A randomised controlled trial to test the effect of targeted parental information on non-urgent paediatric emergency department reattendance

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Abstract

Background:

Year upon year the pressure on emergency and urgent care across the National Health Service (NHS) in England has increased. A rise in non-urgent attendance of young children at paediatric emergency departments (PEDs) has contributed to this pressure.

Aims:

The three key aims of this study were:

(i) To identify the reasons for non-urgent attendance at PED as described in the published literature.

(ii) To develop a targeted intervention that aimed to reduce non-urgent reattendance at PED.

(iii) To evaluate the effect of the targeted intervention on non-urgent reattendance at PED using a randomised controlled trial.

Methodology:

Research activities were mapped to MRC guidance on "Developing and evaluating complex interventions" (Craig *et al.*, 2008). A narrative review identified the reasons that children attend PED with non-urgent health concerns. A systematic review identified interventions that had attempted to address non-urgent PED reattendance. Literature review findings and feedback from stakeholders (including families with young children) were used to generate a theoretical mechanism for reducing non-urgent PED reattendance. The evidence base, a theoretical framework and caregiver and stakeholder involvement were combined with an awareness of the population context and the application of behavioural insights to develop

the educational bundle. This educational bundle was evaluated using a multicentre, two-armed RCT with balanced randomisation (1:1).

Results:

Overall, the educational bundle did not have a detectable effect on non-urgent PED reattendance. The educational bundle may have reduced the proportion of non-urgent reattendances for families that initially attended with male children (but not for those that initially attended with female children).

Conclusion:

Although no effect was detected, an informative and evidence-based intervention was successfully developed in collaboration with caregivers and healthcare professionals. This thesis demonstrates the utility of the MRC Framework, patient and public involvement and the application of behavioural insights in response to a healthcare system challenge.

Declaration of Originality

I hereby declare that this thesis and the research it describes are the products of my own work and that where it has been the result of collaboration with others, this is fully described. References from work by other researchers are acknowledged in accordance with standard referencing practice. I declare that I have received support and guidance from my MD (Res) supervisor, Professor Mitch Blair, to carry out the research presented in this thesis.

I am grateful to the Behavioural Insights Team (BIT) for providing access to data scientists and data analysts during this work. I declare that the data analysis described in this report was conducted by research collaborators from the Behavioural Insights Team and overseen by myself.

Copyright Declaration

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Many thanks to my research collaborators within the Behavioural Insights Team. Their refreshing perspective on health policy challenges provided valuable innovation to this project.

I am extremely grateful to all members of the multi-disciplinary steering group that input into the development of this project and the final intervention. In particular, I am grateful to the parents and carers with experience of caring for unwell children that volunteered their time to input into this research project.

List of Abbreviations

ASK SNIFF	Acutely Sick Kids – Safety Netting Interventions for Families
BIT	Behavioural Insights Team
CASP	Critical Appraisal Skills Programme
CC4C	Connecting Care For Children
COVID-19	Coronavirus disease 2019
EAST	Easy, Attractive, Social and Timely
ED	Emergency department
GP	General practitioner
HRA	Health Regulatory Authority
ID	Identifer
IMD	Index of Multiple Deprivation
IPE	Implementation and process evaluation
ITT	Intention-to-treat
MRC	Medical research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OLS	Ordinary least-squares
PED	Paediatric emergency department
PICO	Population, Intervention, Comparison, Outcome
PICo	Population, [phenomenon of] Interest, Context
PICOS	Population, Intervention, Comparison, Outcome, Study Type
PPI	Patient and public involvement
RCEM	Royal College of Emergency Medicine
RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised controlled trial
REC	Research ethics committee
RoB	Risk of bias

SD	Standard deviation
SE	Standard error
UCC	Urgent care centre
UK	United Kingdom
WSIC	Whole systems integrated care

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Chapter 1:
Introduction

1.1 Chapter introduction

This introductory chapter describes the context of the research and gives a comprehensive background to the healthcare system challenges that this project seeks to address. The importance of the family perspective is highlighted and the concept of behavioural insights introduced. The chapter summarises the aims and objectives of the research, gives an overview of the methodology and describes the structure of this thesis.

1.2 Context of the research

Year upon year the pressure on emergency and urgent care across the National Health Service (NHS) in England has increased. From 2008–09 to 2018–19, total emergency hospital attendances increased by 27% (NHS Digital, 2019).

Data published in 2019 showed that the number of people attending hospital emergency departments (EDs) is at a record high. In 2018/19 there were nearly 25 million attendances at EDs, a 4.1% increased on the previous year (NHS Digital, 2019). The four-hour ED target (of seeing 95% of patients that arrive at ED within four hours) has not been achieved within a year since 2013/14, and this standard has been missed every month since July 2015 (NHS Digital, 2019; The King's Fund, 2019).

Discussions regarding emergency and urgent care pressures are typically dominated by a focus on older adults. This appears to be understandable as compared to other age groups, those aged over 65 years have more emergency admissions, stay longer in emergency

departments, are more likely to be admitted in an emergency and account for the majority of emergency bed days in hospital (Blunt, 2014).

There are around 12 million children (aged 0 to 18 years) in England, making up around a fifth of the country's population (Office for National Statistics, 2019). The healthcare needs of children are different to adults; their health can deteriorate or recover quickly, and specialist advice or support is often required in their management (Keeble and Kossarova, 2017). However, similarly to older people, children can be especially vulnerable and dependent on carers.

Hospital data demonstrates that children in England are more frequent users of ED compared to other age groups. In 2018/19 there were 5.4 million ED attendances of children aged 0 to 18 years old (almost a quarter of the total ED attendances), whereas there were 4.7 million attendances by people aged 65 years and above in the same year (NHS Digital, 2019). Data from the last two years is summarised in Table 1.1.

Table 1.1: ***ED Attendances by Age Group, 2017–18 and 2018–19*** *(NHS Digital, 2019).*

Age group	**2017–18** **Percentage of total ED attendances** (number of attendances)	**2018–19** **Percentage of total ED attendances** (number of attendances)
0–18 years old	**24.5%** (5,223,251)	**24.2%** (5,408,419)
65+ years old	**21.3%** (4,522,669)	**21.1%** (4,711,438)
Total ED attendances (all age groups)	*n = 21,278,504*	*n = 22,367,847*

Up to 40% of these attendances have been classified as 'non-urgent' (Martin *et al.*, 2002). The definition of 'non-urgent' is discussed further in Section 1.2.1 but mainly refers to ED presentations for minor illnesses which could have been managed outside of hospital (for example, at a local pharmacy, GP practice or at home).

In 2013, the NHS England Urgent and Emergency Care Report (NHS England, 2013) stated that 40% of all ED attendances were discharged requiring no hospital treatment, and a National Audit Office report (2013) noted that 20% of these were for known conditions which could be managed effectively by primary or community care. However, a study from the College of Emergency Medicine published shortly after these reports suggested that only 15% of cases attending ED could have been appropriately managed by a GP (general practitioner) without a need for assessment in ED (Mann and Tempest, 2014). Although a difference in figures was reported, these studies agree that the proportion of non-urgent presentations to ED has put additional burden on emergency and urgent care, despite these cases being appropriate for safe management outside of hospital.

The greatest increase in childhood ED attendance in recent decades has been seen in those aged under 5 years (Gill *et al.*, 2013). In the UK in 2018–19, there were 2.2 million emergency department attendances by patients aged 0–4. This is a 50% increase since 2009–10 (NHS Digital, 2019). This is supported by a recent study from Ruzangi *et al.* (2020), which reports that the age-standardised ED visit rate increased by 1.6% per year for all children (aged 0–18 years). There was a much larger (3.9% per year) increase in annual ED visit rates for infants compared with older children.

Similarly, there is a high percentage of non-urgent attendances in the paediatric population. Studies over several decades suggest that the non-urgent proportion of children attending EDs in England varies from 30% to 58% (Prince and Worth, 1992; Smith and Roth, 2008; Mason *et al.*, 2014). Further evidence from hospitals in England suggests that non-urgent attendances make up a greater proportion of paediatric ED visits compared to the proportion seen in the adult populations (McHale *et al.*, 2013; Butun *et al.*, 2018).

This pattern is not just seen in England but is reported internationally. A recent study across 12 hospitals in Belgium identified that 40% of children's ED attendances were non-urgent (Benahmed *et al.*, 2012). In the USA, studies state that between 37% and 60% of paediatric ED visits each year are non-urgent (Brousseau *et al.*, 2007; Kubicek *et al.*, 2012), and in Australia 53% of ED attendances by children were given the same category (Unwin *et al.*, 2016). Furthermore, the findings of a recent review of 31 studies, which found the average proportion of non-urgent attendance at paediatric EDs across ten countries was 41% (Alele *et al.*, 2019), suggests that many of these attendances could potentially have been treated safely elsewhere.

Although this study was originally conceived in late 2016, the context described above remains equally relevant three years on. There continues to be a drive in England and across the globe to reduce the demand on emergency and urgent care.

1.2.1 Non-urgent attendance

The terms non-urgent, unnecessary and inappropriate attendances are used synonymously in academic literature (Uscher-Pines *et al.*, 2013). They typically refer to ED presentations for minor illnesses which could have been managed outside of hospital (for example, at a local pharmacy, GP practice or at home).

Non-urgent attendances have been defined as "*patients who attend A&E but whose injury or ailment does not require hospital treatment*" (Liggins, 1993), *"patients who self-refer with low urgency problems that are unlikely to require admission and are more suitable for other services, such as primary care, telephone advice helplines or pharmacy*" (McHale *et al.*, 2013), or attendances that "*could have used a different care provider such as an urgent care centre, minor injury unit, walk-in centre, primary care service or self-care*" (Rowe *et al.*, 2015).

Other studies use clinical criteria to define a non-urgent attendance. For example, attendances that are "*assigned to non-urgent triage categories*" (Ogilvie *et al.*, 2016) or "*Category 4 and 5 [in the] Triage System*" (Williams *et al.*, 2009).

NHS Digital, which is the national information and technology partner to the health and care system in England, has adopted the definition of non-urgent ED attendance from research undertaken by the Centre for Urgent and Emergency Care Research at the University of Sheffield. This research defines a non-urgent attendance as the *"First attendance with some recorded treatments or investigations all of which may have been reasonably provided by a GP, followed by discharge home or to GP care"* (O'Keeffe *et al.*, 2018).

Whether an attendance is classified as urgent or non-urgent may be a matter of perspective. It is understandable that parents or carers feeling anxious or stressed about an unwell infant may consider the situation an emergency, and seek hospital accordingly. This behaviour is supported by the National Institute for Health and Care Excellence (NICE) guidance regarding the management of childhood fever. This recommends that families should seek further support from healthcare professionals (although not specifically emergency care) when: "*the parent or carer is more worried than when they previously sought advice"* or "*the parent or carer is distressed, or concerned that they are unable to look after their child*" (NICE, 2019).

For the study described in this thesis, the adopted definition of non-urgent attendance is clearly defined in the methodology section (section 4.4.2.1).

1.2.1.1 Non-urgent reattendance

As stated in the title of this thesis, the research project focuses on non-urgent paediatric emergency department reattendance.

This is because there was a requirement from the study funders for the intervention to be based in emergency and urgent care settings. This meant that families could be targeted with an intervention provided by the ED or UCC, and any research participants had to be recruited from within ED or UCC. In view of this, the decision was made for the intervention to focus on preventing non-urgent repeat attendances and would be targeted at those that had already made an initial non-urgent attendance. This is discussed further in section 3.7.1.

In summary, this thesis discusses non-urgent attendance more broadly, before specifically focusing on repeat non-urgent attendance. The designed intervention from this project targeted repeat non-urgent attendances (reattendances).

1.2.2 Identification of seriously unwell children

In the context of rising demand on EDs, and a high proportion of non-urgent attendances by paediatric patients, it is important to consider the challenges associated with recognising seriously unwell children.

Healthcare professionals recognise that differentiating a seriously ill child from a child with a minor ailment can be difficult (Burke, 2011). This is particularly true for healthcare professionals (such as those working in primary care) that are not accustomed to examining babies or young children (Coote, 2010). For example, it is recognised that children may be more unwell than they initially appear as they are compensating. This can lead children to deteriorate rapidly and can explain cautious behaviour with regards to hospital attendance and primary care referral (Carrol *et al.*, 2018).

For children, the most frequent medical presentations to emergency care are: breathing difficulties, febrile illness (high temperature), diarrhoea with or without vomiting, rash and cough (Sands *et al.*, 2012). This has remained constant over a number of years (Armon *et al.*, 2001). All of these presentations could be serious, however the majority are the result of non-urgent, minor ailments (Williams *et al.*, 2009; Ogilvie *et al.*, 2016).

In view of the difficulty associated with the assessment of paediatric patients, the high proportion of non-urgent ED attendances appears understandable, especially when decisions to attend hospital may be made by parents or carers with minimal healthcare expertise.

Any intervention that aims to reduce the demand on emergency and urgent care caused by non-urgent paediatric attendances should strike a balance between encouraging self-management outside of hospital for minor illness, but also encouraging hospital presentation if there is a risk that the child is seriously unwell (Jones *et al.*, 2014).

A process called "safety netting" can support the most appropriate management. As described by Roland *et al.* (2014) "…*safety netting refers to the provision of information to help patients or carers identify the need to consult a healthcare professional if a health concern arises or changes*." Given the challenges discussed above, this advice is especially important given the dynamic nature of acute childhood illness (Roland *et al.*, 2014). Safety netting is discussed further in section 2.6.

1.2.3 The healthcare system in England

The National Health Service (NHS) is the umbrella term used to refer to the publicly funded healthcare systems of the United Kingdom (UK). The NHS consists of four separate healthcare systems: NHS England, NHS Scotland, NHS Wales and Health and Social Care in Northern Ireland. Coverage is universal, which means that all UK citizens are entitled to healthcare under this system. In addition, citizens may also choose to pay for privately funded healthcare outside of this system (NHS, 2019).

This research study was carried out in England, and therefore the methodology, results and implications are discussed in the context of the English NHS. Although learning from this project will likely apply to many different healthcare systems (including all four UK nations), the specific context should be acknowledged.

The subsections below summarise the structure of the child health system in England.

1.2.3.1 Primary and community care

In England, the majority of childhood illness is managed by general practitioners (GPs), also known as family doctors. Data from the Royal College of Paediatrics and Child Health (RCPCH) states that during an average year, a preschool child will visit their GP six times, and a school-aged child will attend on two to three occasions. Between 6 and 10% of all children will be admitted to hospital (Royal College of General Practitioners, 2013). As of December 2019 there were 34,708 GPs working across England (NHS Digital, 2020). These primary care doctors provide a gatekeeping role in the NHS and it is standard practice that all referrals to

paediatricians should be made by a GP. This structure may be bypassed when a child is taken directly to an emergency department.

Additional child health provision comes from community paediatricians. These are specialist paediatricians that work in community settings. Community paediatricians see children that are considered particularly vulnerable, and this includes those in the care of the state (looked-after children) and those in the safeguarding system. In addition, community paediatricians care for children with developmental disorders, mental health issues and those with complex neurodisabilities. They are not primary care paediatricians. They work separately to GPs and other primary care providers, and require a referral (in a similar way to specialist secondary care paediatricians) (Wolfe *et al.*, 2016).

Health visitors and school nurses (sometimes grouped together and called 'public health nurses') provide a valuable service to children in the community. Health visitors have a background in nursing or midwifery and receive specialist training in supporting families and young children. They provide a universal public health service and work closely with social care, GPs and other community health services. For example, they may provide support with maternal mental health, feeding difficulties in a child's early years, baby and toddler sleeping problems and general parenting guidance. In addition, health visitors play an essential role in identifying and escalating child protection or safeguarding concerns (Institute of Health Visiting, 2019). School nurses have an additional public health qualification and will co-ordinate and deliver public health interventions for school-aged children (5–19 years old). Service delivery models vary across England, but in some cases school nursing services are co-commissioned with schools (RCN, 2019).

In recent years there has been a national policy drive towards the integration of healthcare in England. The main focus of integrating care has been to bridge the gap between primary and secondary care through closer collaboration of services. This was initially described in the NHS England's *Five Year Forward View* (2014) and then further supported by the publication of *The NHS Long Term Plan* (NHS England, 2019b). The development of integrated care systems in England is ongoing, but the overall aim is to develop local integrated children's services that integrate across primary and secondary care for children and young people, and into education and social care. The overall goal of this is to provide care tailored to each child's physical and mental health needs in the context of their family and social conditions (RCPCH, 2018). To date, there are a number of examples of successes in child health integration including the Connecting Care for Children programme, which is working across North West London (Klaber *et al.*, 2017; NHS England, 2019a).

1.2.3.2 Secondary care

In 2017, there were 242 hospitals providing emergency care for paediatric patients. These departments are staffed by a mix of paediatricians, emergency specialists and GPs. 105 of these hospitals have a specialist paediatric emergency department (PED) (RCPCH, 2019). The others have either a dedicated area for children, or in smaller hospitals children are managed in the same areas as adult patients.

As of March 2017, there were 178 short-stay paediatric assessment units across the UK. These units have emerged as an increasingly common component of emergency and urgent care for children that do not require a longer hospital admission. In addition, they provide a hub for the coordination of emergency ambulatory care (RCPCH, 2017).

Across the UK, there are 189 hospitals that have paediatric inpatient units (RCPCH, 2019). The majority of these include general paediatric services and are staffed by general paediatricians; the largest group of paediatricians. This group provide acute hospital-based interventions for children and are increasingly working closely with professionals in the community as the system moves to embrace integrated care. Consultant paediatricians from all specialities run outpatient hospital-based clinics with a team of healthcare professionals (Wolfe *et al.*, 2016).

1.2.3.3 Tertiary care

In situations when a child requires specialist paediatric care, a general paediatrician can refer to a specialist paediatrician (there are currently 18 recognised paediatric subspecialties). These specialists are typically based in tertiary academic centres and cover areas such as gastroenterology, cardiology, neurology, infectious diseases, endocrinology, paediatric surgery and child and adolescent mental health. There are very few private paediatric hospitals in the UK, but some NHS hospitals offer private facilities to fee-paying private patients (Wolfe *et al.*, 2016).

1.3 Rationale of the study

The rising pressure on emergency departments is an important challenge requiring action. A number of literature reviews have described the negative impact of ED overcrowding on patient outcomes. Morley *et al.* (2018) report delayed assessment and care of patients and increased patient mortality. In addition, they identified that staff are less likely to adhere to best practice guidelines when departments are crowded. Busy EDs have been linked to increased lengths of patient stay in hospital, and an increased likelihood of readmission (Johnson and Winkelman, 2011). The review by Carter *et al.* (2014) describes that ED overcrowding also increases the number of patients leaving the department before being assessed by a healthcare professional. This puts potentially unwell patients at risk of deteriorating in the community without receiving care.

For paediatric patients, a less-crowded ED can help ensure that severely ill children are treated more quickly and reduce hospital waiting times generally (Derlet and Richards, 2000). Long wait times and overcrowding in EDs are associated with delays in delivering specific urgent treatments such as antibiotics for sepsis (Hitti *et al.*, 2012). A reduction in non-urgent ED attendances also represents a large potential cost saving for the NHS in England, estimated at around £100m in 2011–12 (McHale *et al.*, 2013).

Interventions that aim to reduce the demand that non-urgent ED attendances place on the healthcare system provide an opportunity to address this important challenge, and improve patient outcomes.

1.3.1 Underlying causes of non-urgent attendance

The underlying causes of non-urgent ED attendance are complex, and made up of a combination of behavioural and structural factors (Rowe *et al.*, 2015). There are various reported reasons why individuals may choose to attend ED with a non-urgent health problem. These include: a lack of access to community or primary care (Byrne *et al.*, 2003; Patton and Thakore, 2013), increased anxiety about the health problem (O'Cathain *et al.*, 2008; Adamson *et al.*, 2009), social network influence (Leaman *et al.*, 2006), confusion regarding what is defined as emergency care (McGuigan and Watson, 2010; Nelson, 2011), or referrals from another urgent care provider (for example the NHS telephone triage service) (Cook *et al.*, 2010). The reasons for children's non-urgent ED attendance is explored in more detail in *Chapter 2, Literature Review* (section 2.3).

1.3.2 A focus on children under five years old

In view of the complexity of the influencing factors causing non-urgent demand (discussed in greater detail in section 2.3), the decision was made to focus this research on one patient subgroup. This ensures a more targeted approach that aims to address specific factors related to that subpopulation.

As described in section 1.2, young children are a patient subgroup that are more likely to seek emergency and urgent care. In a study of hospital episode data the College of Emergency Medicine identified that of the 15% of attendees considered appropriate for care outside of hospital, the largest subgroup were young children presenting with non-urgent illness (Mann and Tempest, 2014). This is not a new finding; over two decades

earlier, Bolton and Storrie (1991) reported that children with minor illness attending ED are more likely to fall into the younger age groups.

McHale *et al.* (2013) identified that the highest proportion of "inappropriate attendance" at ED in England was in the very young with the peak non-urgent attendances in the one- and two-year olds. This is supported by international data demonstrating the same findings in Canada, the USA and Brazil (Afilalo *et al.*, 2004; Carret *et al.*, 2007; Davis *et al.*, 2010).

In view of the above, the literature suggests that intervention to reduce non-urgent attendance should be targeted towards early childhood, acknowledging that parents and carers are the decision-makers for this population subgroup (McHale *et al.*, 2013).

1.4 Support available to families with an unwell child

There are many healthcare services which parents might use to manage the health of their unwell child. Figure 1.1 shows a leaflet produced by the NHS which summarises six main services (self-care, NHS 111, pharmacies, GPs, minor injury units, and ED and 999) and provides advice on when to use them (NHS, 2016a). This guidance covers mild illnesses, like a cough or sore throat, to life-threatening situations such as chest pain or serious blood loss.

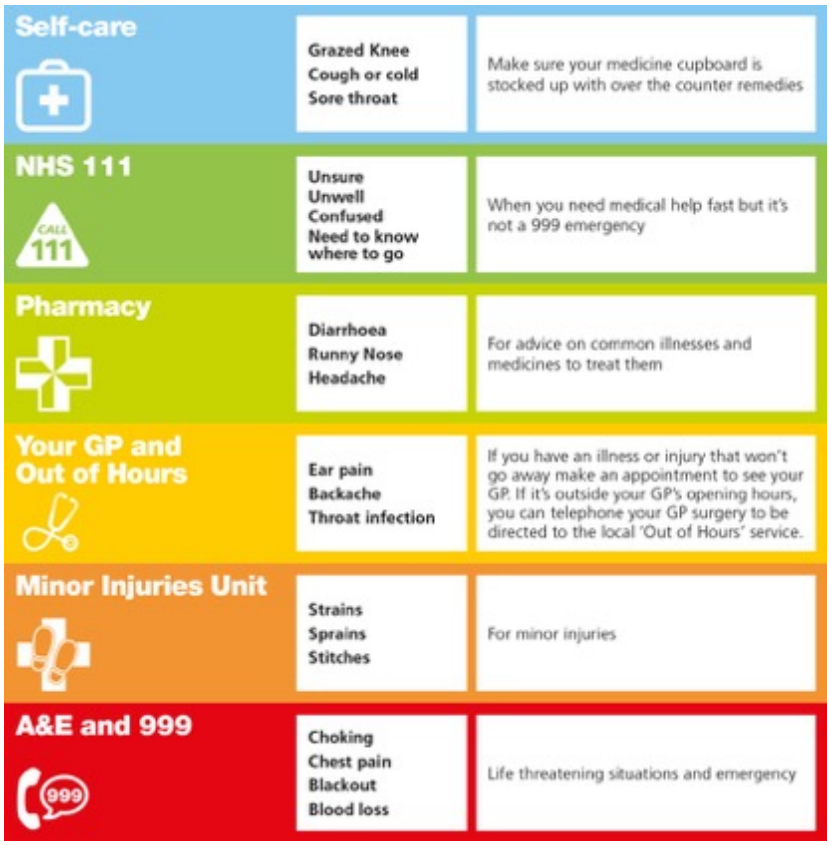


Figure 1.1: ***A page from a "Choose Well" leaflet*** (NHS, 2016a). *Image reproduced with permission of the rights holder, NHS Digital.*

The 111 telephone service is the NHS's non-emergency number. NHS 111 call handlers are not clinically trained but are supported by healthcare professionals. A 2017 report from the Nuffield Trust acknowledges that between 2015 and 2017, the number of people calling NHS 111 that were advised to attend their local emergency department, or were sent an ambulance, increased from around 150,000 a month to over 200,000. However, surveys asking callers what action they would have taken if they had been unable to ring the service indicate that 111 appears to steer people away from emergency and urgent care. A total of 20% of callers were advised to go to A&E or sent an ambulance, compared with 45% who say they would have pursued emergency and urgent care had 111 not been available (Dayan, 2017).

The inclusion of pharmacists in this leaflet highlights the important role they play in the healthcare system as community-based specialists. Many pharmacies offer a walk-in minor ailment service which diagnoses and treats minor childhood illnesses (NHS, 2017b). The leaflet highlights that out-of-hours GP services are also often available (these can also be accessed through the 111 service). Minor injuries units are a type of walk-in clinic service that is usually staffed by emergency nurse practitioners who can work autonomously (without input from doctors) to treat minor injuries.

Urgent care centres (UCCs) offer a similar service to minor injuries units, but were omitted from the leaflet. UCCs are medical facilities located near emergency departments. Their purpose is to treat health conditions that need immediate care but that do not need to be seen in an emergency department.

In addition to the services described in Figure 1.1, parents can also access health advice online. For example, the NHS website (www.nhs.uk), which received 538 million visits in 2015 and accounts for a quarter of all health-related web traffic in the UK (NHS, 2017a), provides health information through articles and videos. For example, a parent who searches “fever” on the NHS website can access text and video resources describing the causes of high temperature, guidelines on when to seek medical advice, methods of treatment, and advice on when fever may indicate serious illness (NHS, 2016b). Other popular informal services are the forums Mumsnet (2017b) and Netmums (2017). Both websites offer parenting advice, including information about child health, and combined receive over 1 billion views per year (Mumsnet, 2017a). How and when these resources are

used by parents and their effectiveness remain a relatively under-researched area (this is discussed further in section 2.4).

1.5 Role of behavioural insights

The application of behavioural science is increasingly being used across the healthcare system to address a wide range of challenges. For example, patient drug charts can be formatted to reduce errors and identify risk earlier (King *et al.*, 2014), reminders can be issued to prevent missed outpatient appointments (Gurol-Urganci *et al.*, 2013), and nudges can be introduced to improve treatment compliance (Crossland *et al.*, 2015).

The decision to bring a child to PED with a non-urgent healthcare problem is driven by human behaviour. By applying a 'behavioural insight' lens to the challenge of non-urgent attendance, there is the potential to bring about greater healthcare system efficiencies and improve patient care quality and experience.

1.5.1 Behavioural economics and 'nudging' behaviour

'Behavioural economics', 'behavioural insights' and 'nudges' are terms that are often used interchangeably. The underpinning observation of behavioural economics, a field that draws on economics and psychology, is that human behaviour is "*determined by the very fallible brain and greatly influenced by the environment or context in which choices are made*" (King *et al.*, 2013). Behavioural insights has been described as 'the application of behavioural science to policy and practice with a focus on "automatic" processes' (BIT, 2017).

Both behavioural economics and behavioural insights draw on the idea that people have two systems for processing information and decision-making – the automatic and the

reflective. The automatic (also known as System 1) refers to a system that is typically fast, intuitive and unconscious, requiring little cognitive effort or time (Kahneman, 2012). The reflective (also known as System 2) is typically slower, conscious, rational and more time-consuming (Van Bavel *et al.*, 2012).

Traditional health policy tools, it has been argued, have focused too much on System 2, ignoring the fact that much of human behaviour is automatic (King *et al.*, 2013). Nudges may be thought of as a particular type of behaviour change intervention that operates mainly through the automatic system (System 1) and has a particular focus on choice (Marteau *et al.*, 2011; Perry *et al.*, 2015). This thesis focuses specifically on the application of behavioural insights through nudges, and their potential to improve health outcomes.

Literature regarding the role of nudge-type interventions in healthcare was reviewed and summarised as part of the literature review chapter in this thesis (see section 2.7).

1.5.2 The Behavioural Insights Team

The Behavioural Insights Team (BIT), also known unofficially as the 'Nudge Unit,' is a social purpose organisation that generates and applies behavioural insights to inform policy and improve public services. BIT works in partnership with governments, local authorities and healthcare organisations and aims to tackle major policy challenges (BIT, 2018).

BIT aims to translate the most appropriate learning from behavioural science into policy and practice. The team is comprised of ex-civil servants, policy specialists and academics from disciplines including behavioural economics, social psychology, neuroscience and

anthropology (BIT, 2018). Members of BIT were able to provide their expertise in the development of this research project, and formed a key part of the multi-disciplinary steering group that maintained oversight for the design of the targeted intervention and research trial.

1.6 Developing and evaluating complex interventions

The matter of complexity, and how to evaluate complex interventions, remains a key challenge for health service researchers. *Medical Research Council* (MRC) Guidance (Craig *et al.*, 2008) provides a definition of complexity in terms of health research.

> "*Complex interventions are usually described as interventions that contain several interacting components. There are, however, several dimensions of complexity: it may be to do with the range of possible outcomes, or their variability in the target population, rather than with the number of elements in the intervention package itself*" (Craig *et al.*, 2008).

These complex interventions often cover diverse fields including health services, health behaviour change interventions, and health promotion and areas of social policy (such as education, housing and transport) that have important health consequences (Petticrew, 2011). Due to several interacting components the evaluation of these interventions often presents issues for communities, practitioners and decision-makers (Datta and Petticrew, 2013).

In 2008, the *Medical Research Council* (MRC) updated guidance on "Developing and evaluating complex interventions" (Craig *et al.*, 2008). This guidance has been used successfully across disciplines, which suggests its flexible approach may be usefully applied to the design processes used in the development of new complex interventions (Paul *et al.*, 2007; Smith *et al.*, 2012; Lakshman *et al.*, 2014). The guidance supports the use of a good theoretical understanding in the design of interventions and the importance of adapting designed interventions to local settings.

It was anticipated that the intervention developed as part of this research project would be complex. This was because of the expectation of multiple interactions between components within the experimental and control interventions, various behaviours of those receiving the intervention and the differences between two hospital sites identified for the trial.

Figure 1.2 details the key elements of the development and evaluation process proposed by the MRC in the 2008 guidance (Craig *et al.*, 2008). This framework was applied to the development and evaluation of the targeted intervention for the project to maximise effectiveness and reproducibility of the project output. The structure of this thesis has therefore been aligned to this framework. The research activities in this project have been mapped to the MRC framework in Table 1.2.

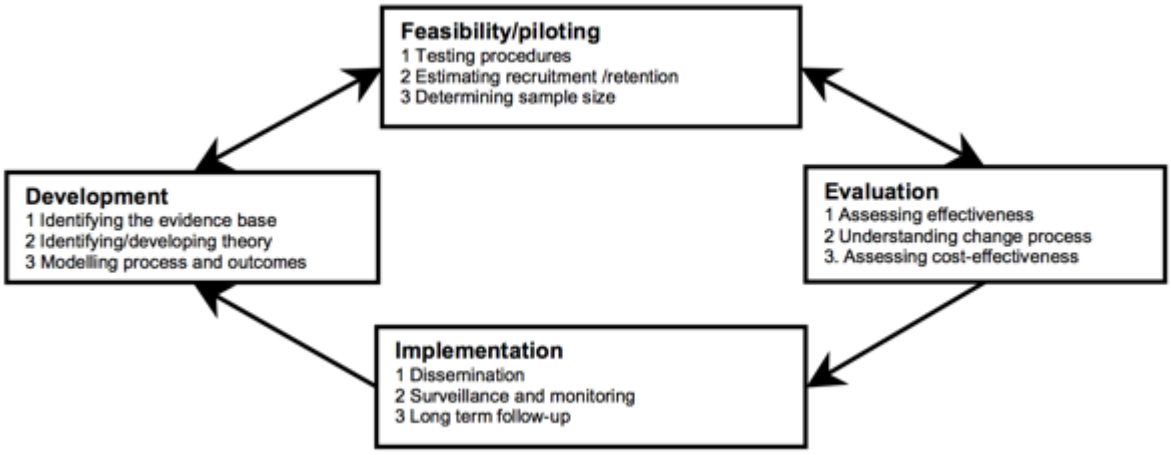


Figure 1.2: ***Key elements of the development and evaluation process*** *(Craig et al., 2008). Image reproduced with permission of the rights holder, the Medical Research Council (MRC).*

Table 1.2: ***Mapping research activities to the MRC framework.***

1	**Developing a complex intervention**		
1.1	Identifying the evidence base	i.	Narrative review of the underlying reasons for children's non-urgent attendance at PED
		ii.	Systematic review of interventions that have attempted to reduce children's non-urgent reattendance at PED
1.2	Identifying and developing theory, plus intervention design	i.	Use of literature review findings, meeting with stakeholders and subject experts to decide on theory and intervention strategies
		ii.	Qualitative studies with stakeholder groups to develop intervention content
1.3	Modelling process and outcomes	i.	Used causal modelling approach to link determinants of behaviour to attendance behaviour
2	**Assessing feasibility and piloting methods**		
2.1	Testing procedures	i.	Tested components for feasibility and acceptability with caregivers and healthcare professionals
		ii.	Pilot of delivery process of the intervention
2.2	Estimating recruitment and retention	i.	Scoping exercise of attendance data for both hospital sites to estimate baseline reattendance
2.3	Determining sample size	i.	Data from previous years used to estimate sample size and minimal detectable effect size.

3	**Evaluating a complex intervention**		
3.1	Assessing effectiveness	i.	Set up a randomised controlled trial (RCT: *ISRCTN74381956*) across two hospital sites in North West London to evaluate intervention effectiveness. The primary outcome was whether families enrolled into the trial made at least one non-urgent reattendance with a patient aged under five years during the follow-up period. Secondary outcomes assessed were whether the age and gender of the patient at initial attendance influenced the effectiveness of the intervention.
3.2	Understanding change processes	i.	Further work following on from the trial to conduct an implementation and process evaluation of the trial and evaluation to understand the trial results is ongoing.
3.3	Assessing cost-effectiveness	i.	Estimation of the cost-effectiveness of the intervention was not conducted as part of this MD thesis. It is anticipated that this will be incorporated into the follow-up implementation and process evaluation.
4	**Implementation and beyond**		
4.1	Dissemination	i.	Peer review publications, conference presentations, public engagement activities, availability of tools used to develop and deliver intervention
4.2	Surveillance, monitoring, and long-term outcomes	i.	Process and outcome data may inform additional pragmatic trials. It is anticipated that this research will inform additional work at both hospital sites, and across North West London.

1.7 Aims, objectives and research questions

The three key aims of this study are summarised below.

Aim 1: To identify the reasons for non-urgent attendance at PED as described in the published literature.		
Objectives	Research question	Methods
Undertake a critical review of published literature describing the underlying reasons for children's non-urgent attendance at PED.	*Why do children attend PED with non-urgent health conditions?*	Literature review
Undertake a critical review of published literature describing interventions that have attempted to reduce children's non-urgent attendance at PED.	*What interventions attempting to reduce non-urgent PED attendances have previously been evaluated?*	Literature review

Aim 2: To develop a targeted intervention that aims to reduce non-urgent reattendance at PED.
Objectives
Use evidence from the critical literature review to inform the design of a targeted intervention.
Gather qualitative feedback from families and healthcare professionals to inform the intervention design.
Apply learning from behavioural insights to the intervention design.

Aim 3: To evaluate the effect of the targeted intervention on non-urgent reattendance at PED using a randomised controlled trial.		
Objectives	Research question	Methods
Identify whether the intervention reduced the likelihood of non-urgent PED reattendance during the trial period.	*Are families that receive the intervention less likely to reattend PED with a non-urgent problem?*	Randomised controlled trial and (OLS) linear regression
Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient gender.	*Are families that initially attend with a male child less likely to reattend PED with a non-urgent problem following receipt of the intervention?*	
Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient age.	*Are families that initially attend with a child aged 0–2 years old less likely to reattend PED with a non-urgent problem following receipt of the intervention?*	

1.8 Overview of the methodology

Figure 1.3 summarises the key steps of this research study. The methods described here are discussed in detail in *Chapter 2: Literature Review*, *Chapter 3: Intervention Design* and *Chapter 4: Research Trial Methodology*.

