therapy Research and Education Lead and Dietitian
Imperial College Healthcare NHS Trust and Adjunct
Imperial College London
Nutrition and Dietetics
Floor 13 Lab Block,
Charing Cross Hospital
Fulham Palace Road,
London
W6 8RF

Dear Dr Mary Hickson

RE: JRCO Study Approval

Project Title: An observational study to investigate the impact of nutrition risk status on utilisation of health and social care resources and patient-centred outcomes in older people living in the community

Short Title: The impact of nutrition risk status on older people in the community

Joint Research Compliance Office Reference number: 15/HH2599 **CSP Ref:** 171279

Ethics reference number: 15/YH0094

Principal Investigator: Dr Mary Hickson

I confirm that this project has now been approved by the Joint Research Compliance Office. The project may now start at Imperial College Healthcare NHS Trust sites. Please note that the start date of the project is the date of this letter and the duration is the same as that provided in your application form.

The list of documents reviewed and approved by the Joint Research Compliance Office under requirements of the Research Governance Framework are as follows:

Document	Version	Date
R&D Form (Signed)	171279/783370/14/630	11 May 2015
SSI Form (Signed)	171279/8/2448/6/130/277742/327275	07 July 2015
NRES Committee Yorkshire & The Humber – Leeds East – Favourable Opinion Letter	Favourable Opinion Letter – Conditions Met	18 March 2015
NRES Committee Yorkshire & The Humber – Leeds East – Favourable Opinion Letter	Substantial Amendment 1 [Updated Protocol]	12 June 2015
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 1	21 May 2015
Copies of advertisement materials for research participants	1.0	10 February 2015
GP/consultant information sheets or	1.0	04 February 2015

letters [Letter to GP] - Patient		
Other [GP letter consultee]	1.0	04 February 2015
Research protocol or project proposal [Cohort Study Protocol]	2.0 [AM1]	17 May 2015
NIHR Funding Letter	Funding Letter	18 November 2013
Other: Funding Award Letter	Imperial College Finance Department	19 December 2013
Other [CV for student supervisor]	Mary Hickson	19 January 2015
Summary CV for Chief Investigator (CI) [CI CV]	Elizabeth Weeks	17 February 2015
Summary CV for student [CV for student]	Ana Julian	15 January 2015
Summary CV for supervisor (student research) [CV for student supervisor]	Gary Frost	16 March 2014
Other [consultee Information Booklet]	1.1	12 March 2015
Other [Consultee Declaration form]	1.1	12 March 2015
Other [Information booklet for person regaining capacity]	1.0	12 March 2015
Other [Consent form for person regaining capacity]	1.0	12 March 2015
Other [Information booklet for nominated consultee]	1.0	12 March 2015
Other [Declaration form for nominated consultee]	1.0	12 March 2015
Participant consent form [Consent form]	1.1	12 March 2015
Participant information sheet (PIS) [Participant Information Booklet - patient]	1.1	12 March 2015
CPG Approval		07 July 2015

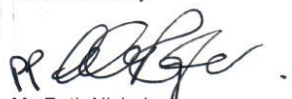
Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the Research Governance indicators 17 (Data Protection); 25 (Health and Safety) and 22 (Financial Probity). Details of the requirements to be met can be found in the Research Governance Framework available on www.dh.gov.uk.

Under the Research Governance regulations, Serious Adverse Event Reports, Adverse Reactions and amendments to the protocol or other supporting documents must be forwarded to the Joint Research Compliance Office and Ethics Committee.

In accordance with the Research Governance Framework, research projects carried out in the Trust will be randomly chosen by the Joint Research Compliance Office for auditing. Please see the attached checklist for documentation that will be required during the audit.

I wish you well in your research.

Yours sincerely



Ms Ruth Nicholson
Research Governance Manager

9.1.2: Ethical approval letter, study 2: An observational study to investigate the impact of nutrition risk status on utilisation of health and social care resources and patient-centred outcomes in older people living in the community


Health Research Authority
NRES Committee Yorkshire & The Humber - Leeds East
Room 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT
Telephone: 0191 428 3444

18 March 2015

Dr Elizabeth Weekes
Consultant Dietitian and NIHR Clinical Lecturer
Guy's & St Thomas' NHS Foundation Trust
Department of Nutrition & Dietetics
St Thomas' Hospital, Westminster Bridge Road
London
SE1 7EH

Dear Dr Weekes

Study title:	An observational study to investigate the impact of nutrition risk status on utilisation of health and social care resources and patient-centred outcomes in older people living in the community
REC reference:	15/YH/0094
Protocol number:	N/A
IRAS project ID:	171279

Thank you for your letter of 13 March 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Sarah Grimshaw at nrescommittee.yorkandhumber-leedseast@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable** ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

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.

Management permission ('R&D approval') should be sought from all NHS organisations involved in the study 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 a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ('participant identification centre'), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non-registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the 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).

Ethical review of research sites

NHS 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).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [Advertisement material]	1	10 February 2015
Covering letter on headed paper [REC submission letter]	1	17 February 2015
Covering letter on headed paper [REC submission letter]		13 March 2015
GP/consultant information sheets or letters [Letter to GP]	1	04 February 2015
IRAS Checklist XML [Checklist_13032015]		13 March 2015
Other [GP letter consultee]	1	04 February 2015
Other [CV for student supervisor]		15 January 2015
Other [consultee Information Booklet]	1	18 February 2015
Other [Consultee Declaration form]	1	10 February 2015
Other [consultee Information Booklet]	1.1	12 March 2015
Other [Consultee Declaration form]	1.1	12 March 2015
Other [Information booklet for person regaining capacity]	1	12 March 2015
Other [Consent form for person regaining capacity]	1	12 March 2015
Other [Information booklet for nominated consultee]	1	12 March 2015
Other [Declaration form for nominated consultee]	1	12 March 2015
Participant consent form [Consent form]	1	04 February 2015

A Research Ethics Committee established by the Health Research Authority

Participant consent form [Consent form]	1.1	12 March 2015
Participant information sheet (PIS) [Participant Information Booklet - patient]	1	04 February 2015
Participant information sheet (PIS) [Participant Information Booklet - patient]	1.1	12 March 2015
REC Application Form [REC_Form_18022015]		18 February 2015
Research protocol or project proposal [Cohort Study Protocol]	1	04 February 2015
Summary CV for Chief Investigator (CI) [CI CV]	1	17 February 2015
Summary CV for student [CV for student]		15 January 2015
Summary CV for supervisor (student research) [CV for student supervisor]		17 February 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

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
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

A Research Ethics Committee established by the Health Research Authority

With the Committee's best wishes for the success of this project.

Yours sincerely
pp



Dr Rhona Bratt
Chair

Email: nrescommittee.yorkandhumber-leedseast@nhs.net

Enclosures: 'After ethical review – guidance for
Researchers' [SL-AR2]

Copy to: Kate Blake, Guy's & St Thomas' NHS Foundation Trust
Ms Elizabeth Bruna, Guy's & St Thomas' NHS Foundation Trust

Appendix 9.2: Patient information

Appendix 9.2.1: Patient information booklets

Participant Information Booklet

An observational study to investigate the impact of nutrition risk status on patient-centred outcomes and utilisation of health and social care resources in older people living in the community

REC Reference Number: 15/YH/0094

R&D number: 171279

PART 1

Can you help with a research project?

We would like to invite you to take part in a research project. Before you decide we would like you to understand why the research is being carried out and what it would involve for you.

One of our team will go through the information booklet with you and answer any questions you have. This should take about 10 - 15 minutes.

Please talk to others about the study if you wish and ask us if anything is not clear.

What is the purpose of the study?

The main purpose of the study is to better understand the impact of nutrition on peoples' health.

We know that people who are malnourished (thin or losing weight) are more likely to have poor health than those who are well nourished. Malnourished people also have an increased need for support from their family and friends and their GP.

In this study we will identify people who are malnourished and compare them to people who are well-nourished.

We want to find out if there are any differences between the malnourished and the well-nourished so we will look at how nutrition affects:

Quality of life (how people feel about their life)
Ability to do everyday activities such as shopping or cooking
Muscle strength and ability to move around
How often people see their GP and/or go to hospital
Healthcare costs

Why have I been invited?

You have been invited to take part in this study because we are looking for people who are aged 60 years and over who have recently been in hospital or have visited their GP. We are also looking for people who are receiving health or social care at home or who live in an extra care or sheltered housing community.

We need to recruit people who are malnourished as well as those who are well-nourished.

Do I have to take part?

It is up to you to decide if you want to take part in the research. We will describe the study and go through this information booklet with you.

If you agree to take part we will ask you to read and sign a consent form.

You are free to withdraw at any time, without giving a reason. This will not affect any of the care you receive.