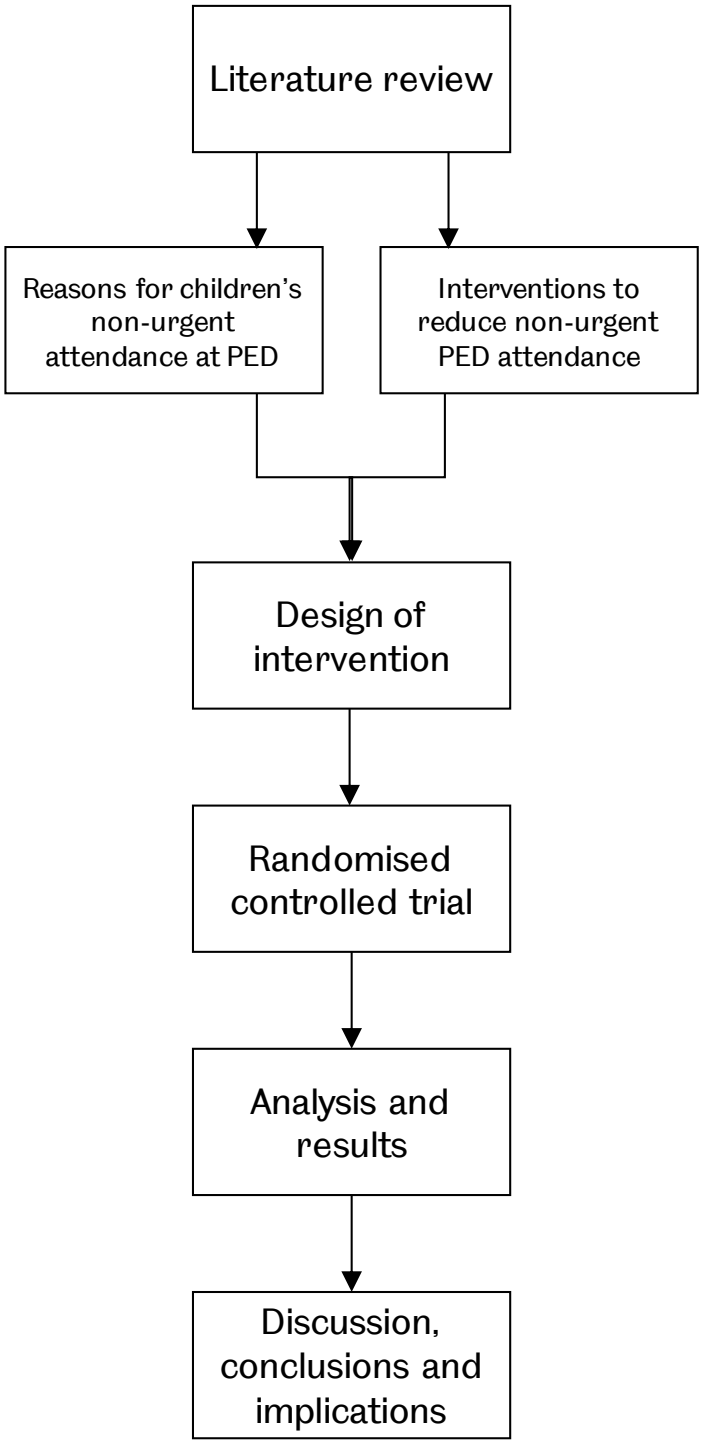


Figure 1.3: ***Summary of the research study methodology.***

1.9 Study significance

Sections 1.2 and 1.3 have highlighted the additional burden that non-urgent attendances at PED of children aged under five years old provide, and the negative impacts these attendances can have on patient and staff outcomes. This study seeks to appraise available information regarding the cause of non-urgent attendances in childhood, design an intervention to address this issue, and use robust methodology to test the intervention.

This project is particularly unique in that it combines learning from previously published studies in this area, with an understanding of behavioural insights. By incorporating an understanding of the tools and techniques that can be utilised to influence human behaviour, the likelihood of success of the final designed intervention can be maximised (Perry *et al.*, 2015).

In addition to an academic focus on understanding human behaviour, this research will test the intervention in a randomised controlled trial (RCT). This prospective study design will provide a robust measure of the effectiveness of the final intervention. The act of randomisation balances the characteristics of participants (both known and unknown) between control and intervention groups, thereby reducing bias and providing a rigorous tool to evaluate cause-effect relationships (Hariton and Locascio, 2018).

The findings from this study will include:

1) a critical summary of the reasons why families choose to attend PED with non-urgent healthcare concerns,

2) critical appraisal of previously trialled interventions that have attempted to reduce non-urgent PED attendance,

3) development of a behaviourally informed intervention targeting families caring for unwell children, and

4) an evaluation of the effect of this intervention in two North West London hospitals.

Together these results will provide valuable insights into how the challenge of non-urgent PED attendance can be addressed. This will contribute to the health policy debate, and provide evidence of the impact of behaviourally informed interventions focusing on a paediatric population.

1.10 Collaboration of services

This trial was conceived through a cross-departmental and cross-professional collaboration, led by the author at Imperial College London, in collaboration with the Behavioural Insights Team (BIT).

BIT provided valuable knowledge regarding behavioural insights, and input into the multi-disciplinary steering group. In addition, BIT provided access to data scientists and data analysts who were able to run the trial analysis detailed within this thesis.

1.11 Structure of the thesis

This thesis consists of seven chapters. Each of these is briefly summarised below.

Chapter 1: Introduction – This chapter introduces the thesis, gives the context to the research study and describes the rationale for this research. It provides background information on the English healthcare system, and introduces the concept of behavioural insights. In addition, the chapter states the aims and objectives of this study.

Chapter 2: Literature review – Chapter 2 includes two detailed literature reviews. The first critically reviews published literature that identifies the reasons for children's non-urgent attendance at PED. The second reviews studies that have evaluated interventions aimed at reducing non-urgent attendance at PED. The chapter concludes with a number of recommendations.

Chapter 3: Intervention design – This chapter discusses the development of theory underpinning the design of the complex intervention that aimed to reduced non-urgent reattendance of children at urgent and emergency care locations. The chapter describes the design of the final targeted intervention and aligns to the relevant steps of the MRC guidance on "Developing and evaluating complex interventions" (Craig *et al.*, 2008).

Chapter 4: Research trial methodology – This chapter discusses the methodology underpinning the RCT. It describes the logistics of trial implementation and provides a comprehensive explanation of the process of data collection and analysis of the trial data.

Chapter 5: Results and analysis – Chapter 4 presents the findings from the RCT. It summarises both the primary analysis and the two pre-specified subgroup analyses explored during the trial.

Chapter 6: Discussion – The final chapter interprets the results from the trial and discusses the findings in the context of other published literature. It reviews the limitations of the results and identifies those that were unexpected. In addition, it discusses the limitations of the study and summarises the overall significance of this research. This chapter provides the policy and practice implications of this study, and gives clear recommendations for the future direction of work in this area.

1.12 Acknowledging the impact of COVID-19

The vast majority of the work described in this thesis was completed before the identification of the novel coronavirus disease 2019 infection (COVID-19). However, it is important to note that the effects of this global pandemic will be felt across health and social care systems for years to come (Bedford *et al.*, 2020). Although COVID-19 did not feature in the planning, implementation or analysis of this research project; it is crucial to consider the impact of these research findings in the current climate. Therefore, the discussion chapter will acknowledge the learning from this work in the context of a healthcare system and society adapting to the impact of COVID-19 (see section 6.7).

1.13 Chapter summary

This first chapter provides an introduction and comprehensive background to this project. Through provision of a rationale for the completion of the study the chapter has demonstrated the need for research to reduce the pressure on emergency and urgent care, and subsequently improve child health outcomes. In addition, the chapter summarised the study methodology and structure of this thesis.

Chapter 2: Literature Review

2.1 Chapter introduction

This chapter details two separate literature reviews carried out to inform the design of this research project. The first is a narrative review that sought to identify the underlying reasons for non-urgent attendance at the Paediatric Emergency Department (PED). The second is a systematic review that aimed to evaluate the effectiveness of previously trialled interventions that have attempted to reduce non-urgent PED attendance.

This chapter covers section 1.1. of the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008) (Table 2.1).

Table 2.1: ***Section 1.1 of the MRC Framework - Extracted from Table 1.2.***

1	**Developing a complex intervention**		
1.1	Identifying the evidence base	i.	Narrative review of the underlying reasons for children's non-urgent attendance at PED
		ii.	Systematic review of interventions that have attempted to reduce children's non-urgent reattendance at PED

2.2 Aims of the literature review

The overall aim of this research was to design a targeted intervention that aimed to reduce non-urgent reattendance at PED, and then evaluate the impact of that intervention on non-urgent reattendance. In order to design an effective intervention, it was important to critically appraise the published literature regarding reasons for non-urgent PED attendance and previously tested interventions that attempted to address this. A review of the literature using systematic methods to search and quality appraise relevant literature informed the design of a putative targeted intervention.

The literature review was split into two main sections. The first (section 2.3) focused on identifying why families attend PED with children with non-urgent health conditions. The second (section 2.4) identified evaluations of interventions that attempted to reduce non-urgent PED attendance. Further evidence was then reviewed regarding safety-netting interventions and the application of behavioural insights.

2.3 Why do children attend PED with non-urgent health conditions?

Any intervention with the goal of influencing human behaviour should be informed by the most up-to-date evidence regarding the reasons for this behaviour. This literature review drew upon the evidence base to identify underlying reasons for why parents or carers bring children to ED with a non-urgent health condition.

2.3.1 Framing the research question

The PICO (Population, Intervention, Comparison, Outcome) formulation is often adopted in the generation of research questions; however, this is typically used in systematic reviews of clinical evidence and is not suitable for all research projects. Therefore, a number of alternative question structures that accommodate different types of research have been proposed (Methley *et al.*, 2014).

For this literature review, the PICo (Population; [phenomenon of] Interest; Context) formulation was selected (Stern, Jordan and Mcarthur, 2014). This is presented below in Table 2.2.

Table 2.2: ***PICo framework components***

PICo framework for research question	
Population	Parents or carers of children with a non-urgent condition
Interest (phenomenon of)	Reason for attending ED
Context	Emergency and urgent care services

A narrative review methodology was used to answer the research question:

Why do children attend PED with non-urgent health conditions?

2.3.1.1 Aim

- To identify the reasons why parents or carers bring children to ED with a non-urgent health condition.

2.3.1.2 Objectives

1. Search for and critically review a comprehensive body of literature.

2. Identify the key themes relating to why parents or carers bring children to ED with a non-urgent health condition within that literature.

3. Describe the themes identified and provide support for a theoretical framework for the development of a targeted intervention to reduce children's non-urgent ED attendance.

2.3.2 Literature review methodology

This narrative review was underpinned by a systematic and replicable search strategy to minimise bias and collate all relevant literature. This methodology allows all studies with relevant content to be included in this study, and does not limit study design or publication type. This allows a wide range of data to generate debate and ultimately inform the development of a theoretical framework and intervention design to reduce non-urgent PED reattendance (Ferrari, 2015).

2.3.2.1 Eligibility criteria

Initial scoping searches determined that few studies existed on this subject. To maximise the total number of relevant factors identified as part of this review, the eligibility criteria were intentionally broad. This meant they included reasons for all non-urgent PED attendance, and was not limited to only non-urgent repeat attendances at PED.

Inclusion criteria

All publications that meet the following criteria were included:

(i) Described attendance at emergency or urgent care services of children (those aged under 18 years old).

(ii) Literature related to the reasons why parents or carers of unwell children with non-urgent illness made the decision to attend hospital.

(iii) Any type of study design from articles in peer-reviewed journals or identified in grey literature.

Exclusion criteria

Publications that met the following criteria were excluded from the review:

(i) Article not available in the English language.

(ii) Population described in the article which did not include children.

(iii) Only referred to urgent conditions or trauma.

(iv) No description included of reasons for non-urgent attendance.

(v) Setting was not emergency or urgent hospital care.

2.3.2.2 Information sources

This review utilised a broad range of sources of information to ensure a comprehensive search strategy. Searches were conducted using electronic databases (for peer-reviewed and grey literature), hand-searching of reference list citations and search engines to identify relevant policy documents.

The five electronic databases that were used were:

- MEDLINE (1946 to December 2016);
- EMBASE (1947 to December 2016);

- CINAHL (1981 to December 2016);
- PsychINFO (1806 to December 2016); and
- OpenGrey (1986 to December 2016).

These databases covered the topic areas relevant to this review: medical and health literature related to the biological and physical sciences, plus literature related to nursing and allied health professionals, psychology, sociology and economics. *OpenGrey* is a repository of grey literature that covers biomedical science, technology, social science, economics and humanities (OpenGrey, 2017).

No date limit was put on the electronic database searches as part of this project. Searches were only limited by the date ranges available through each individual electronic database. This was to ensure the searches were as broad as possible.

Searches were also conducted using the *Google* search engine[i] to identify any further policy documents published in this area. In addition, the reference lists of included articles were screened for further citations of potential relevance.

2.3.2.3 Search strategy

The search strategy drew upon synonyms for parents and carers taken from a 2013 systematic review examining a similar population (Cousino and Hazen, 2013).

[i] www.google.co.uk

The following search strategy was applied to the databases mentioned above:

MEDLINE (via Ovid) Search strategy

1. exp Parents/ or exp Caregivers/ or exp Family/ or parent*.tw. or carer*.tw. or caregiv*.tw. or famil*.tw.
2. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
3. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
4. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
5. 1 and 2 and 3 and 4

Examples of the full search strategies used for each electronic database are included in *Appendix A*.

2.3.2.4 Study selection

After completion of the electronic database searches, all citations were transferred into *Mendeley* (reference management software). Any duplicate articles were removed using the 'deduplication' function within *Mendeley* prior to the screening of publications (Mendeley, 2016).

Titles were assessed against the prespecified eligibility criteria. Following the title screening stage, the references were screened and the reasons for exclusion noted. For all the remaining studies, the full-text articles were reviewed against the inclusion and exclusion criteria.

2.3.2.5 Data collection

Data extraction was completed using a form generated within *Microsoft Excel*.[ii] All relevant quotes from the included publications were summarised as themes and included within the *Microsoft Excel* extraction form.

An electronic extraction form was used to simplify data analysis. The extraction form was piloted on two studies to ensure that relevant information was captured. The extraction was refined following this pilot.

2.3.2.6 Quality assessment

To ensure transparency, wherever possible studies were evaluated using an adapted version of the Critical Appraisal Skills Programme's (CASP) tool for appraising qualitative research (CASP, 2013). This adapted version of the CASP tool had previously been augmented with four domains from the Joanna Briggs Institute Qualitative Assessment and Review Instrument (The Joanna Briggs Institute, 2014). The adapted CASP tool was developed to include items that consider descriptive, interpretive and theoretical validity (Verboom, Montgomery and Bennett, 2016).

This tool, labelled the 'CASP instrument', has been designed to aid interpretation of narrative review findings by assigning an overall score of methodological quality (either 'high quality', 'moderate quality' or 'low quality'). The 12 items in the instrument aim to generate a quality assessment to inform interpretation of the data, not to exclude studies from the review. A blank copy of the CASP instrument that was used for this review is

[ii] An electronic spreadsheet program used for storing, organising, and manipulating data.

included in *Appendix B*.

2.3.2.7 Data analysis and synthesis

The text data and quotes extracted from all included studies were treated as qualitative data. This descriptive data was analysed using thematic analysis. Thematic analysis was carried out using the methods described by Thomas and Harden (2008), whose approach allows qualitative data from a diverse range of studies to be brought together and integrated into key themes. These themes were evaluated through narrative synthesis. Where possible, a judgement was made on the reliability of each identified theme. A reliability rating was used to combine the quality of each study that contributed to the identified themes and the number of times each theme was represented in the included studies.

2.3.3 Literature review findings

The results from this literature review are discussed in the following sections.

2.3.3.1 Identified studies

Searches of the five electronic databases were completed using the search strategy described in section 2.3.2.3. The number of results from each of these searches is detailed in Table 2.3.

Table 2.3: ***Results of electronic database searches***

Search number	Database	Number of references returned by search
1	MEDLINE (1946 to December 2016)	475
2	EMBASE (1947 to December 2016)	1,253
3	CINAHL (1981 to December 2016)	257
4	PsychINFO (1806 to December 2016)	99
5	OpenGrey (1986 to December 2016)	279
Total references:		2,363

The combined search strategies identified 2,363 publications. The duplicates were removed and the eligibility criteria were applied to all remaining studies. The flowchart in Figure 2.1 summarises the stages at which studies were excluded.

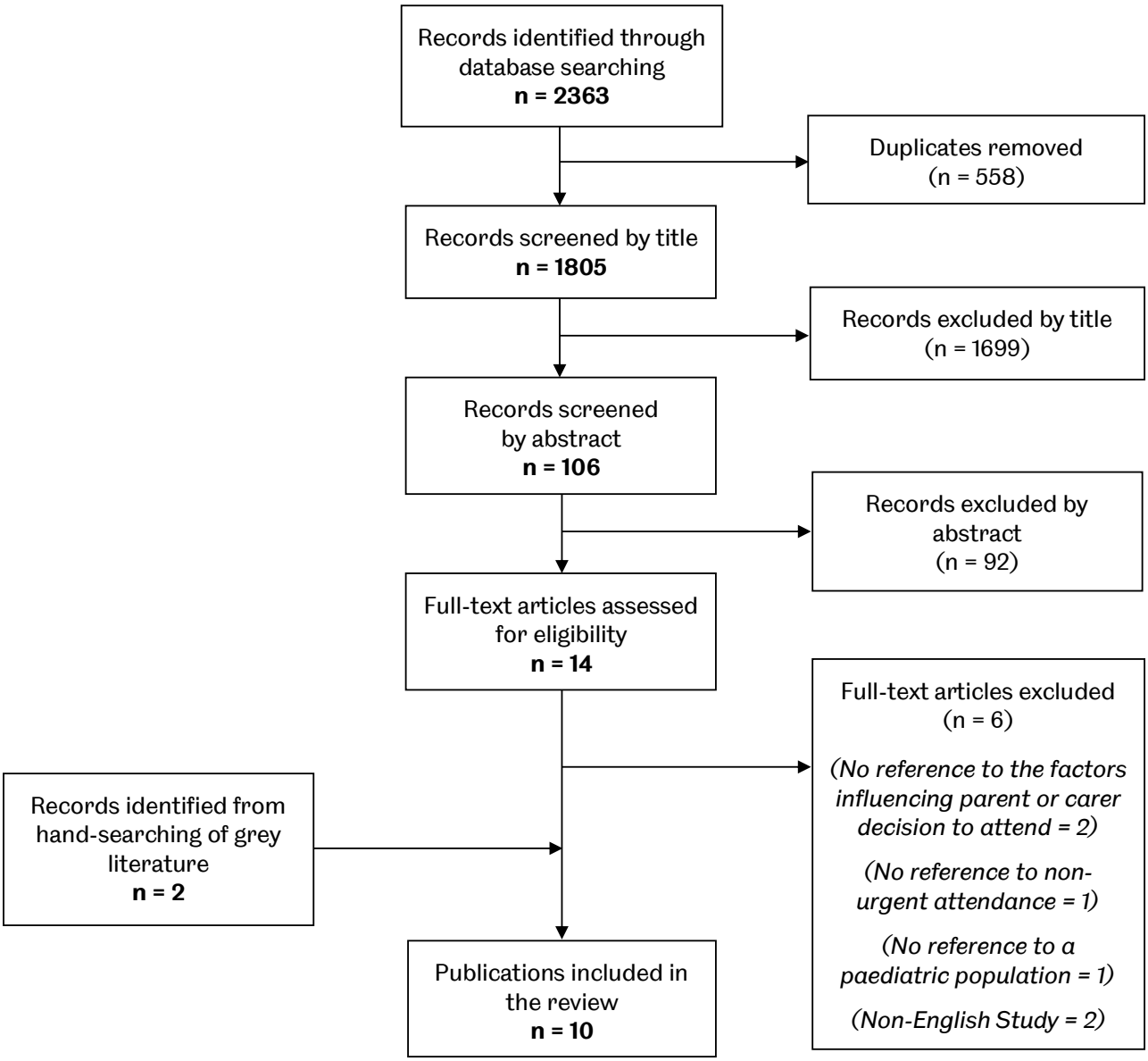


Figure 2.1: ***Flowchart of Study Selection Process****. This flowchart is amended from that presented in "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement" by Moher et al., 2009).*

The explanation for why six studies were excluded at the full-text review stage is summarised in Table 2.4.

Table 2.4: ***Reason for study exclusion after full-text review***

Article	Reason for exclusion
Atenstaedt and Evans (2015)	Publication does not make reference to a paediatric population.
Rati *et al. (*2013)	The study is not written in English.
Vinelli *et al. (*2011)	The study is not written in English.
Poirier *et al.* (2010)	Publication does not make reference to non-urgent attendance.
MacFaul *et al.* (1998)	No description of the factors that influence a parent or carer's decision to attend hospital with an unwell child.
Roberts (1992)	No description of the factors that influence a parent or carer's decision to attend hospital with an unwell child.

Eight publications were identified from electronic databases for this review, and a further two publications were identified from additional grey literature searches. The final ten included publications are summarised in Table 2.5.

Table 2.5: ***Studies included in this narrative review***

Publication details	Country	Study design and analysis	Participants	Study setting
Berry, A., Brousseau, D., Brotanek, J. M., Tomany-Korman, S., & Flores, G. (2008). **Why do parents bring children to the emergency department for non-urgent conditions? A qualitative study.** *Ambulatory Pediatrics.*	USA	Qualitative research (semi-structured face-to-face interviews). Thematic analysis used.	31 parents (from separate families). Non-urgent attendances only.	One Children's Hospital ED
Chin, N. P., Goepp, J. G., Malia, T., Harris, L. & Poordabbagh, A. (2006). **Non-urgent Use of a Paediatric Emergency Department: A Preliminary Qualitative Study.** *Pediatric Emergency Care*.	USA	Qualitative research (semi-structured face-to-face interviews). Thematic analysis used.	12 caregivers (from separate families). Non-urgent attendances only.	One PED
Costet Wong, A., Claudet, I., Sorum, P., & Mullet, E. (2015). **Why do parents bring their children to the emergency department? A systematic inventory of motives**. *International journal of family medicine.*	France	Quantitaive research (descriptive survey research using numerically rated items on a questionnaire). Appropriate statistical anlayses were used.	500 caregivers (from separate families). Includes both urgent and non-urgent attendances.	One PED
Graham, J. M., Fitzpatrick, E. A. & Black, K. J. (2010). **"My child can't keep anything down!" Interviewing parents who bring their preschoolers to the emergency department for diarrhea, vomiting, and dehydration.** *Pediatric Emergency Care*.	USA	Qualitative research (structured telephone interviews). Thematic analysis used.	10 parents (from separate families). Non-urgent attendances only.	One PED
Guttman, N., Zimmerman, D. R. & Nelson, M. S. (2003). **The Many Faces of Access: Reasons for Medically Non- urgent Emergency Department Visits.** *Journal of Health Politics, Policy and Law.*	USA	Qualitative research (semi-structured face-to-face interviews). Thematic analysis used.	331 parents or carers (from separate families). Non-urgent attendnaces only.	Two hospital EDs
Hendry, S. J., Beattie, T. F., & Heaney, D. (2005). **Minor illness and injury: factors influencing attendance at a paediatric accident and emergency department**. *Archives of Disease in Childhood.*	Scotland	Quantitaive research (descriptive survey research using binary questions and numerically rated items on a questionnaire). Appropriate statistical anlayses were used.	465 parents or carers (from separate families). Non-urgent attendances only.	One PED
NHS Newcastle Gateshead CCG. (2015). **Children and Young People's Attendance at A&E.** *NHS Newcastle Gateshead CCG Report.*	England	Qualitative research (initial qualitative questionnaire, followed by semi-structured telephone interviews). Summary statistics and narrative synthesis to describe results.	184 parents or guardians (from separate families). Non-urgent attendances only.	One PED
Ogilvie, S., Hopgood, K., Higginson, I., Ives, A., & Smith, J. E. (2016). **Why do parents use the emergency department for minor injury and illness? A cross-sectional questionnaire.** *JRSM Open*.	England	Quantitaive research (descriptive survey research using numerically rated items on a questionnaire). Appropriate statistical anlayses were used.	337 parents or carers (from separate families). Non-urgent attendances only.	One hospital ED
Rowe, B., Cook, C., Wootton, R., & Brown, T. (2015). **A&E: Studying parental decision making around non-urgent attendance among under 5s.** *ESRO & Department of Health Report*.	England	Qualitative research (semi-structured face-to-face interviews). Thematic analysis used.	35 parents or carers (from separate families). Non-urgent attendnaces only.	Sampled from different locations across England.
Williams, A., O'Rourke, P., & Keogh, S. (2009). **Making choices: why parents present to the emergency department for non-urgent care.** *Archives of Disease in Childhood*.	Australia	Quantitaive research (descriptive survey research using numerically rated items on a questionnaire). Appropriate statistical anlayses were used.	355 parents or carers (from separate families). Non-urgent attendances only.	One PED

2.3.3.2 Study characteristics

The ten publications in this review include eight peer-reviewed publications and two research reports identified from the grey literature. All references relate to work undertaken in high-income countries and were published between 2003 and 2016 (Table 2.5).

Six of the studies used a qualitative study design. Five of these used semi-structured interviews for data collection methods, and one used a structured telephone interview format. All studies used thematic analysis to evaluate the findings except for NHS Newcastle Gateshead CCG (2015). The qualitative studies included between 10 and 331 participants (Table 2.5).

The other four studies used quantitative methods. All of these quantitative studies used descriptive survey research methods, and results were analysed using appropriate statistical analysis. Between 337 and 500 participants were included in each of these four studies (Table 2.5).

2.3.3.3 Quality assessment

The CASP instrument described in section 2.3.2.6 was used to critically appraise the research studies included in this narrative review. A summary of the quality assessment results is shown below in Table 2.6.

Table 2.6: ***Quality assessment of included studies***

Publication	Quality assessment
Berry *et al. (*2008)	**Medium**
Chin *et al.* (2006)	**High**
Costet Wong *et al.* (2015)	**Medium**
Graham *et al.* (2010)	**Low**
Guttman *et al.* (2003)	**High**
Hendry *et al.* (2005)	**Medium**
NHS Newcastle Gateshead CCG (2015)	**Low**
Ogilvie *et al.* (2016)	**Medium**
Rowe *et al.* (2015)	**Low**
Williams, O'Rourke and Keogh (2009)	**Low**

As the studies by NHS Newcastle Gateshead CCG (2015) and Rowe *et al.* (2015) were not published in peer-reviewed journals, quality assessment was particularly important.

The two studies authored by Chin *et al*. (2006) and Guttman *et al.* (2003) were considered high quality. This was because each study stated a research question that was appropriate for the chosen study design and qualitative methodology. They employed a robust recruitment strategy, considered ethical issues and collected sufficient data. In both studies, data analysis was rigorous, findings were presented clearly and logical conclusions were drawn.

Berry *et al. (*2008), Costet Wong *et al.* (2015), Hendry *et al.* (2005) and Ogilvie *et al.* (2016) were all lacking in detail regarding the relationships between the researchers and

participants. The studies by Berry *et al. (*2008) and Hendry *et al.* (2005) did not specifically consider ethical issues in their articles; however, there were no obvious ethical concerns apparent in their report. Authors of Costet Wong *et al.* (2015) did not explain their choice of data analysis, and they did not interpret all relevant results in the discussion and conclusion. The rationale for the methods of data collection by Ogilvie *et al.* (2016) was also lacking. For this reason, it was not possible to identify whether the authors considered all relevant aspects discussed, and therefore the four studies were assessed as medium quality.

The studies authored by Graham *et al.* (2010), NHS Newcastle Gateshead CCG (2015), Rowe *et al.* (2015) and Williams *et al.* (2009) were all considered low-quality studies. None of them considered the relationship between researchers and participants, and their conclusions did not clearly relate to the analysis and results interpretation described in the studies.

Furthermore, Graham *et al.* (2010), NHS Newcastle Gateshead CCG (2015), and Williams *et al.* (2009) did not demonstrate sufficiently rigorous processes for data analysis.

A lack of a robust recruitment strategy increases the risk of introducing selection bias. Those involved in the research project may not be representative of the population that researchers wish to investigate. This further supports the conclusion that NHS Newcastle Gateshead CCG (2015), Williams *et al.* (2009) and Rowe *et al.* (2015) should be considered low-quality studies.

2.3.3.4 Thematic analysis

All publications were reviewed and relevant data regarding the underlying reasons that families choose to attend PED with a non-urgent health concern was extracted. The identified reasons were organised into sub-themes, and then these were grouped together into five main themes. The identified themes are summarised in Table 2.7 and discussed in more detail overleaf.

Table 2.7: ***Identified factors influencing non-urgent PED attendance***

Main theme	Sub-theme	Number of times cited	Reliability of findings
A. Parental worry	Perception of the seriousness of the child's illness	8	High reliability
	Need for reassurance	4	High reliability
B. Perceived advantages of PED	PED staff have greater expertise with children	3	Medium reliability
	PED is convenient and provides better quality of care	4	High reliability
C. Perception that other healthcare services were not suitable	Lack of access to primary care services	7	High reliability
	Dissatisfaction with quality of primary care	3	High reliability
D. Social network influence	Desire to be considered by others as a responsible parent	1	Low reliability
	Pressure from family, friends and social media	4	Low reliability
	Erosion of traditional support networks	1	Low reliability
E. Structural factors	Referred by a healthcare service	4	Medium reliability
	Out of hours	2	Medium reliability

Key for reliability ratings*

High reliability	The identified barrier is supported by several studies of medium quality and one high-quality study, or the study is supported by at least two high quality studies.
Medium reliability	The identified factor is supported from several medium-quality studies, or the factor is identified from at least one high quality study.
Low reliabillity	The identified factor is supported by several low-quality studies and/or one medium quality study.

*It should be noted that the confidence in these findings (reliability) does not relate to the generalisability of the findings.

A. Parental worry

Parents that are particularly worried about their child's illness are more likely to attend PED non-urgently. This worry often arises because parents misdiagnose their child's illness as requiring urgent treatment. Indeed, Williams *et al.* (2009) found that 60% of parents rated the perceived severity of their child's illness as the primary or secondary reason for their PED attendance, even though all the children in that survey were ultimately classed as having non-urgent illnesses. Another survey found that 63% of 106 parents whose child was triaged as non-urgent described the child's condition as "very" or "extremely" urgent (Berry *et al.*, 2008). Lastly, 64% of parents making non-urgent presentations at PED in Edinburgh reported the highest degree of worry about their child's condition on a scale of one to five (Hendry *et al.*, 2005). These studies show that parents often perceive PED as the most appropriate place for their child's illness, even when this illness turns out to be non-urgent (Ogilvie *et al.*, 2016).

How much a parent worries about their child's health can vary depending on the parent's age and how much childcare experience they have. For example, Ogilvie *et al.* (2016) found that young parents (aged 24 and under) reported much higher levels of stress when attending PED than older parents in the same situation. They also reported higher levels of worry, and less confidence in their ability to manage their child's illness. Costet Wong *et al.* (2015) found that parents of a single child, who also tended to be less experienced with managing unwell children, were more likely to rate the concern they felt for their child's suffering as an important reason for their PED attendance. Graham *et al.* (2010) describe how parents managing their first child were more likely to attend ED because they were worried about missing something serious and were seeking reassurance. The age of the

child also influences parental perceptions of illness. For example, Ogilvie *et al.* (2016) found that parents tended to be particularly worried about non-urgent illnesses when the child was under the age of one.

These feelings of worry and anxiety can encourage parents to attend PED, partly out of a desire for reassurance that they are doing the right thing. Rowe *et al.* (2015) quote one parent as saying "*When you go into A&E you think 'Am I worrying about nothing?' but they always reassure you – they tell you that you've done the right thing and that you're not wasting their time*." Costet Wong *et al.* (2015) found that two of the most strongly endorsed reasons for attendance were "*I was anxious for my child*", and "*I wanted quickly to have a diagnosis for my child*".

Graham *et al.*'s (2010) study states that several caregivers expressed anxiety about not knowing the cause of their child's illness, or what treatment to give: "*We were nervous, we were afraid, we really didn't know what was causing it, and what we could really do*." Further evidence comes from Guttman *et al.* (2003), with a parent describing that "*children can't tell you what's wrong, and parents want to make sure everything is OK.*" Some parents from the same study explained that they were hoping "*to be told nothing's wrong*" or "*to make sure everything is OK.*"

B. Perceived advantages of ED

Parents often reported attending PED non-urgently because they thought PED staff had the training and resources to treat sick children to a high standard (Rowe *et al*., 2015). These findings are supported by Hendry *et al.*'s (2005) survey, in which 31% of parents indicated

they chose PED because a child will be seen more quickly, and 18% of families attended PED non-urgently to "*get better treatment.*"

Williams *et al.* (2009) found that 18% of parents cited their perception of PED as a 'one-stop shop' where their child could receive a large array of medical treatment and tests as a main reason for attending. In the study by Guttman *et al.* (2003), one parent explains that at ED a child "*could get the most complete care*". Another caregiver from the same study states that the ED is "*fast – no waiting here."*

The PED environment is also seen by some parents as being more child-friendly than local health services. Berry *et al.* (2008) quote one parent as saying that attending PED means "*a better interaction with children than if you go to just any clinic, because I think [PED is] prepared for children*."

C. Perception that other healthcare services were not suitable

Parents often contrast this perception of PED as a high-quality provider of child healthcare with the issues they face when accessing or using primary care. Of the ten studies included in the review, seven highlight a lack of access to primary care as a key reason for parents attending PED non-urgently. Parents who did receive a GP appointment sometimes reported dissatisfaction with the quality of care they received. Rowe *et al.* (2015) found that "*when it came to seeking medical attention for their children, some parents felt that GPs may lack the kind of specialist paediatric knowledge needed to be able to diagnose and treat their child appropriately*". Some parents in the reviewed studies were supportive of their

primary care experiences (Chin *et al.*, 2006), whereas others explained that "*it takes too long to get an appointment at the* [primary care] *clinic*" (Guttman *et al.,* 2003). Dissatisfaction with other services can lead to parents preferring to attend PED, where they feel that they have access to more specialised medical care. For example, Williams *et al.* (2009) found that 24% of parents cited the expertise of doctors at PED as a key reason for attendance. A positive past experience in PED can also encourage parents to reattend in the future (Berry *et al.*, 2008).

A commonly reported reason by parents for PED attendance is because they are unable to get a GP appointment. The majority of the surveys highlight that parents and carers attend PED because of a lack of access or perceived lack of access to other services (particularly primary care) (Hendry *et al.*, 2005; Berry *et al.*, 2008; Williams *et al.*, 2009; Graham *et al.*, 2010; NHS Newcastle Gateshead CCG, 2015; Rowe *et al.*, 2015).

D. Social network influence

Costet Wong *et al.* (2015) found that some parents viewed going to PED as a sign of responsible and loving parenthood, although this was not among the main reasons for attendance. Rowe *et al.* (2015) found that a minority of parents attended PED partially to placate their family members' concern, quoting one parent as saying "*I wasn't too concerned when [the child] started wheezing as he had a cold at the time…but I felt I should go [to PED] because my sister was so worried.*"

Hendry *et al.*'s (2005) survey agrees with this. 28% of families stated their reason for non-urgent PED attendance was because they were advised by somebody else to attend. Further

evidence in Graham *et al.*'s (2010) study describes how the advice offered by other parents or day care staff shaped parents' expectations about their unwell child.

Reaching a decision on where and when to seek medical attention is often a social process, meaning that parents often attend PED after receiving advice from a friend or relative (Berry *et al.*, 2008). For example, Ogilvie *et al.* (2016) found that 29% of parents reported advice they received from someone as being an important reason for their attendance at PED. Rowe *et al.* (2015) identified some social factors explaining why concern for an unwell child may be more likely to translate into attending PED compared to in the past. For example, modern family structures tend to be more dispersed compared to previous generations, meaning that parents are less able to draw on grandparents for help when their child is unwell.

Another issue is that modern parents have access to online forums and search websites. Although these websites can provide parents with valuable healthcare information, they also rely on the reader to curate their contents and judge which sources of information are reliable and relevant to their own situation (Graham *et al.*, 2010). In some cases, these websites increase parental anxiety. For example, Rowe *et al.* (2015) quotes one parent as saying "*Google is very useful sometimes, but it can also be dangerous – you put in a symptom and it tells you that your child has meningitis*." Similarly, some respondents in that survey reported being confused by conflicting healthcare advice on forums like Mumsnet compared to official websites like NHS Choices.

E. Structural factors

Parents may attend PED because of external or structural reasons. For example, parents may have followed the advice of a medical professional to attend PED (Rowe *et al.*, 2015). In Chin *et al.*'s (2006) study, 10 out of 12 participants had been sent to PED by a primary care physician. These participants were confused about this, and in some cases angry about a PED attendance for an illness they considered to be minor.

Families also stated that primary care facilities are not always open, and therefore they choose to attend an ED out of hours as EDs are open 24 hours a day. This was supported by two participants in Guttman *et al.*'s (2003) study: *"Nowhere to go this late"* and *"Nothing else is open."*

The inability to take time off work, and therefore a requirement to attend out of hours, was also identified as a reason. Families attended ED because they would not be able to get a GP appointment in the morning before going to work. Parents described having few options to choose from, and so opted for ED. One parent in Berry *et al.*'s (2008) study confirmed this: *''… I work [a] second shift, and I can't afford to take time off work, with all my children. That's why, of course, I'm here.''*

However, although physicians and healthcare experts often cite structural factors as an important reason for non-urgent PED attendances, only 6% of parents in Costet Wong *et al.*'s (2015) survey stated that they attended PED because of these factors.

2.3.4 Discussion of literature review findings

This narrative review identified a number of underlying reasons for non-urgent PED attendance. Using thematic analysis, the identified reasons were categorised into 11 sub-themes. These sub-themes were then grouped into five main themes (Table 2.7).

The literature indicates that families attend PED with a non-urgent health concern because caregivers may not be confident in their ability to manage the health of their sick child. The evidence suggests first-time parents are more likely to attend PED seeking advice regarding the health of their unwell child. Parents or carers that lack this confidence or lack health knowledge may also seek reassurance from healthcare professionals when they have already taken the right steps at home.

The studies included in this review identified that in many cases, families attended non-urgently because they were either dissatisfied with their GP or perceived a lack of availability of GP appointments. Some caregivers reported that they felt GPs are not equipped to deal with the specialist nature of childhood illness. Distrust of other healthcare services combined with a positive perception of PED may mean that PED is considered the default option whenever a child becomes unwell, regardless of how seriously unwell they are.

Although cited in fewer studies, the impact of social network influence has been identified in this review. Parents' decision to attend PED for a child with a non-urgent illness can be influenced by friends and relatives. In addition, media campaigns and websites (such as blogs and social forums) may be contributing to a family's decision to non-urgently attend at

hospital. In England, the changing nature of social support structures may mean that parents that would previously have drawn on older relatives for support now explore alternative options for support when their child is unwell.

Structural factors such as direct referral by another healthcare professional (e.g. a GP) or the fact that all other services were closed when they required health support out of hours. In England, out-of-hours support for managing minor illness and access to primary care is currently available. It may be that these findings are less generalisable to the NHS in England.

Five sub-themes were identified as having high reliability as they were cited multiple times and identified in high-quality studies (these are highlighted in Table 2.8). The remaining sub-themes were considered to be medium or low quality, and were identified in fewer of the included studies.

Table 2.8: ***Factors influencing non-urgent PED attendance*** *(those identified as having 'high reliability' are highlighted in green).*

Main theme	Sub-theme	Number of times cited	Reliability of findings
A. Parental worry	Perception of the seriousness of the child's illness	8	High reliability
	Need for reassurance	4	High reliability
B. Perceived advantages of PED	PED staff have greater expertise with children	3	Medium reliability
	PED is convenient and provides better quality of care	4	High reliability
C. Perception that other healthcare services were not suitable	Lack of access to primary care services	7	High reliability
	Dissatisfaction with quality of primary care	3	High reliability
D. Social network influence	Desire to be considered by others as a responsible parent	1	Low reliability
	Pressure from family, friends and social media	4	Low reliability
	Erosion of traditional support networks	1	Low reliability
E. Structural factors	Referred by a healthcare service	4	Medium reliability
	Out of hours	2	Medium reliability

The findings from this study suggest that the five sub-themes that influenced parents' or carers' decision to attend PED, and can be considered most reliable, were:

- “Perception of seriousness of the child’s illness”;
- “need for reassurance”;
- “PED is convenient and provides better quality of care”;
- “lack of access to primary care services”; and
- “dissatisfaction with quality of primary care”.

Although this is a narrative review, and these findings cannot be considered generalisable to the contexts beyond the identified studies, these findings provide an indication of the underlying factors that may be more likely to lead to non-urgent attendance at PED and are therefore also applicable to non-urgent reattendance. These findings suggest there is an opportunity to reduce non-urgent PED reattendance by attempting to address the main themes: “parental worry”, the “perceived advantages of PED” and the “perception that other healthcare services were not suitable”.

2.3.4.1 Limitations

With any search strategy there is a risk of key papers or references being unintentionally missed. This may be due to the search terms selected, or the limitations of chosen databases. To reduce the risk of missed references, the search strategy for this project was intentionally broad and utilised electronic databases from multiple subject areas.

Publication bias may exist in this review because the majority of searches were undertaken in electronic databases of peer-reviewed journals. There is increasing awareness that studies that include positive or interesting findings are more likely to be published, and indexed higher, in these electronic databases. In order to address this limitation, grey literature searches were also conducted using search engines.

2.3.5 Conclusion

This literature review identified a number of underlying reasons why parents and carers bring their children to PED. These reasons fall into five broad categories: (i) parental worry, (ii) perceived advantages of PED, (iii) perception that other healthcare services were not suitable, (iv) social network influence and (iv) structural factors.

A 'reliability rating' for identified sub-themes in this review, comprised of the quality assessment of the studies citing the theme and the number of times cited, was generated. This reliability rating indicated that of the most reliable key reasons for non-urgent attendance at PED, three predominated: "parental worry", the "perceived advantages of PED" and the "perception that other healthcare services were not suitable". Any intervention that attempts to address the challenge of non-urgent PED attendance should target these key factors to improve patient outcomes and reduce the burden on PED.

2.4 What interventions attempting to reduce non-urgent PED attendances have previously been evaluated?

This thesis describes a research project that developed and evaluated an intervention designed to reduce non-urgent reattendance at PED. Prior to the development of this intervention it was important to systematically review the literature from previous studies that have evaluated the effectiveness of interventions with a similar objective. This systematic literature review analysed randomised controlled studies (RCTs) of interventions targeting non-urgent emergency reattendance in paediatric populations.

2.4.1 Framing the research question

The PICOS (Population; Intervention; Comparison; Outcome; Study Type) formulation was selected for the formulation of the research question in this systematic review (Methley *et al.*, 2014). This review question was formed from the PICOS components listed in Table 2.9.

Table 2.9: ***PICOS framework components***

PICOS framework for research question	
Population	Families attending ED with a child aged 0 to 18 years old, presenting with a non-urgent condition
Intervention	Any intervention attempting to reduce non-urgent ED reattendance delivered by the ED or PED
Comparison	Usual ED or PED care
Outcome	Measure of non-urgent reattendance at ED or PED
Study Type	Randomised controlled studies

This systematic review sought to answer the research question: what interventions have successfully reduced non-urgent PED reattendances, compared to usual PED care, using an RCT study design?

2.4.1.1 Aim

- To identify interventions that have been successful or unsuccessful at reducing the rate of non-urgent reattendance at PED.

2.4.1.2 Objectives

1. Search for and critically review a comprehensive body of literature.

2. Identify the key learning from the reviewed studies.

3. Provide recommendations for development of a targeted intervention to reduce children's non-urgent ED reattendance.

2.4.2 Systematic review methodology

Systematic reviews are considered the gold standard method for searching, collating, critiquing and summarising the best available evidence regarding the effectiveness of an intervention in a clinical context (Liberati *et al.*, 2009). Systematic review findings provide the most valid evidence base to inform the development of clinical guidelines, and support clinical decision-making. They follow a structured research process, requiring rigorous methods to ensure reliable and meaningful results (Aromataris and Pearson, 2014).

Initial scoping searches confirmed that a number of RCTs evaluating the effectiveness of interventions delivered in PED on non-urgent reattendance had previously been published. In view of the existence of robust studies, it was confirmed that a systematic review was the most appropriate review methodology to answer this research question.

2.4.2.1 Eligibility criteria

Inclusion criteria

All publications that met the following criteria were included:

(i) Population includes children aged between 0 and 18 years old.

(ii) Refers to non-urgent attendances.

(iii) Compares the effect of the intervention to usual ED care.

(iv) Study design is a randomised controlled trial.

(v) Outcomes include a measurement of non-urgent reattendance.

Exclusion criteria

Publications that met the following criteria were excluded from the review:

(i) Article not available in the English language.

(ii) Population described in the article does not include children.

(iii) Study describes urgent attendances or trauma.

(iv) Children reattending ED for follow-up tests requested by clinicians.

(v) Any observational studies.

(vi) Any non-randomised studies.

2.4.2.2 Information sources

This review utilised a range of relevant electronic databases. The three electronic databases that were used were:

- MEDLINE (1946 to December 2016);
- EMBASE (1947 to December 2016);
- CINAHL (1981 to December 2016);

In addition, the trial registries '*ISRCTN*' and '*clinicaltrials.gov*' were searched for any unpublished RCTs relating to the research question.

These databases covered the topic areas relevant to this review: medical literature and allied healthcare professions research. No date limit was put on the electronic database searches as part of this review. Searches were only limited by the date ranges available through each individual electronic database.

2.4.2.3 Search strategy

The components of the research question were used to generate the search strategy. The strategy used free text synonyms for non-urgent attendance. These synonyms were obtained from a 2013 literature review exploring the effect of primary care interventions on non-urgent attendance in adults (Ismail, Gibbons and Gnani, 2013).

The following search strategy was applied to the databases mentioned above:

MEDLINE (via Ovid) Search strategy

1. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
2. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
3. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
4. exp Randomized Controlled Trial/ or exp Random Allocation/ or exp Clinical Trial/ or Random* allocate*.tw. or (allocate* adj2 random*).tw
5. 1 and 2 and 3 and 4

Examples of the full search strategies used for each electronic database are included in *Appendix C*.

2.4.2.4 Study selection

Following the electronic database searches, all citations were transferred into *Mendeley*. Duplicate articles were removed using the 'deduplication' function within *Mendeley* prior to the screening of publications (Mendeley, 2016).

Initial decisions regarding eligibility were based on the publication titles. These were assessed against the prespecified eligibility criteria. Following title screening, the references were screened by their abstracts. For all the leftover studies, the full-text articles were reviewed against the inclusion and exclusion criteria stated in section 2.4.2.1. Finally, any

studies identified from the trial registries ISRCTN and 'clinicaltrials.gov' were assessed against the same inclusion and exclusion criteria.

2.4.2.5 Data collection

An example of a completed data extraction form can be found in *Appendix D*. The data extraction form was developed from the *Cochrane Public Health Data Extraction and Assessment Template* (Cochrane Public Health, 2016). Use of a standardised data extraction form provides consistency in a systematic review, reduces bias and improves validity. Use of an electronic extraction form simplified analysis of the data. The form was piloted on two studies to ensure that relevant information was captured, and time was not used to extract unwanted data.

2.4.2.6 Quality assessment

A number of well-established methodological tools have been developed for assessing the risk of bias in RCTs, with the Cochrane Collaboration's RoB (Risk of Bias) Tool now considered the standard (Jørgensen *et al.*, 2016). For this systematic review the *RoB 2* (Cochrane Risk-of-bias Tool for Randomized Trials version 2.0) was used (Higgins *et al.*, 2016).

2.4.2.7 Data analysis and synthesis

Principal summary measures were dependent on how data was collected and presented in the included studies.

Scoping searches suggested that due to limited published literature on this topic, included studies were likely to vary in study type and quality. For this reason, it was anticipated that narrative synthesis would be utilised to explore study findings. Narrative synthesis allows patterns and differences in study methods and data to be explored.

Combining the results from diverse non-randomised study types is discouraged. Meta-analysis in this situation may compound any errors and biases between studies and give traction to poor-quality studies. Due to the expected large amount of heterogeneity between studies, meta-analysis was not deemed appropriate for this systematic review (Sterne, *et al.*, 2008).

2.4.3 Systematic review findings

The results from this systematic review are discussed in the following sections.

2.4.3.1 Identified studies

Searches of the three electronic databases were completed using the search strategy described in section 2.4.2.3. The number of results from each of these searches is detailed in Table 2.10.

Table 2.10: ***Results of electronic database searches***

Search number	Database	Number of references returned by search
1	MEDLINE (1946 to December 2016)	105
2	EMBASE (1947 to December 2016)	278
3	CINAHL (1981 to December 2016)	79
Total references:		462

The combined search strategies identified 462 publications. The duplicates were removed, and the eligibility criteria were applied to all remaining studies. The PRISMA flowchart in Figure 2.2 summarises the stages at which studies were excluded.

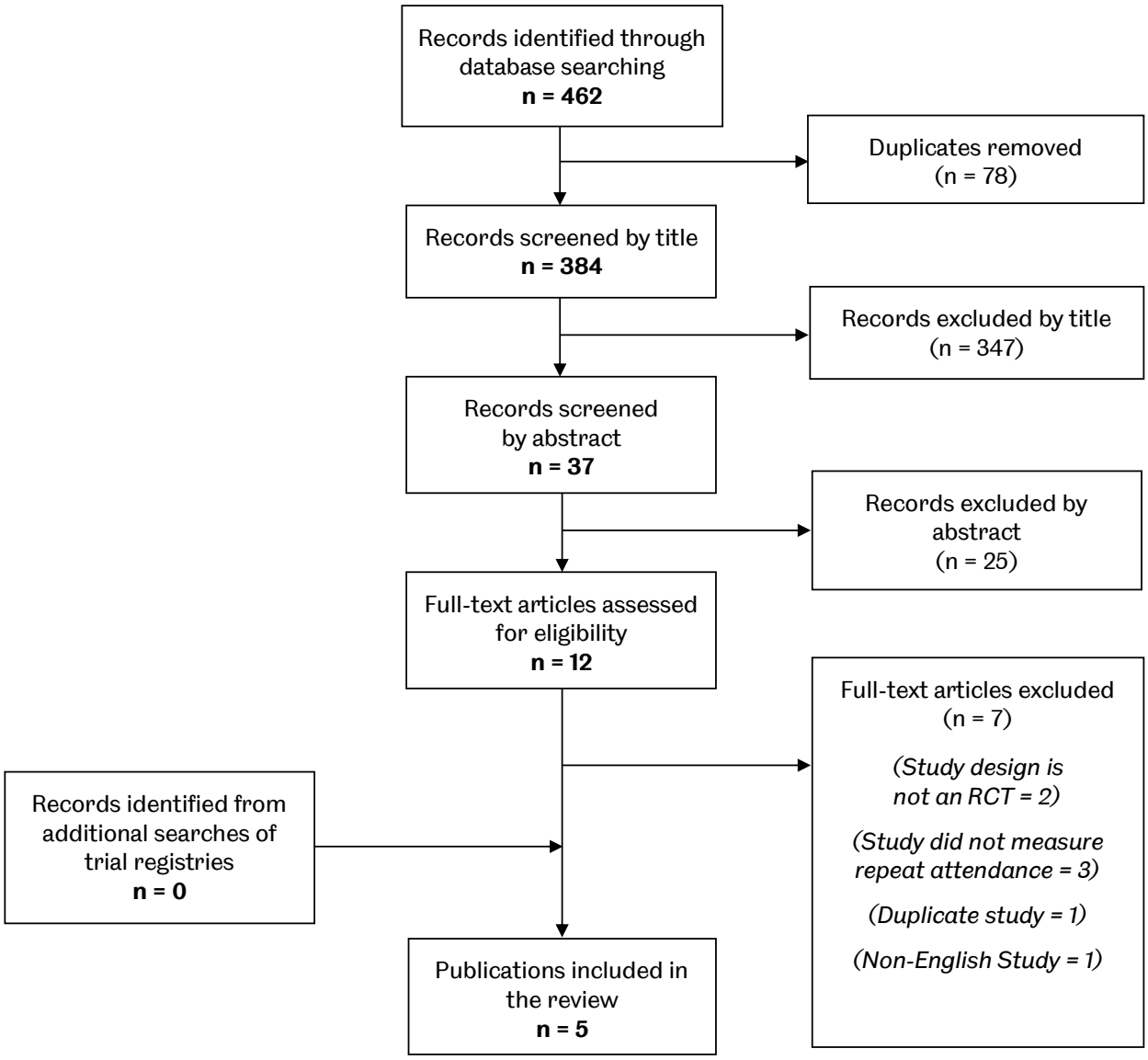


Figure 2.2: ***PRISMA Flowchart of Study Selection Process.***
This flowchart is amended from that presented in "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement" by Moher et al., 2009).

The explanation for why six studies were excluded at the full-text review stage is summarised in Table 2.11.

Table 2.11: ***Reason for study exclusion after full-text review***

Article	Reason for exclusion
(Mark D Baker *et al.*, 2009)	Study type is not an RCT.
(Huang, Huang and Chang, 1997)	Non-English study.
(O'Keefe, 2010)	The study did not measure repeat non-urgent attendance.
(Shenoi *et al.*, 2010)	The study did not measure repeat non-urgent attendance.
(Sturm and Simon, 2011)	Duplicate reference of a study already included in this review.
(Yang and Chen, 2012)	Study type is not an RCT.
(Zorc *et al.*, 2003)	The study did not measure repeat non-urgent attendance.

Five publications were identified from electronic databases for this review. No further RCTs were identified from additional searches of trial registries '*ISRCTN*' and '*clinicaltrials.gov*'. The final five included publications are summarised in Table 2.12.

2.4.3.2 Study characteristics

All five included studies were undertaken in the USA and aimed to determine the effectiveness of additional health information and/or follow-up support in reducing repeat non-urgent PED attendances. The studies were published in peer-reviewed journals between 1991 and 2014, and all used a prospective RCT study design (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Racine *et al.*, 2009; Sturm *et al.*, 2014). None of the studies were found to be registered on the trial registries *ISRCTN* or *clinicaltrials.gov*. The characteristics of each study are summarised in Table 2.12 and Table 2.13.

Table 2.12: ***Characteristics of included studies***

Study author (study date)	Study design	Population	Definition of non-urgent attendance	Intervention	Comparator	Outcome
Chande *et al.* (1996)	RCT	Families of children (aged 0–18 years) attending PED of a university hospital.	As determined by triage nurse's categorisation of presenting complaint.	**Booklet** on common childhood medical problems, and watched a **10-minute video** in ED about common conditions and role of primary care.	The control group received the standard PED discharge instructions	No statistical difference between the intervention group and those in the control group (p=0.46).
Chande and Kimes (1999)	RCT	Children under 13 months old that presented to the PED for evaluation of minor illness.	As determined by triage nurse's categorisation of presenting complaint.	**30-minute session to review child's medical record** with a parent, discussion on primary care roles, and 24-hour telephone advice service.	Families in the control group did not receive the health promotion intervention and did not have a follow-up appointment scheduled.	No significant difference between intervention and control groups who made at least one (p=0.59) or two or more (p=0.95) ED visits for minor illness at a year follow-up.
Nelson *et al.* (1991)	RCT	Parents of children younger than eight years who sought care in the ED for acute illnesses and required primary care centre follow-up.	Case is free of active chronic illness, and a chief complaint suggesting an acute infectious or allergic condition.	**Follow-up call with a nurse practitioner** who offered both individualised guidance and further telephone follow-up if required.	The control group received "usual" follow-up advice during ED visits.	No difference between the intervention group and those in the control group. No statistical analysis.
Racine *et al.* (2009)	RCT	Parents or carers of patients (aged 0–21 years) of four primary care paediatric practices attending PED of a children's hospital.	Cases diagnosed as having "an episodic illness" by an ED physician. Retrospectively categorised.	**Telephone contact** with participants 72 hours after non-urgent PED visit to provide advice, counsel on PED use and schedule any primary care follow-up.	Patient families in the control patients received routine PED care.	Significant reduction in the number of visits to PED by subjects in the intervention groups (p<0.001) 12 months after the index PED visit.
Sturm *et al.* (2014)	RCT	Parents or carers of patients (aged three months to 16 years) that presented to the PED for a low acuity condition.	Attendances with low triage score that did not require investigations or admission after ED physician assessment.	Provided **a hand-out at discharge** that identified information about primary care practice, managing common conditions. Plus, **a ten-minute session** for explanation and questions.	Control patients were managed with the standard of care; they were given routine discharge instructions by the PED nurse.	No significant difference at six months follow-up between the two groups (p=0.14). At 12 months follow-up, there was a significant difference (p=0.046).

Population

Across the five studies identified there was a total of 5,087 participants. For four of the studies, the overall number of participants was between 130 and 332 (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Sturm *et al.*, 2014). However, the sample size (n = 4246) for Racine *et al.*'s (2009) study was much greater than the four other studies combined. The majority of participants in all studies were registered with a primary care service and reported to have medical insurance. Two studies (Chande *et al.*, 1996; Chande and Kimes, 1999) report that a small number of participants had underlying chronic health conditions, although these numbers were reported to be comparable between the intervention and control groups. The numbers of participants in the intervention and control groups for each table are included in Table 2.13.

Table 2.13: ***Further details regarding included studies***

Study author (study date)	Country of origin	Source of funding	Study setting	Number of participants	Length of study
Chande *et al.* (1996)	USA	Clinical research initiation grant from *Rainbow Babies and Children's Hospital, Cleveland, Ohio.*	PED of an academic children's hospital.	Intervention, n = 69 Control group, n = 61.	6 months
Chande and Kimes (1999)	USA	No research funding stated.	ED of a children's hospital.	Intervention, n = 102 Control, n = 93.	12 months
Nelson *et al.* (1991)	USA	*Robert Wood Johnson Foundation General Pediatric Academic Development Award.*	Urban university hospital PED.	Intervention, n = 91 Control, n= 93.	8 days
Racine *et al.* (2009)	USA	Supported by grant funding from *The Commonwealth Fund of New York City .*	PED of an academic children's hospital.	Intervention, n = 2166 Control, n = 2080.	12 months
Sturm *et al.* (2014)	USA	Supported by an institutional grant from *Children's Healthcare of Atlanta*.	ED of a children's hospital.	Intervention, n = 164 Control, n = 168.	12 months

<u>Non-urgent attendance definition</u>

Three studies defined non-urgent attendance based on the triage scores allocated to children on arrival at ED (Chande *et al.*, 1996; Chande and Kimes, 1999; Sturm *et al.*, 2014). The definitions from the remaining two studies relied on ED physician assessment, taking into account relevant diagnoses and investigations required (Nelson *et al.*, 1991; Racine *et al.*, 2009).

This means that three studies that recruited families therefore enrolled patients prospectively after ED nurse evaluation (Chande *et al.*, 1996; Chande and Kimes, 1999; Sturm *et al.*, 2014). Racine *et al.* (2009) recruited participants retrospectively from ED administrative data, and Nelson *et al.* (1991) enrolled participants retrospectively after ED physician evaluation.

Interventions

In four of the studies, interventions were based in the EDs and delivered as part of the ED discharge procedure (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Sturm *et al.*, 2014), whereas in Racine *et al.*'s (2009) study the intervention was delivered by a designated primary care provider 72 hours following the participants' non-urgent ED visit.

All interventions were targeted at the parent or carer. The content of the interventions included medical information on the self-management of minor illness at home (Chande *et al.*, 1996), primary-care-specific information regarding the conditions typically managed by primary care and out-of-hours services (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Racine *et al.*, 2009; Sturm *et al.*, 2014), information on "appropriate ED services usage" (Chande and Kimes, 1999; Racine *et al.*, 2009) and follow-up of participants to arrange and encourage subsequent visits to primary care (Nelson *et al.*, 1991; Racine *et al.*, 2009). Interventions were delivered either through printed materials (Chande *et al.*, 1996; Sturm *et al.*, 2014), videotapes (Chande *et al.*, 1996), in-person sessions (Chande *et al.*, 1996; Chande and Kimes, 1999; Sturm *et al.*, 2014) or telephone sessions (Nelson *et al.*, 1991; Racine *et al.*, 2009). Studies either used one mode of delivery (Nelson *et al.*, 1991;

Chande and Kimes, 1999; Racine *et al.*, 2009) or multiple (Chande *et al.*, 1996; Sturm *et al.*, 2014).

Four of the five studies (Nelson *et al.*, 1991; Chande *et al.*, 1996; Racine *et al.*, 2009; Sturm *et al.*, 2014) did not report on the theoretical construct of the interventions they developed. None of the studies involved parents or carers in the development of content. However, paediatric nurses were involved in the development of the intervention in Sturm *et al.*'s (2014) study.

Comparator

The comparator used in each of the studies remained consistent across all five studies. All control groups received standard or usual care in the ED (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Racine *et al.*, 2009; Sturm *et al.*, 2014).

Outcome measurement

The primary outcome measure reported by all the studies was repeat non-urgent ED attendance. In all studies, the monitoring of non-urgent reattendance occurred only within the same ED as for the original non-urgent attendance (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999; Racine *et al.*, 2009; Sturm *et al.*, 2014). This means that if a family chose to attend another hospital ED elsewhere, they would not be included in the analysis.

2.4.3.3 Quality assessment

Four of the included studies were assessed to be of moderate quality (Nelson *et al.*, 1991; Chande and Kimes, 1999; Racine *et al.*, 2009; Sturm *et al.*, 2014). Only Chande *et al.* (1996) was deemed to be a poor-quality RCT following quality assessment. The risk of bias scores is summarised in Figure 2.3. Reasons for each score are provided in Table 2.14.

No study used a true randomisation process for allocation of participants to intervention or control groups. In addition, all studies were unable to blind participants or staff members delivering care to the interventions. Only one study (Nelson *et al.*, 1991) explicitly referred to the blinding of outcome assessors to participants group allocation, and only Chande and Kimes (1999) detailed a clear and specific analysis plan. Four studies managed to include all trial participants in their analysis of outcome date.

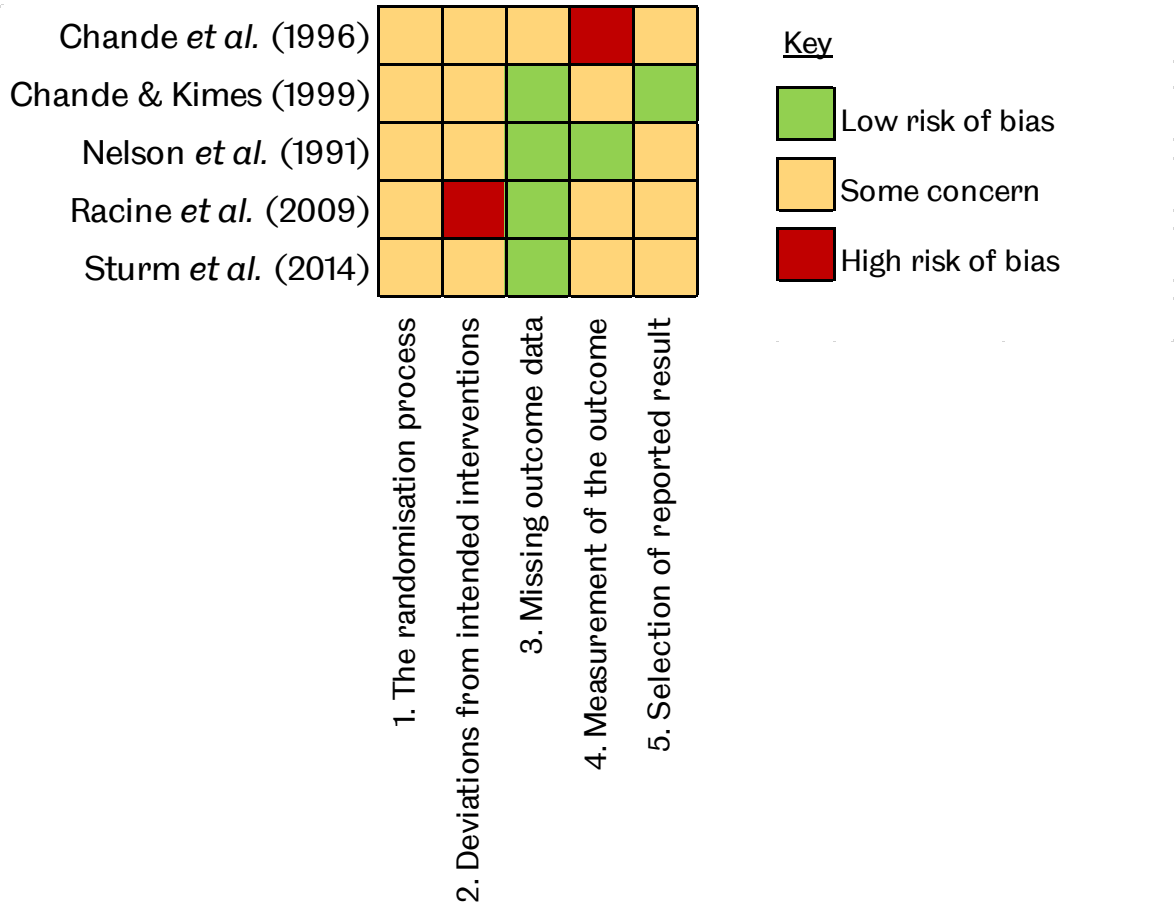


Figure 2.3: ***Risk of bias assessment*** *- calculated using the RoB 2 checklist.*

Table 2.14: ***Risk of bias assessment results for included studies***

Study author (study date)	Domain 1: The randomisation process	Domain 2: Deviations from intended interventions	Domain 3: Missing outcome data	Domain 4: Measurement of the outcome	Domain 5: Selection of reported result
Chande *et al.* (1996)	**Some concern**: Although groups were randomly allocated. No evidence of true randomisation (i.e. centralised randomisation process, sequential allocation etc.)	**Some concern**: No blinding of participants, carers or staff, although the outcome is unlikely to be affected. Not addressed in the article.	**Some concern**: Missing outcome data acknowledged. However, no information regarding how missing data is balanced across intervention and control groups.	**High-risk:** No blinding of outcome assessment. Assessment of outcome likely to be influenced by knowledge of intervention received.	**Some concern**: No information regarding whether multiple analyses were planned prior to trial. No pre-published protocol.
Chande and Kimes (1999)	**Some concern**: Although groups were randomly allocated. No evidence of true randomisation.	**Some concern**: No blinding of participants, carers or staff, although the outcome is unlikely to be affected. Not addressed in the article.	**Low-risk:** Data available for all participants in trial.	**Some concern**: No information regarding blinding of outcome assessment. Unlikely to be impacted by knowledge of intervention allocation.	**Low-risk:** Limited and specific outcome measures detailed in trial report. No indication of additional analyses.
Nelson *et al*. (1991)	**Some concern**: Although groups were randomly allocated. No evidence of true randomisation.	**Some concern**: No blinding of participants, carers or staff, although the outcome is unlikely to be affected. Not addressed in the article.	**Low-risk:** Data available for all participants in trial.	**Low-risk:** Outcome assessors were blinded to the participants' intervention allocation.	**Some concern**: No information regarding whether multiple analyses were planned prior to trial. No pre-published protocol.
Racine *et al.* (2009)	**Some concern**: Although groups were randomly allocated. No evidence of true randomisation.	**High-risk:** Interventions may deviate from those allocated at start of trial resulting in unbalanced allocation and incorrect analysis.	**Low-risk:** Data available for all participants in trial.	**Some concern**: No information regarding blinding of outcome assessment. Unlikely to be impacted by knowledge of intervention allocation.	**Some concern**: No information regarding whether multiple analyses were planned prior to trial. No pre-published protocol.
Sturm *et al.* (2014)	**Some concern**: Although groups were randomly allocated. No evidence of true randomisation	**Some concern**: No blinding of participants, carers or staff, although the outcome is unlikely to be affected. Not addressed in the article.	**Low-risk:** Data available for all participants in trial.	**Some concern**: No information regarding blinding of outcome assessment. Unlikely to be impacted by knowledge of intervention allocation.	**Some concern**: No information regarding whether multiple analyses were planned prior to trial. No pre-published protocol.

2.4.3.4 Assessment of study outcomes

Two out of five of the RCTs reported trials with statistically significant reductions in repeat non-urgent PED attendance.

Racine *et al*.'s (2009) study identified participants after their ED visit for a non-urgent illness. This involved the largest number of participants. Families in the intervention group were contacted via telephone by a primary care service 72 hours after their non-urgent ED attendance. They were counselled about the primary care services available and given advice on the "appropriate" use of ED. Callers then supported them to arrange primary care follow-up appointments, if required. The authors reported a 3% statistically significant difference in non-urgent PED reattendance between the intervention and control groups at 12 months.

The RCT study by Strum *et al.* (2014) also recruited participants into their trial after assessment by an ED clinician. As part of the discharge care, participants in the intervention group were provided with written information on the service provided by primary care, plus a 10-minute session for explanation and questions. At six months follow-up, no significant reduction in non-urgent ED visits was identified in the intervention group; however, at 12 months, a statistically significant difference of 11.5% between the two groups was reported.

The three remaining studies reported no statically significant effects following the interventions (Nelson *et al.*, 1991; Chande *et al.*, 1996; Chande and Kimes, 1999).

2.4.4 Discussion of systematic review findings

This review assessed the effectiveness of interventions aimed at families of children presenting to PED with non-urgent illness. The interventions appear to have addressed some of the underlying reasons for non-urgent PED attendance described in the literature review in section 2.3. The interventions addressed knowledge about the seriousness of the child's illness, perceived advantages of PED care and availability of primary care services through the provision of additional information following discharge, support on self-management of minor illness in children, and access to primary care services.

Overall the review findings demonstrate inconclusive evidence for the effectiveness of additional information at discharge, or follow-up support on non-urgent reattendance. Only two studies reported a statistically significant difference in the number of repeat attendances after 12 months, and both studies were of moderate quality (Racine *et al.*, 2009; Sturm *et al.*, 2014).

There was insufficient evidence from the studies described that brief additional support provided in the PED at the point of discharge had an impact on reattendance. These interventions may be counterintuitive to parents' instincts and behaviours regarding the health of their children, demonstrated by a desire to seek PED care for their children in non-urgent situations (Guttman *et al*. 2003; Hendry *et al*. 2005; Berry *et al.*, 2008). A greater focus on the underlying reasons and parent or carer behaviours in the design of an intervention may provide a greater chance of success. Any future intervention should also involve parents or carers in the design process. Co-design with this caregiver population

may allow underlying factors to be taken into account and therefore reduce non-urgent PED reattendance.

All studies included in this review were undertaken in the USA, and therefore findings may not be generalisable to other healthcare systems and national contexts. Potential contextual confounders include health insurance, socioeconomic status and the provision of specialised paediatric primary care.

As discussed in the introductory chapter of this thesis (section 1.3.1), the underlying causes of non-urgent attendance are complex and influenced by both behavioural and structural factors. It should be acknowledged that the impact of interventions such as those described in this review may only be part of the complex solutions required for this multifaceted health policy challenge.

2.4.4.1 Limitations of the review

As anticipated, there was a high level of heterogeneity observed in participant characteristics, interventions and outcome measurement of included studies. This meant that meta-analysis could not be used to synthesise observed results from the studies to produce a pooled estimate of intervention effects. Four of the included studies had small sample sizes and no study reported the 95% CI for the reported primary outcome measure. This limited the conclusions that could be drawn in this review.