Who are the researchers?

The research will be conducted by a team based at Guy's and St Thomas' NHS Foundation Trust and at Imperial College Healthcare NHS Hospitals.

The main investigators are:

Dr Elizabeth Weekes, Consultant Dietitian and NIHR Clinical Lecturer, Guy's & St Thomas' NHS Foundation Trust, London (Chief Investigator)

Dr Mary Hickson, Adjunct Professor and Dietitian, Imperial College London (Principal Investigator)

Anna Julian, Dietitian and PhD student, Imperial College London (Investigator)

PART 2

When will the research take place?

The research will start once you have given your consent and will continue for 12 months. During this time you will be contacted four times to arrange for a member of the research team (dietitian or research nurse) to visit you. This will be for the first assessment, then to collect follow-up information at 3, 6 and 12 months.

During each visit you will be asked some questions and some measurements will be made. The visits will be kept as short as possible and should last no longer than an hour.

Some information will be obtained from electronic medical records which we can request from your GP surgery, local hospital or community teams and from the Department of Health.

What will happen to you if you take part?

If you agree to take part in this study, the researcher will contact you to make the first visit at a time and in a place that is convenient for you. This may be at your home, your GP surgery or a local clinic.

During the visit the researcher will ask you (or your carer) short questions about the following:

your weight

your medical history

if you have been admitted to hospital or visited your GP recently

any prescription drugs you are taking

if you have had any falls or pressure sores

your age, sex, ethnicity, marital status and postcode

your living conditions and any care you receive from family, friends, the local council or other organisations

your quality of life and ability to do everyday activities such as shopping and cooking

During the first visit your height will be measured. You will also be weighed. If it is not possible for you to stand safely we will obtain information about your weight and height from you or your carer.

To test your muscle strength you will be asked to squeeze as hard as you can using a piece of equipment called a dynamometer. The researcher may also ask you about your food intake over the last 24 hours.

It will take no more than an hour to make these measurements and collect this information.

The researcher will contact you again after 3, 6 and 12 months and arrange a time to meet you. At these follow up visits the researcher will ask you some of the same questions again and weigh you (since things might have changed). The researcher may also ask you about your food intake over the last 24 hours. It will take no more than 30 – 45 minutes to collect this information and make the measurements.

What will happen next?

In addition to the information we collect from you directly, we will also request information from your electronic medical records and from a national data warehouse known as the “Hospital Episode Statistics” (HES). The HES contains details of all hospital admissions to NHS hospitals in England.

We will ask for information on the following:

The number of times you are admitted to hospital including the admission and discharge dates, as well as details of your diagnosis and any nutritional care you receive. This information will be collected from HES.

The number of visits you make to your GP surgery and the number of times your GP or other practice staff (e.g. a nurse) visit you at home, as well as details of your diagnosis and any nutritional care you receive. This information will be requested from records held by your GP.

The number of times you receive healthcare from other professionals such as community nurses, physiotherapists, occupational therapists, speech and language therapists or dietitians, as well as details of your diagnosis and any nutritional care you receive. This information will be requested from records held by the community healthcare teams.

We require your permission to legally request this information from the electronic databases and from your GP. When you sign the consent form for this study you will be giving us permission to request this specific information, but nothing more.

What do I need to do?

Once you have agreed to take part in this study you do not need to do anything. We will contact you to arrange the first assessment and will contact you at regular intervals to organise visits to collect the information described above. You will have our contact details should you need to contact us at any other time.

Why is this research important?

This research is important because it will help us to understand three main things:

whether people who are malnourished have a worse quality of life and poorer ability to do everyday activities than those who are well-nourished

whether someone who is malnourished requires more health and social care than someone who is well-nourished
what nutritional care is received by malnourished people

The information we collect will help us to understand how malnutrition affects individuals and will help us to plan the best nutritional care for people who are malnourished.

Are there any benefits to taking part?

We cannot promise the study will help you, but the information we get from this research will help to improve health care practices in the future and improve the outcomes of patients who are malnourished.

Your treatment will not be affected by taking part in this study. We do not expect the study to cause you any pain, discomfort or distress.

What will happen when the research is finished?

A summary of the results will be available and we will send you a copy if you request it.

The results of the research will be published in reports and will be presented at conferences. The research may also be used for teaching purposes.

Any information presented about you will be done in such a way that you cannot be recognised i.e. your name, address and date of birth, will be removed.

What will happen if I decide that I do not want to carry on in the study?

You are free to stop the research at any time and you do not have to give a reason why. We will not collect any more information about you after that time.

If you stop the research before the study is finished, we would like your permission to use the information we have already collected.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers. They will do their best to answer your questions. Their contact details are on the last page of this booklet.

If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS).

Patient Advice and Liaison Service
Knowledge and Information Centre (KIC),
Ground Floor, North Wing,
St Thomas' Hospital,
Westminster Bridge Road,
London SE1 7EH
Tel: 0207 188 8801 or 0207 188 8803
Email: pals@gstt.nhs.uk

Patient Advice and Liaison Service
Ground floor,
Charing Cross Hospital,
Fulham Palace Road,
London W6 8RF
London, SE5 9RS
Tel: 020 3313 0088
Email: pals@imperial.nhs.uk

This trial is sponsored by Guy's and St Thomas' NHS Foundation Trust. All professional staff involved in the study hold professional indemnity to work within Guy's and St Thomas' NHS Foundation Trust. In the event that you are harmed during the research, and this is due to negligence, then you may have grounds for legal action for compensation against Guy's and St Thomas NHS Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms are still available to you.

What will happen to the information we collect?

The Chief Investigator (Dr Elizabeth Weekes) will be responsible for ensuring that all the information we collect about you during the study is kept strictly confidential.

Any information about you which leaves the hospital, GP surgery or other agency will have your name and address removed so that you cannot be identified.

All the procedures used for handling, processing, storage and destruction of your information will be in compliance with the Data Protection Act 1998.

All the information we collect and receive (after obtaining the required approvals) will be stored on a password protected computer, specifically purchased for this study.

Only members of the research team will have access to the information we collect.

Thank you for your interest

Please ask if you have any questions

Contact details

If you have any questions about the study please talk to one of the researchers:

Chief Investigator
Dr Elizabeth Weekes
Consultant Dietitian and NIHR Clinical Lecturer
Department of Nutrition & Dietetics
Guy's & St Thomas' NHS Foundation Trust
Westminster Bridge Road
London SE1 7EH
Telephone: 0207 188 2012
Fax: 0207 188 2015
Email: elizabeth.weekes@gstt.nhs.uk

Principal Investigator
Dr Mary Hickson
Honorary Professor

Division of Diabetes, Endocrinology & Metabolism
Imperial College London
Tel: 020 331 25093
Email: mary.hickson@imperial.ac.uk

Investigator
Ms Anna Julian
Dietitian and PhD student
Division of Diabetes, Endocrinology & Metabolism
Imperial College London
Tel: 020 331 25093
Email: a.julian14@imperial.ac.uk

Personal Consultee Information Booklet

An observational study to investigate the impact of nutrition risk status on patient-centred outcomes and utilisation of health and social care resources in older people living in the community.

REC Reference Number: 15/YH/0094

R&D number: 171279

Appendix 9.2.2: Consultee information booklet

An observational study to investigate the impact of nutrition risk status on patient-centred outcomes and utilisation of health and social care resources in older people living in the community.

REC Reference Number: 15/YH/0094

R&D number: 171279

Introduction

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about taking part in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend.

Can your relative/friend help with a research project?

We would like to invite your relative/friend to take part in a research project. Before you decide we would like you to understand why the research is being carried out and what it would involve for your relative/friend.

One of our team will go through the information booklet with you and answer any questions you have. This should take about 10 – 15 minutes.

Please talk to others about the study if you wish and ask us if anything is not clear.

What is the purpose of the study?

The main purpose of the study is to better understand the impact of nutrition on peoples' health.

We know that people who are malnourished (thin or losing weight) are more likely to have poor health than those who are well nourished. Malnourished people also have an increased need for support from their family and friends and their GP.

In this study we will identify people who are malnourished and compare them to people who are well-nourished.

We want to find out if there are any differences between the malnourished and the well-nourished so we will look at how nutrition affects:

Quality of life (how people feel about their life)
Ability to do everyday activities such as shopping or cooking
Muscle strength and ability to move around
How often people see their GP and/or go to hospital
Healthcare costs

Why has your relative/friend been invited?

Your relative/friend has been invited to take part in this study because we are looking for people who are aged 60 years and over who have recently been in hospital or have visited their GP. We are also looking for people who are receiving health or social care at home or who live in an extra care or sheltered housing community.

We need to recruit people who are malnourished as well as those who are well-nourished.