The robust nature of the search strategy excluded non-experimental studies from this review. This may mean relevant studies of lower methodological quality were not included.

In order to capture the learning from additional non-experimental studies, narrative synthesis of a number of relevant studies is included in section 2.5. Furthermore, this review limited searches to the English language, which may have excluded relevant studies published in other languages.

2.4.5 Conclusion

This systematic review demonstrates that there is currently no conclusive evidence to support the effectiveness of specific intervention in reducing non-urgent PED reattendance. There is a need for further in-depth research to evaluate interventions in healthcare systems outside of the USA. Future research should consider involvement of families in the design and testing of the intervention.

2.5 Narrative synthesis of additional relevant studies

As highlighted in the discussion on the limitations of the systematic review (section 2.4.4.1), non-experimental studies were not included in the review. This is because research that does not use RCT study design is considered to be less robust. However, there are a number of examples of educational interventions targeted at families of children presenting to PED with a non-urgent illness. To ensure this research project is adequately informed by additional relevant literature, this section includes a narrative synthesis of studies that did not meet the systematic review inclusion criteria.

Potentially useful literature has described interventions targeting specific conditions such as asthma, fever, and respiratory infections. A literature review by Walsh and Edwards (2006) of studies published from 1980 to 2004 found that educational interventions can improve parents' ability to manage feverish children. For example, Robinson *et al.* (1989) describe a US study targeting over 500 children that attended a paediatric clinic because of fever. Half of the parents were shown a ten-minute slideshow entitled "Fever in children: Fears and facts". All parents were given a pamphlet which covered the main points in the slideshow. Compared to parents who only received the pamphlet, parents who also saw the slideshow itself had significantly better fever knowledge after three months, and after six months had 35% fewer fever-related reattendances.

Francis *et al.* (2009) examined the effect of training clinicians in the use of an eight-page interactive booklet about respiratory tract infections in children. This booklet was designed to improve communication during consultation with patients and act as a take-home resource for parents to improve their ability to self-care. Using a cluster RCT design

involving 61 GPs across England and Wales and 558 parents, the authors found that 55% of parents who received the booklet self-reported being likely to attend the GP in the future for a similar illness compared to 76% of parents who did not receive the booklet.

Another study from 2010 involving almost 600 parents in 35 US states evaluated an easy-to-read self-help guide called 'What to Do When Your Child Gets Sick' (Herman and Jackson, 2010). Parents who received the booklet self-reported to be 58% less likely to attend PED and 42% less likely to attend a GP over a three-year period. Another RCT from 1990 involving 98 families attending a Danish GP examined the effect of a 15-page booklet on managing childhood illness (Hansen, 1990). The authors found that parents who received this booklet were significantly more likely to undertake self-treatment at home. Lastly, an RCT reported by Thomson *et al.* (1999) tested the effect of providing parents with an illustrated 'Baby Check' booklet for evaluating illness in very young babies. This study found that the booklet did not affect the mothers' use of healthcare services.

An alternative intervention delivery mechanism that has been studied is video education. An RCT by Baker *et al.* (2009) involving 280 parents presenting to PED with feverish young children tested the effect of providing a brief educational video on the home management of fever (during their time in PED). While parents who watched the video were measured to have improved knowledge about childhood fever, they were as likely to return to PED because of fever as parents who had not seen the video. A similar study in Canada involving 246 children exposed parents in a PED waiting room to a video about managing common childhood illness (Rosenberg and Pless, 1993). These parents were also provided with a

pamphlet containing similar information. This intervention had no significant effect on PED reattendance measured through number of repeat visits to PED.

Although not all of these educational interventions were successful, and the outcomes measured varied between studies, they provide an example of the types of intervention that may be effective at influencing parent and carer behaviour regarding PED attendance. Adaptation of interventions that are both acceptable to parents and successful is likely to help address non-urgent reattendance of children at emergency and urgent care settings.

2.6 The importance of safety netting

As discussed in section 1.2.2, there are challenges associated with the recognition of seriously unwell children. Clinical assessment of unwell children can be challenging as children can be more unwell than they first appear, and their condition can rapidly deteriorate. Any designed intervention that aims to reduce non-urgent attendance should also ensure children that are seriously unwell receive prompt medical attention. This highlights the importance of safety netting.

The ASK SNIFF (Acutely Sick Kids – Safety Netting Interventions for Families) research programme has explored this challenge in detail. The aim of the ASK SNIFF research is to help families with young children understand signs and symptoms of acute illness, to enable them to identify when their child is sick (Jones *et al.*, 2013).

Neill *et al.*'s (2016) study, conducted as part of the ASK SNIFF research programme, sought to identify the underlying reasons for parent and carer decision-making during acute childhood illness at home. Parents reported that decision-making during acute childhood illness was influenced by personal, social and health service factors such as the nature of the child's illness; parents' experience and knowledge of childhood illness; social support; access to health services; trust in healthcare professionals; and social expectations of parents during acute childhood illness. The study findings clearly overlap with those identified from the narrative review in this thesis (section 2.3.3.4).

Neill *et al*. (2016) conclude by acknowledging that current professional and political solutions have not reduced demand, and that collaborative approaches that involve the public and professionals are needed. They identify that research is needed to determine the most effective methods for increasing parents' knowledge and confidence in the assessment and management of childhood illness.

Additional research by the ASK SNIFF programme identified the desirable safety-netting attributes of resources developed to support parents and carers in the identification of serious illness (Jones *et al.*, 2014). These mechanisms were identified by parents and clinicians, and are summarised in Figure 2.4.

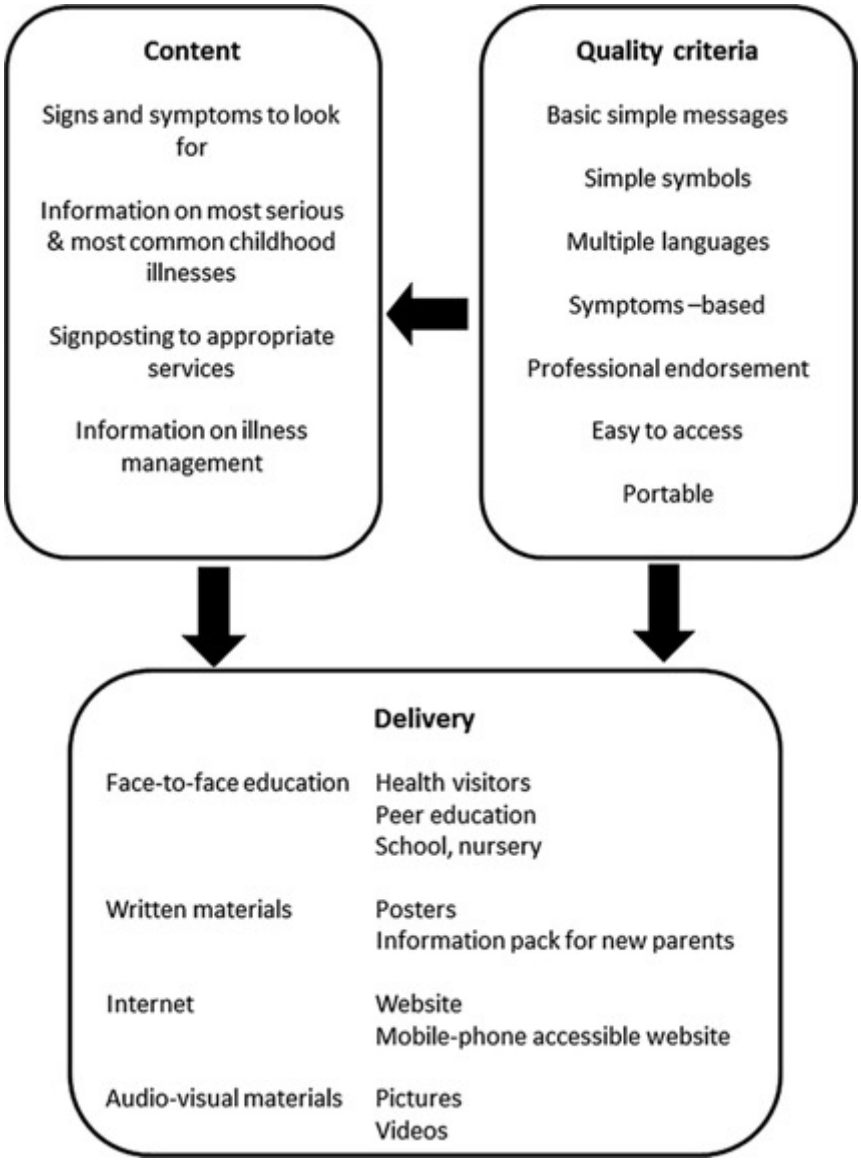


Figure 2.4: ***Content, quality criteria and delivery mechanisms for safety netting information, suggested by the parents and clinicians****. Figure taken from Jones et al. (2014). Image reproduced with permission of the rights holder, BMJ Publishing Group Limited.*

These criteria, combined with the literature review findings, provide a firm foundation for the development of a targeted intervention that seeks to reduce non-urgent reattendance and appropriately safety net, ensuring seriously unwell children continue to attend hospital for emergency care.

2.7 Nudge-type interventions with potential for changing behaviours

As introduced in section 1.5, the application of behavioural science is increasingly being used across the healthcare system to address a wide range of challenges.

None of the studies evaluated as part of this literature review chapter have explicitly drawn upon behavioural insights to inform an effective intervention to reduce non-urgent PED reattendances. The decision to bring a child to PED with a non-urgent healthcare problem is driven by human behaviour. By applying a 'behavioural insight' lens to the challenge of non-urgent attendance, there is the potential to bring about greater healthcare system efficiencies and improve patient care quality and experience.

Nudge theory is a concept in behavioural economics, which proposes indirect suggestions and small changes to information or the environment as ways to influence the behaviour and decision-making of groups or individuals. Nudging contrasts with other ways to achieve compliance, such as education, legislation or enforcement (King *et al.*, 2013).

The techniques evaluated below use behavioural insights to influence individual behaviour. They give examples of the types of nudges that may be effective in a healthcare context.

‘Messenger effect’

The degree of weight or influence that individuals give to information is dependent on their automatic reactions to the perceived authority of the source of the information. The information source can be termed the ‘messenger’. Published evidence suggests that indications of authority (or credibility) can generate compliant behaviour (Mulgan, 2010).

This authority can be generated through delivery of the information by experts. One study demonstrated that health interventions delivered by research assistants and health educators were more effective in changing behaviour compared with interventions delivered by either trained facilitators or teachers. In addition, the specialist health educators were considered more persuasive than the research assistants (Webb and Sheeran, 2006).

Further studies show that a professional recommendation or endorsement can be effective at changing healthcare behaviours (Wardle *et al.*, 2015). For example, ‘*delivery [that] comes from a trusted source*’ has been identified as an important active ingredient of audit and feedback interventions. Trust in clinical guidelines is likely to be much higher when the source is a professional association, in comparison to insurance companies, even with identical recommendations (Tunis *et al.*, 1994).

For patients, trust in the source of information is an important determinant of vaccination uptake (Rubinstein *et al.*, 2015). Two studies provide evidence that recommendations from a clinician increase vaccination uptake (Rosenthal *et al.*, 2011; Gargano *et al.*, 2013).

Similarly, a lack of a clinician's recommendation is one of the most common reasons for an individual not having a vaccine (Johnson *et al.*.

Hewitson *et al.* (2011) looked at whether a general practitioner's (GP) letter encouraging participation and a more explicit leaflet explaining how to complete a faecal occult blood test (FOBT) included with the England Bowel Cancer Screening Programme invitation materials would improve uptake. The inclusion of both an endorsement letter and a more explicit procedural leaflet was estimated to increase participation in the English Bowel Cancer Screening Programme by ~10%, a relative improvement of 20% on prior performance (Hewitson *et al.*, 2011). A recent review article identifies further evidence that a GP's signature on a screening invitation letter has a positive effect on uptake (Camilloni *et al.*, 2013).

This 'messenger effect', which is likely due to an automatic deference to formal sources of authority, appears to prompt behaviour that would not take place without the suggestion from an authority figure or expert.

Personalisation

Evidence suggests that people pay more attention to personalised messages than general ones (Service *et al.*, 2014). This builds on the theory that all members of society develop strategies for noting information that may be more relevant to them as individuals. For example, as certain names (like a person's own name) take on significance, their attention is drawn to them quickly and effortlessly when they occur (Newman, 2005).

In addition, personalised messages make it easier for the recipient to imagine the costs or benefits of a particular action. In other words it allows them to identify 'what this means for me' (Parker *et al.*, 2015).

A study based in a US city added personalised post-it notes to sewer bill envelopes which read '*John, you really need to read this*.' Along with changes to the letter (including a 'Pay Now' stamp), payment rates within 29 days rose by 137 per cent, from 8.1 per cent to 18.6 per cent (Garner, 2005). In a very similar study, a handwritten post-it note request on envelopes increased response rates to a survey by the Irish Revenue from 19.2% to 36.0% after 15 working days (Irish Revenue, 2013).

Further examples of personalisation being used to encourage payment have shown that adding someone's name to an otherwise generic text message increased the amount of money paid in a trial conducted with HM Courts Service (Haynes *et al.*, 2013). Another research group used tax letters that ensured that doctors knew that they were being focused on as a distinct group, rather than as generic taxpayers. This considerably increased response rates (Parker *et al.*, 2015).

A systematic review from 2009 included a meta-analysis of randomised controlled trials investigating the effects of personalisation of covering letters accompanying postal questionnaires (Edwards *et al.*, 2009). The results suggested that an approach in the form of personalised letters, questionnaires or envelopes improved final response rates by a modest amount (odds ratio 1.16, 95% confidence interval (1.07, 1.26)). Together these examples

suggest there is particular scope for attracting attention and making information more pertinent through personalisation.

Making an intervention timely

Members of society appear to be more receptive to changes at moments that seem significant to them. Evidence suggests that these moments can be prompted by an external event that disrupts existing patterns of behaviour, or by an individual's personal reflection on a recent situation (Shum, 1998; Alter and Hershfield, 2014).

Events related to health can act as moments for change. A large study from the US suggests that having major surgery doubles the likelihood of quitting smoking. This is particularly true for surgery related to smoking such as treatment of cancer and heart disease (Shi and Warner, 2010). Another study demonstrated that minor operations also increased stop smoking rates by 28 percent and, due to their high occurrence, they have a major impact on population level quitting rates (Keenan, 2009). Timing an intervention around the surgery can increase this effect. People given a brief preoperative consultation by a nurse (involving smoking cessation brochures, referral to a quit helpline and access to six weeks of nicotine replacement), were 2.7 times more likely to achieve long-term cessation than people who received treatment as usual (Lee *et al.*, 2015).

Timing is also crucial when considering the behaviour of healthcare professionals. Professionals' hand hygiene compliance deteriorates over the course of a shift, with small peaks in compliance directly after breaks (Dai *et al.*, 2015). This highlights that self-control may be a limited resource, and that interventions need to be timed to counter the '*decision*

fatigue' that can develop over a demanding shift. There are examples of timely handwashing interventions that could be used to do this. This includes messages used to prompt handwashing, but some others that are more creative and use ideas such as creating 'clean' smells as triggers (Judah *et al.*, 2009; Grant and Hofmann, 2011; King *et al.*, 2016).

Simple and clear information design

Information design both in terms of text and language (for example, the use of 'plain English' and behaviourally specific, concrete statements and a clear presentation of risk) and appearance (for example, colour, visual stimuli, images) may all influence how engaging or persuasive health information is (Michie and Lester, 2005; Thorndike *et al.*, 2014). There are numerous forms of healthcare information that might be better designed with implications for behaviour change, including clinical guidelines, discharge and handover templates, checklists, patient information sheets and educational resources (Perry *et al.*, 2015).

For information to be effective in changing behaviour, it is important to direct attention to key messages and be as clear as possible about required actions or behaviours. The Behavioural Insights Team (BIT) has identified several principles of information presentation for more effective communication:

- ensuring key messages are presented as early as possible;
- keeping language simple; being specific about recommended actions;
- providing a single point of contact for responses;
- removing all information not absolutely necessary for performing a desired behaviour; and

- the broader idea of breaking down complex goals into simpler, easier actions (Service *et al.*, 2014).

Examples of how the use of simple, clear information and actions has improved health outcomes include a study that trialled the development of a clear self-care plan with patients during hospital discharge. This reduced readmission rates by 30% over the following month, compared to usual discharge procedure, and was shown to work in both acute care and nursing homes (Jack *et al.*, 2009). Another study developed a 'fast and frugal tree' (a decision tree that asks one question at a time) to reduce the number of factors that clinicians have to consider. This significantly increases the accuracy of predicting heart attacks, compared to more complex systems that try to account for many risk factors (Gigerenzer, 2008).

Other work has shown that identifying how a complex goal (e.g. 'stopping smoking') can be broken down into simpler, easier actions (e.g. ordering a quit kit) can change behaviour and improve patient outcomes. This is based on the insight that it is easier to effect change through simple steps ('stages of change') and that we learn by using simple 'chunks' of information (Gobet *et al.*, 2001).

2.7.1 Opportunity of nudges

These examples demonstrate how relatively small changes can improve the effectiveness of interventions. It has been argued that these nudges are not dissimilar to 'common sense'. However, common sense or rational thinking is not always applied to healthcare service or intervention design (Ebbeling *et al.*, 2002; Leventhal *et al.*, 2011).

Standard economic theory is based on the simplifying assumption that people always behave rationally. However, behavioural economics and nudge theory are based on the assumption that people sometimes act "human" and irrational (Thaler and Sunstein, 2008). It is this reasoning that has led to the example studies described in this section that aim to prove (through experimentation) that common sense changes do make a difference.

There is evidence to suggest that the effect of the nudges described can be further enhanced by combining several nudges. For example, incorporating messenger effect into a personalised intervention with some simple and clear messaging (Taylor *et al.*, 2013; Backman *et al.*, 2015).

In the context of this thesis, nudges provide an opportunity to enhance the effectiveness of a developed intervention. Nudge theory is an additional tool that can be combined with stakeholder input, the evidence base and a theoretical understanding of the problem to address a health policy issue such as non-urgent PED reattendance.

2.8 Implications of literature review

Together both the narrative review (section 2.3) and systematic review (section 2.4) provide valuable insights into the potential causes of and solutions to the issue of non-urgent PED attendance. The findings provide useful context for the design and development of the overall research project.

The reasons why parents or carers choose to attend PED with a child with non-urgent illness have been categorised into 11 sub-themes. These sub-themes can be prioritised and combined with learning from the behavioural insights literature to design an intervention supported by relevant theory. The findings from the literature review aid prioritisation of these sub-themes as the following five were identified has having 'high reliability:'

- "Perception of seriousness of the child's illness";
- "need for reassurance";
- "PED is convenient and provides better quality of care";
- "lack of access to primary care services"; and
- "dissatisfaction with quality of primary care".

Further evidence for the design and development of a relevant and effective intervention is provided by through the evaluation of experimental studies that have tried and tested other interventions in this area. The evidence regarding effective interventions is inconclusive. However, it does highlight the need for future research in this area and provides useful learning on how future studies could improve on previous ones. For example, involving caregivers in the design of the proposed intervention, trialling interventions outside of the

USA and providing a theoretical basis to intervention development may all increase the effectiveness of a designed intervention in reducing non-urgent reattendance.

Important findings from the literature regarding safety netting provide important context for any designed intervention. This work highlights the content and the quality criteria that should be incorporated into interventions; for example, information on illness management and the signs and symptoms to look out for.

The systematic review (section 2.4) did not identify studies that explicitly utilised an understanding of behavioural science or methods to influence behaviour when attempting to reduce non-urgent PED reattendance. This highlights an opportunity to incorporate behavioural insights into the design of a novel intervention that targets non-urgent PED reattendance through the use of nudge-type interventions. Examples of nudges that could be incorporated into intervention design include the use of the 'messenger effect,' personalisation and simplification of key messages.

Using the findings from both literature reviews, a list of key recommendations has been produced. These recommendations may be considered as requirements for the development of an intervention to address non-urgent reattendance, and design of an effective study to evaluate the intervention.

2.8.1 Recommendations

1) **Any designed intervention should have a greater focus on the underlying reasons for non-urgent attendance.** Through targeting the "perception of seriousness of the child's illness" and caregivers' "need for reassurance", an intervention may have a greater chance of success.

2) **Interventions developed to address the rise of non-urgent PED attendance should have a strong theoretical basis**. They should be informed by the factors that influence parent or carer PED attendance behaviour.

3) **Nudge-type interventions should be considered as a useful method to increase the effectiveness of proposed interventions**. Evidence-based behavioural insights provide an opportunity to improve the efficacy of designed interventions.

4) **Parents and carers should be involved in the intervention design process**. Participatory design methods can empower participants to adapt an intervention to suit their own contexts. Interventions need to have contextual fit, to be responsive to the community and the target population (Jagosh *et al.*, 2012).

5) **Future studies should employ rigorous methods, such as randomised controlled trials with adequate sample sizes to provide sufficiently powered results**. Emergency and urgent care is an evolving context, and randomisation can ensure distribution of all known and unknown confounders.

6) **The effectiveness of any developed intervention should be tested in a UK healthcare setting**. Non-urgent PED attendance is a challenge internationally. However, there is currently no robust experimental data from countries other than the USA. More evidence is required from different global contexts.

7) **Any study should acknowledge that the challenge presented by non-urgent PED attendance is complex and multifactorial**. Any designed intervention is unlikely to address behavioural and structural factors.

2.7 Chapter summary

This chapter provides detail on two robust literature reviews carried out to inform the overall research project. The narrative review draws upon systematic methodology to identify the factors that influence a family's decision to attend PED with a non-urgent health concern. The systematic review identifies that current evidence regarding interventions has not been explicit in how they were meant to reduce non-urgent reattendance. Overall the findings from previous evaluations of interventions are inconclusive, and further research in this area is required. The chapter ends with a discussion of the research implications and a list of recommendations drawn out from the literature review findings.

Chapter 3: Intervention Design

3.1 Chapter introduction

This chapter describes the development of theory underpinning the design of a complex intervention that aims to reduce repeat non-urgent attendance of children at urgent and emergency care locations. This theory is then used to inform the design of a targeted intervention. These processes follow the framework described in the MRC guidance on "Developing and evaluating complex interventions" (Craig *et al.*, 2008).

This chapter covers section 1.2 and 1.3 of the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008) (Table 3.1).

Table 3.1: ***Section 1.2 and 1.3 of the MRC Framework*** *– Extracted from Table 1.2.*

1	**Developing a complex intervention**		
1.2	Identifying and developing theory, plus intervention design	i.	Use of literature review findings, meeting with stakeholders and subject experts to decide on theory and intervention strategies
		ii.	Qualitative studies with stakeholder groups to develop intervention content
1.3	Modelling process and outcomes	i.	Used causal modelling approach to link determinants of behaviour to attendance behaviour

3.2 Aim of the study

The second key aim of this study is develop a targeted intervention that aims to reduce the non-urgent reattendance of children at urgent and emergency care locations. This will be achieved through the achievement of these three objectives:

Aim 2: To develop a targeted intervention that aims to reduce non-urgent reattendance at PED.
Objectives
Use evidence from the critical literature review to and review of theoretical models to inform the design of a targeted intervention.
Gather qualitative feedback from families and healthcare professionals to inform the intervention design.
Apply learning from behavioural insights to the intervention design.

3.2.1 Revisiting the overall project aim

The overall aim of this research was to develop an intervention that reduced non-urgent paediatric reattendance at urgent and emergency care facilities and to test its effectiveness.

Practically, this means that instead of choosing to reattend a PED or UCC following a previous attendance for a non-urgent health concern, the family would instead choose to do one of the following:

- Self-manage the condition at home and not seek healthcare advice;
- contact NHS 111 for health advice and access to healthcare services;

- visit a community care location (such as a pharmacy for supporting managing minor illnesses); or
- visit a primary care facility (see a GP).

The designed intervention sought to shift demand of repeat attendances away from ED or UCC and instead to one of the alternative options listed above (and discussed in Section 1.4).

3.2.2 Project requirements

In line with agreements in place with the study funder and identified research sites, there were two key requirements of the overall research study. These were:

1. Any designed intervention must be based in emergency and urgent care settings.
2. Behavioural insights should be applied to any designed intervention.

3.3 Identifying the evidence base

The literature review in Chapter 2 identified seven recommendations for intervention and trial design (section 2.8.1). These are summarised below:

1) Any designed intervention should have a greater focus on the underlying reasons for non-urgent attendance.

2) Interventions developed to address the rise of non-urgent PED attendance should have a strong theoretical basis.

3) Nudge-type interventions should be considered as a useful method to increase the effectiveness of proposed interventions.

4) Parents and carers should be involved in the intervention design process.

5) Future studies should employ rigorous methods, such as randomised controlled trials with adequate sample sizes to provide sufficiently powered results.

6) The effectiveness of any developed intervention should be tested in a UK healthcare setting.

7) Any study should acknowledge that the challenge presented by non-urgent PED attendance is complex and multifactorial.

Development of a targeted intervention to address non-urgent PED reattendance, and the trial designed to evaluate the effectiveness of the intervention, set out to encompass all seven of these recommendations.

3.4 Identifying and developing theory

The MRC guidance on "Developing and evaluating complex interventions" suggests that an intervention is likely to be more effective if based on relative theory (Craig *et al.*, 2008). In order to design the targeted intervention, a theoretical understanding of the likely process of change was developed from the review of the evidence base, an existing model regarding parental decision-making and interviews with stakeholders.

3.4.1 Multi-disciplinary steering group

An expert multi-disciplinary steering group was established to support the intervention design process and eventual trial development. This group included parents and carers that had experience of managing unwell children and a range of professionals from healthcare and academic organisations. The membership of this group is summarised in Table 3.2.

Table 3.2: ***Intervention and trial design steering group membership****.*

Intervention and Trial Design Steering Group		
Parents and carers with experience managing unwell children *North West London communities*	Consultants in Paediatric Emergency Medicine *Acute NHS Trusts*	Consultants in General Paediatrics *Acute NHS Trusts*
General Practitioners *Various North West London locations*	Clinical Commissioning Leads for Children and Young People *Clinical Commissioning Groups*	Patient Information and Communications leads *Acute NHS Trust*
Consultant in Paediatric Infectious Diseases *Acute NHS Trust*	Professor of Paediatrics & Child Public Health *Academic institution*	Policy specialists and academics with a background in behavioural economics and social psychology

3.4.2 Parental worry

The narrative review (section 2.3) identified 11 factors (sub-themes) that are likely to influence non-urgent PED attendance and therefore impact repeat attendance behaviour. Five of these sub-themes were rated as having high reliability. These have been extracted from Table 2.7 and are presented below with their corresponding main themes in Table 3.3.

Table 3.3: ***Identified influencing factors with a high reliability****.*

Main theme	Sub-theme	Reliability of findings
A. Parental worry	Perception of the seriousness of the child's illness	High reliability
	Need for reassurance	High reliability
B. Perceived advantages of PED	PED is convenient and provides better quality of care	High reliability
C. Perception that other healthcare services were not suitable	Lack of access to primary care services	High reliability
	Dissatisfaction with quality of primary care	High reliability

The main themes identified from the review were evaluated by members of the multi-disciplinary steering group in order to prioritise the focus of the designed intervention. It was concluded that as this research study was required to take place in emergency and urgent care locations (see requirements outlined in section 3.2.2), this project was unable to address the sub-themes "Lack of access to primary care services" and "Dissatisfaction with quality of primary care."

Further discussion led to the conclusion that "PED is convenient and provides better quality of care" is a positive concept and that this study sought to support alternative avenues of care, not reduce the quality of existing care provision.

This discussion and prioritisation exercise led to the exclusion of two main themes from the focus of the intervention ("B. Perceived advantages of PED," and "C. Perception that other healthcare services were not suitable"). It was agreed that this research project would seek to address "A. Parental worry" in order to reduce childhood non-urgent reattendance at urgent and emergency care.

3.4.2.1 Health literacy

The systematic review that evaluated previously trialled interventions aiming to reduce non-urgent reattendance at PED (section 2.4) did not identify any commonly used theory to inform the interventions used. The theoretical construct of the intervention was only referred to in one out of the five included studies, and this theory was not explored in any detail (Chande and Kimes, 1999). However, although the delivery mechanisms of the interventions varied, they all appeared to have a common goal: to improve caregivers' health literacy.

Health literacy is defined as "*the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions*" (Kindig *et al.*, 2004).

Published literature suggests that over half of parents presenting to the emergency department (ED) with their children have low health literacy, which affects their ability to make health decisions for their child (Morrison *et al.*, 2014). One study identified that a child had 50% more ED visits if their parents had low health literacy, regardless of whether the child has a chronic illness (Kindig *et al.*, 2004). Another study suggests that of children without a chronic illness, those whose parents had low health literacy had more than three times the odds of presenting to the ED for a non-urgent visit, such as for a cold or a rash illness (Tran *et al.*, 2008). Further evidence demonstrated that children older than 2 years presenting to the ED with fever were more likely to have a non-urgent visit if their parent had low health literacy (Morrison *et al.*, 2014).

In the absence of an identified theory from the systematic literature review, discussion with the expert steering group led to the consideration of relevant published theories in this area (section 3.4.2.2).

3.4.2.2 Personal control and perceived threat

In 1996, Kai evaluated 'parental worry' with regards to acutely unwell preschool children and identified that a "lack of personal control" was paramount to a caregiver's decision to seek advice from other healthcare professionals or attend an ED (Kai, 1996b). In multiple studies, Kai describes the correlation between perceived threat of harm from illness and a parent's sense of control (Kai, 1996b, 1996a).

Kai's in-depth exploration of parental worry identified that the two factors fundamental in shaping their responses were parents' sense of personal control when faced with illness in

their child and the perceived threat posed by an illness. The studies identify that a caregiver's personal control was lessened by a lack of experience in managing an unwell child and difficulty establishing the severity of a childhood illness (Kai, 1996b).

Kai (1996b) theorised that perceived threat resulting from parental worry could be seen as a continuous process that corresponded to the perceived effect of the illness and could be regulated by a parent's personal control. This is summarised in Figure 3.1.

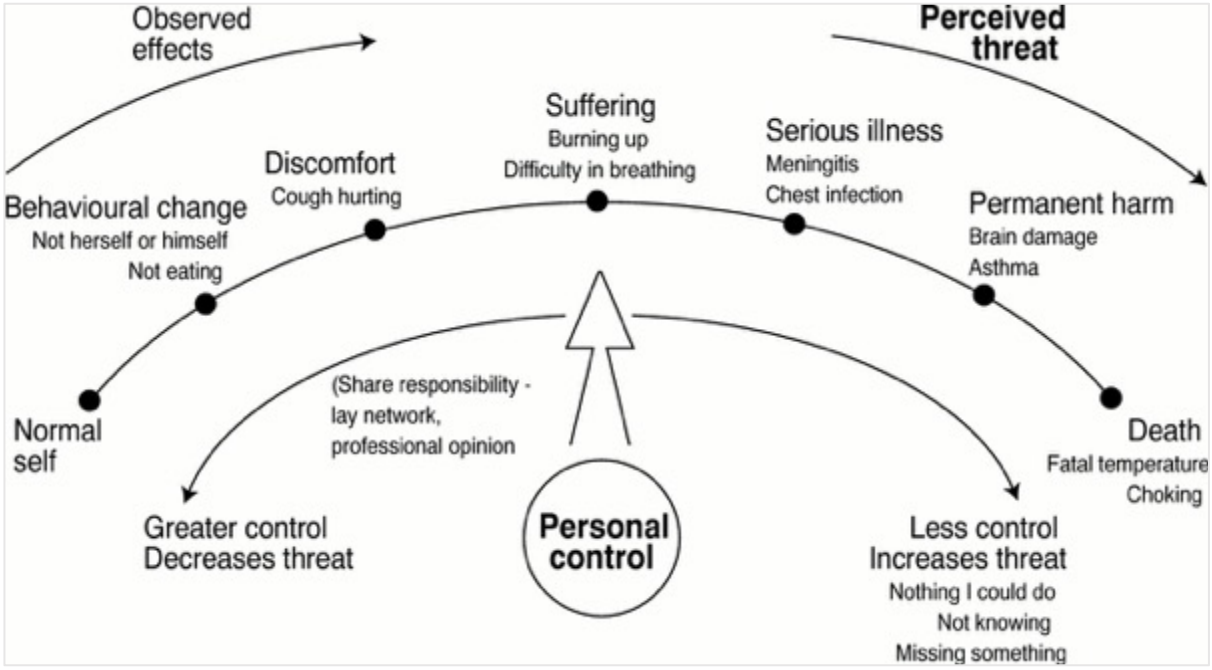


Figure 3.1: ***Interaction of personal control and perceived threat*** *(Kai, 1996b). Image reproduced with permission of the rights holder, BMJ Publishing Group Limited.*

Parental worry about failing to recognise a serious illness serves as a reminder that what is considered common knowledge for clinicians may not be readily accessible to parents and carers. Information and education that address parents' concerns may empower parents by

influencing perceptions of threat posed by an illness and enhancing personal control (Kai, 1996b).

A linked study by Kai (1996a) suggests that the education of caregivers, to improve health literacy can reduce parental worry and the associated healthcare behaviours. He theorised that the provision of healthcare information for parents and carers can reassure parents, allow them to identify severity of childhood illness and empower self-management (Kai, 1996a). This in turn may shift behaviour of parents and carers to alternative care facilities such as pharmacy, primary care or NHS 111.

3.4.3 Causal modelling of a theoretical framework

A theoretical framework for the targeted intervention was proposed. This was based on the findings from the literature reviews, an appreciation of health literacy and the theory of personal control and perceived threat proposed by Kai (1996). A causal model was used to link theoretically relevant determinants described in section 3.4.2 with the desired effect on parental worry. This model is summarised in Figure 3.2.

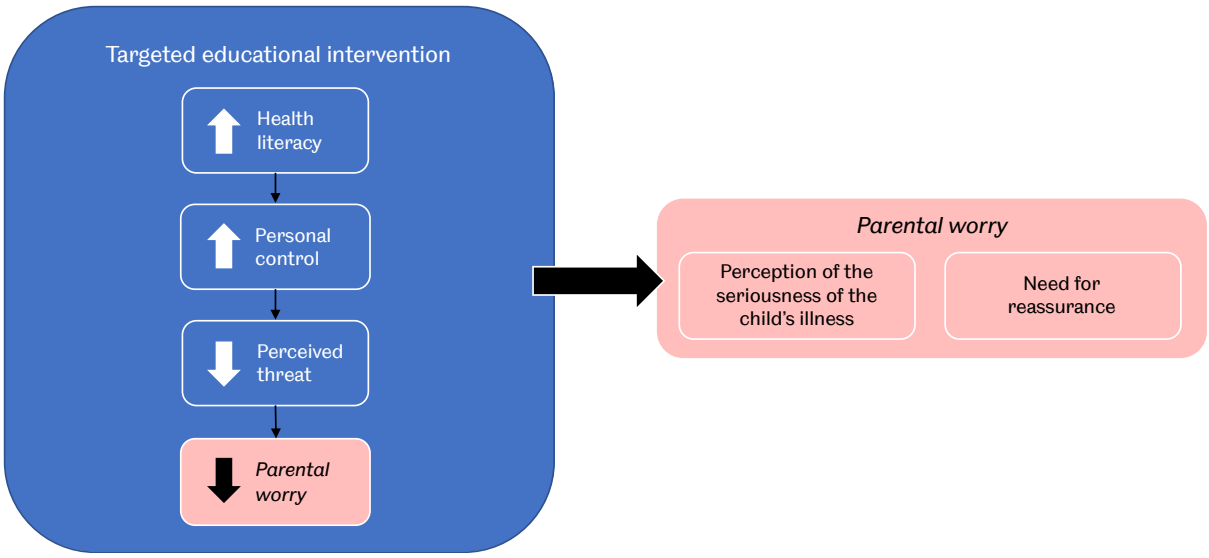


Figure 3.2: ***Hypothesised causal pathway for the targeted educational intervention****.*

This hypothesised causal pathway suggests that the provision of a targeted educational intervention will increase the health literacy of caregivers, thereby increasing the parent or carer's sense of personal control and reducing the level of perceived threat, which leads to an overall reduction in parental worry. This intervention should address the caregiver's need for reassurance and help support their ability to identify the seriousness of childhood illness.

It is important to note that from this point on, this thesis will refer to the concept of "parental worry" and its mitigation. Parental worry is used as a concept to summarise caregiver anxiety regarding child illness. This includes the anxiety of various situations included in Figure 3.1, such as the anxiety of serious illness, the anxiety of permanent harm coming to child or the anxiety of death. This also includes the anxiety that comes from being unable to contain illness within the home and associated anxiety that comes from accessing help for childhood illness described by Neill *et al*. (2016).

3.5 Qualitative research

Semi-structured interviews were conducted with caregivers that had experience managing unwell children, and healthcare professionals. All participants gave informed consent to take part in an anonymous interview. In total, eight parents and 12 healthcare professionals were interviewed (see Table 3.4 for details).

Table 3.4: ***Summary of semi-structured interview participants****.*

Interviewee	Number of interviews at each site			
	St Mary's PED	Northwick Park PED	Northwick Park UCC	Local community
Parent or carer				**8**
Healthcare professional *(breakdown below)*	**6**	**3**	**3**	
PED consultant	*1*	*1*		
PED registrar	*1*	*1*	*1*	
Paediatric nurse	*4*	*1*		
UCC GP			*1*	
Emergency nurse practitioner			*1*	

Although the healthcare professionals interviewed were recruited from St Mary's PED, Northwick Park PED and Northwick Park UCC, we did not interview parents in the hospital environment itself. This was because we wanted to avoid the potential risk of causing emotional distress to the families. Instead, parents for the interviews were contacted through the Connecting Care for Children (CC4C) practice champion programme, that linked into local community events such as '*Mother and Toddler*' groups and '*Enjoy your baby*'

classes. All the parents interviewed lived in White City, a district in the London Borough of Hammersmith and Fulham.

3.5.1 Patient and public involvement

Patient and public involvement (PPI) in research is where research is "*being carried out 'with' or 'by' members of the public" not just "'to', 'about' or 'for' them*" (NIHR, 2017). Involving members of the public in research is important for both ethical and practical reasons. Ethically, PPI is advocated on the grounds that those affected by a condition, or the wider public in the case of public health research, have a right to have a say in decisions about research that may affect them. Practically, involvement of members of the public can benefit the research process by ensuring research is relevant, that it is participant-friendly and that the research findings are made accessible and provided with sensitivity to study participants and the wider public once the study is complete (Bagley *et al.*, 2016).

The importance of PPI was reaffirmed through the findings of the literature review presented in Chapter 2 of this thesis. Recommendation 3 was "Parents and carers should be involved in the intervention design process". In order to satisfy a need for PPI in this project, parent and carer representation was included in the expert multi-disciplinary steering group for intervention design, and qualitative feedback was sought from caregiver volunteers recruited through the Connecting Care for Children (CC4C) programme.

Public and patient engagement is a key component of the CC4C programme that focuses on the paediatric population, and aims to tackle the disproportionally high rate of unscheduled paediatric care use in North West London. The key part to this is the practice champion

initiative (CC4C, 2015), which is modelled on the experience and expertise of similar initiatives, both locally and nationally, such as North West London's Community Champions Project (Stothard, 2012) and the award-winning community health champion model pioneered by Altogether Better in York (Altogether Better, 2017). Altogether Better was established in 2008 and since then has engaged over 18,000 volunteers as community health champions, who have in turn reached 104,000 others. Evaluation of their work has demonstrated positive behaviour change, improving health, more appropriate use of healthcare services and decreasing hospital admissions in adult populations (Woodall *et al.*, 2013).

CC4C practice champions are a group of patients, young people, parents and carers of children that receive training and support to become practice champions. Trained practice champions volunteer their time to work with patients and staff at their local GP surgery. They lead patient engagement and co-production by providing other children, parents and carers with peer support, signposting and education, facilitating self-management of care and offering a bridging role between the GP and the local community.

3.5.2 Semi-structured interview findings

In the qualitative interviews, healthcare professionals and parents were asked what they thought would improve the way caregivers managed the health of unwell children, with the goal of reducing their need to return to PED or UCC. One healthcare professional noted what a complex issue it is – "*there are many other factors other than health education that will influence reattendance, including how long they have to wait, whether they got seen by*

a doctor after initial assessment, whether they got any medication." However, both parents and healthcare professionals indicated a desire for improved discharge instructions.

3.5.2.1 Improving discharge instructions

Both caregivers and healthcare professionals noted the lack of clear discharge instructions for parents of children with a minor illness provided at discharge. One healthcare professional expressed that patients need "*advice as to where to go next time*" before leaving. If advice is provided, it is typically given verbally. In the words of one healthcare professional, "*nurses will try and talk about [the health issue] at triage and then the doctor will talk about it again when they assess*."

Another healthcare professional cited the existence of "*leaflets … which are quite good. I often say to parents, take this information and put it on your fridge, and if you are going to nursery give one to the nursery so they know what to look out for as well*." Similarly, another staff member said "*usually we give [parents] a booklet about injuries or medical problems."*

The absence of clear discharge instructions was perceived by several parents. One said "*They discharged my son and they said 'it's normal'. It would be good if they gave you an explanation so that in the future if it happened again, you would be aware of the situation and how to handle it*." Another said "*I didn't feel reassured with the information that was given about why I'd presented. Yes, they are telling me my child is fine, but I didn't feel like she was*." A different parent said "*There was no 'This is how you can manage it at home' or 'This is what you need to do'. Literally I cannot recall ever receiving a leaflet*." Another said

"*If they had given me something [to take away] I would have maybe felt a bit more empowered.*" One parent, talking about her request for written information at discharge, said "*It's not helpful, honestly… Nothing to do with the staff or anything, the staff are perfect – they are so good, but when it comes to a report or a proper document, they don't [provide one]".* The interviews explored what kind of information parents would like at discharge and two parents highlighted that the information should be specific: *"It would have to be related to why I was in A&E in the first place; if it was just general information about unwell children I probably wouldn't look at it."*

Several healthcare professionals cited time pressure as the main barrier to delivering more comprehensive discharge instructions. One said "*If you are a doctor on your own in the middle of the night, you can't spend 10 minutes with everyone patiently describing a detailed plan*." Another healthcare professional made the point that parents are often mentally exhausted to the point where they may not take in detailed instructions. Similarly, another healthcare professional said that parents would only take in information "*once they have been reassured that their child is well. Triage especially is not the time to give them a leaflet to read as nothing is going to sink in then.*" Another barrier to staff providing detailed discharge instructions is the tendency for staff members to shift into 'fire-fighting' mode during particularly busy shifts. At this time, staff prioritise the sickest patients and have limited capacity to give detailed discharge instructions for non-urgent attendances.

3.5.2.2 Improving discharge information

When asked what materials could improve the discharge procedure, one healthcare professional said "*Where I worked before we had a really useful 'Ways to Care for a Sick Child' leaflet. A booklet that directed different example illnesses to particular services, I think we need something like that again. Something like 'Where is right for me?*" Similarly, another healthcare professional expressed a desire for a written booklet covering '*What you encounter in the first five years' – maybe the very many common things that a child could have in the first five years of life, so diarrhoea and vomiting, wheeze, colds and viral illnesses.*" Another said "*Maybe something for [patients] to take away that says, this didn't need to be taken care of in A&E, this is the service you could have attended.*" Parents supported this and suggested some ideas: "*I would love to have something clear with child-specific healthcare advice on, like a fridge magnet or something that you would look at regularly" and "Something clear and simple, and easy to refer to would have been really helpful when my kids were young."*

In addition to providing materials during the PED pathway, several healthcare professionals expressed a desire for more parent education about child illness generally. One gave the opinion that there was a need for "*a massive drive for parent education, specifically on 'what to do if your child is unwell', what to look for, but …you would need to reprogramme what has already been taught and teach them again. Parents need to constantly be taught self-management skills and what to look for.*" Similarly, another healthcare professional said that some parents needed "*a bit more education on when it's appropriate to call an ambulance*." Another expressed a desire for more tools for parents outside the PED environment, saying "*I think we need to be more proactive – [providing information] in A&E*

is a bit reactive, but advice leaflets are as good as we've got really. There are apps out there as well, but I don't use them or signpost people to them."

These findings complement the narrative systematic review published by Neill *et al.* (2015), which states that educational material that addressed the assessment of illness severity as well as management of minor illness is more effective in supporting parents to care for their children and seek help when necessary. Findings from this review also identified that interventions providing information on multiple childhood illnesses or symptoms appeared to be more effective compared to interventions addressing single symptoms (S. Neill *et al.*, 2015).

3.6 Intervention context

It was important that the targeted intervention and research trial design were appropriate for the study contexts. In order to ensure a suitable trial and locally informed intervention, further information was collected regarding the study sites.

3.6.1 Description of the two research sites

This research study was conducted across two hospital sites in North West London: St Mary's Hospital and Northwick Park Hospital. Both sites have academic paediatric expertise and established programmes of research into paediatric urgent and emergency care through Imperial College London. However, the hospitals have disparate patient populations.

St Mary's Hospital is part of Imperial College Healthcare NHS Trust[iii] and is one the specialist major acute hospitals for North West London. It is a major trauma centre which provides a full range of services including paediatric and adult emergency departments, general paediatric inpatient wards and tertiary specialist paediatric services. There are around 27,000 attendances per year of children aged 17 and below at St Mary's PED.

Northwick Park Hospital is part of London North West Healthcare NHS Trust[iv] and is a major acute (general) hospital in the London Borough of Harrow. The hospital provides a full range of services including paediatric and adult emergency departments, and paediatric inpatient wards. Northwick Park Hospital Urgent Care Centre (UCC) is part of another healthcare

[iii] https://www.imperial.nhs.uk/

[iv] https://www.lnwh.nhs.uk/

organisation called Greenbrook Healthcare[v] and is located within the Northwick Park Hospital building, co-located with the paediatric and adult emergency departments. There are around 36,000 attendances per year of children aged 17 and below at Northwick Park PED and UCC.

3.6.2 Differences in emergency and urgent care systems

The structure of the emergency and urgent care departments differs between the two hospital sites. In order to better understand these differences, observations of the patient journey at St Mary's and Northwick Park Hospital were undertaken. The patient journey of each site is summarised in a process diagram in *Appendix E.*

As discussed in section 1.4, UCCs are medical facilities staffed by primary care physicians (GPs) and allied healthcare professionals. They provide immediate care for conditions that do not need to be seen in an ED. Many UCCs are based on hospital sites and are co-located with EDs. Both St Mary's Hospital and Northwick Park Hospital have a UCC and an ED on their hospital sites; however, the process for seeing non-urgent attendances differs between the hospital sites.

The two hospitals have a different relationship with and approach to the UCCs. The main difference is that, at Northwick Park Hospital, children presenting to hospital are first seen by a nurse in the UCC (streaming) who decides if the patient's illness is severe enough for

[v] http://www.greenbrook.nhs.uk/

PED. This process is almost reversed in St Mary's, where patients are first seen by a nurse in PED (triage) who determines if a patient is non-urgent and can be seen in UCC.

3.6.3 Background data of the two sites

In order to better understand the pattern of non-urgent attendance and reattendance at both hospital sites, previous attendance data was evaluated. Initially, a broad definition of non-urgent attendance was constructed using the data fields available in the St Mary's Hospital PED and Northwick Park Hospital UCC data set.

For this initial scoping exercise, the following criteria were used to define a non-urgent attendance at each hospital.

In St. Mary's the patient must:

(i) receive a triage score of 4 or 5 on the Manchester Triage System (this ranges from 1 (most severe) to 5 (least severe));

(ii) not have been admitted to the hospital; and

(iii) not have received any medical investigations (e.g. X-rays or blood tests).

In Northwick Park, the patient must:

(i) be streamed into the UCC, not PED;

(ii) not be triaged as 'urgent' at any point; and

(iii) not be referred to a paediatric or other specialist at any point.

These different criteria reflect the slightly different procedures at the two hospitals, but produce similar groups of children with non-urgent health concerns. Any attendance that has a non-UK postcode, or any attendances which are made by the same patient less than two hours apart (these are presumed to be duplicates) were excluded from the analysis.

3.6.3.1 Identifying a target population

After restricting the data to all attending children (aged 0–15) that met the non-urgent criteria outlined above, attendance rates were examined by age. Table 3.5 summarises the non-urgent attendances from January to December 2016. In that year, there were 12,935 non-urgent attendances at St. Mary's Hospital and 22,291 non-urgent attendances at Northwick Park Hospital. The average age for all non-urgent attendance was 4.4 (SD = 4.3) at St Mary's Hospital and 5.5 (SD = 4.5) at Northwick Park Hospital.

Table 3.5: ***Number of non-urgent attendances in 2016, by patient age, at St Mary's PED and Northwick Park UCC***

Age of child at presentation	St. Mary's PED	Northwick Park UCC
0	2631 (20.3%)	2363 (10.3%)
1	1958 (15.1%)	3224 (14.1%)
2	1227 (9.5%)	2136 (9.3%)
3	1077 (8.3%)	2052 (9.0%)
4	919 (7.1%)	1799 (7.8%)
5	826 (6.4%)	1657 (7.2%)
6	690 (5.3%)	1276 (5.6%)
7	508 (3.9%)	1159 (5.1%)
8	534 (4.1%)	1088 (4.8%)
9	466 (3.6%)	912 (4.0%)
10	459 (3.6%)	932 (4.1%)
11	380 (2.9%)	965 (4.2%)
12	361 (2.8%)	917 (4.0%)
13	309 (2.4%)	838 (3.7%)
14	292 (2.3%)	807 (3.5%)
15	298 (2.3%)	796 (3.5%)
Total	**12,935**	**22,291**

This table demonstrates that the highest proportion of non-urgent attendances occurs in the youngest age groups. In this data scoping exercise, children under five years old accounted for 60.4% of the 2016 non-urgent attendances at St Mary's Hospital PED, and 52.0% of those at Northwick Park Hospital.

These findings supports the evidence from national and international attendance data presented in section 1.2. It is widely reported that younger children are more likely to seek emergency and urgent care for non-urgent medical problems (Gill *et al.*, 2013; McHale *et al.*, 2013; Mann and Tempest, 2014; Ruzangi *et al.*, 2020).

3.6.3.2 Descriptive statistics

Table 3.6 summarises a number of descriptive statistics for both hospital sites from January to December 2016. These statistics only include children who meet all the non-urgent criteria outlined above (in section 3.4.3) and are aged under five years.

Table 3.6: ***Descriptive statistics for children aged under five years in the non-urgent samples from St Mary's PED and Northwick Park UCC****.*

Demographics	St. Mary's PED	Northwick Park UCC
Average age in years (standard deviation)	1.5 (1.4)	1.8 (1.4)
Age distribution of non-urgent attendees (%)	0: 33.6% 1: 25.0% 2: 15.7% 3: 13.8% 4: 11.8%	0: 20.4% 1: 27.9% 2: 18.5% 3: 17.8% 4: 15.5%
Proportion of female (%)	43.7%	N/A

Attendances	St. Mary's PED	Northwick Park UCC
Number of non-urgent attendances	7,820	11,543
Number of families	5,754	8488

Details of attendance	St. Mary's PED	Northwick Park UCC
Triage assessment	1. Unwell child (32.2%) 2. Shortness of breath (10.2%) 3. Diarrhoea, vomiting (8.2%) 4. Rashes (7.7%) 5. Worried parent (7.7%)	N/A
Discharge instructions	N/A	No follow-up (57.2%) Discharge to GP (42.8)

This summary of non-urgent attendance data in those under five years old shows that the average patient age of attendees was 1.5 years at St. Mary's Hospital and 1.8 years at Northwick Park Hospital, and around 50% of attendances in this group were aged under two years. The number of non-urgent attendances in 2016 was 7,820 in St. Mary's (originating from 5,754 families) and 11,543 in Northwick Park (originating from 8,488 families).

Different types of detail regarding attendance were available from the two sites. At St. Mary's Hospital, the top five coded reasons for attendance (as noted by a healthcare professional during the triage assessment) are listed. This information is not available in the Northwick Park UCC electronic record management system. At St. Mary's PED the most common reason for a non-urgent attendance is "unwell child." At Northwick Park (but not at St. Mary's), there is a record of what discharge instructions the patient receives. At St. Mary's Hospital, 57% of non-urgent attendances result in a discharge with no follow-up instructions; the remainder are directed to attend a GP.

3.6.3.3 Most common clinical presentations at PED

This data scoping exercise provides some indication of the most common reasons for non-urgent attendance at St Mary's PED. These are detailed in the row labelled 'Triage assessment' in Table 3.6. This helpfully identified three clinical presentations (shortness of breath, diarrhoea and vomiting, and rashes). However, it also identified 'Unwell child' and 'Worried parent.' Further delineation of the triage assessment label of 'Unwell child' was required.

An unpublished audit of the St Mary's Hospital PED attendances in 2016 was undertaken in 2017 (CC4C *et al.*, 2017). As part of this audit the PED attendances that were unlabelled, or labelled with general terms such as 'unwell child' or 'other presentation', were categorised by a team of paediatricians. CC4C and colleagues (2017) summarised 24,039 attendances from 2016 of children aged from 0 to 15 years. The 12 most common clinical presentations are summarised in Table 3.7.

Table 3.7: ***The most common clinical presentations identified from St Mary's Hospital attendance data****, for children aged 0–15 years old attending from January to December 2016.*

Presenting problem	Number of presentations (percentage of total)	Rank
Injury/ musculoskeletal	4145 (17.2)	1
Upper respiratory tract infection	3842 (16.0)	2
Diarrhoea & vomiting/ gastroenteritis	1780 (7.4)	3
Head Injury	1468 (6.1)	4
Wheeze (including asthma)	1376 (5.7)	5
Rash/skin infection	1314 (5.5)	6
Well child/worried parents	856 (3.6)	7
Neonatal presentations: Feeding issues/colic/ jaundice	727 (3.0)	8
Generally unwell/fever	711 (3.0)	9
Abdominal Pain	675 (2.8)	10
Ear problem	622 (2.6)	11
Lower respiratory tract infection	613 (2.6)	12

The findings from the St Mary's Hospital data are also supported by published literature briefly discussed in section 1.2.2 (Sands *et al.*, 2012). Sands and colleagues (2012) summarised and described the most common medical presenting problems of 39,394 children attending a UK university hospital PED compared with 10 years previously. The 12 most common clinical presentations identified by Sands *et al.* (2012) are summarised in Table 3.8.

Table 3.8: ***The most common medical presentations identified by Sands et al. (2012)****, for children aged 0–15 years old attending from February 2007 to February 2008.*

Presenting problem	Number of presentations (percentage of total)	Rank
Breathing difficulty	2494 (20.1)	1
Febrile illness	1752 (14.1)	2
Diarrhoea & vomiting	1731 (14.0)	3
Rash	1066 (8.6)	4
Cough	835 (6.7)	5
Abdominal pain (not surgical)	810 (6.5)	6
Seizure	781 (6.3)	7
Other	644 (5.2)	8
Ingestion	509 (4.1)	9
Headache	272 (2.2)	10
Allergic reaction	234 (1.9)	11
Ear problem	216 (1.7)	12

A key difference between these data sets are that the St Mary's Hospital data includes injuries presenting to PED. Sands *et al.* (2012) limited their study to medical presentations only and therefore excluded injuries from the data set. Both studies include both non-urgent and urgent attendances at PED. Unfortunately, this data was not available through the Northwick Park UCC electronic record system. However, this information provides useful context to the most common reasons for paediatric emergency attendance.

3.7 Development of the targeted intervention

The expert multi-disciplinary steering group discussed in section 3.4.1 agreed upon the research problem, theoretical basis to the project and the underlying principles guiding intervention development process. Following group agreement, the intervention was developed through consideration of the information provided in this chapter.

Written logs were kept of the iterative steps of intervention development, and all members of expert multi-disciplinary steering group reviewed the final intervention prior to commencement of the research trial.

3.7.1 Project requirements

As described in section 3.2.2, there was a requirement for the intervention to be based in emergency and urgent care settings. This meant that families could be targeted with an intervention provided by the ED or UCC, and any research participants had to be recruited from within ED or UCC. In view of this the decision was made for the intervention to focus on preventing non-urgent repeat attendances, and would be targeted at those that had already made an initial non-urgent attendance. This also ensures that the intervention is targeted at those families that have attended non-urgently once, and may attend non-urgently again. They have demonstrated this attendance behaviour, and they may benefit from the intervention which is then targeted at them as a non-urgent attender.

The steering group discussed the possibility of extending the intervention beyond ED and UCC; however, this was beyond the scope of the study requirements. Therefore, further

spread of the interventions will be considered depending on the findings of this research project.

In summary, the designed intervention will target repeat non-urgent attendances (reattendances).

3.7.2 Underpinned by theory

The targeted educational intervention was designed by drawing upon the theoretical concept generated in section 3.4. The targeted intervention will aim to increase health literacy, thereby increasing caregivers' personal control, decreasing the perceived threat of the acute childhood illness and reducing overall parental worry. In turn, this should prevent non-urgent reattendance at PED or UCC, encouraging self-management of minor illness at home or attendance at a community or primary care service.

As the intervention must be based in an emergency or urgent care setting, this intervention will be targeted at those families that have already attended hospital with a child with a non-urgent health concern. It was therefore hypothesised that the impact of this intervention will be as summarised overleaf in Figure 3.3.

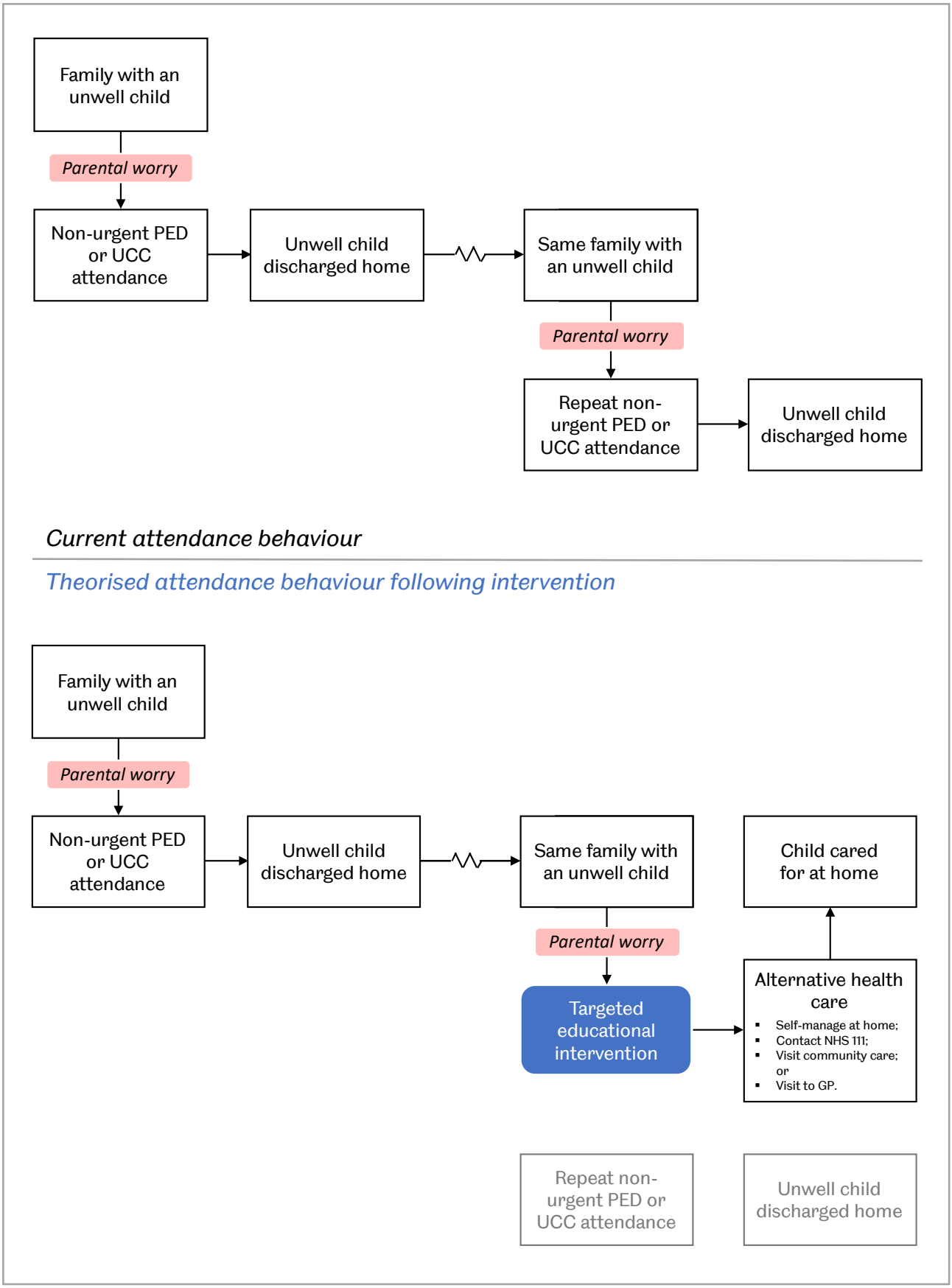


Figure 3.3: ***Hypothesised effect of intervention on family attendance behaviour.***

3.7.3 Stakeholder involvement

Active involvement of parents and carers with experience of caring for an unwell child, and consultation with healthcare professionals working in emergency and urgent care was essential for intervention development. Qualitative feedback was gathered from families and professionals working in St Mary's Hospital PED and Northwick Park Hospital UCC and was summarised in section 3.5.

Parents requested improved discharge information and instructions following hospital discharge. Although staff members said that these were available, there appeared to be inconsistency in when written or verbal information was provided to families at the end of their hospital attendance.

Useful feedback on the types of intervention that might be considered effective were noted by caregivers and healthcare staff. This included written information in booklets that covered common minor illnesses seen in young children. Parents agreed with this and requested further education on managing child illness and what steps to take in the future.

Healthcare professionals provided feedback that suggested that relying on staff members to provide additional and regular discharge education and advice to families would be a challenge. Due to levels of staffing, and a need to prioritise seriously unwell patients out of hours, it is unlikely that staff could reliably provide the same intervention consistently between shifts. A further challenge noted as part of the qualitative feedback was that parents are often mentally exhausted at the end of PED or UCC attendance and may not be

receptive to detailed discharge instructions. It may be more appropriate to consider discharge follow-up in the days following hospital attendance.

3.7.4 Site of the intervention

Fieldwork at both St Mary's Hospital and Northwick Park Hospital confirmed that both hospitals had different processes with regards to non-urgent hospital attendances. Therefore, any designed intervention needs to be able to be implemented at both healthcare sites, taking into account the study requirements and hospital site processes.

Discussions with the multi-disciplinary steering group highlighted that given the qualitative feedback and the alternative setup at each hospital site, it is likely to be most appropriate for the targeted intervention to be delivered to the family following their initial non-urgent attendance. This would not rely on the logistics of the intervention being delivered in the department alongside clinical care at any point during a 24-hour period. It was agreed that postal delivery of written information is likely to be the most effective method of ensuring non-urgent attendances consistently receive the targeted intervention and would allow for effective evaluation through a randomised controlled trial (RCT). This postal delivery process was led centrally by the lead researcher (myself) and did not require any additional work by healthcare professionals providing care in the clinical departments.

3.7.5 Identifying a target population

Following a review of the local attendance data for St Mary's Hospital PED and Northwick Park UCC (section 3.6.3.1), the decision was made to focus the targeted intervention on the

subpopulation of families attending with children aged 0 to 4 years old (aged under 5 years old). There are three main reasons for the focus on this age group:

(i) Children under 5 years old account for the majority of non-urgent attendances in 2016 at St. Mary's Hospital and Northwick Park Hospital.

(ii) Children under 5 years old that attend PED are there because of a decision by a parent or carer to attend, not because the individual chose to attend of their own volition. This means that the intervention can be specifically designed to target the decision-making of caregivers, rather than an intervention which targets both parents (of attending young children) and older adolescents (who may attend themselves without caregiver input).

(iii) Infants and younger children require different care to adolescents (Papalia and Feldman, 2011). Children under 5 typically attend PED with different types of health complaints than older children. Focus on this group allows the design of a more targeted intervention aimed to support caregiver decision-making.

3.7.6 Focus on the most common clinical presentations

The local data from St Mary's Hospital identified the most common reasons for attendance at PED (section 3.6.3.3). This is complemented by similar findings in the published literature. Both the local data and published data are combined in Table 3.9.

Table 3.9: ***Most common clinical presentations to St Mary's Hospital PED and those identified by Sands et al. (2012)****.*

Rank	St Mary's Hospital Audit	Rank	Sands *et al.* (2012)
1	Injury/ musculoskeletal	1	Breathing difficulty

2	Upper respiratory tract infection	2	Febrile illness
3	Diarrhoea & vomiting/ gastroenteritis	3	Diarrhoea & vomiting
4	Head Injury	4	Rash
5	Wheeze (including asthma)	5	Cough
6	Rash/skin infection	6	Abdominal pain (not surgical)
7	Well child/worried parents	7	Seizure
8	Neonatal presentations: Feeding issues/colic/ jaundice	8	Other
9	Generally unwell/fever	9	Ingestion
10	Abdominal Pain	10	Headache
11	Ear problem	11	Allergic reaction
12	Lower respiratory tract infection	12	Ear problem

The list of the most common clinical presentations at St Mary's Hospital were compared with that in Sands *et al.*'s (2012) study, and reviewed by clinical experts from the multi-disciplinary steering group. This included Consultant Paediatricians (generalists and specialists) and GPs.

The attendances for injury (for example, 'head injury' and 'musculoskeletal injury') at St Mary's Hospital were excluded. The remaining clinical presentations were reviewed and assessed for potential severity. In the case of those clinical presentations that were deemed to require an assessment by a clinician to identify if they were urgent or non-urgent, including "breathing difficulty" and "wheeze", the clinical experts decided that these required a clinical assessment by a qualified medical professional to determine urgency, and

therefore should not be considered non-urgent attendances. The remaining medical presentations to PED were reviewed and prioritised with PED consultants. They were able to consolidate these common conditions into five key clinical presentations (highlighted in blue in Table 3.9). The chosen five clinical presentations were:

1. Coughs and coryzal symptoms.
2. Gastroenteritis (including information on abdominal pain).
3. Febrile illness (fever).
4. Ear problems.
5. Rashes and dry skin.

The targeted intervention will therefore focus specifically on providing education and advice in the management of these common clinical presentations to emergency and urgent care.

These five common conditions were reviewed by parents and carers that were members of the steering group, and these were reworded into language that was more readily understood by caregivers. These five common clinical presentations were described as follows:

1. Coughs and colds.
2. Diarrhoea and vomiting.
3. Fever (high temperature).
4. Ear problems.
5. Rashes and dry skin.

It was also highlighted by caregivers that they would welcome specific advice regarding the types of equipment that they should keep at home to self-manage minor illness in children. It was therefore agreed that additional resource recommending which items should be kept at home in a "first aid kit" would also be included in the targeted intervention.

3.7.7 Applying nudge theory

This section describes the process behind the inclusion of nudges in the design of the targeted educational intervention for this research project.

3.7.7.1 Applying the EAST framework

The EAST framework is a tool that was developed by the Behavioural Insights Team (BIT) in early 2012. The EAST framework combines elements of behavioural economics and psychology to understand and influence behaviour change through the use of nudges. The key idea is if you want to encourage a behaviour, make it Easy, Attractive, Social and Timely (EAST). It is important to note that an intervention does not have to incorporate all of these factors, but achieving a number of them can enhance the effectiveness of an intervention at influencing behaviour. The four components of the framework are discussed briefly below (Service *et al.*, 2014).

Make it easy:

As discussed in section 1.5, the human brain is fallible and often relies on 'automatic' processes. These automatic processes rely on inherent biases and heuristics. To facilitate behaviour change, BIT recommend reducing the effort required to start the new behaviour.

This may be through the simplification of written communications or providing the information people require in a way that is easy to access (Service *et al.*, 2014).

Make it attractive

Behavioural science tells us that the world is full of cognitive stimulation, and information needs to do two things to be considered 'attractive'. It should grab attention and feel appealing. To grab attention, information can be personalised and include stimuli that are emotive and accessible. This is done to maximise appeal and to make things simple, visually stimulating and easy to understand (Service *et al.*, 2014).

Make it social

Humans are social creatures that are likely to be influenced by the behaviour of those around them. Highlighting behaviours that are common in a group (social norms) or using the power of networks and encouraging people to make a commitment to others can be effective ways to nudge people in a particular direction (Service *et al.*, 2014).

Make it timely

Research suggests that individuals respond differently to exactly the same information depending on when it is received. To make the most out of timing, periods of transition where habits can be disrupted should be taken advantage of. Behaviours can also be prompted at a time when individuals are more likely to be receptive to information (Service *et al.*, 2014).

3.8 The educational bundle

The final intervention design was informed by all the components described in this chapter. The evidence base, theoretical framework, caregiver and healthcare professional feedback, data describing the population context of the two hospitals and nudge theory were compiled to produce an educational bundle. This educational bundle consisted of four items:

(i) Personalised cover letter – containing the child's name and hand-signed by a clinician

(ii) "How to help your unwell child" – 16-page information booklet

(iii) A5 factsheet with information on how to identify serious childhood illness

(iv) NHS 111 fridge magnet

The items were contained in an envelope with a handwritten address on the front and delivered by post two to three days after the non-urgent attendance at St Mary's Hospital PED or Northwick Park Hospital UCC.

The components used to inform the design of the educational bundle are summarised in Figure 3.4. Each aspect of the educational bundle is described in greater detail in sections 3.8.1 to 3.8.5. A copy of the full contents of the educational bundle can be found in *Appendix F*.

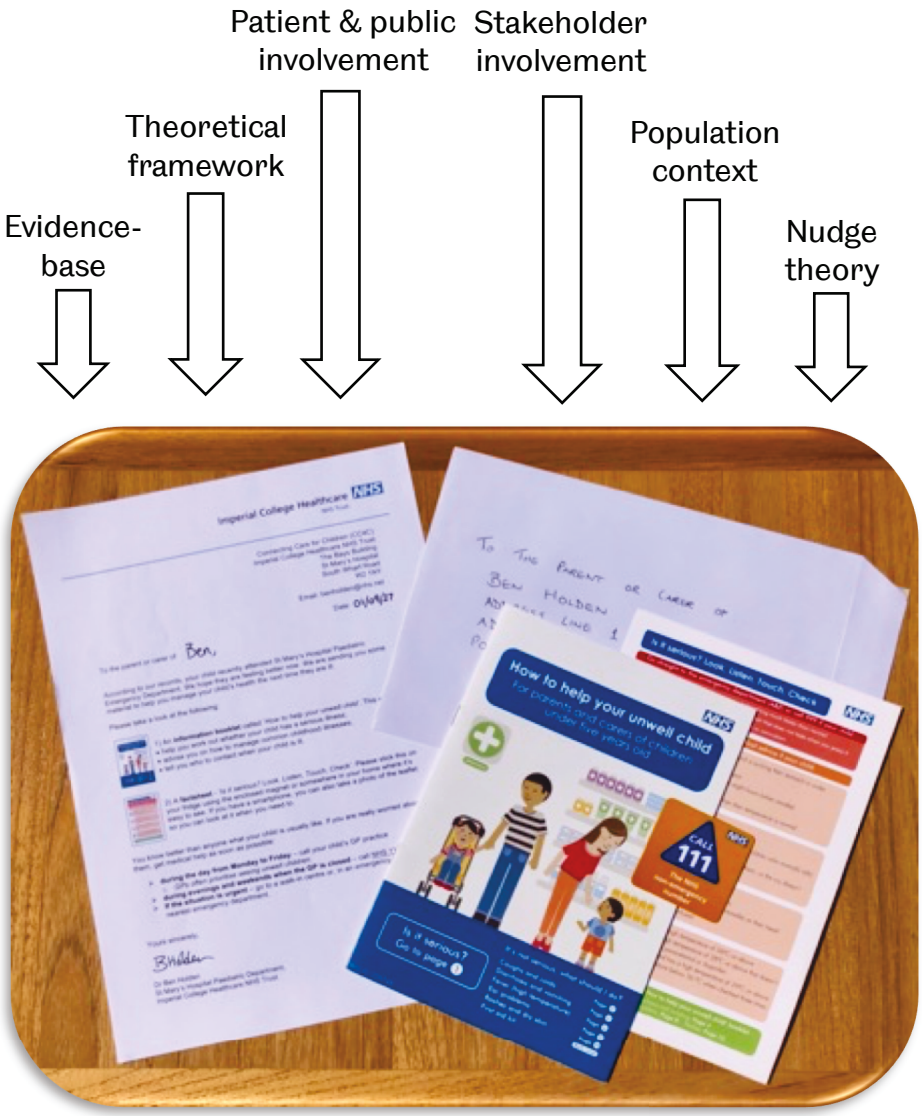


Figure 3.4: ***The components that input into the 'educational bundle' design.***

3.8.1 Method of delivery

It was agreed that the educational bundle would be posted from each hospital site to the family that had attended hospital with a non-urgent health concern. This relied on a clinician from the research team reviewing hospital attendance records and arranging that the intervention be posted to the family shortly after a non-urgent PED or UCC attendance.