Does your relative/friend have to take part?

It is up to you to decide if your relative/friend would want to take part in the research. We will describe the study and go through this information booklet with you.

If you decide your relative/friend would agree to take part we will ask you to read and sign the personal consultee declaration form.

You are free to refuse or to request to withdraw your relative/friend at any time, without giving a reason. This will not affect any of the care your relative/friend receives.

Who are the researchers?

The research will be conducted by a team based at Guy's and St Thomas' NHS Foundation Trust and at Imperial College Healthcare NHS Hospitals.

The main investigators are:

Dr Elizabeth Weekes, Consultant Dietitian and NIHR Clinical Lecturer, Guy's & St Thomas' NHS Foundation Trust, London (Chief Investigator)

Dr Mary Hickson, Adjunct Professor and Dietitian, Imperial College London (Principal Investigator)

Anna Julian, Dietitian and PhD student, Imperial College London (Investigator)

When will the research take place?

The research will start once consent has been given and will continue for 12 months. During this time your relative/friend or their carer will be contacted four times to arrange for a member of the research team (dietitian or research nurse) to visit them. This will be for the first assessment, then to collect follow-up information at 3, 6 and 12 months.

During each visit your relative/friend will be asked some questions and some simple measurements will be made. The visits will be kept as short as possible and should last no longer than an hour.

Some information will be obtained from electronic medical records which we can access through your friend/relative's GP surgery, local hospital or community teams and from the Department of Health.

What will happen to your relative/friend if he/she takes part?

If your friend/relative takes part in this study, the researcher will contact them or their carer to make the first visit at a time and in a place that is convenient for them. This may be at their home, their GP surgery or a local clinic.

During the visit the researcher will ask your friend/relative (or their carer) short questions about the following:

- their weight
- their medical history
- if they have been admitted to hospital or visited their GP recently
- any prescription drugs they are taking
- if they have had any falls or pressure sores
- their age, sex, ethnicity, marital status and postcode
- their living conditions and any care they receive from family, friends, the local council or other organisations
- their quality of life and ability to do everyday activities such as shopping and cooking

During the first visit their height will be measured. They will also be weighed. If it is not possible for them to stand safely we will obtain information about their weight and height from their carer.

To test their muscle strength your relative/friend will be asked to squeeze as hard as they can using a piece of equipment called a dynamometer. The researcher may also ask about their food intake over the last 24 hours.

It will take no more than an hour to make these measurements and collect this information.

The researcher will contact your relative/friend (or their carer) again after 3, 6 and 12 months and arrange a time to meet them. At these follow up visits the researcher will ask some of the same questions again and weigh your relative/friend (since things might have changed). The researcher may also ask about their food intake over the last 24 hours. It will take no more than 30 – 45 minutes to collect this information and make the measurements.

If at any time during an assessment your relative/friend shows any sign of distress or unwillingness to take part, the researcher will immediately stop.

What will happen next?

In addition to the information we collect from your relative/friend or their carer directly, we will also request information from their electronic medical records and from a national data warehouse known as the “Hospital Episode Statistics” (HES). The HES contains details of all hospital admissions to NHS hospitals in England.

We will ask for information on the following:

The number of times your relative/friend is admitted to hospital including the admission and discharge dates, as well as details of their diagnosis and any nutritional care they receive. This information will be requested from HES.

The number of visits your relative/friend makes to their GP surgery and the number of times their GP or other practice staff (e.g. a nurse) visit them at home, as well as details of their diagnosis and any nutritional care they receive. This information will be requested from records held by their GP.

The number of times your relative/friend receives healthcare from other healthcare professionals such as community nurses, physiotherapists, occupational therapists, speech and language therapists or dietitians, as well as details of their diagnosis and any nutritional care they receive. This information will be requested from records held by the community healthcare teams.

We require your permission to legally request this information relating to your relative/friend from the electronic databases and from their GP. When you sign the consent form on their behalf for this study you will be giving us permission to request this specific information, but nothing more.

What do I need to do?

Once you have decided that your relative/friend would be willing to take part in this study you do not need to do anything. We will contact your relative/friend or their carer to arrange the first assessment and will contact them at regular intervals to organise visits to collect the information described above. They will have our contact details should they need to contact us at any other time.

Why is this research important?

This research is important because it will help us to understand three main things:

whether people who are malnourished have a worse quality of life and poorer ability to do everyday activities than those who are well-nourished

whether someone who is malnourished requires more health and social care than someone who is well-nourished

what nutritional care is received by malnourished people

The information we collect will help us to understand how malnutrition affects individuals and will help us to plan the best nutritional care for people who are malnourished.

Are there any benefits to taking part?

We cannot promise the study will help your relative/friend, but the information we get from this research will help to improve health care practices in the future and improve the outcomes of patients who are malnourished.

Your relative/friend’s treatment will not be affected by taking part in this study. We do not expect the study to cause him/her any pain, discomfort or distress.

What will happen when the research is finished?

A summary of the results will be available and we will send your relative/friend or their carer a copy if they request it.

The results of the research will be published in reports and will be presented at conferences. The research may also be used for teaching purposes.

Any information presented about your relative/friend will be done in such a way that he/she cannot be recognised i.e. their name, address and date of birth, will be removed.

What will happen if I decide that my friend/relative would not want to carry on in the study?

You are free to stop the research at any time and you do not have to give a reason why. We will not collect any more information about your friend/relative after that time.

If you stop the research before the study is finished, we would like your permission to use the information we have already collected.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers. They will do their best to answer any questions. Their contact details are on the last page of this booklet.

If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS).

Patient Advice and Liaison Service
KIC, Ground Floor, North Wing,
St Thomas' Hospital,
Westminster Bridge Road,
London SE1 7EH
Tel: 0207 188 8801 or 0207 188 8803
Email: pals@gstt.nhs.uk

Patient Advice and Liaison Service
Charing Cross Hospital, ground floor
Fulham Palace Road,
London W6 8RF
London, SE5 9RS
Tel: 020 3313 0088
Email: pals@imperial.nhs.uk

This trial is sponsored by Guy's and St Thomas' NHS Foundation Trust. All professional staff involved in the study hold professional indemnity to work within Guy's and St Thomas' NHS Foundation Trust. In the event that your friend/relative is harmed during the research and this is due to negligence then they may have grounds for legal action for compensation against Guy's and St Thomas NHS Trust but your friend/relative may have to pay their legal costs. The normal NHS complaints mechanisms are still available to your friend/relative.

What will happen to the information we collect?

The Chief Investigator (Dr Elizabeth Weekes) will be responsible for ensuring that all the information we collect about your relative/friend during the study is kept strictly confidential.

Any information about your relative/friend which leaves the hospital, GP surgery or other agency will have their name and address removed so that they cannot be identified.

All the procedures used for handling, processing, storage and destruction of your friend/relative's information will be in compliance with the Data Protection Act 1998.

All the information we collect and receive (after obtaining the required approvals) will be stored on a password protected computer, specifically purchased for this study.

Only members of the research team will have access to the information we collect.
Contact details

If you have any questions about the study please talk to one of the researchers:

Chief Investigator
Dr Elizabeth Weekes
Consultant Dietitian and NIHR Clinical Lecturer
Department of Nutrition & Dietetics

Guy's & St Thomas' NHS Foundation Trust
Westminster Bridge Road
London SE1 7EH
Telephone: 0207 188 2012
Fax: 0207 188 2015
Email: elizabeth.weekes@gstt.nhs.uk

Principal Investigator
Dr Mary Hickson
Honorary Professor
Division of Diabetes, Endocrinology & Metabolism
Imperial College London
Tel: 020 331 25093
Email: mary.hickson@imperial.ac.uk

Investigator
Ms Anna Julian
Dietitian and PhD student
Division of Diabetes, Endocrinology & Metabolism
Imperial College London
Tel: 020 331 25093
Email: a.julian14@imperial.ac.uk

Thank you for your interest

Please ask if you have any questions

Appendix 9.2.3: Patient consent form

CONSENT FORM

Title of Project: An observational study to investigate the impact of nutrition risk status on patient-centred outcomes and utilisation of health and social care resources in older people living in the community

Name of Researcher: **Dr Mary Hickson**

Centre Number: ICL

R&D number: 171279

REC reference: 15/YH/0094

Patient Identification Number for this trial: ___ / ___

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 12th March 2015 (version 1.1) 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 relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Guy's & St Thomas' NHS Foundation Trust, or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. If I withdraw from the study I give permission for any information collected up to that time to be used for the research ☐

OR

If I withdraw from the study I do not want any information collected to be used for the research. ☐

6. I consent to information about my hospital admissions being requested from the Hospital Episode Statistics database. ☐

7. I consent to information about my use of general practice services being from records held by my GP. ☐

☐

8. I consent to information about my use of community healthcare services being requested from records held by my community healthcare team.

☐

9. I agree to take part in the above study.

_____	_____	_____
Name of participant	Date	Signature

_____	_____	_____
Name of person	Date	Signature

taking consent

Appendix 9.2.4: Consultee consent form

CONSENT FORM – NOMINATED CONSULTEE

Title of Project: An observational study to investigate the impact of nutrition risk status on patient-centred outcomes and utilisation of health and social care resources in older people living in the community

Name of Researcher: **Dr Elizabeth Weekes**

Centre Number:

Study Number:

Patient Identification Number for this trial:

Please initial all boxes

10. I confirm that I have read and understand the information sheet dated 4th February 2015 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

11. I understand that I can withdraw the patient from the study at any time without giving a reason without their medical care or legal rights being affected. ☐

12. I understand that relevant sections of the patient's medical notes and data collected during the study, may be looked at by individuals from Guy's & St Thomas' NHS Foundation Trust or regulatory authorities, where it is relevant to their taking part in this research. I give permission for these individuals to have access to their records. ☐

13. I agree to the patient's GP being informed of their participation in the study. ☐

14. If I withdraw the patient from the study I give permission for any information collected up to that time to be used for the research ☐

OR

If I withdraw them from the study I do not want any information collected to be used for the research. ☐

15. I agree to information about the patient's hospital admissions being collected from the Hospital Episode Statistics database. ☐

☐

16. I agree to information about the patient's use of general practice services being collected from records held by their GP.

17. I agree to information about the patient's use of community healthcare services being collected from records held by their community healthcare team.

☐

18. In my capacity as consultee it is my opinion that the patient would give his/her permission to participate in the above study..

☐

_____	_____	_____
Name of participant	Date	Signature

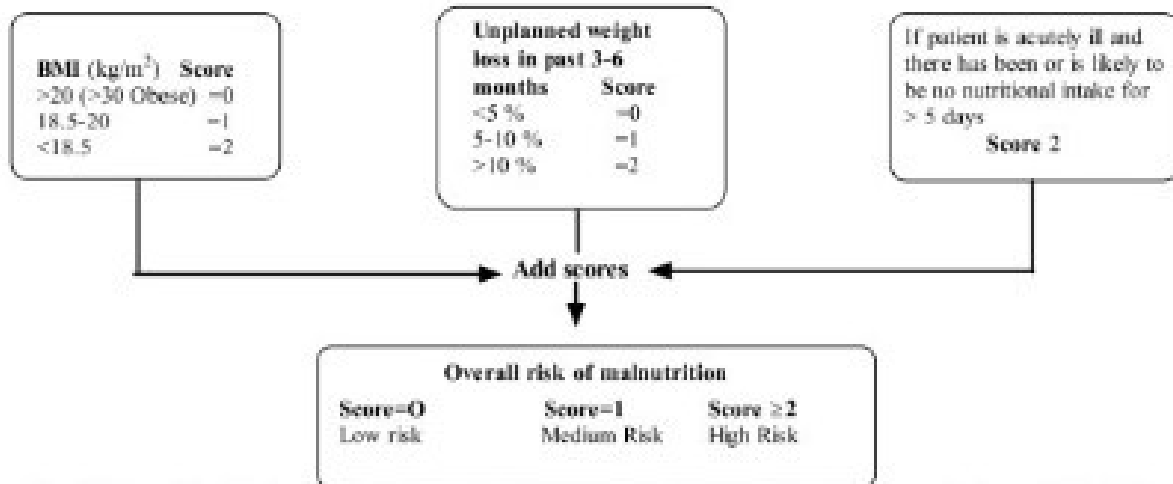
_____	_____	_____
Name of nominated consultee	Date	Signature

_____	_____	_____
Name of person	Date	Signature

Appendix 9.3: Assessment tools

Appendix 9.3.1: The 'Malnutrition Universal Screening Tool' ('MUST')

The 'Malnutrition Universal Screening Tool' ('MUST') is reproduced here with the kind permission of BAPEN (British Association for Parenteral and Enteral Nutrition)



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Appendix 9.3.2 The Nutritional Risk Screening tool (NRS-2002)

(Kondrup, 2003a)

Table 2 Final screening			
Impaired nutritional status		Severity of disease (≈ increase in requirements)	
Absent Score 0	Normal nutritional status	Absent Score 0	Normal nutritional requirements
Mild Score 1	Wt loss > 5% in 3 mths or Food intake below 50–75% of normal requirement in preceding week	Mild Score 1	Hip fracture* Chronic patients, in particular with acute complications: cirrhosis*, COPD*, Chronic hemodialysis, diabetes, oncology
Moderate Score 2	Wt loss > 5% in 2 mths or BMI 18.5 – 20.5 + impaired general condition or Food intake 25–60% of normal requirement in preceding week	Moderate Score 2	Major abdominal surgery* Stroke* Severe pneumonia, hematologic malignancy
Severe Score 3	Wt loss > 5% in 1 mth (>15% in 3 mths) or BMI <18.5 + impaired general condition or Food intake 0–25% of normal requirement in preceding week in preceding week.	Severe Score 3	Head injury* Bone marrow transplantation* Intensive care patients (APACHE>10).
Score:	+	Score:	= Total score
Age	if ≥ 70 years: add 1 to total score above	= age-adjusted total score	
Score ≥ 3: the patient is nutritionally at-risk and a nutritional care plan is initiated			
Score <3: weekly rescreening of the patient. If the patient e.g. is scheduled for a major operation, a preventive nutritional care plan is considered to avoid the associated risk status.			

Table 1 Initial screening			
		Yes	No
1	Is BMI <20.5?		
2	Has the patient lost weight within the last 3 months?		
3	Has the patient had a reduced dietary intake in the last week?		
4	Is the patient severely ill ? (e.g. in intensive therapy)		
Yes: If the answer is 'Yes' to any question, the screening in Table 2 is performed. No: If the answer is 'No' to all questions, the patient is re-screened at weekly intervals. If the patient e.g. is scheduled for a major operation, a preventive nutritional care plan is considered to avoid the associated risk status.			

Appendix 9.3.3: The Charlson co-morbidity index

(Charlson, 1987)

Scoring: Co-morbidity Component (Apply 1 point to each unless otherwise noted)

1. Myocardial Infarction
2. Congestive Heart Failure
3. Peripheral Vascular Disease
4. Cerebro-vascular Disease
5. Dementia
6. COPD
7. Connective Tissue Disease
8. Peptic Ulcer Disease
9. Diabetes Mellitus (1 point uncomplicated, 2 points if end-organ damage)
10. Moderate to Severe Chronic Kidney Disease (2 points)
11. Hemiplegia (2 points)
12. Leukaemia (2 points)
13. Malignant Lymphoma (2 points)
14. Solid Tumour (2 points, 6 points if metastatic)
15. Liver Disease (1 point mild, 3 points if moderate to severe)
16. AIDS (6 points)

Score -----

Scoring: Age

1. Age 0-49 years: 0 points
2. Age 50-59 years: 1 point
3. Age 60-69 years: 2 points
4. Age 70-79 years: 3 points
5. Age 80-89 years: 4 points
6. Age 90-99 years: 5 points

Appendix 9.3.4: Euroqol Health questionnaire

Appendix 9.3.4.1: Euroqol Health questionnaire (EQ-5D-5L and VAS)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐

SELF-CARE

I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities	☐
I have slight problems doing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to do my usual activities	☐

PAIN / DISCOMFORT

I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐

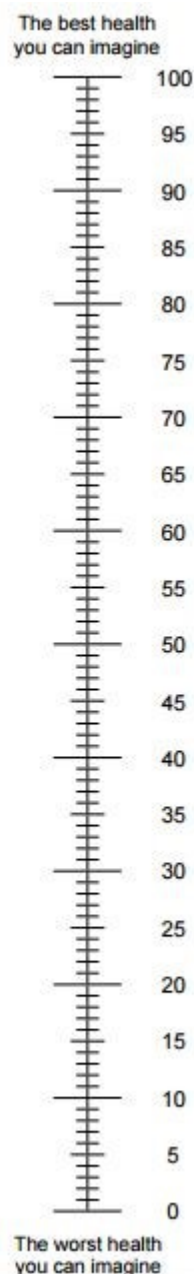
ANXIETY / DEPRESSION

I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐

UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



Appendix 9.3.4.2: Euroqol Health questionnaire proxy version

By placing a tick in one box in each group below, please indicate which statements (*insert name of person whose health is being assessed, e.g. Mr/Ms. Smith or Jane*) would choose to describe his/her health state TODAY if he/she could tell us.