The reason for the choice of postal delivery was twofold. Firstly, non-urgent attendances at PED or UCC occur 24 hours a day, seven days per week. There was not sufficient resource to arrange for a member of the research team to be on site at both hospital sites at all times during the study to provide the intervention to families. Fielding work and interviews with stakeholders (healthcare professionals working in PED and UCC) identified that they could not consistently provide the intervention on site over the course of the study, as their focus is on delivery of clinical care and this would make evaluation of the intervention challenging.

Secondly, in line with the EAST framework and recommendation to "make it easy", postal delivery to the home ensured that families had the educational bundle within their household and would be able to access it if it was required (for example, when a child became unwell).

The additional benefit of postal delivery to the family's home address following attendance at hospital was that it ensured the intervention was received at a 'timely' moment. Published literature suggests that events related to health can act as a moment for change (Keenan, 2009; Shi and Warner, 2010). Receipt of the intervention shortly after an initial non-urgent attendance should ensure that memory of the childhood illness and hospital visit is still fresh, thereby ensuring the intervention is pertinent to the recent situation.

3.8.1.1 Envelope

The envelope containing the educational bundle was personalised with the child's name, and the child's name and address were handwritten on the front of the envelope. This was because evidence suggests that handwritten messages appear more attractive to individuals, and make people more likely to appreciate the written information (Garner, 2005; Irish Revenue, 2013). It was hypothesised that a handwritten envelope was more likely to be opened by members of the household than a generic word-processed address on an envelope.

3.8.1.2 Personalised cover letter

A personalised cover letter addressed to the parent or carer of the child that had attended PED or UCC was developed. This letter included the child's handwritten name and was specific to the hospital that they had attended. This design was informed by evidence that suggests greater engagement with written information when it is personalised (Edwards *et al.*, 2009; Haynes *et al.*, 2013; Parker *et al.*, 2015).

Use of simple language, concrete statements and attractive appearance have been demonstrated to improve how engaging or persuasive health information is (Michie and Lester, 2005; Thorndike *et al.*, 2014). This was considered in the design of the letter content. The contents of the educational bundle were clearly described in the cover letter, and colour images showing the booklet and factsheet were also included. The language was reviewed by caregivers from the steering group to ensure the language was appropriate for the target audience. The letter also provided information on other healthcare services that families could use (for example, NHS 111 and their own GP).

The personalised letter used the concept of "messenger effect" in the design. Published studies show that a professional recommendation or endorsement can be effective at changing healthcare behaviours (Hewitson *et al.*, 2011; Camilloni *et al.*, 2013; Wardle *et al.*, 2015). The personalised letter was hand-signed by a registered medical professional that worked at both hospital sites, and was a member of the research team. This aimed to provide additional credibility to the source of the educational bundle and increase family engagement with the resource when it was delivered to their homes.

Two versions of the personalised cover letter were used for the intervention. One letter specifically named St Mary's Hospital in the text and used the relevant organisation header. The second letter named Northwick Park Hospital in the text and used a letter header relevant to the different organisation.

3.8.1.3 Information booklet

The information booklet titled '*How to help your unwell child*' was the largest part of the educational bundle. This 16-page booklet provided the following:

- An introduction that aimed to reassure families and explained that it is common for children to develop minor illness. It explained the rationale for the booklet, and how it was designed. Below this introduction was a prompt for families to be able to write the contact details for their child's GP, and details of the local pharmacy.
- Safety-netting advice (informed by the ASK SNIFF work discussed in section 2.6) that identified the signs of serious illness in children. This page provided a checklist of the symptoms and signs of serious illness that caregivers should look out for when their child becomes unwell. The content of this page was based on the NHS England

information campaign “Spotting sepsis in under 5's” (NHS England, 2017). This ensured messages provided by the educational bundle were consistent with those being spread by national campaigns across England.

- Information on the management of the five common clinical presentations identified by the multi-disciplinary steering group: coughs and colds, diarrhoea and vomiting, fever (high temperature), ear problems and rashes and dry skin.
- Advice on what medications and equipment it is useful to keep at home in case a child becomes unwell. This resource was labelled “first aid kit” in line with parent and carer suggestions.

The content of the information booklet was developed by clinical experts using the most up-to-date National Institute for Health and Care Excellence (NICE) guidance (NICE, 2013). Initially compiled by general paediatricians, the content was reviewed by Consultants in Infectious Diseases and Emergency Medicine. This was also reviewed by GPs with expertise in paediatric management. Behavioural science experts provided advice on how to simplify the language, and improve the layout of the booklet to make it more in line with the EAST framework. For example, all information pages related to specific conditions were broken down into simple actions that could be undertaken to make the steps in management of an unwell child easier to follow.

The final booklet was generated by a graphic designer. They were commissioned to make the final product colourful and visually stimulating. The development of the booklet and the A5 factsheet (section 3.8.1.4) was an iterative process, and feedback of several draft

versions was sought from all members of the multi-disciplinary steering group, including parents and carers that experience caring for unwell children.

3.8.1.4 Factsheet and fridge magnet

The final components of the educational bundle were the A5 factsheet titled "*Is it serious? Look, Listen, Touch, Check*" and an NHS 111 fridge magnet. The factsheet was identical to the first page of the 16-page information booklet and presented the key safety-netting information. This provided a checklist of the serious signs of childhood illness that should be excluded before attempting self-management at home. The idea behind this intervention was that it could be stored in an accessible place in the home (for example, on the fridge door or on a noticeboard) and that when a child became unwell a caregiver could review the factsheet, hopefully excluding the signs of serious illness, and be directed to the information booklet for support in the management of the non-urgent childhood illness.

The list of signs and symptoms to identify were separated into sections that directed caregivers to specific actions. This aimed to make the specific steps easier to follow, and to give parents and carers the tools to assess the severity of the childhood illness.

The fridge magnet was provided at the request of parent and carer volunteers who offered qualitative feedback into the design of the intervention. They suggested that an NHS 111 fridge magnet would be a helpful prompt to the telephone service, which could provide healthcare support when they were managing an unwell child.

3.9 Chapter summary

This chapter summarised the development of an educational bundle that aimed to reduce non-urgent PED and UCC reattendance of children under 5 years old. It described the evidence base, theoretical framework, caregiver and healthcare professional feedback, data describing the population context in North West London and nudge theory that informed the design of the final targeted intervention. The chapter ends by presenting each of the components of the educational bundle.

Chapter 4: Research Trial Methodology

4.1 Chapter introduction

This chapter presents the methodology of the research trial that seeks to evaluate the effectiveness of the educational bundle described in *Chapter 3*. A randomised controlled trial (RCT) was designed to test the effect of the educational bundle on childhood non-urgent reattendance at PED and UCC. The chapter describes the relevant steps in the MRC guidance on "Developing and evaluating complex interventions", presents the RCT methodology and discusses the analytical strategy for this research. The final section reviews the important ethical and regulatory considerations.

This chapter covers section 2.1 to 2.3 of the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008) (Table 4.1).

Table 4.1: ***Section 2.1, 2.2 and 2.3 of the MRC Framework*** *- Extracted from Table 1.2.*

2	**Assessing feasibility and piloting methods**		
2.1	Testing procedures	i.	Tested components for feasibility and acceptability with caregivers and healthcare professionals
		ii.	Pilot of delivery process of the intervention
2.2	Estimating recruitment and retention	i.	Scoping exercise of attendance data for both hospital sites to estimate baseline reattendance
2.3	Determining sample size	i.	Data from previous years used to estimate sample size and minimal detectable effect size.

4.2 Aim of the study

The third key aim of this study is to evaluate the educational bundle that aims to reduce the non-urgent reattendance of children at urgent and emergency care locations. This will be achieved through the fulfilment of these three objectives:

<table>
<tr><td colspan="3">Aim 3: To evaluate the effect of the targeted intervention on non-urgent reattendance at PED using a randomised controlled trial.</td></tr>
<tr><td><u>Objectives</u></td><td><u>Research question</u></td><td><u>Methods</u></td></tr>
<tr><td>Identify whether the intervention reduced the likelihood of non-urgent PED reattendance during the trial period.</td><td>Are families that receive the intervention less likely to reattend PED with a non-urgent problem?</td><td rowspan="3">Randomised controlled trial and (OLS) linear regression</td></tr>
<tr><td>Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient gender.</td><td>Are families that initially attend with a male child less likely to reattend PED with a non-urgent problem following receipt of the intervention?</td></tr>
<tr><td>Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient age.</td><td>Are families that initially attend with a child aged 0–2 years old less likely to reattend PED with a non-urgent problem following receipt of the intervention?</td></tr>
</table>

4.3 Assessing feasibility and piloting methods

The MRC guidance on "Developing and evaluating complex interventions" highlights the importance of preparatory work to ensure feasibility of an intervention and the associated evaluation (Craig *et al.*, 2008). This was completed as part of the study to ensure that the intervention could be delivered as intended.

4.3.1 Acceptability of intervention to caregivers and healthcare staff

Prior to the design of the RCT, the intervention was shared with volunteer parents and carers that were identified through the CC4C practice champion programme (discussed in section 3.5.1). They provided verbal and written feedback on the intervention prior to the development of the agreed final intervention. This ensured acceptability of the intervention to a sample population of patient families that attend St Mary's Hospital PED and Northwick Park Hospital UCC.

The intervention was also provided to healthcare professionals working in primary and secondary care. They provided supportive feedback and welcomed the introduction of the intervention. This feedback was important in the agreement of the final intervention.

4.3.2 Pilot of intervention delivery process

Prior to the design of the RCT the processes required to recruit families, identify those to be included in the study, and arrange postal delivery of the educational bundle were tested. At both hospital sites, hospital attendance data from the previous two days was extracted from the hospital systems and evaluated. In addition, sample packs of the educational bundle were delivered to members of the steering group. This ensured timely receipt of the

intervention following a hypothetical PED or UCC non-urgent attendance. The pilot process of data extraction and intervention delivery was repeated over three consecutive weeks. This confirmed that the processes for identification of research participants and intervention delivery were robust.

However, it was recognised that there were a number of issues with the quality of the data recorded in each hospital's electronic records. Occasionally, due to human error, an attendance would be labelled with criteria that would indicate it was a non-urgent attendance; however, closer inspection of the free-text comments made by healthcare professionals during the attendance indicated that the attendance should be considered an urgent attendance, and would not be appropriate for the intervention. This demonstrated a need to include an additional clinical review step, in which a registered medical professional reviewed the electronic records to ensure appropriate application of the inclusion criteria. This additional step is explained further in section 4.4.2.2.

4.4 RCT design

The evaluation of this research trial was run as a multicentre, two-armed RCT with balanced randomisation (1:1). In the trial, families making non-urgent PED attendances were randomly assigned to:

(i) an Intervention group, where they were sent an educational bundle about minor illnesses in young children within a few days of the initial attendance; or

(ii) a Control group, where they received usual care (no special follow-up contact).

Families were inducted into the trial from 9th October 2017 until 8th June 2018 (for eight months), with follow-up outcome measures elicited until 8th September 2018 (a further three months). This is summarised in the diagram below (Figure 4.1).

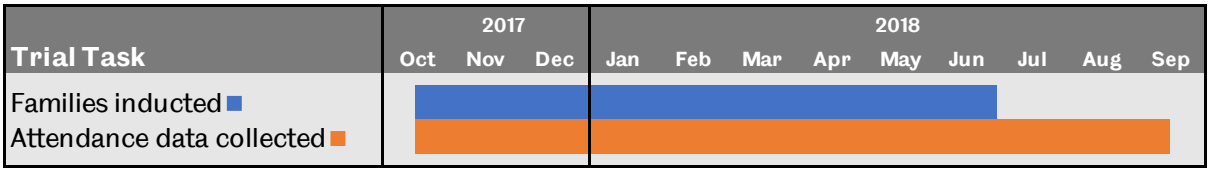


Figure 4.1: ***Summary of trial timeline.***

A flowchart summarising the overall trial design is included in Figure 4.2.

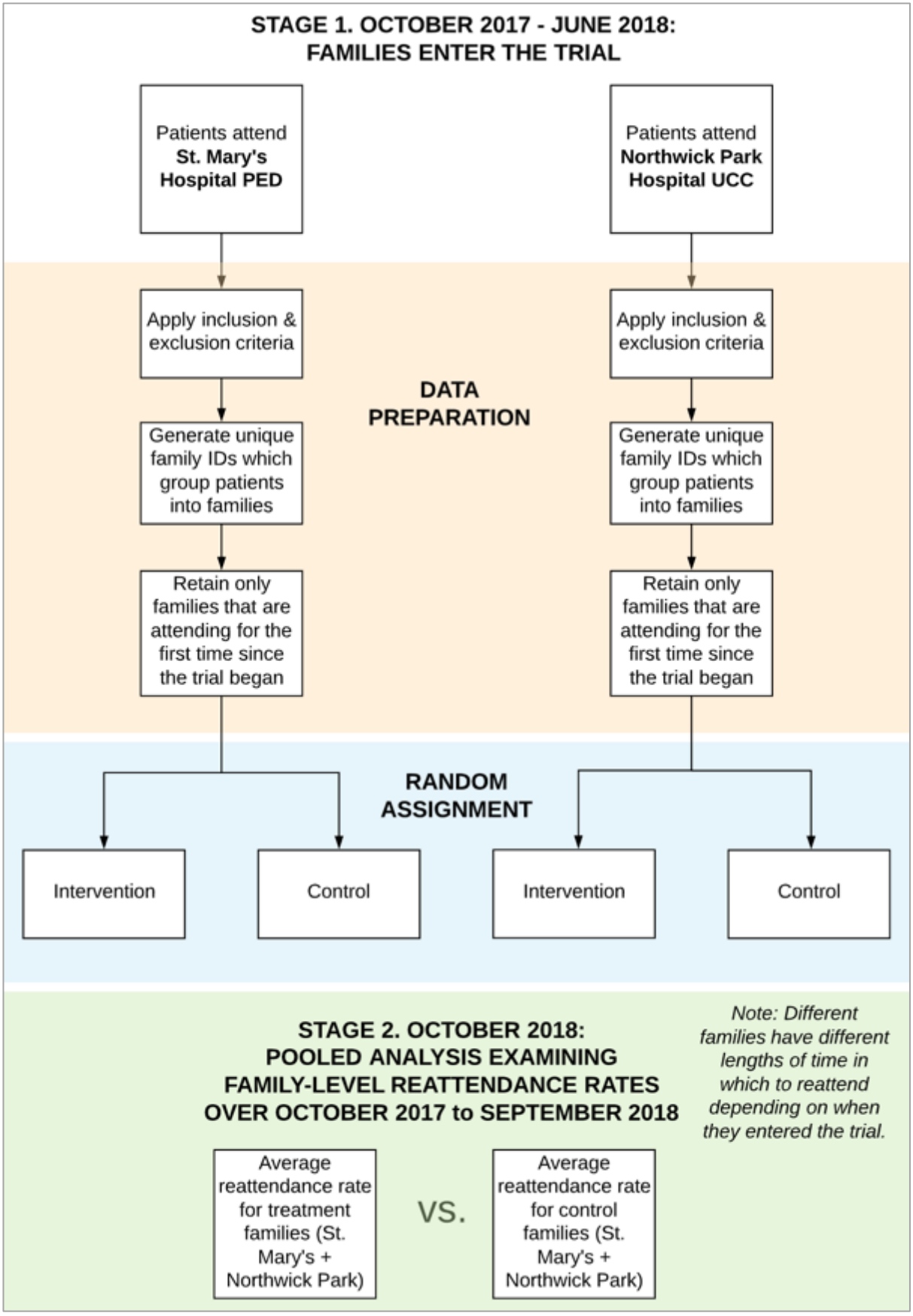


Figure 4.2: ***Flowchart summarising key steps in RCT design****.*

4.4.1 Study setting

This was a multi-centre study. The RCT was undertaken at two hospital sites. These were:

- St Mary's Hospital (PED), run by Imperial College Healthcare NHS Trust.
- Northwick Park Hospital (UCC), run by London North West Healthcare NHS Trust and Greenbrook Healthcare.

4.4.2 Participants

This trial inducted families that attended St. Mary's PED or Northwick Park UCC with a child aged between 0 and 4 years and 364 days (under 5 years old), that was considered to have a non-urgent illness. Non-urgent attendances were defined using different clinical criteria across the two hospital sites, reflecting the different practices at those hospitals. However, both criteria were identified by clinical teams to select very similar groups of children, as explained below.

4.4.2.1 Inclusion criteria

The criteria used to classify attendances as non-urgent were derived from the data set reviewed by the clinical research team prior to trial commencement.

St. Mary's Hospital PED

To be classified as a non-urgent attendance in this unit, attendances must:

(i) receive a triage Category score of '4' or '5' out of 5 (on a scale where 1 is most urgent and 5 is least urgent);

(ii) have arrived at the hospital by 'foot', 'other', 'private transport', 'public transport', or 'taxi';

(iii) not have received any imaging investigation or pathology investigation, and

(iv) have a postcode starting with E, HA, N, NW, SE, TW, SW, UB, W, WC (London postcodes and Harrow, Twickenham, and Uxbridge, areas from which large numbers of St. Mary's attendees originate);

(v) have a disposal of 'discharged', and

(vi) not receive any of the following triage presentation codes: 'Abscesses and local infections', 'Abused or neglected child', 'Allergy', 'Asthma', 'Back Pain', 'Bites and Stings', 'Burns and Scalds', 'Chemical exposure', 'Chest Pain', 'Dental Problems', 'Diabetes', 'Facial Problems', 'Falls', 'Fits', 'Foreign Body', 'GI Bleeding', 'Head Injury', 'Limb Problems', 'Limping Child', 'Neck Pain', 'Overdose and Poisoning', 'Palpitations', 'PV Bleeding', 'Testicular Pain', 'Torso Injury', 'Urinary Problems' and 'Wounds'.

Northwick Park Hospital UCC

To be classified as a non-urgent attendance in this unit, attendances must:

(i) have a 'case type' classification of "illness" or "illness (failed redirect)";

(ii) not have received any prescriptions in the ED;

(iii) have a postcode starting with E, HA, N, NW, SE, TW, SW, UB, W, WC (London postcodes and Harrow, Twickenham, and Uxbridge, areas from which large numbers of St. Mary's attendees originate);

(iv) have an 'informational outcome' beginning with the words 'discharge'; and

(v) have a 'priority after streaming' classification of 'routine' or 'under 2'.

4.4.2.2 Clinical judgement

As highlighted in section 4.3.2, a review of the quality of the data collected in the patients'

electronic records at each hospital site highlighted inconsistencies in data recording. For example, clinicians would record additional details indicating that an attendance was urgent in free text comments. These would not always be picked up by the automated data collection methods and were a limitation of the software used to record PED and UCC attendance details in the hospital electronic records.

This included any mention in free text of the variables listed in section 4.4.2.1, but also included a number of further examples. These indications of a need for medical assessment in hospital are summarised in Table 4.2.

Table 4.2: ***Additional exclusion criteria identified through clinical judgement of free-text comments****.*

Additional reasons for exclusion from study, identified from healthcare professional's free text comments in the patient record
Patient arrived via ambulance (incorrect data coding/data entry)
Patient received prescription (incorrect data coding/data entry)
Attendance for an 'injury' (incorrect data coding/data entry)
Patient administered medication during the attendance
Patient did not wait for clinical assessment
Family attended seeking assistance for allergic reaction (urgent health concern)
Attendance was for a serious presentation requiring specialist paediatric input
Patient had a safeguarding alert on their health record

Unfortunately, a large-scale redesign of the electronic patient records at each hospital site was beyond the scope of this project. Therefore, the decision was made to undertake an additional step prior to participant recruitment.

Following the application of the automated exclusion criteria to the data extracts, the free-text entries relating to the individual PED or UCC attendance were reviewed. These entries have been inputted into the systems by a clinician delivering direct care during the hospital attendance, and additional detail has been provided about the clinical presentation and reason for the patient's attendance. This was an additional step in the exclusion criteria termed a "clinical judgement".

4.4.3 Intervention

Families allocated to the control group received standard level of care following their hospital attendance. Practically, for the non-urgent attendances this will mean no follow-up contact. Families in the treatment group had the educational bundle posted to the address on the patient record shortly after they attended PED or UCC. This educational bundle contained these four components:

(i) **Hand-signed letter**: A targeted (personalised with the child's name) letter which is hand-signed, explaining the information pack and signposting to NHS services.

(ii) **Information booklet**: An approximately 12-page booklet titled 'How to help your unwell child' with advice on recognising serious illness and information on how to manage the top five non-urgent childhood conditions that are most likely to attend emergency and urgent care services.

(iii) **Factsheet**: An A5 sheet summarising the key things to look out for to identify serious illness in children.

(iv) **Fridge magnet**: An NHS 111 fridge magnet (advocating the NHS 111 service) to stick the A5 one-page factsheet sheet to a fridge.

Full copies of the educational bundle contents can be found in *Appendix F*. Table 4.3 summarises the different trial conditions that families were allocated during the RCT.

Table 4.3: ***Summary of the two trial arms****.*

Condition	Description
Control	This will be the standard level of care currently delivered to patients ('Business as usual').
Intervention	This will be the educational bundle which will include a: (i) hand-signed letter; (ii) information booklet; (iii) fridge magnet; and (iv) factsheet.

4.4.4 Outcome measures

4.4.4.1 Primary outcome

The primary goal of the educational bundle was to reduce non-urgent reattendances at the two hospitals. In other words, once families had made an initial non-urgent attendance, the intervention sought to discourage them from making an unnecessary repeat non-urgent attendance during the trial period.

The primary outcome examined a binary measure of non-urgent reattendance, coded as follows:

- 0 = family made only an initial non-urgent attendance with a patient aged 0 to 4 years old (i.e. during the trial period they did not make a non-urgent reattendance after their initial attendance during the study).
- 1 = family made at least 1 non-urgent reattendance with a patient aged 0 to 5 years old.[vi]

Families were enrolled into the trial on a rolling basis from October 2017 to June 2018, and we measured whether these families made non-urgent reattendances from October 2017 to September 2018. This means that families that were enrolled in the trial in October 2017 had 11 months in which they could have reattended (from October 2017 to September 2018); families that enrolled in June 2018 had three months in which they could reattend (June 2018 to September 2018).

[vi] Although the trial only inducted families who attended with a patient aged 0–4 years old, the outcome variable included patients that were aged 5 years, to account for the fact that some 4-year-old patients randomised into the trial turned 5 years old during the trial period.

4.4.4.2 Secondary outcome

Further analyses were conducted to identify whether the effect of the educational bundle was influenced by the gender of the patient at the initial attendance, or influenced by the age of the patient at the initial attendance.

In summary, we undertook subgroup analysis to determine whether the intervention:

(i) differentially affected male and female patients;

(ii) differentially affected patients by age. One of these analyses will interact the treatment indicator with a categorical indicator of age coded as 0 = patient aged under 2, 1 = patient aged 2–4.

4.4.5 Estimating enrolment and retention

This section details the scoping exercise of attendance data undertaken for both hospital sites to estimate baseline reattendance, and describes why minimal attrition was expected.

4.4.5.1 Baseline non-urgent reattendance

As discussed in section 4.4.4.1, the primary outcome was whether a patient reattends the hospital non-urgently after an initial non-urgent attendance. A patient was coded as 0 if they attended St. Mary's or Northwick Park UCC non-urgently once only during the trial, and coded as 1 if they re-attended the same hospital non-urgently at any point during the trial (after their initial attendance). The length of time a family has in which to reattend was dependent upon when they were inducted into the trial.

The trial ran from 9th October 2017 until 8th June 2018, with follow-up outcome measures elicited until 8th September 2018. This meant a family that entered in the trial in October

2017 had 11 months in which to reattend, whereas a family that entered the trial in late May 2018 (the final month in which new families were inducted into the trial) had 3 months in which to reattend before data collection ended.

During the trial design stage, the baseline family reattendance was estimated using non-urgent attendance data from 2015 and 2016. Table 4.4 demonstrates the different reattendance rates calculated, and how these were dependent on when the family entered the trial. For example, the first row shows that 854 families attended St. Mary's Hospital PED or Northwick Park Hospital UCC non-urgently in August 2015, and that 37% of these families reattended non-urgently by May 2016.

Table 4.4: ***Number of families non-urgently attending St. Mary's PED and Northwick Park UCC****, with patients aged 0–4 from October 2015 to May 2016.*

Month	St Mary's PED new families entering trial	Northwick Park UCC new families entering trial	Total number of new families entering trial	Number of months in which they can reattend during the trial	Reatten-dance rate (%)
October 2015	695	928	1623	10	37%
November 2015	614	940	1554	9	35%
December 2015	668	863	1531	8	32%
January 2016	444	688	1132	7	30%
February 2016	476	671	1147	6	27%
March 2016	378	806	1184	5	25%
April 2016	419	560	979	4	22%
May 2016	353	621	974	3	20%
Total	4047	6077	10124	-	29%

This data was unable to utilise the full exclusion criteria able to be processed as part of the 2017 and 2018 PED and UCC data, as the PED and UCC data recorded prior to 2017 did not include the variables used in this study. System updates in 2017 ensured data collected at St Mary's Hospital PED and Northwick Park Hospital UCC was more granular, and allowed for a clearer definition of non-urgent attendance. This baseline reattendance data did not exclude certain attendance characteristics because they could not be identified from the data sets. In addition, this estimate does not take into account the clinical judgement exclusion step. Therefore, it is likely to overestimate the number of families that attend PED and UCC. Despite this, it provides a helpful estimation of the baseline reattendance. The

October 2015 to May 2016 data were used to inform the sample size calculation presented in 4.4.6.

4.4.5.2 Attrition

There was little scope for attrition over time as families were automatically inducted into the trial (provided they meet the inclusion criteria). Families were not required to actively engage with the trial, and therefore they were not given opportunity to leave the trial (ethical considerations regarding informed consent are discussed in section 4.6.1.1).

Families that were allocated to the control group received no follow-up contact from the intervention, meaning that there were no points of contact during which participants could attrit from. Similarly, families in the intervention group were sent materials in the post, but they are not required to provide us with their addresses directly as these will be taken from their medical record.

That said, it is possible that families may leave the intervention without our knowledge. They may move to a different location or begin using a different hospital for other reasons. Unfortunately, because the hospital data sets are limited to two hospital sites, any families attending alternative hospitals or changing address during the trial could not be identified.

4.4.6 Sample size

Power analyses were used to estimate the minimum detectable effect that could be identified by the end of the trial. These analyses were specified with a significance level of 0.05 and power of 0.8. The baseline family-level reattendance was, based on non-urgent

attendance data from October 2015 to May 2016, assumed to be 29% across St. Mary's Hospital PED and Northwick Park UCC. Estimates are provided for different sample sizes ranging from 5,840 to 10,124 families.

This formula used to estimate the minimal detectable effect size was:

$n = (Z_{\alpha/2}+Z_{\beta})^2 * (p_1(1-p_1)+p_2(1-p_2)) / (p_1-p_2)^2$

where $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p_1 and p_2 are the expected sample proportions of the two groups.

In consultation with the multi-disciplinary steering group it was agreed that on a system-wide level, any relatively small reduction in non-urgent reattendance would be considered 'clinically important'. Studies published in the USA during the 1990s expected a designed intervention to result in a reduction in the rate of non-urgent reattendance of between 20% and 30%. However, neither study identified a statistically significant difference of this magnitude (Chande *et al.*, 1996; Chande and Kimes, 1999). As discussed in section 2.4.3.4, Racine *et al*. (2009) reported a 3% statistically significant difference in non-urgent PED reattendance between the intervention and control groups at 12 months, and Strum *et al.* (2014) reported a statistically significant difference of 11.5% between the two groups at 12 months.

Therefore, the minimum clinically significant effect size was agreed to be a 5% reduction in non-urgent reattendance in the intervention group compared to the control group.

The study was powered to detect a relative decrease of between 8.7 and 10.1%, varying slightly depending on the sample size (see Table 4.5). With 10,124 families, it was deemed likely that a significant difference between a control group with a 28.5% average reattendance and an intervention group with a 26.0% reattendance could be detected. Note that this was a conservative estimate as it did not take into account the effect of adjusting for baseline variables used in the analytical strategy.

Table 4.5: ***Summary of power calculations for a 2-arm RCT beginning in October 2017 with reattendance data collection taking place in September 2018****.*

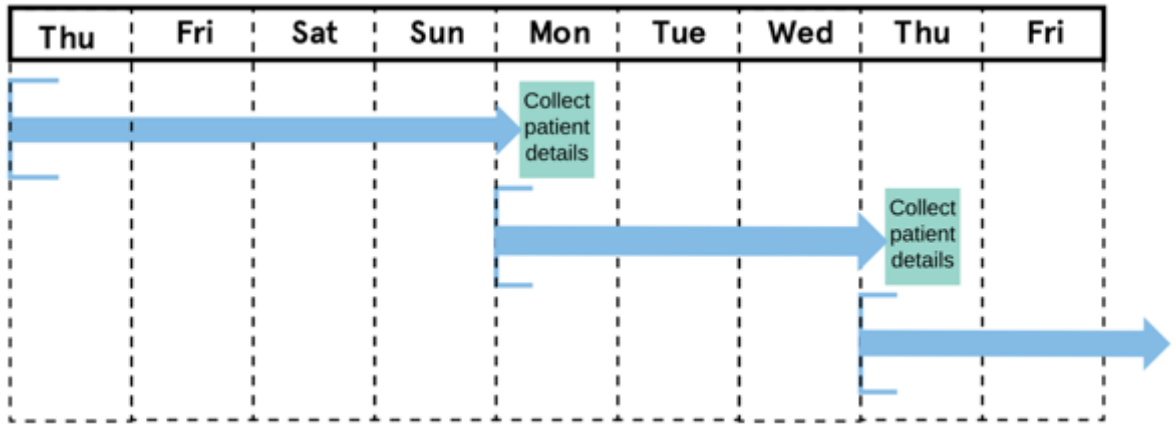
Number of families inducted	Final month families presumed to enter trial	Baseline reattendance	Reattendance at which a statistically significant decrease could be detected	Relative detectable decrease in % terms
10124	May 2017	28.5%	26.0%	8.7%
9150	April 2017	29.7%	27.1%	8.8%
8171	March 2017	31%	28.1%	9.3%
6987	Feb 2017	32.2%	29.1%	9.6%
5840	Jan 2017	33.5%	30.1%	10.1%

4.4.7 Trial implementation

The trial was implemented on site at each hospital twice per week by the lead researcher. The lead researcher visited Northwick Park Hospital UCC on two working days, Monday and Thursday. They visited St Mary's Hospital PED to implement the trial weekly on a Tuesday and a Friday.

During this visit the lead researcher would collect the patient details and allocate families recruited to the study. Data analysis and audit tools within the respective hospital information technology systems were used to identify families that had attended within the previous 2 or 3 days, and those that should be included in the study. This process is summarised in Figure 4.3 below.

Northwick Park Hospital UCC trial implementation process



St Mary's Hospital PED trial implementation process

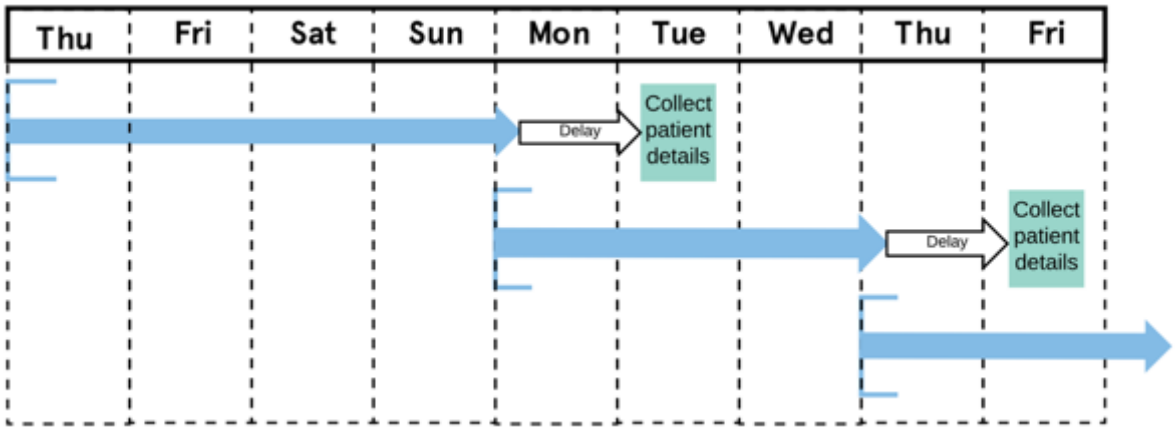


Figure 4.3: ***Trial implementation process at each hospital site.***

Figure 4.3 shows that on Monday, the lead researcher collected patient details for families that have attended Northwick Park Hospital UCC on the preceding Thursday, Friday, Saturday and Sunday. On Tuesday, they collected patient details for families that have attended St Mary's Hospital PED on the Thursday, Friday, Saturday and Sunday.

On Thursday they collected patient details for families that have attended Northwick Park Hospital UCC on the preceding Monday, Tuesday and Wednesday. On Friday they collected patient details for families that have attended St Mary's Hospital PED on the preceding Monday, Tuesday and Wednesday.

The lead researcher identified all children under 5 years old that attended non-urgently in the specified time period, applied the exclusion criteria, and generated a family identifier (ID). They then checked whether that family ID has been previously allocated to a control or intervention group. This is discussed further in section 4.4.8.

4.4.8 Randomisation and allocation

Data preparation and random assignment was completed on site, twice weekly at each research site. This process is summarised below.

4.4.8.1 Generation of a 'Family ID'

The outcome measure was elicited using daily-level, anonymised attendance data for St. Mary's and Northwick Park. This enabled the measurement of reattendance using objective hospital attendance data. However, one issue with the hospital data was that it did not indicate when patients that attended PED or UCC were members of the same family. For example, patient A from family X might attend St. Mary's Hospital on Monday. Patient B from the same family (family X) might then attend St. Mary's Hospital on Tuesday. There is no identifier in the electronic patient record that would ensure recognition that patient A and patient B were both from the same family.

This was an RCT in which families were randomly assigned to the intervention or control group. This means that, in the analysis, the patient observations were clustered by a family indicator. Although patients were clustered by family, this is not a cluster RCT because the outcome (non-urgent reattendance) is also measured at the family level. Generation of a family identifier (ID) aimed to ensure that attendances by siblings were not analysed as independent from one another.

As there was no existing variable in the data that identified patients as being from the same family, for this project a family ID variable was generated. This family ID was created by combining two variables: the patient's (anonymised) last name and their (anonymised) full postcode.

This method of generating a family ID assigned 4-year-old patient J. Smith of postcode ABC123 to the same family as 2-year-old patient B. Smith of postcode ABC123, on the presumption that they were both siblings.

This method was anticipated to accurately classify family members the majority of the time, particularly since full postcodes identify specific locations. However, if, for example, ABC123 denoted a large apartment building, and if the surname was relatively common, there was a risk that unrelated individuals may be classified as belonging to the same family. Another flaw with this method was that it did not allow identification of family members with different surnames or different addresses. This could have been the situation for step-siblings who have different surnames, or siblings that spend time living with separated parents or other family members at different addresses.

Although taking these weaknesses into account, it was considered that the family ID generation method did increase the accuracy of family identification. This was examined through a basic fidelity check using past St. Mary's Hospital and Northwick Park Hospital attendance data.

One indicator of whether the family IDs generated were accurate was whether they identified families as having the expected number of children (for example, ensuring that they did not classify multiple families with 10 children). Table 4.6 overleaf summarises this statistic for 2016 attendances at both hospital sites (children aged 0–4 years). For both hospitals it was identified that around 90% of non-urgently attending children aged under 5 years do not have a sibling present in the data. There were only a small number (1%) of cases where the family ID identified 3 or more children as belonging to the same family. This suggested that the method of identifying families was accurate.

Table 4.6: ***Number of attending children per family in 2016****. This data includes non-urgent attendances of children aged 0–4 years using criteria listed in section 4.4.2.*

Number of attending children per family	St. Mary's Hospital PED (n = 3834)	Northwick Park (n = 4675)
1	90.9% (3477)	89.6% (4189)
2	8.5% (326)	9.2% (430)
3 or more	0.8% (31)	1.2% (56)
Total	100% (3834)	100% (4675)

4.4.8.2 Randomisation sequence

Randomisation was done at the family level. This was to ensure that a family cannot attend with sibling A, be randomised into the control group, and then later attend with sibling B and be randomised into the intervention group.

The randomisation procedure works as follows:

Families will be identified in the data using the generated family ID. Families were enrolled into the trial three times per week, every week for 8 months. Randomisation was therefore done continuously throughout the trial.

Three times a week, the lead researcher received updated data showing recent attendances at the two hospital sites. These attendances were ordered by time and date in an electronic spreadsheet program (Microsoft Excel). For example, for a given day the first row in the data may be an attendance at 00:20 on 20th August 2017 and the last row may be 23:58 on the same day. A family ID will be generated across the attendances to count how many families have attended (e.g. 1,000 patient attendances in a month might originate from 850

families). A single column of randomly ordered 1s and 0s will then be added to that data set. This will mean that each family ID is randomly assigned a 0 (denoting they will be assigned to the control group) or a 1 (denoting assignment to the intervention group).

The detailed randomisation protocol used at each site is included in *Appendix G*.

4.4.8.3 Allocation

Following allocation to the control or intervention group (summarised in the randomisation section 4.4.7.2). A personalised educational bundle was generated for those families allocated to the intervention group and be posted to the family's contact address on that day.

The full trial process including data preparation and random assignment is summarised in Figure 4.2.

4.4.9 Blinding

The term "blinding" refers to withholding information about the assigned intervention group from those involved in the trial that may potentially be influenced by this knowledge. Blinding is an important safeguard against bias, particularly when assessing subjective outcomes (Wood *et al.*, 2008).

In this trial procedures were established to maintain separation between the lead researcher responsible for participant enrolment and allocation (application of exclusion

criteria, clinical judgement criteria, randomisation process and group allocation), and the outcome assessors and data analysts that reviewed fully anonymised data at the end of the trial.

The lead researcher was aware of the family allocation at the time of intervention delivery, but all further follow-up of the objective measure of non-urgent attendance was undertaken through anonymised records. These anonymised records grouped by an anonymised Family ID were reviewed by the outcome assessor and data analyst team. The outcome assessor and data analyst did not have access to any patient identifiable data.

4.5 Analytical strategy

The statistical analysis used to evaluate the results of the RCT was longitudinal multivariate linear regression. This terminology is clarified below:

- The study was 'longitudinal' as participant outcomes (whether or not a family had a non-urgent reattendance) were collected at multiple time points. Each participant was assessed as having a reattendance for each month they were included in the trial.
- 'Multivariate' (also called multiple regression) describes an analysis that involves more than one statistical variable. This study included adjustment for multiple baseline variables in the analysis.
- 'Linear regression' is explained in further detail in section 4.5.1.

This was an 'intention-to-treat' analysis. Intention-to-treat analysis refers to the method for analysing results in a prospective randomised study in which all participants that are randomised are included in the statistical analysis, and they are analysed according to the

intervention group that they were originally assigned, regardless of what intervention or treatment they received during the trial. This was because participant families were not followed up after initial enrolment and posting of the intervention. It was not possible to identify those that definitively received postal delivery of the intervention.

Either linear regression or logistic regression methods can both be used for hypothesis testing of binary dependent variables (Hellevik, 2009). In this study, linear regression was the chosen method because the results generated have an intuitively meaningful interpretation. This provides results that are easier to communicate research to broader audiences without compromising on robust methods of statistical analysis.

4.5.1 Linear regression

Linear regression is a statistical model that examines the linear relationship between two or more variables, a dependent variable and one or more independent variables. If there is just one independent variable the process is called simple linear regression. If there are two or more independent variables the process is multiple linear regression (Lee *et al.*, 2014).

A linear relationship is one where increasing or decreasing one variable will cause a corresponding increase or decrease in the other variable too. A linear relationship can be positive (independent variable goes up, dependent variable goes up) or negative (independent variable goes up, dependent variable goes down). This is summarised in Figure 4.3.

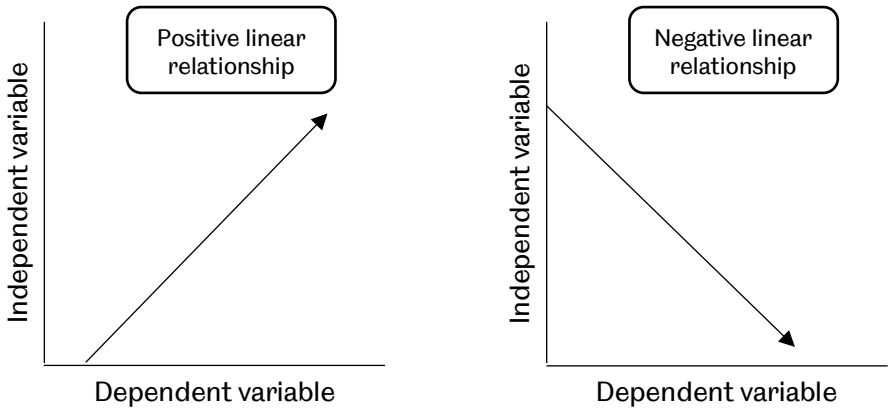


Figure 4.3: Diagrammatic representation of linear relationships.

As linear regression models are able to identify whether changes in one variable is in response to another variable, this means that they can be used for hypothesis testing (Kirkwood and Sterne, 2003).

4.5.1.1 Simple linear regression

A linear relationship between variables Y and X is represented by this linear equation:

$$Y_i = mX + b$$

In this equation, *Y* is the dependent variable (the response variable that is being estimated); *X* is the independent variable (the explanatory variable being used to influence the outcome of the response variable); *m* is the slope of the regression line (it represents the effect that *X* has on *Y*). In other words, if *X* increases by 1 unit, *Y* will increase by exactly *m* units. *b* is a constant (also known as the Y-intercept). If *X* equals 0, *Y* would be equal to *b.*

This equation can also be summarised using the beta coefficient (β) as:

$$Y_i = \beta_0 + \beta X_i$$

In which β_0 represents the constant and β is the slope.

Note that this is not necessarily applicable in real life. Observers will not always know the exact relationship between *X* and *Y*, or they will not have an exact linear relationship.

In a simple linear regression model, a model is built based on data, the slope and the constant (Y-intercept) derived from the data. The relationship between *X* and *Y* does not need to be exactly linear. Simple linear regression models also include the errors in the data (also known as residuals). In a regression model, these errors are minimised by the model finding the "line of best fit" (i.e. the point at which the regression line from the errors would be minimal) (Montgomery *et al.*, 2012).

4.5.1.2 Multiple linear regression

Multiple linear regression is useful because it can identify any independent variables ('explanatory variables') that may be associated with the dependent variable ('response variable'). Multiple linear regression can be also used to investigate the extent to which one or more explanatory variables are linearly related to the response variable after adjusting for other variables that may be related to it. It can be used to investigate the influence of several explanatory variables simultaneously on the outcome.

The regression equation for a multiple linear regression relationship is similar to the simple regression equation, except that it includes more variables. This is represented as follows:

$$Y_i = \beta_0 + \beta_1 X_{1i} + \beta_2 X_{2i} + \beta_3 X_{3i} + \varepsilon$$

ε represents the 'error term'. The error term refers to the difference in the actual outcome variables and the outcome variables predicted by the "true" model. However, when given a sample, one is only able to *estimate* the "true" statistical model (e.g., in a regression equation, one can only estimate the regression coefficients for the population based on the sample) (Kirkwood and Sterne, 2003).

4.5.1.3 Hypothesis testing

As described above, linear regression models are able to identify whether changes in one variable are in response to another variable. This means that they can be used for hypothesis testing.

The slope, represented by the beta coefficient (β), indicates the strength of the relationship between *X* and *Y*. The beta coefficient is the degree of change in the response variable for every 1-unit of change in the explanatory variable (Montgomery *et al.*, 2012).

The beta coefficients can be negative or positive, and have a *t*-value and significance of the *t*-value associated with each. The beta coefficient is the degree of change in the outcome variable for every 1-unit of change in the predictor variable. The *t*-test assesses whether the beta coefficient is significantly different from zero. If the beta coefficient is not statistically

significant (i.e., the *t*-value is not significant), the variable does not significantly predict the outcome. If the beta coefficient is significant, examine the sign of the beta. If the beta coefficient is positive, the interpretation is that for every 1-unit increase in the explanatory variable, the response variable will increase by the beta coefficient value. If the beta coefficient is negative, the interpretation is that for every 1-unit increase in the explanatory variable, the response variable will decrease by the beta coefficient value. For example, if the beta coefficient is 0.8 and is statistically significant, then for each 1-unit increase in the explanatory variable, the response variable will increase by 0.8 units.

Another way of hypothesis testing the beta coefficient is to examine the confidence intervals for the estimated slope and see whether or not they include zero. Statistical programs will calculate the *t*-value and confidence intervals as part of a multiple regression model.

4.5.1.4 Ordinary least-squares regression

Ordinary least-squares (OLS) regression is one of the most popular linear techniques used in the social sciences. It is used to predict the strength of the relationships between a number of variables. The OLS regression method estimates the relationship by minimising the sum of the squares in the difference between the observed and predicted values of the dependent variable configured as a straight line (Hutcheson and Sofroniou, 1999).

OLS regression assumes that all variables entered into the analysis are continuous and the regression procedure attaches importance to actual values. Dependent variables (also called

the ‘response variables’), i.e. those variables that are being modelled, must be continuous and be recorded on at least an interval scale if they are to be modelled using OLS regression.

Though there is a preference for independent variables (also called ‘explanatory variables’) to be continuous, dichotomous data can legitimately be used in a regression model. This is particularly useful as it makes it possible to include multi-category ordered and unordered categorical explanatory variables in a regression model provided that they are appropriately coded into a number of dichotomous ‘dummy’ categories (Hutcheson and Sofroniou, 1999).

OLS regression is a generalised linear modelling technique, which, as the name suggests, models linear relationships. The three components of generalised linear models for OLS regression are a random component for the response variable, which is assumed to be Normally distributed, a systematic component representing the fixed values of the explanatory variables in terms of a linear function, and finally, a link function which maps the systematic component onto the random component. In OLS regression, this is simply an identity link which means that the fitted value of the response variable is the same as the linear predictor arising from the systematic component (Hutcheson and Sofroniou, 1999).

In this research project, the dependent variable is the non-urgent reattendance (%), and a number of continuous and dichotomous independent variables are included in the regression model. These independent variables are summarised in Table 4.7**.**

4.5.2 Primary analysis

The analytical strategy used longitudinal linear regression to examine the effect of the intervention on a month-by-month binary indicator of whether the family ever reattended non-urgently after an initial non-urgent attendance (0 = no, 1 = yes) with a child in the age group 0–4 years. The analysis was pooled, combining attendance data from St. Mary's Hospital and Northwick Park Hospital.

Primary analysis

As stated above, the primary outcome measure is a binary indicator of non-urgent reattendance measured on a month-by-month basis. It was coded as follows:

- 0 = family made initial non-urgent attendance with a patient aged 0–4 years
- 1 = family made non-urgent reattendance with a patient aged 0–5 years.

Although the trial only inducted families that attended with a patient aged 0–4, the outcome variable included patients aged up to 5 years to account for the fact that a patient aged 4 years and 11 months old that was randomised into the trial might have turned 5 years old during the trial period.

The detail of the longitudinal structure of the analysis was as follows. Each family had multiple rows of data generated, one for each month in which 'whether or not they re-attended at hospital' was recorded. New families were inducted into the trial from 9th October 2017 (start of month 1) to 8th June 2018 (end of month 8). However, attendance data was collected up until 8th September 2018 (end of month 11). Therefore, a family that entered the trial in month 1 (between 9th October and 8th November 2017) had 11 rows of

data, one for each month in which they could have reattended (i.e. from 9th October to 8th September 2018). A family that was inducted into the trial on the last day of recruitment (8th June 2018) had three rows of data, one for each month from 9th June 2018 to 8th September 2018. The maximum number of rows of data that a family could have was 11, and the minimum amount was three. For each month, there was a binary indicator of whether the patient had attended non-urgently within that month (this will be a re-attendance by definition rather than first-time attendance, as they must have already initially attended the hospital in order to be inducted into the trial).

It is important to note that the unit of randomisation in this RCT was the family (identified using a combination of patient last name and postcode) and the unit of analysis is also the family. Standard errors were therefore clustered by family in the analysis.

The regression equation for this analysis is detailed in Figure 4.4.

The regression equation for this analysis is:

$$Non-urgent\ reattendance_{tif} = \beta_0 + \beta_1 Intervention_{if} + \beta_2 Patient\ age_i + \beta_3 Patient\ gender_i + \beta_4 Month_t + \beta_5 Distance\ from\ hospital_{if} + \beta_6 Ease\ of\ getting\ GP\ appointment_{if} + \beta_7 Hospital_{if} + \beta_8 Indices\ of\ multiple\ deprivation_{if} + \beta_9 Number\ of\ previous\ nonurgent\ attendances_f + \varepsilon_{ft}$$

Where:

t =month t, which can range from 1 (9th October to 8th November 2017) to 11 (9th August to 8th September 2018)

i = individual patient i

f = family f

$Non-urgent\ reattendance$ denotes whether patient i in family f non-urgently re-attends the hospital during month t after having made an initial non-urgent attendance;

$Intervention$ is the intervention group allocation for patient i in family f;

$Patient\ age$ is a continuous indicator (coded as 0, 1, 2, 3, or 4, 5) of the patient's age during their attendance;

$Patient\ gender$ is a binary indicator coded as 0 for male and 1 for female;

$Month$ is a categorical variable which indicates the month of the non-urgent attendance (the first month of the trial, October 2017, will be coded as month 0, November 2017 as month 1, up until September 2018 which will be coded as month 11);

Figure 04.4: ***Regression equation for trial analysis.*** *(Note: Figure continued overleaf)*

$Distance\ from\ hospital$ is the distance in miles of the patient's home from the hospital (estimated using the first half of the patient's postcode);

$Ease\ of\ getting\ GP\ appointment$ is a continuous variable; it refers to people's responses, taken from the GP Patient Survey, for each GP practice in the data regarding how easy it is to get an appointment at that GP practice;

$Hospital$ is a binary indicator of whether the patient attended St. Mary's Hospital PED (coded as 0) or Northwick Park UCC (coded as 1);

$Indices\ of\ multiple\ deprivation$ is a continuous variable which, coded in deciles, ranges from 1 (most deprived) to 10 (least deprived);

$Number\ of\ previous\ nonurgent\ attendances$ *Number of previous nonurgent attendances* is the number of nonurgent attendances made by each family, with patients of any age, in the 3 years before the intervention (from 1st October 2014 to 30th September 2017);

ε_{ft} is the error term.

Figure 4.4: ***Regression equation for trial analysis.***

The independent variables (also referred to as baseline variables) listed above are described in further detail in section 4.5.2.1.

4.5.2.1 Baseline variables

Table 4.7 describes the baseline variables used in the primary and secondary analyses. These were included in the multivariate linear regression equation summarised in Figure 4.4. All covariates listed have been selected as they are known to be predictors of ED attendance, and were listed in a recent scoping review by Krieg *et al.* (2016).

Table 4.7: *Baseline variables used in the analyses*

Variable	Description	Source	Rationale
Patient age at initial attendance	Continuous variable ranging from 0 to 4.	Hospital	Standard baseline variable.
Patient gender at initial attendance	0 = male, 1 = female	Hospital	Standard baseline variable.
Month of attendance	Categorical variable coded as 0 = Oct 2017 1 = Nov 2017 2 = Dec 2017 3 = Jan 2018 4 = Feb 2018 5 = Mar 2018 6 = Apr 2018 7 = May 2018 8 = Jun 2018 9 = Jul 2018 10 = Aug 2018 11 = Sep 2018	Hospital	To adjust for temporal variation in the likelihood of reattendance (e.g. likely to be higher in winter than spring, more likely to reattend at least once as more time passes).
Miles between patient postcode and hospital of initial attendance	Coded as a continuous variable ranging from 0.3 to 15.8 miles	Doogal .co.uk[vii]	Families who live further away from the hospital may be less likely to reattend.
% of patients saying	Coded as a	GP	Families registered with GP

[vii] www.doogal.co.uk is a website that has curated data available under a public domain licence. The site provides an open source travel distance calculator that uses postcode data to generate the distance required to travel between two locations.

"Yes" or "Yes, but I had to call back closer to or on the day I wanted the appointment" in response to "Last time you wanted to see or speak to a GP or nurse from your GP surgery, were you able to get an appointment to see or speak to someone?"	continuous variable ranging from 49.1% to 97.3%	Patient Survey[viii]	practices where it is easy to get an appointment may be less likely to go to a hospital PED.
Hospital of initial attendance	0 = Northwick Park 1 = St. Mary's	Hospital	To take into account whether families are more likely to reattend depending on whether their initial attendance was made at Northwick Park Hospital or St. Mary's Hospital.
Index of multiple deprivation (excluding the health domain)[ix]	Coded in 5 quintile categories where 1 = least deprived, 5 = most deprived	Gov.uk[x]	Area deprivation is a known predictor of healthcare usage.
Number of non-urgent attendances made in the 3 years before the intervention (from 1st October 2014 to 30th September 2017)	0 = 0 attends 1 = 1–3 attends 2 = 4+ attends	Hospital	Different families have different propensities to utilise healthcare services. Adjusting for this behaviour in the past is likely to be an important determinant of attendance behaviour during the intervention period.

[viii] The GP Patient Survey is an independent survey administered annually on behalf of NHS England. Each year the survey is sent out to over two million people across the UK. The results show how people feel about their GP practice. The survey was originally developed by the University of Exeter and the University of Cambridge (Campbell *et al.*, 2009).

[ix] The health domain is excluded from the Index of Multiple Deprivation score as this domain is partly calculated using information on local emergency department attendance rates.

[x] Indices of multiple deprivation statistics are provided by the National Government in England (Department for Communities & Local Government, 2016).

4.5.3 Secondary analysis

A secondary analysis was carried out to identify whether the educational bundle had any unintended consequences. This analysis was undertaken to identify whether the intervention, which was intended to reduce non-urgent attendances, also reduced urgent attendances.

It was considered possible that the designed intervention may also influence urgent attendances. In some circumstances, families that received the educational bundle may have been less likely to attend the hospital with urgently ill children if the educational bundle improved their general ability to manage the health of their children. In other circumstances, the educational bundle may have made parents overconfident about this ability and result in them not attending the hospital when they needed to.

As a robustness check, these possibilities were examined by re-running the regression equation in two forms:

(i) Changing the binary outcome measure to “Any reattendance” (non-urgent or urgent)

(ii) Changing the binary outcome measure to “Urgent reattendance”.

The secondary analysis followed the same format as the primary analysis (detailed in section 4.5.2) but used the different binary outcome measure stated above.

4.5.4 Subgroup analyses

Finally, subgroup analyses were conducted to determine whether the educational bundle:

(i) differentially affected the non-urgent attendance of families attending with male versus female children;

(ii) differentially affected the non-urgent attendance of families attending with younger versus older children.

Both subgroup analyses were selected because previous literature has suggested some differences with regards to non-urgent PED attendance in different age groups (McHale *et al.*, 2013; Mann and Tempest, 2014), and children of different genders (Singhi *et al.*, 2004). As this data was available in the hospital data sets used for this trial, analysis was undertaken in case it provided additional insights regarding how to target this and any future interventions.

These subgroup analyses were completed by interacting the intervention group variable with the gender or age variable. The independent effects of each variable (e.g. both intervention group and gender) were also entered into the regression, in addition to the interaction variable itself.

To summarise, the subgroup analyses follow the same format as the primary analysis (detailed in section 4.5.2) but added interaction variables to the primary analysis. The interaction effects identified through subgroup analyses were:

(i) an interaction of the intervention group and patient gender at initial attendance (coded as 0 = male, 1 = female)

(ii) an interaction of the intervention group and patient age at initial attendance (coded as 0 = age under 2, 1 = age 2–4).

4.5.5 Post-hoc analysis

Post-hoc analysis was carried out on all independent variables, to determine deviations from the normal distribution, degree of skewness, and covariance with other independent variables. The post-hoc analysis showed that none of the independent variables required further transformation.

Stata (version 15.1)[xi] was used to conduct all statistical analysis.

[xi] *Stata* is a general-purpose statistical software package – https://www.stata.com/

4.6 Ethical and regulatory considerations

Ethical issues were considered in detail during study design. The identified ethical and regulatory considerations, and the required review processes, are discussed below.

4.6.1 Assessment and management of risk

The risk of harm to participants and families from the intervention and enrolment in the study was considered to be low. The educational bundle provided accurate and publicly available information on the management of the most common minor illnesses in children. It was developed in collaboration with clinical experts (NHS hospital staff). The letter did not blame caregivers for having attended PED or UCC with their child and included a reminder that people should go to PED or call 999 in cases of emergency. In this way, the intervention was safeguarding as considered clinically appropriate by the steering group.

One risk of the intervention was that it could inadvertently discourage parents from appropriately bringing very ill children to PED by placing unwarranted responsibility on them to diagnose their child's illness. In order to prevent this from occurring, the educational bundle focused on how to identify serious illness first, and gave key safety-netting information to encourage parents that had children requiring emergency or urgent care to seek it. This highlighted key signs and symptoms of serious illness that should be excluded before families start to manage non-urgent illness.

There was a risk that any child identified as attending non-urgently may have clinically deteriorated since their attendance and returned to hospital urgently. The lead researcher undertook the 'clinical judgement exclusion' step to ensure that the child had not

reattended urgently since their initial attendance, and that they were not a current hospital inpatient at the time of study enrolment and group allocation.

4.6.1.1 Informed consent was not required

The research trial did not involve any clinical intervention. The participants received an educational bundle containing information that was freely available to the public. Following a PED or UCC visit, hospitals were already writing to patients' GPs, and intermittently posting discharge letters to patients' homes. This intervention formalised this practice to also send a letter to the families themselves, in the same way that families would receive a letter before and after a hospital outpatient appointment.

Obtaining informed consent from participants was considered disproportionate to the intervention and had the potential to cause more burden on the participants than the intervention itself. In addition, acquiring consent would have produced a sample of self-selecting participants and may have invalidated the study. Unlike in the traditional medical model, where participants that consent to receive a drug as part of a trial are plausibly biologically the same as participants that refuse consent, participants that actively choose to take part in a research trial may be more aware than those within the general population (and therefore are also more responsive to the developed intervention). This may have created an upward bias in the estimated effect of the intervention (identified through the research trial). This could in turn result in the widespread adoption of an intervention that could only be effective on a self-selecting sample.

Further to this, the act of seeking consent could have made the "non-urgent" nature of participants' hospital visits more salient to them, reducing their likelihood of repeat attendance even in the absence of an intervention. Given the relatively low level of repeat non-urgent attendances at baseline, this would create the risk of a "floor effect", whereby interventions that would be effective in a natural context are rendered ineffective by experimenting.

Finally, information used for the evaluation of the trial is aggregated and anonymised, so there is no risk of participant identification.

This above decision regarding consent was supported by a precedent set by a previous approved ethics application for study on adult patients run with the research collaborators (The Behavioural Insights Team). This previous randomised controlled trial was given ethical approval for the delivery of a postal intervention to patients' homes after they had been discharged, and did not require informed consent from participants (IRAS project ID: 165111) (HRA, 2017).

4.6.2 Data protection and patient confidentiality

During the study, patients' personal data remained on the hospital's servers. No personal data was shared between the two hospital sites. Personal addresses were used by the lead researcher (who was also a staff member at both NHS hospital sites) within hospital premises to address letters to patients assigned to the intervention group. All information used in evaluating the trial was aggregated and anonymised so there was no risk of patient identification.

For evaluation purposes, data analysts received anonymised data. Patients were assigned unique generic numbers (not potentially identifiable NHS or hospital numbers), and data included only basic information such as date of PED or UCC visits, gender, age and the postcode district. The data will not include information on patients' names, addresses, dates of birth or any information on underlying medical conditions.

Personal identifiable data was not and will not be accessed or stored after the study has ended. For analysis, the data analysts only had access to anonymised data, including basic demographic information such as age, gender and postcode district.

4.6.3 Ethics Approval

Full ethical approval was obtained prior to trial commencement. The study was given a favourable ethical opinion by the Health Regulatory Authority (HRA) and the NHS London Bridge Research Ethics Committee (REC reference number: 17/LO/1390).

4.6.4 Trial registration

The research trial was registered through the ISRCTN registry (IRSCTN, 2017). The registration number is ISRCTN74381956.

4.7 Chapter summary

This chapter summarised the methodology of the multicentre, two-armed RCT with balanced randomisation (1:1). It described the relevant steps in the MRC guidance on "Developing and evaluating complex interventions", which included assessing feasibility and

piloting methods (for example, testing procedures, and estimating recruitment and retention). The chapter presented the RCT design and the analytical strategy was discussed. The final section reviews the important ethical and regulatory considerations.

Chapter 5: Trial Results

5.1 Chapter introduction

The fifth chapter of this thesis summarises the results of the RCT undertaken to test the effectiveness of the targeted intervention described in chapter 3. This chapter summarises the descriptive statistics regarding trial participants and enrolment procedures. The primary and secondary analysis of the main outcome data is described, and the results of the sub-group analyses are also presented.

This chapter covers section 3.1 of the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008) (Table 5.1).

Table 5.1: ***Section 3.1 of the MRC Framework*** *- Extracted from Table 1.2.*

3	**Evaluating a complex intervention**		
3.1	Assessing effectiveness	i.	A randomised controlled trial (RCT: *ISRCTN74381956*) across two hospital sites in North West London to evaluate intervention effectiveness.

5.2 Aim of the study

The third and final aim of this research project is to evaluate the impact of the intervention on non-urgent PED reattendance. The objectives of the RCT and the research questions the study seeks to answer are summarised below:

<table>
<tr><td colspan="3">Aim 3: To evaluate the effect of the targeted intervention on non-urgent reattendance at PED using a randomised controlled trial.</td></tr>
<tr><td><u>Objectives</u></td><td><u>Research question</u></td><td><u>Methods</u></td></tr>
<tr><td>Identify whether the intervention reduced the likelihood of non-urgent PED reattendance during the trial period.</td><td>Are families that receive the intervention less likely to reattend PED with a non-urgent problem?</td><td rowspan="3">Randomised controlled trial and (OLS) linear regression</td></tr>
<tr><td>Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient gender.</td><td>Are families that initially attend with a male child less likely to reattend PED with a non-urgent problem following receipt of the intervention?</td></tr>
<tr><td>Identify whether the impact of the intervention on the likelihood of non-urgent PED reattendance was influenced by patient age.</td><td>Are families that initially attend with a child aged 0–2 years old less likely to reattend PED with a non-urgent problem following receipt of the intervention?</td></tr>
</table>

5.3 Trial results

The results of the RCT were evaluated in line with the analysis plan described in section 4.5. This section summarises the descriptive statistics from the research trial, followed by the regression analyses undertaken to answer the research questions.

5.3.1 Descriptive statistics

Table 5.2 shows the number of families enrolled in the intervention over the trial period (13th October 2017 to 8th June 2018).

The RCT included 3,932 families making non-urgent attendances with patients aged 0–4 at one of two London hospitals (St. Mary's and Northwick Park) over the October 2017 to June 2018 period.

These families were randomly assigned to either:

- **The control group**, which received no special follow-up care in the days after making the non-urgent attendance (i.e. they received usual care).
- **The intervention group**, which received the educational bundle, hand-addressed to the child that had made the non-urgent attendance.

Table 5.2: ***Cumulative number of families in the trial over time****.*

Month	Cumulative number of families		
	Total	**Control group**	**Intervention group**
Oct 2017	351	179	172
Nov	1017	517	500
Dec	1708	859	849
Jan 2018	2215	1103	1112
Feb	2692	1351	1341
Mar	3097	1555	1542
Apr	3459	1735	1724
May	3853	1924	1929
June / Total	**3932**	**1969**	**1963**

Of the 3,932 families, 1,969 (50%) were in the control group and 1,963 (50%) were in the intervention group. A total of 2,517 (64%) families were from Northwick Park Hospital and 1,415 (36%) were from St. Mary's Hospital.

A detailed flow diagram summarising trial enrolment, allocation and analysis for each hospital site is summarised in Figure 5.1. Further information regarding the exclusion of records based on clinical judgement is summarised in Appendix H.

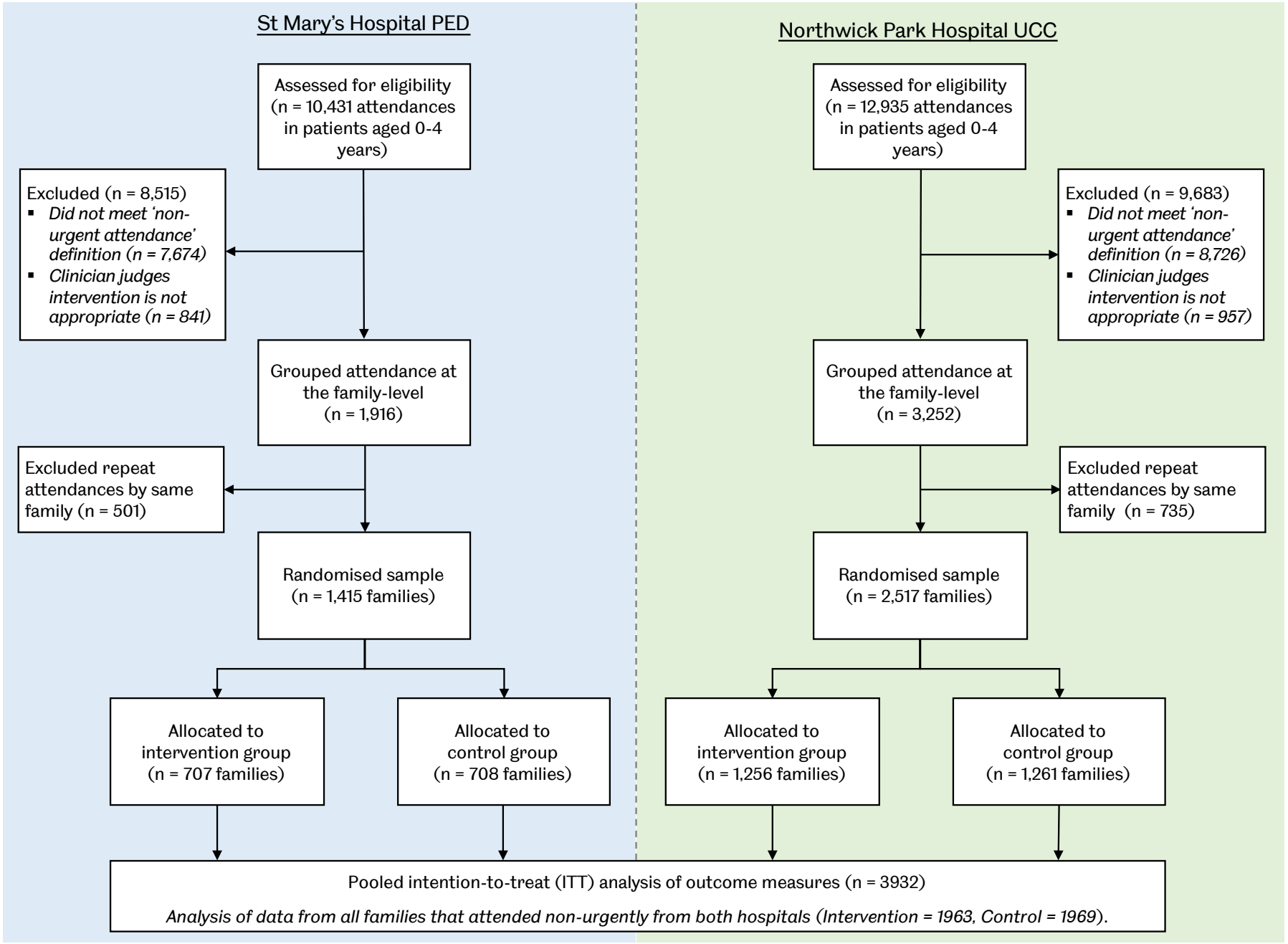


Figure 5.1: ***Flow diagram summarising trial enrolment, allocation and analysis.***

Baseline variables

Table 4.7 describes the control variables used in the primary and secondary analyses. This is copied here from section 4.5 to provide additional context to the results interpretation.

Table 4.7: ***Baseline variables used in the analyses.***

Variable	Description	Source	Rationale
Patient age at initial attendance	Continuous variable ranging from 0 to 4.	Hospital	Standard baseline variable.
Patient gender at initial attendance	0 = male, 1 = female	Hospital	Standard baseline variable.
Month of attendance	Categorical variable coded as 0 = Oct 2017 1 = Nov 2017 2 = Dec 2017 3 = Jan 2018 4 = Feb 2018 5 = Mar 2018 6 = Apr 2018 7 = May 2018 8 = Jun 2018 9 = Jul 2018 10 = Aug 2018 11 = Sep 2018	Hospital	To adjust for temporal variation in the likelihood of reattendance (e.g. likely to be higher in winter than spring, more likely to reattend at least once as more time passes).
Miles between patient postcode and hospital of initial attendance	Coded as a continuous variable ranging from 0.3 to 15.8 miles.	Doogal .co.uk	Families who live further away from the hospital may be less likely to reattend.
% of patients saying "Yes" or "Yes, but I had to call back closer to or on the day I wanted the appointment" in response to “Last time you wanted to	Coded as a continuous variable ranging from 49.1% to 97.3%.	GP Patient Survey	Families registered with GP practices where it is easy to get an appointment may be less likely to go to a hospital PED.

see or speak to a GP or nurse from your GP surgery, were you able to get an appointment to see or speak to someone?"			
Hospital of initial attendance	0 = Northwick Park 1 = St. Mary's	Hospital	To take into account whether families are more likely to reattend depending on whether their initial attendance was made at Northwick Park Hospital or St. Mary's Hospital.
Index of multiple deprivation (excluding the health domain)	Coded in 5 quintile categories where 1 = least deprived, 5 = most deprived	Gov.uk	Area deprivation is a known predictor of healthcare usage.
Number of non-urgent attendances made in the 3 years before the intervention (from 1st October 2014 to 30th September 2017)	0 = 0 attends 1 = 1–3 attends 2 = 4+ attends	Hospital	Different families have different propensities to utilise healthcare services. Adjusting for this behaviour in the past is likely to be an important determinant of attendance behaviour during the intervention period.