MOBILITY

- No problems in walking about ☐
- Slight problems in walking about ☐
- Moderate problems in walking about ☐
- Severe problems in walking about ☐
- Unable to walk about ☐

SELF-CARE

- No problems washing or dressing him/herself ☐
- Slight problems washing or dressing him/herself ☐
- Moderate problems washing or dressing him/herself ☐
- Severe problems washing or dressing him/herself ☐
- Unable to wash or dress him/herself ☐

USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

- No problems doing his/her usual activities ☐
- Slight problems doing his/her usual activities ☐
- Moderate problems doing his/her usual activities ☐
- Severe problems doing his/her usual activities ☐
- Unable to do his/her usual activities ☐

PAIN / DISCOMFORT

- No pain or discomfort ☐
- Slight pain or discomfort ☐
- Moderate pain or discomfort ☐
- Severe pain or discomfort ☐
- Extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- Not anxious or depressed ☐
- Slightly anxious or depressed ☐
- Moderately anxious or depressed ☐
- Severely anxious or depressed ☐
- Extremely anxious or depressed ☐

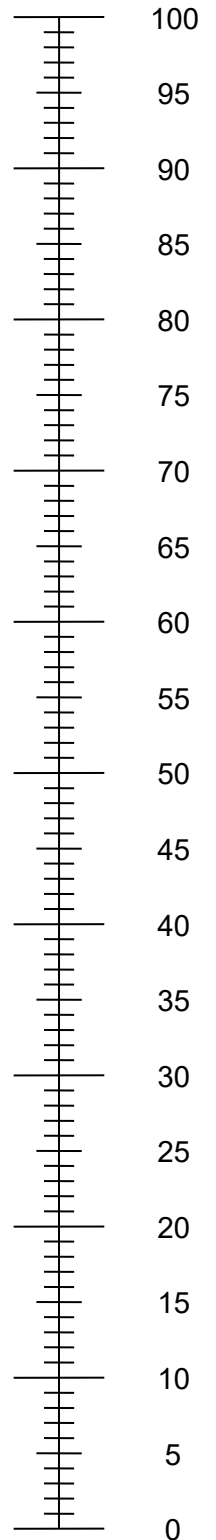
- We would like to know how good or bad you think (*insert name of person whose health is being assessed, e.g. Mr/Ms. Smith or Jane*) would say his/her health is TODAY, if he/she could tell us.
- This scale is numbered from 0 to 100.
- 100 means the best health imaginable.
0 means the worst health imaginable.
- Mark an X on the scale to indicate how good or bad you think (*insert name of person whose health is being assessed, e.g. Mr/Ms. Smith or Jane*) would say his/her health is TODAY.
- Now, please write the number you marked on the scale in the box below.

(Name of person whose health is being assessed,

e.g. Mr/Ms. Smith or Jane) would rate his/her

OWN HEALTH TODAY AS:

The best health
imaginable



The worst
health
imaginable

Appendix 9.3.5: The CSHA Clinical Frailty Scale

(Rockwood et al, 2005)

Reprinted from K Rockwood "A global clinical measure of fitness and frailty in elderly people". Canadian Medical Association Journal 30 August 2005: 173(5), page 489-495. © Canadian Medical Association 2005. This work is protected by copyright and the making of this copy was with the permission of the Canadian Medical Association Journal (www.cmaj.ca) and Access Copyright. Any alteration of its content or further copying in any form whatsoever is strictly prohibited unless otherwise permitted by law.

The CSHA Clinical Frailty Scale	IADL
1 Very fit – Robust, active, energetic, well motivated and fit; these people commonly exercise regularly and are in the most fit group for their age 2 Well – Without active disease, but less fit than people in category 1 3 Well, with treated comorbid disease – Disease symptoms are well controlled compared with those in category 4 4 Apparently vulnerable – Although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms 5 Mildly frail – With limited dependence on others for instrumental activities of daily living 6 Moderately frail – Help is needed with both instrumental and non-instrumental activities of daily living 7 Severely frail – Completely dependent on others for the activities of daily living, or terminally ill	Activities required to live in the community • Meal preparation • Ordinary housework • Managing finances • Managing medications • Phone use • Shopping • Transportation
	ADL
	Non-instrumental activities of daily living; related to personal care • Mobility in bed • Transfers • Locomotion inside and outside the home • Dressing upper and lower body • Eating • Toilet use • Personal hygiene • Bathing

Appendix 9.3.6: The SARC-F Screen for Sarcopenia

(Malmstrom and Morley, 2013)

SARC-F Screen for Sarcopenia

Component	Question	Scoring
Strength	How much difficulty do you have in lifting and carrying 10 pounds?	None = 0 Some = 1 A lot or unable = 2
Assistance in walking	How much difficulty do you have walking across a room?	None = 0 Some = 1 A lot, use aids, or unable = 2
Rise from a chair	How much difficulty do you have transferring from a chair or bed?	None = 0 Some = 1 A lot or unable without help = 2
Climb stairs	How much difficulty do you have climbing a flight of 10 stairs?	None = 0 Some = 1 A lot or unable = 2
Falls	How many times have you fallen in the past year?	None = 0 1–3 falls = 1 4 or more falls = 2

Appendix 9.3.7: The Modified Townsend activities of daily living scale questionnaire

(Bowling and Grundy, 1997)

Interviewer instruction:

“These questions give us with some information on your mobility and the activities you do on a daily basis. Think about how you are with each activity on an **average** day.

Do you or would you* have any difficulty (or find troublesome, exhausting or worrying):”

*If you do not currently perform this activity, think about whether you *could* do it

	No difficulty Score 0	Slight difficulty Score 1	Moderate difficulty Score 2	Severe difficulty Score 3	Unable to do alone Score 4	Unable to do at all Score 5
Mobility						
Getting in/out of bed						
Transferring from a chair						
Going up/down stairs						
Getting on/off toilet						
Getting in/out of bath						
Getting about indoors						
Getting about outdoors						
Using public transport						
Personal care						
Washing/shaving (men)						
Bathing self						
	No difficulty Score 0	Slight difficulty Score 1	Moderate difficulty Score 2	Severe difficulty Score 3	Unable to do alone Score 4	Unable to do at all Score 5
Dressing self						
Brushing/combing hair						
Washing hair						

Cutting toenails						
Domestic activity						
Cooking/preparing meal						
Housework						
Laundry						
Shopping						
Doing odd jobs						

Townsend score = _ _ _ _ _

Appendix 9.3.8: Satisfaction with food-related life

(Grunert et al., 2007)

Interviewer instructions	
To introduce the 'Satisfaction with Food-Related Life' section, say:	In this next section, please think of all the things you do and experience in relation to food and meals e.g. planning meals, shopping, preparing meals, eating meals. Then I would like you to tell me how much you agree with each of the following statements I am going to make.
Show respondent SHOWCARD and say:	For this set of questions I would like you to use this scale.

1) "Food and meals are very positive elements in your life."

SHOWCARD

Strongly disagree	Score=1
Disagree	Score=2
Neither agree nor disagree	Score=3
Agree	Score=4
Strongly agree	Score=5

2) "You are generally very pleased with your food."

SHOWCARD

Strongly disagree	Score=1
Disagree	Score=2
Neither agree nor disagree	Score=3
Agree	Score=4
Strongly agree	Score=5

3) "Your life in relation to food and meals is close to your ideal."

SHOWCARD

Strongly disagree	Score=1
Disagree	Score=2
Neither agree nor disagree	Score=3
Agree	Score=4
Strongly agree	Score=5

4) "With regard to food, the conditions of your life are excellent."

SHOWCARD

Strongly disagree	Score=1
Disagree	Score=2
Neither agree nor disagree	Score=3
Agree	Score=4
Strongly agree	Score=5

5) "Food and meals give you a lot of satisfaction in daily life"

SHOWCARD

Strongly disagree	Score=1
Disagree	Score=2
Neither agree nor disagree	Score=3
Agree	Score=4
Strongly agree	Score=5

Appendix 9.4: 24-hour recall tools

Appendix 9.4.1: The US department of Agriculture Multiple-Pass Method for collecting 24-hour dietary recall

USDA 5-Step Multiple-Pass Method

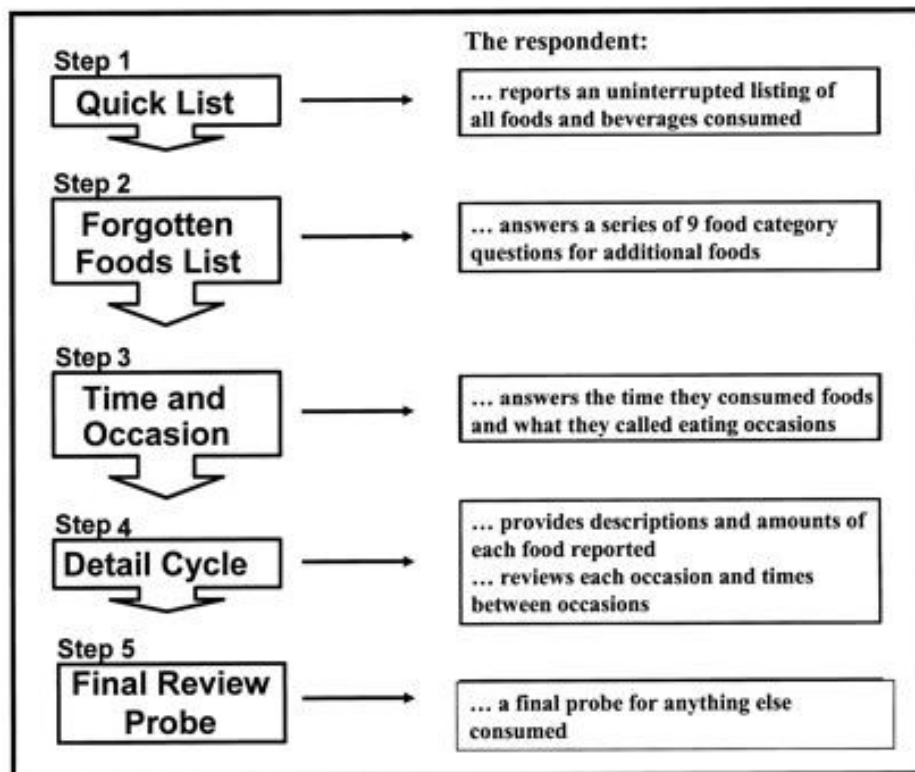


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Appendix 9.4.2: Protocol for 24-hour recall coding

(Adapted from Airwave protocol written and developed by: Rachel Gibson and Rebeca Eriksen)

NUTRICOM study

Standard protocol for 24-hour dietary recall coding

Adapted from Airwave protocol written and developed by: Rachel Gibson and Rebeca Eriksen, Section of Investigative Medicine, Division of Diabetes, Endocrinology & Metabolism Imperial College London

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1.0 Introduction:

The following pages provide an outline of how to input and code the 24h dietary recalls from the NUTRICOM study.

The primary aim of this protocol is to reduce error and to standardise code and portion selection.

Please read through before you start to code and input the data. You will also need to refer to the AIRWAVE code book, the AIRWAVE portion size document, and the Foodbase portion size document.

EXCLUSION CRITERIA for coding:

- Incomplete 24-h period

If a diary cannot be coded due to any of the above it needs to be logged.

2.0 Using recorded responses for code selection

In the first instance select food codes based on what the participant has written in the actual 24h recall. Refer to this document to assist when insufficient information has been provided.

1 MILK - type

This should be the type written in the diet entry. If this section is not completed assume UKN 12-313 'Semi-skimmed milk pasteurized' is consumed, unless otherwise stated in the 24h recall.

2 MILK - amount

Details the amount of milk to input unless otherwise written in the daily entry:

	A lot (g)	Average (g)	Hardly any (g)
Tea	40	30	23
Coffee	64	43	30
Cereal	175	123	91

Source: Foodbase 75th / 50th / 25th centile values 'all age groups' mixed gender. Values calculated by combining the recording portion sizes for semi-skimmed and whole milk and then divided by two and rounded to the nearest whole number.

If this section is not completed assume 'medium' amount is consumed unless otherwise stated in the food diary.

- Tea - add milk (semi-skimmed, average amount) if milk is recorded elsewhere in the recalls
- Cereal - add milk (semi-skimmed, average amount) if milk is recorded elsewhere in the recalls.

Exception: if there is a specific pattern to consumption, e.g. every 'tea' written without milk – then do not include milk.

3 TYPE OF TEA /COFFEE

This should be the type written in the daily diet entry. If not specified, assume caffeinated versions are consumed, unless otherwise stated in the 24h recall.

4 FATS

Details the type of fat used. If not specified, use UKN 17-486 Butter, spreadable consumed unless otherwise stated in the 24h recall.

5 BREAD

NOTE: Brown bread is no longer available in the UK – Code always code wholemeal bread

Details the type of fat used. If not specified, use UKN 11-099 White bread, average is consumed unless otherwise stated in the 24h recall. If noted 'crusts removed' deduct 10g from total portion.

6 FATS – quantity used on bread and crackers

This gives an indication of the amount in grams used on bread and crackers, unless the participant has stated another quantity or referred to the photo images. Refer to the portion size algorithm. NB. This refers to the serving size per slice of bread / bread roll

If participant recorded usage on a 'cracker' use 50% of the quantity

Answer =	Enter as:

thick	14g

medium	10g

thin	7g

Source: Foodbase (1) serving 25th / 50th / 75th centile

If this section is not completed assume 'medium' amount is consumed unless otherwise stated in the 24h recall.

7 MEAT – amount of fat eaten

Answer =	Enter as:

Ate all of the fat	Select a code that states 'lean and fat' every time meat is eaten

Ate some of the fat	Every time meat is eaten enter 50% of the reported weight as a code that states 'lean and fat' and 50% as a code that states 'lean' or 'meat only'.

i.e. sirloin beef steak fried 230g

enter as:

115g UKN 18-066 beef, sirloin steak, fried, lean

115g UKN 18-067 beef, sirloin steak, fried, lean and fat

Ate most of the fat	Every time meat is eaten enter 75% of the reported weight as a code that states 'lean and fat' and 25% as a code that states 'lean' or 'meat only'.
Ate as little as possible	Every time meat is eaten enter 25% of the reported weight as a code that states 'lean and fat' and 75% as a code that states 'lean' or 'meat only'.
Did not eat meat	n/a
No fat eaten	Select a code that states 'lean' or 'meat only' every time meat is eaten

If this section is not completed apply '*Ate some of the fat*' option.

8 POULTRY – amount of skin eaten

Answer =	Enter as:
yes	Select option for 'meat and skin' every time poultry is eaten
sometimes	Every time poultry is eaten enter 50% of the reported weight as a code that states 'meat and skin' and 50% as a code that states 'without /no skin / meat only'.
no	Select option for 'without /no skin' every time poultry is eaten
Did not eat poultry	n/a

If this section is not completed apply 'sometimes' option.

9 GRAVY

Enter as:

With juices / pan RCP AR00008 homemade beef gravy made with meat fat
residues juices added

Without juices / UKN 17-311 Gravy instant granules made up with water
pan residues

Sometimes Every time gravy is consumed enter 50% of the recorded
portion as UKN 17-311 and 50% as RCP AR00008

Don't know Enter as default : UKN 17-311 Gravy instant granules made
up with water

If this section is not completed apply 'sometimes' option.

Use gravity 0.99 for gravy

10 FRUIT

This tells you if the participant eats the skin/peel on fruits where it is edible.

Answer:	Apple	Pear
Skin eaten	UKN 14-012 Apples, eating, average, raw	UKN 14-190 Pears, average, raw
Skin not eaten	UKN 14-014 Apples, eating, average, raw, peeled	UKN 14-192 Pears, average, raw, peeled

If this section is not completed apply 'Skin eaten' option.

3.0 Registering & setting up the assessment in Dietplan7

REGISTRATION SCREEN:

1. From the drop down menu select 'analyse

2. Assessment ID number:

12-figure letter/number combination included in

The screenshot shows the Dietplan6 software interface. The title bar reads 'Dietplan6 Reg 37036'. The menu bar includes File, Edit, Foods, Tasks, Views, Data, Admin, and Help. A toolbar contains icons for file operations and a dropdown menu currently set to 'Analyse Assessment'. On the left, a sidebar lists 'Dietplan functions' with options: File, Edit, Foods, Tasks, Views, Data, Admin, and Help. The main window is titled 'Reg 37036 x' and contains the 'Enter new registration details' form. The form has two columns. The left column contains: 'Registration No' (37036), 'Surname' (AIRWAVE), 'Forenames', 'Address', 'Telephone', and 'E-mail'. The right column contains: 'Sex' (Female), 'Date of birth' (28 July 1976), 'Height (m)', 'Weight (kg)', 'Referred by', and 'Notes'. An 'Accept' button is between the columns. At the bottom left of the form is a 'Created 29 July 2013' label. At the bottom right are 'Continue' and 'Cancel' buttons. Three arrows point from text boxes to the interface: one to the 'Analyse Assessment' dropdown, one to the 'Accept' button, and one to the 'Surname' field. A fourth arrow points from a text box to the 'Surname' field.

3. Surname: NUTRICOM

SELECTION SCREEN:

The screenshot shows the 'Amend/confirm assessment details' window in Dietplan6. The window is divided into several sections: 'Registration' (top), 'Selection' (middle), 'Composition' (bottom left), and 'Scope' (bottom right). The 'Registration' section shows patient details: No 36879, AIRWAVE, Male, Born 02 November 1967. The 'Selection' section shows a table with columns Date, Days, Type, and Title. The 'Composition' section has fields for Height (m), Weight (kg), and Target weight (kg). The 'Scope' section has fields for Max number of days, Max meals per day, Max courses per meal, Date of day 1 or select its weekday, and Enter meal times. The 'Reference values' section has a dropdown menu set to 'None'. The 'Food categories' section has a 'Set up' button. The 'Diet assessments selected' section is at the bottom.

Max number of days: 1

Max number of meals per day: 8

Max courses per meal: blank

Date of day 1: Leave blank

Date: to show the date of diary input.

Type: select intake diary from drop down screen

Reference values 'none'

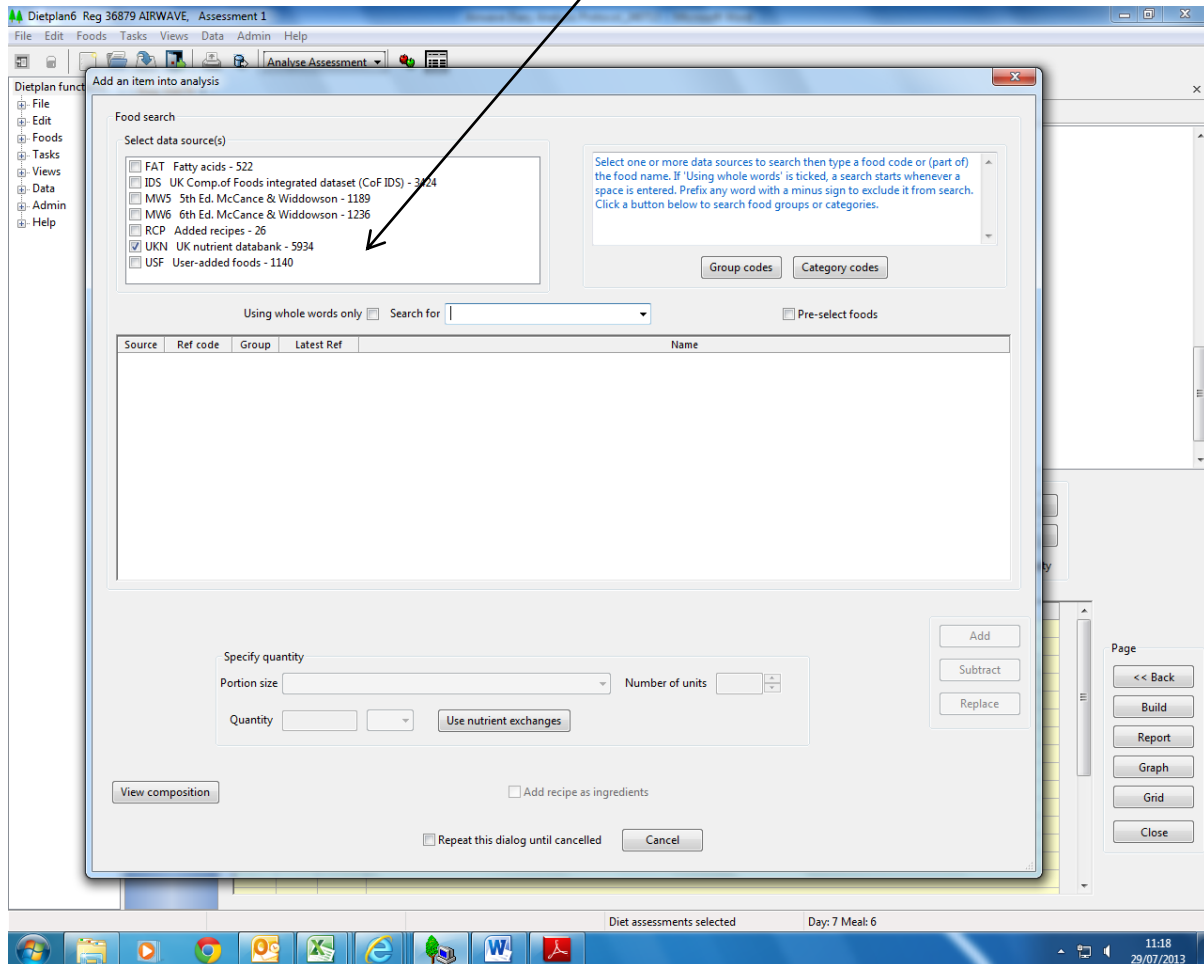
Enter meal times: 'yes'

COMPOSITION SCREEN:

Database selection

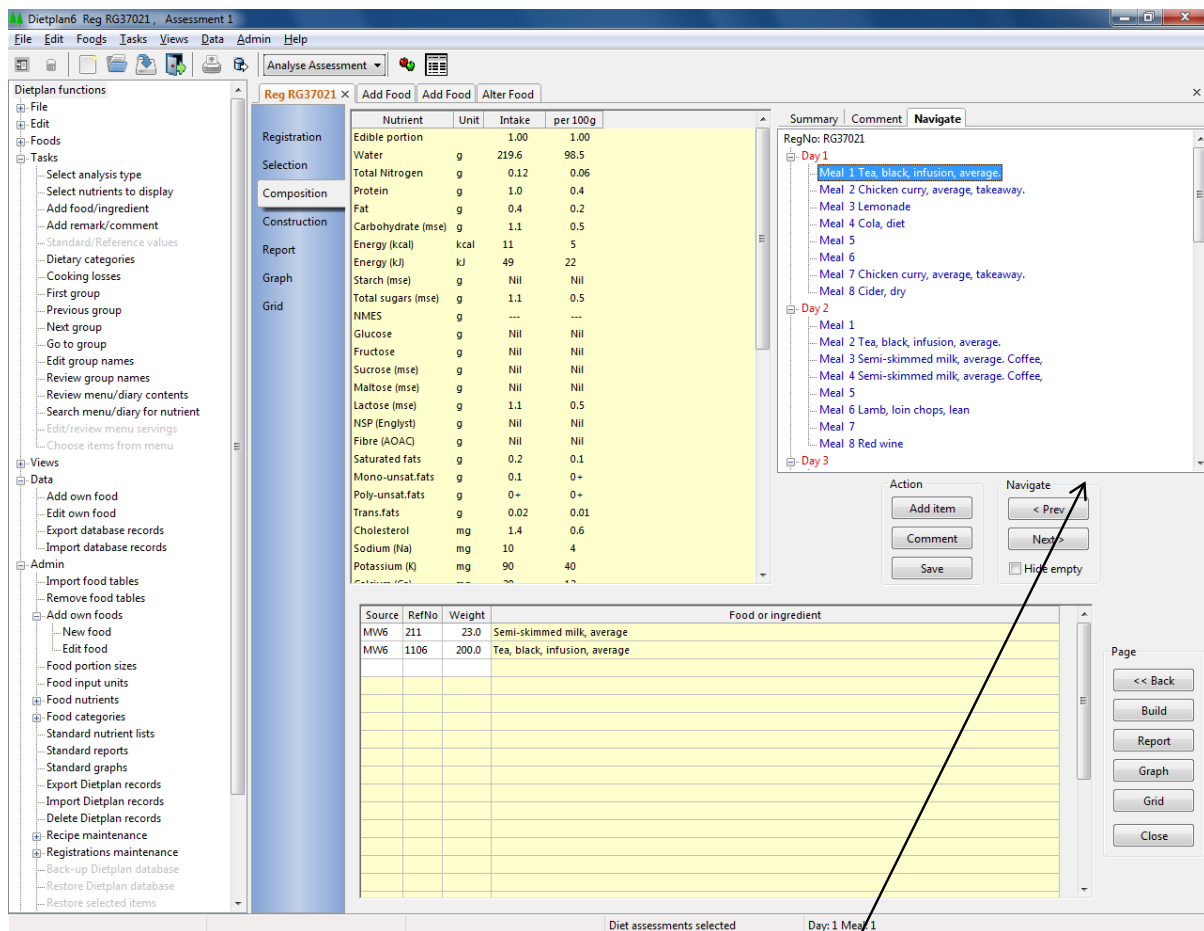
Click on 'add item'

UKN to be the only database selected,
unless otherwise indicated*



*Where participant has an assessment ID with the prefix "ICL" and suffix "01" foods will be provided by the hospital unless otherwise stated. Manufacturer codes should be used instead of UKN - this will be TVF (Tillery Valley Foods). For analysis tick UKN and TVF.

Entering meals



Enter each section of the daily diary under the meal numbers as follows:

<u>Diet plan</u>	<u>Food diary section</u>
Meal 1	before breakfast
Meal 2	breakfast
Meal 3	Mid-morning
Meal 4	lunch
Meal 5	tea
Meal 6	evening meal
Meal 7	later evening

Appendix 9.5: Data collection tools for nutritional interventions

Appendix 9.5.1: Dietetic information form used to collect data from community dietetic services

Dietetic information form

1. Was a dietetic referral received for this patient during the period ____ to ____?

Yes	Date of referral: __/__/__
No	End of data collection Please see the end of the form for return details

2. Who referred the patient for dietetic service?

Referrer	Please tick
Hospital dietitian	
Hospital other	
GP	
Other (please specify)	

3. Was the dietetic referral accepted?

Yes	
No – please state the reason why	

4. Was the dietetic referral due to diagnosis of undernutrition?

Yes	
No	

5. Number of dietetic visits from the period ____ to ____

Health care professional/location	Number of visits
Outpatient clinic setting	
Home visit	
Other (please specify)	

6. Were oral nutritional supplements (e.g. Ensure, Fortisip) prescribed during the period ____ to ____

Yes/ No – if yes please complete the table below

if no please continue to Q7

Name of supplement	Quantity/day	No of days

7. Was an assessment of nutritional status conducted?

Yes	
No – please state the reason why	

8. Were nutritional goals set?

Yes	
No – please state the reason why	

9. Was progress reviewed?

Yes – please state total number of consultations	
No – please state the reason why	

10. Is the episode of care ongoing?

Yes – please state the reason why	
No – please state the reason why and end of episode of care	

11. Were treatment goals achieved?

Yes	
No – please state the reason why	

_____ End of questions _____

Appendix 9.5.2: GP information form used to collect dietary data from general practice

Conditions

Please tick where participant has any of the following conditions. Definitions can be found in the appendix of this document where clarity is required.

17. Myocardial Infarction	
18. Congestive Heart Failure (including arrhythmia, valvular disease and angina)	
19. Peripheral Vascular Disease (including hypertension)	
20. Cerebrovascular Disease	
21. Dementia (including other chronic cognitive deficit, Parkinson's disease, uncontrolled seizures, or syncope without an identified cause)	
22. COPD	
23. Connective Tissue Disease (including systemic lupus erythematosus, polymyositis, 'mixed connective tissue disease', polymyalgia rheumatica, and moderate to severe rheumatoid arthritis)	
24. Peptic Ulcer Disease	
25. A) Diabetes Mellitus – uncomplicated (including diabetes treated with insulin or oral hypoglycaemias, but not diet alone)	
B) Diabetes Mellitus - with end organ damage (including <i>end-organ damage</i> includes patients with retinopathy, neuropathy, or nephropathy)	
26. Moderate to Severe Chronic Kidney Disease (including patients on dialysis, transplant patients, uremic patients and those with serum creatinine >3mg% (265 umol/l))	
27. Hemiplegia	
28. Leukaemia	
29. Malignant Lymphoma	
30. A) Solid Tumour (only patients treated in the last 5 years)	
B) Tumour with metastatic disease (patients treated in the last 5 years)	
31. A) Liver Disease - mild	
B) Liver Disease - moderate to severe	
32. Other (please describe):	

2. Number of GP and nurse visits from the period _/_/_ to _/_/_

Health care professional/location	Number of visits
GP (surgery)	
GP (home visit)	
Practice nurse (surgery)	
Practice nurse (home visit)	

3. Prescriptions for oral nutritional supplements (e.g. Ensure, Fortisip) from the period _/_/_ to _/_/_

Name of supplement	Number of prescriptions

4. Prescriptions for tube feed from the period _/_/_ to _/_/_

Name of supplement	Number of prescriptions
Nil	

5. Prescriptions for vitamin/mineral supplements from the period _/_/_ to _/_/_

Name of supplement	Number of prescriptions

6. Prescriptions for disease-related nutritional products (i.e. coeliac) from the period _/_/_ to _/_/_

Name of product (i.e. generic gluten-free foodstuffs)	Number of prescriptions

7. Prescriptions for any antibiotics from the period _/_/_ to _/_/_

Number of prescriptions (type/reason not required)	0 1 2 3 4 5 other:

8. Number of blood tests received from the period _/_/_ to _/_/_

Number of blood tests (type/reason not required)	0 1 2 3 4 5 other:

9. Influenza vaccination received from the period _/_/_ to _/_/_

Yes	
No	

- End of questions -

Appendix: Conditions - Definitions (Charlson et al. 1987, 1994)

1. **Myocardial infarction** includes patients with one or more definite or probable myocardial infarctions i.e. hospitalized and had electrocardiographic and/or enzyme changes.
2. **Congestive heart failure** includes patients who have had exertional or paroxysmal nocturnal dyspnoea and who have responded symptomatically (or on physical examination) to digitalis, diuretics, or afterload reducing agents. It does not include patients who are on medication but have had no symptomatic response and no evidence of improvement of physical signs.

Arrhythmia includes patients with chronic atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias requiring chronic treatment.

Valvular disease includes patients with hemodynamically significant aortic stenosis and/or insufficiency, those with significant mitral stenosis and/or insufficiency, and those with prosthetic aortic or mitral valves and those with symptomatic mitral valve prolapse, asymmetric septal hypertrophy requiring treatment, or tricuspid insufficiency.

Angina includes patients with chronic exertional angina, those who had coronary artery bypass graft, and those with unstable angina.

3. **Peripheral vascular disease** includes patients with intermittent claudication or those who had a bypass for arterial insufficiency, those with gangrene or acute arterial insufficiency, and those with an untreated thoracic or abdominal aneurysm (6 cm or more).

Hypertension includes patients with diastolic pressures over 120 mm Hg; those with diastolic pressures between 100 and 120; and those with diastolic pressures between less than 100 as well as controlled hypertensives.

4. **Cerebrovascular disease** includes patients with a history of a cerebrovascular accident with minor or no residual and transient ischemic attacks.
5. **Dementia** includes patients with chronic cognitive deficit. Other neurologic conditions includes patients with Parkinson's disease, uncontrolled seizures, or syncope without an identified cause or treatment.
6. **COPD** includes patients who are dyspnoeic with moderate activity without treatment or those who are dyspnoeic only with attacks (e.g. asthma). Moderate pulmonary disease includes patients who are dyspnoeic with slight activity, with or without treatment and those who are dyspnoeic with moderate activity despite treatment. Severe pulmonary

disease includes patients who are dyspnoeic at rest, despite treatment, those who require constant oxygen and those with CO₂ retention.

7. **Connective tissue disease** includes patients with systemic lupus erythematosus, polymyositis, 'mixed connective tissue disease', polymyalgia rheumatica, and moderate to severe rheumatoid arthritis.
8. **Peptic ulcer disease** includes patients who have required treatment for ulcer disease, including those who have bled from ulcers. Gastrointestinal bleeding includes those who have had bleeding requiring transfusions from causes other than ulcer disease.
9. **Diabetes** - *Uncomplicated* diabetes includes diabetes treated with insulin or oral hypoglycaemias, but not diet alone. *End-organ damage* includes patients with retinopathy, neuropathy, or nephropathy. Moderate diabetes includes patients who had previous hospitalizations for ketoacidosis, hyperosmolar coma, or control and those with juvenile onset or brittle diabetics
10. **Moderate to severe chronic kidney disease** – Severe renal disease includes patients on dialysis, those who had a transplant, and those with uraemia. Moderate renal insufficiency includes patients with serum creatinine of >3mg%.
11. **Hemiplegia** includes patients with the dense hemiplegia or paraplegia, whether it occurred as a result of a cerebrovascular accident or other condition.
12. **Leukaemia** includes patients with acute and chronic myelogenous leukaemia, acute and chronic lymphocytic leukaemia, and polycythaemia vera.
13. **Malignant lymphoma** includes patients with Hodgkins, lymphosarcoma, Waldenstrom's macro-globulinemia, myeloma, and other lymphomas.
14. **Solid tumours** include patients initially treated in the last five years, including breast, colon, lung, and other tumours, *without documented metastases*. Metastatic cancer includes patients with metastatic solid tumours, including breast, lung, colon and other tumours *with documented metastases*.
15. **Liver disease** - *Mild liver disease* consists of cirrhosis without portal hypertension or chronic hepatitis. *Moderate liver disease* consists of cirrhosis with portal hypertension, but without bleeding. *Severe liver disease* consists of patients with cirrhosis, portal hypertension and a history of variceal bleeding.

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