Table 5.3 shows key descriptive statistics for the sample of 3,932 families in the analysis data. These families made a total of 5,168 attendances (i.e. including both initial non-urgent attendances and non-urgent reattendances) from 13th October 2017 to 8th September 2018.

Table 5.3: ***Descriptive statistics for key variables.***

	Total (n=3932 families)	Control (n=1969 families)	Intervention (n=1963 families)
	Mean average (standard deviation) / %		
Outcome measure			
Average number of non-urgent attendances (incl. reattendances) from October 2017 to September 2018	1.3 (0.7)	1.3 (0.7)	1.3 (0.8)
% reattendance (0 = no reattendances, 1 = any reattendance)	23.9%	24.6%	23.1%
Patient characteristics			
Patient age at initial non-urgent attendance	1.5 (1.4)	1.5 (1.4)	1.4 (1.4)
% female at initial non-urgent attendance	46.3%	45.6%	46.9%
Distance (miles) between hospital and patient postcode	2.3 (1.6)	2.3 (1.5)	2.3 (1.6)
Non-urgent attendances made by patient's family in 3 years before trial (Oct 2014–Sep 2017)	0 = 64.7% of families 1–3 = 27.7% 4+ = 7.7%	0 = 68.2% of families 1 = 25.6% 2+ = 6.2%	0 = 67.1% of families 1 = 27.7% 2+ = 5.2%
Deprivation quintile	3.0 (1.4)	3.0 (1.4)	3.0 (1.4)

On average, the proportion of families making at least 1 non-urgent reattendance (following an initial non-urgent attendance) was slightly higher in the control group (24.6%) compared to the intervention group (23.1%) during the follow-up period examined.

Table 5.4 confirms that the intervention and control groups were balanced on key characteristics at point of entry into the research trial (i.e. patients in both groups were similar in terms of age, gender, index of multiple deprivation and attendance history).

Table 5.4: ***Balance check on key characteristics****.*

Variable	Number of observations	Control average	Intervention average
Patient age	3932	1.47	1.44
% female patients	3932	45.6%	46.9%
Deprivation quintile	3932	3.0	3.0
Non-urgent attendances made in 3 years before trial	3932	0.76	0.73
Miles between home and hospital	3932	2.3	2.3

A variable was defined as balanced if, in a bivariate OLS regression with the intervention indicator, it returned a p-value greater than 0.05 (i.e. no statistically significant difference between the values was identified at the 5% significance level).

Table 5.5 shows the distribution of non-urgent attendances in the intervention and control groups. The majority of families (76–78%) in both groups made 0 non-urgent reattendances during the trial period, 17–18% of families made 1 non-urgent reattendance only, and 5–6% of families made 2 or more non-urgent reattendances.

Table 5.5: ***Number of non-urgent reattendances per family over the trial period****.*

Total number of reattendances	Control (1969 families)	Intervention (1963 families)
0	1501 (76.2%)	1532 (78.0%)
1	348 (17.7%)	329 (16.8%)
2	81 (4.1%)	67 (3.4%)
3+	39 (2.0%)	35 (1.8%)

Figure 5.2 shows that there were 1969 initial attendances in the control group resulting in 644 non-urgent reattendances, and 1963 initial attendances in the intervention group resulting in 592 non-urgent reattendances. In other words, for a roughly equal number of patients making initial attendances those in the intervention group ended up making around 50 fewer non-urgent reattendances.

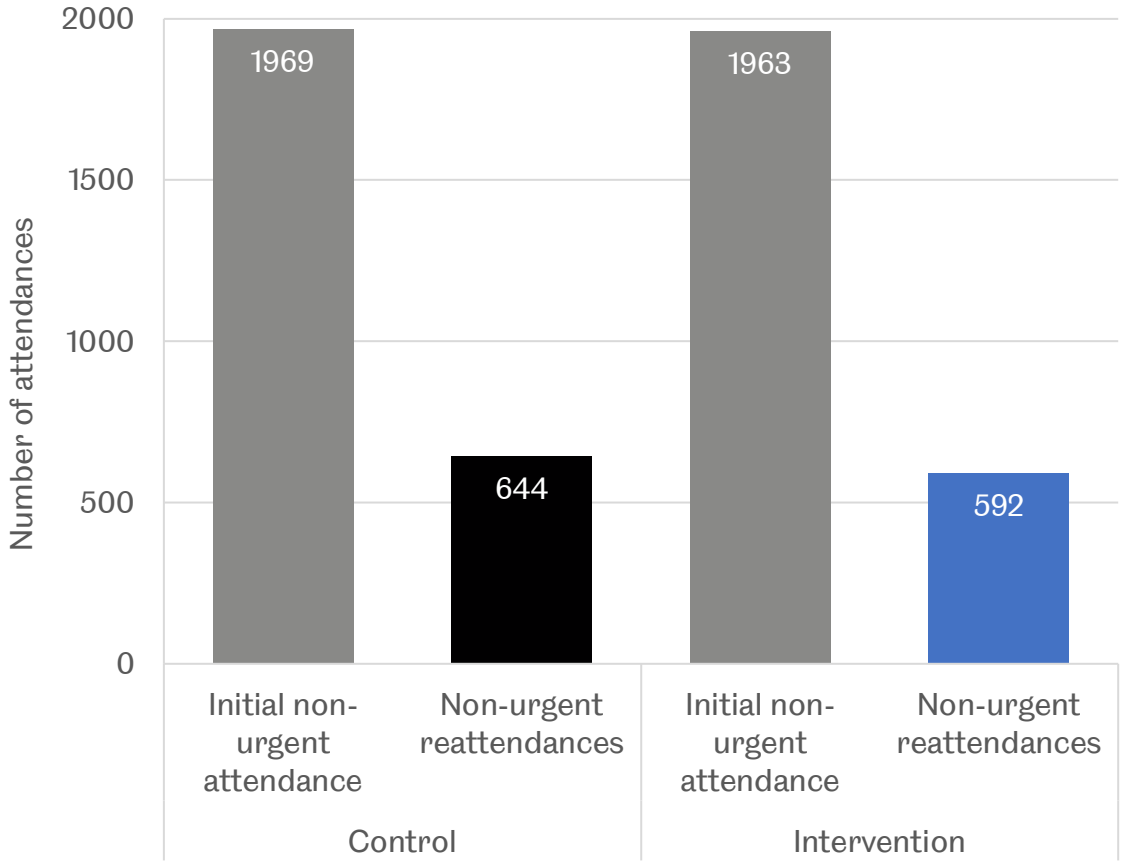


Figure 5.2: ***Number of non-urgent attendances in the control and intervention groups.***

Figure 5.3 breaks these reattendances down by the gender of the patient at the initial attendance. As the reattendances are measured at the family level, a non-urgent reattendance could be by a male or female child. This is because the sibling of the child that made the initial attendance could be male or female.

Figure 5.3a shows that there were 1070 initial non-urgent attendances by male patients in the control group, which resulted in 376 non-urgent reattendances.
There were 1042 initial non-urgent attendances by male patients in the intervention group, which resulted in 291 non-urgent reattendances.

Figure 5.3b shows that there were 899 initial non-urgent attendances by female patients in the control group, which resulted in 268 non-urgent reattendances.
There were 921 initial non-urgent attendances by female patients in the intervention group, which resulted in 301 non-urgent reattendances.

During the trial period, females made up fewer of the non-urgent attendances identified at St Mary's Hospital and Northwick Park Hospital. In both the control and intervention groups, there were over 100 fewer recorded non-urgent attendances of female patients, compared to male patients.

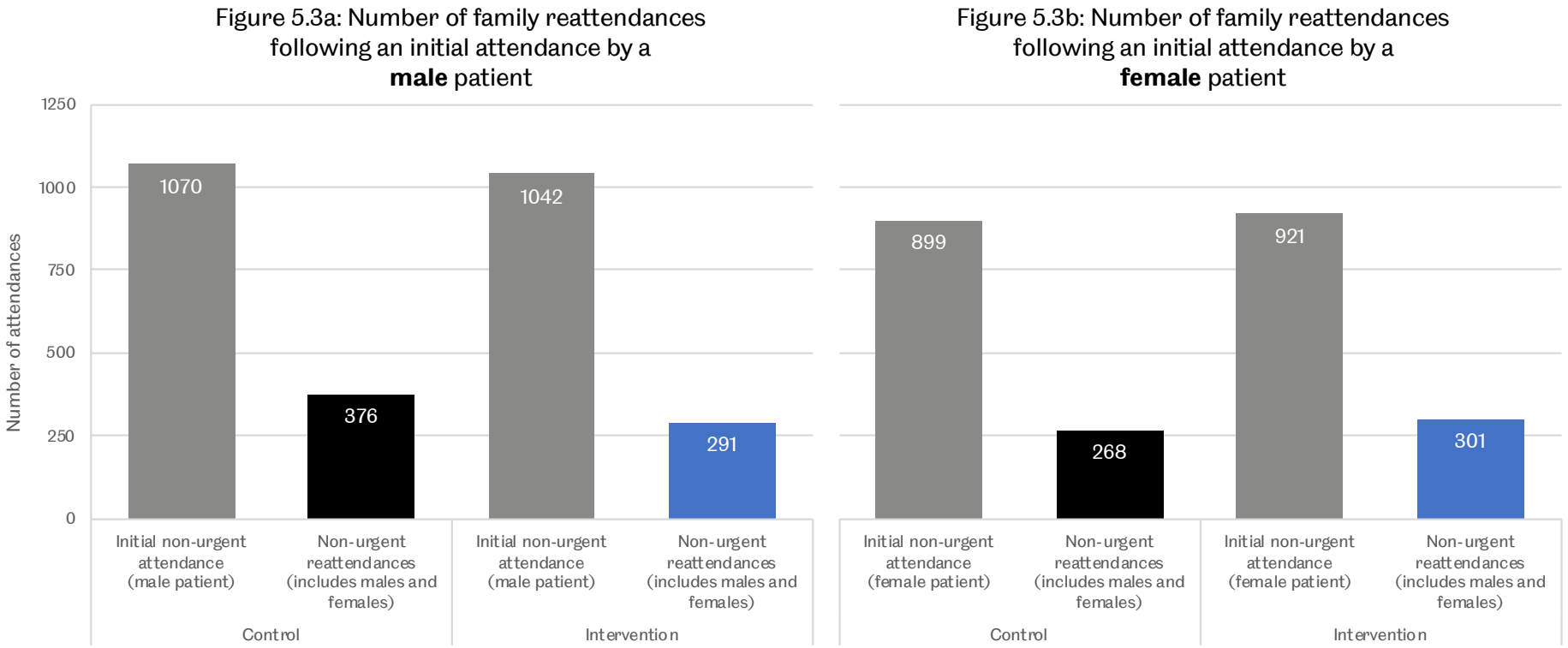


Figure 5.3: ***Number of non-urgent attendances in the control and intervention groups, by patient gender at initial attendance.***

Figures 5.4 and 5.5 show that families in this research trial made fewer non-urgent reattendances if they lived further away from the hospital, or if they were registered with a GP practice where it was reported as easier to get an appointment.

Families that had a home postcode that was within 1 mile of the hospital they attended (either St Mary's Hospital or Northwick Park Hospital) had a non-urgent reattendance of 27.4%. Those that had a home postcode that was more than 3 miles away from the hospital they attended had a non-urgent reattendance of 19.6% (Figure 5.4).

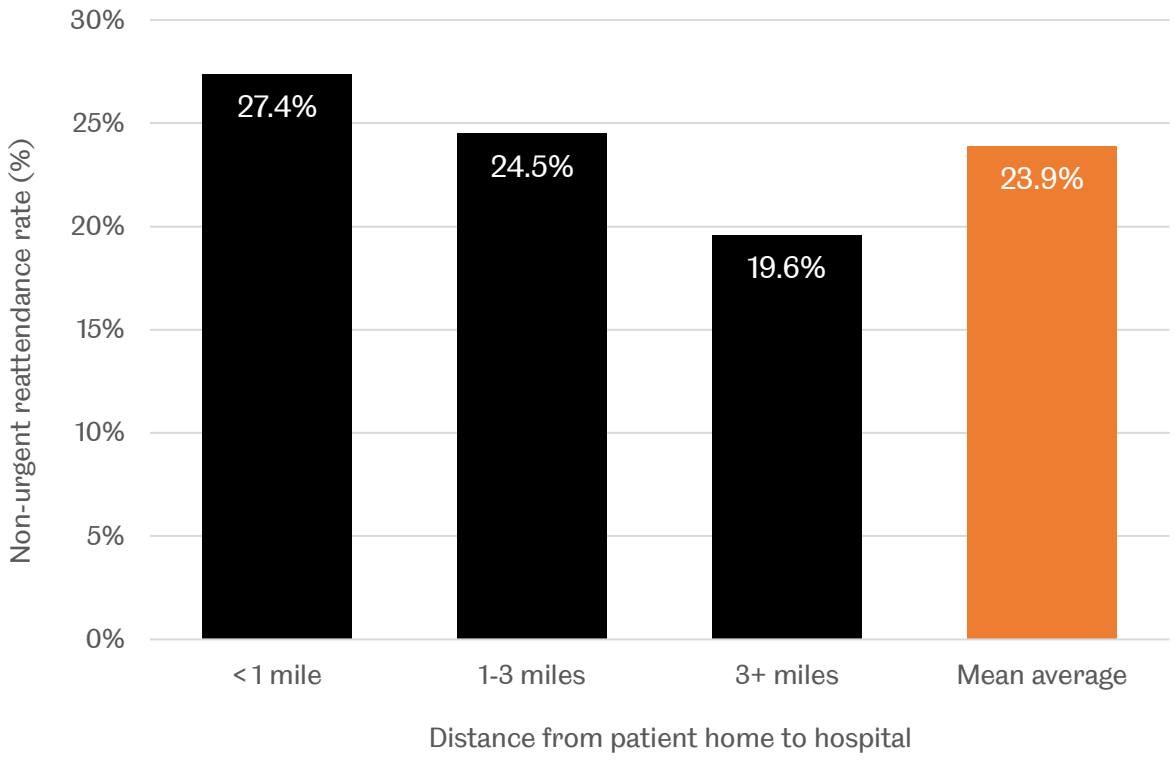


Figure 5.4: ***Non-urgent reattendance rates, by distance from family home to the hospital*** *(N = 5168 attendances across 3932 families).*

The percentage of patients saying "*Yes*" or "*Yes, but I had to call back closer to or on the day I wanted the appointment*" in response to the question:

> "*Last time you wanted to see or speak to a GP or nurse from your GP surgery, were you able to get an appointment to see or speak to someone?*"

...was used as a metric to indicate the ease of obtaining a GP appointment at the GP surgery families were registered at. This data was taken from the GP Patient Survey results published in July 2017 (GP Patient Survey, 2017).

Families that were registered with a GP surgery that reported a result of less than 70 percent of patients surveyed indicating "*Yes*" or "*Yes, but I had to call back closer to or on the day I wanted the appointment*" in response to the above question had a 28.6% non-urgent reattendance, whereas those families that were registered with a GP surgery that reported a result of more than 90 percent had a 14.5% non-urgent reattendance. Note that only 5% of families had a GP surgery that reported a result of greater than 90 percent. These results are summarised in Figure 5.5.

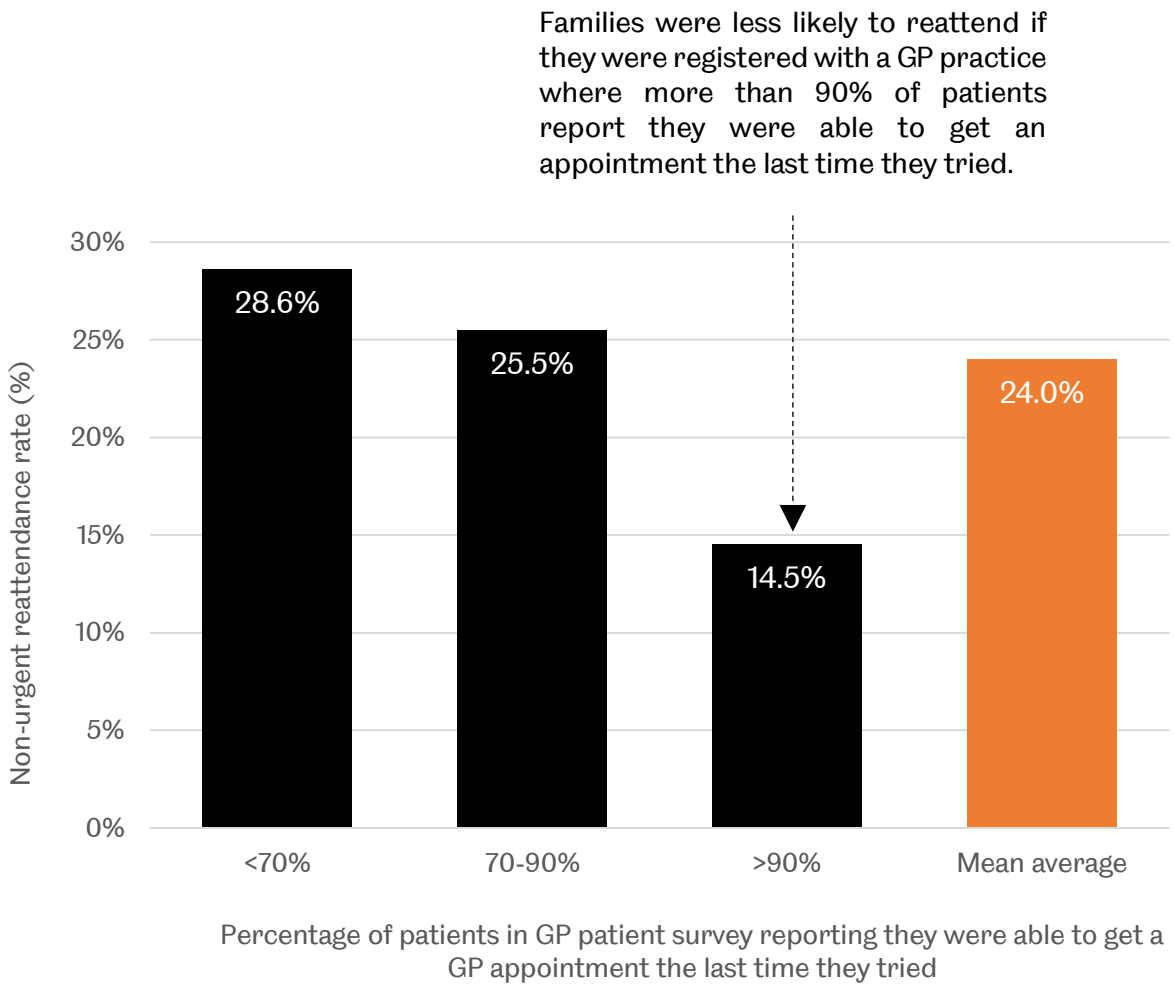


Figure 5.4: ***Non-urgent reattendance rates, by ease of ability to get a GP appointment*** *(N = 4841 attendances across 3694 families).*

Figure 5.6 summarises the differences in family non-urgent reattendance rate by the number of non-urgent attendances the families had made in the 3 years preceding the start of this RCT.

This demonstrates that families enrolled in this trial made more non-urgent reattendances if they had made 4 or more non-urgent attendances in the 3 years before the trial started (from 1 October 2014 to 30 September 2017). These "frequent attender" families make up 6% of the families in the trial (224 out of 3932 families).

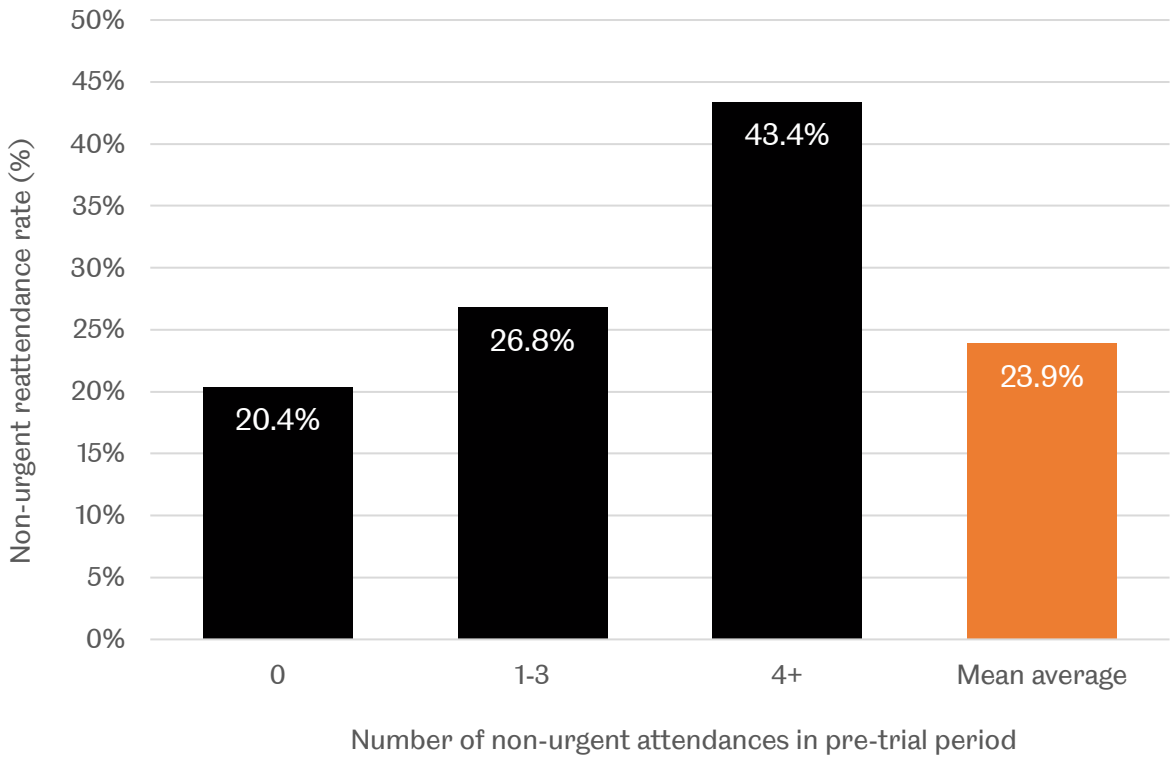


Figure 5.5: ***Non-urgent reattendance rates, by number of non-urgent attendances in the three years before the trial began*** *(N = 5168 attendances across 3932 families).*

5.3.2 The overall effectiveness of the intervention

Research question:

Are families that receive the educational bundle less likely to reattend PED or UCC with a non-urgent health condition?

This section describes the statistical analysis used to assess the primary outcome of the RCT and the secondary analysis undertaken to identify whether the intervention had unintended consequences on urgent PED follow-up attendances.

5.3.2.1 Primary analysis

The analytical strategy used longitudinal linear regression to examine the effect of the intervention on a month-by-month binary indicator of whether the family ever reattended non-urgently after an initial non-urgent attendance (0 = no, 1 = yes) with a child in the age group 0–4 years. The analysis was pooled combining attendance data from St. Mary's Hospital and Northwick Park Hospital.

Figure 5.7 summarises the overall summary statistics to show that the reattendance was lower in the intervention group (23.1%) compared to the control group (24.6%), but this difference was not statistically significant. This result does not take into account the adjustment for baseline variables listed in Table 4.7.

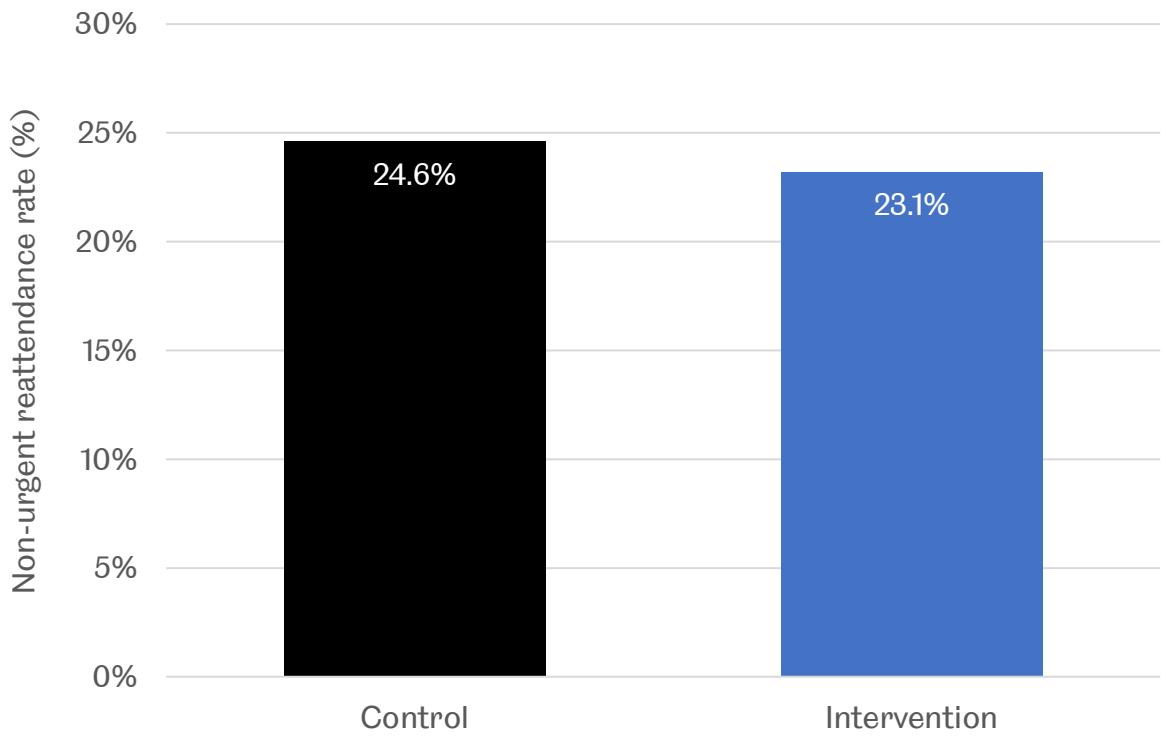


Figure 5.6: ***Non-urgent reattendance rate in the control and intervention groups*** *N = 5168 (across 3932 families).*

Table 5.6 summarises the primary analysis of the main outcome measure for the research trial. The results in Table 5.6 have been summarised for brevity. Detailed versions of all regression tables from this chapter (which include further statistics) are included in *Appendix I*.

Model 1 shows the association between the response variable (main outcome) and the intervention variable only; model 2 adds adjustment for the baseline variables described in Table 4.7. The numbers in the table are presented in terms of percentage points and can be interpreted directly from the table.

The main result, already shown in Figure 5.7, is that families who received the intervention were 1.5 percentage points less likely to make a non-urgent reattendance (relative to a control group reattendance of 24.6%), but the difference was not statistically significant (p=0.25). Adding adjustment for the baseline variables further reduced the intervention effect to 0.6 percentage points (p=0.65).

Table 5.6: OLS regression results showing the predictors of non-urgent reattendance following an initial non-urgent attendance.

Outcome: Any non-urgent reattendance (0=no, 1=yes)				
	Model 1		Model 2	
	Coef. (β)	SE	Coef. (β)	SE
Intervention (vs control)	-1.5	(1.3)	-0.6	(1.2)
Age of patient at initial attendance			-2.3***	(0.4)
Female (vs male) patient at initial attendance			0.2	(1.2)
St Mary's (vs Northwick Park)			-0.4	(1.5)
Miles between patient home and hospital			-1.1***	(0.4)
Index of multiple deprivation (1–5)			0.1	(0.5)
Ease of getting GP appointment			-0.1	(0.1)
Non-urgent attendances 2014–17 (pre-trial)				
0 (base)			-	-
1–3			7.0***	(1.4)
4+			19.6***	(2.4)
Constant	24.6***	(0.9)	16.5**	(7.2)

Sample size (number of families)	3932	3685
Observations included in analysis (attendances)	5168	4831
R-square value (R^2)	0.00	0.21

Beta coefficients and standard errors (SE) are presented in percentage points. Standard errors are clustered at the family level. The analysis was adjusted for month of attendance but this is omitted from the table for brevity.

*** p<0.01 (significant at the 1% level),

** p<0.05 (significant at 5% level),

* p<0.1 (significant at the 10% level).

There are a number of other notable results demonstrated by Table 5.6. These are highlighted below:

- **"Frequent attenders" reattended much more.** Compared to a family that made 0 non-urgent attendances in the 3 years before the trial (68% of families), families that made 4+ non-urgent attendances in that period (6% of families) were 19.6 percentage points more likely to make a non-urgent reattendance during the trial (p<0.001).

- **Older children reattended less**. For each 1-year increase in patient age at initial attendance (measured on a continuous scale from 0 to 4), families were 2.3 percentage points less likely to reattend non-urgently (p<0.001). For example, children aged 2 years old at the time of attendance had a reattendance 2.3% lower than children aged 1 year old at the time of attendance.

- **Families with a home address closer to the hospital reattend more.** Families were 1.1 percentage points less likely to reattend for each 1-mile increase in distance from the family home to the hospital ($p<0.01$). For example, on average families that had a home address postcode 3 miles from the hospital they attended (either St Mary's or Northwick Park) had a non-urgent reattendance that was 1.1% lower than those that had a home address postcode 2 miles from the same hospital.

- **No significant effect of deprivation quintile or hospital that the family attended.** Families were no more likely to reattend depending on whether they first attended St Mary's or Northwick Park ($p=0.71$), or whether they lived in more or less deprived areas ($p=0.79$). There was no statistically significant difference between the values for either of the two explanatory variables. In addition, there was no average effect of increasing ease of ability to secure an appointment at one's GP practice (according to the GP patient survey data).

5.3.2.2 Secondary analysis

A secondary analysis was carried out to identify whether the educational bundle had any unintended consequences. This analysis was undertaken to identify whether the intervention, which was intended to reduce non-urgent attendances, also reduced urgent attendances. The results of this secondary analysis are summarised in Table 5.7 and Table 5.8.

Table 5.7 demonstrates that the educational bundle did not significantly affect the likelihood that patients would make *any* type of reattendance (i.e. urgent or non-urgent) following their initial non-urgent attendance.

Table 5.8 demonstrates that the educational bundle did not significantly affect the likelihood that patients would make any type of reattendance an *urgent* reattendance following their initial non-urgent attendance.

In both Table 5.7 and Table 5.8, Model 1 shows the association between the response variable (main outcome) and the intervention variable only; Model 2 adjusts for the baseline variables described in Table 4.7. The difference between intervention and control groups was not statistically significant for Model 1 or Model 2 in either secondary analysis.

Table 5.7: OLS regression results showing the predictors of any reattendance (urgent or non-urgent) following an initial non-urgent attendance.

Outcome: Any reattendance (0=no, 1=yes)				
	Model 1		Model 2	
	Coef. (β)	SE	Coef. (β)	SE
Intervention (vs control)	-1.8	(1.3)	0.5	(1.2)
Baseline variables included	*No*		*Yes*	
Constant	44.6***	(1.0)	16.4**	(8.1)
Sample size (number of families)	3,932		3,685	
Observations included in analysis (attendances)	6,988		6,556	
R-square value (R^2)	0.00		0.25	

Beta coefficients and standard errors (SE) are presented in percentage points. Standard errors are clustered at the family level. *Baseline variables* are all those listed in Table 4.7.

*** p<0.01 (significant at the 1% level),

** p<0.05 (significant at 5% level),

* p<0.1 (significant at the 10% level).

Table 5.8: OLS regression results showing the predictors of urgent reattendance following an initial non-urgent attendance.

Outcome: Any urgent reattendance (0=no, 1=yes)				
	Model 1		Model 2	
	Coef. (β)	SE	Coef. (β)	SE
Intervention (vs control)	-1.5	(1.3)	-0.4	(1.2)
Baseline variables included	*No*		*Yes*	
Constant	32.4***	(1.0)	5.9	(7.7)
Sample size (number of families)	3,932		3,685	
Observations included in analysis (attendances)	5,752		5,397	
R-square value (R^2)	0.00		0.27	

Beta coefficients and standard errors (SE) are presented in percentage points. Standard errors are clustered at the family level. *Baseline variables* are all those listed in Table 4.7.

*** p<0.01 (significant at the 1% level),

** p<0.05 (significant at 5% level),

* p<0.1 (significant at the 10% level).

5.3.3 The impact of patient gender on the effect of the intervention

Research question:

Are families that initially attend with a male child less likely to reattend PED or UCC with a non-urgent health condition following receipt of the educational bundle?

The first subgroup analysis was conducted to determine whether the intervention differentially affected families that initially attended with male patients compared to those that initially attended with female patients. This was a pre-specified interaction analysis. The aim of this analysis was to identify whether the education bundle had a different impact depending on patients' gender.

The overall findings from this subgroup analysis are presented in Figure 5.8 and the regression analysis is summarised in Table 5.9.

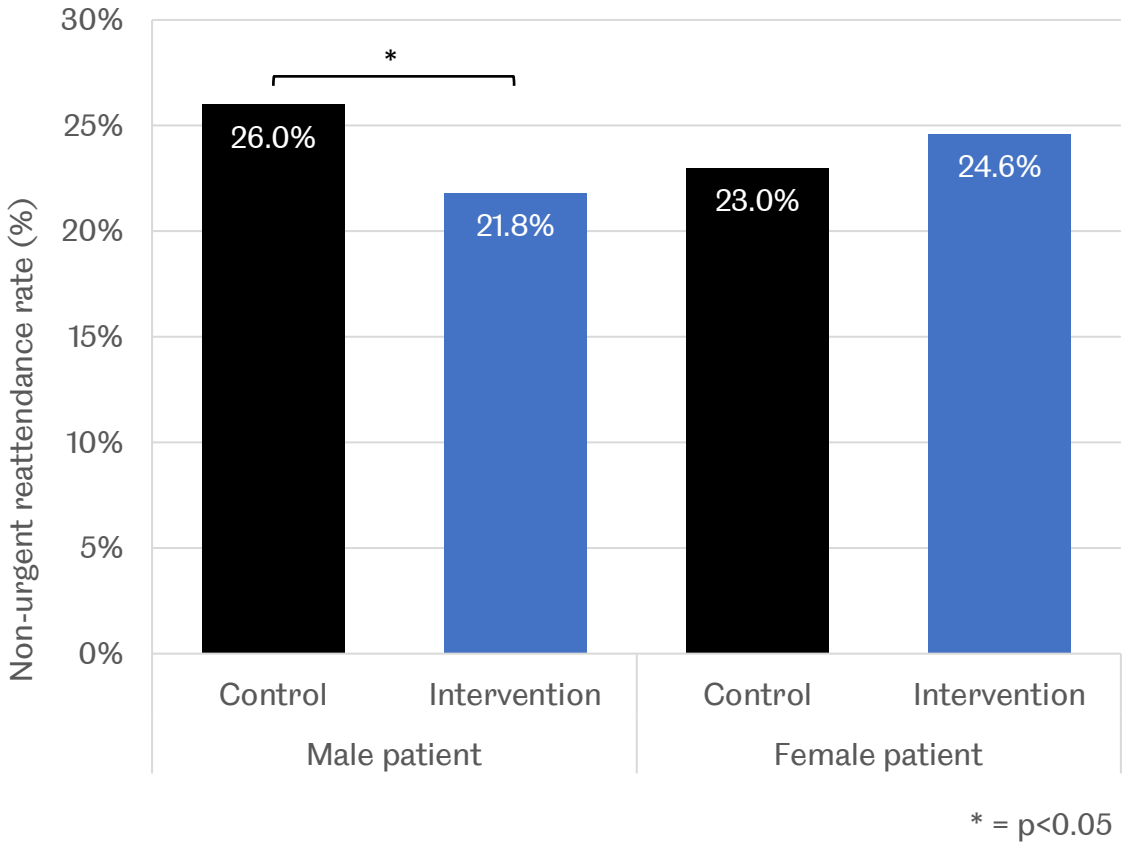


Figure 5.7: ***Non-urgent reattendance rate in the control and intervention groups, by patient gender at initial attendance*** *- N = 5168 attendances (across 3932 families).*

Figure 5.8 demonstrates the overall results identified in Model 1 of the linear regression analysis presented in Table 5.9 (Model 1 shows the association between the response variable and the intervention variable only).

This result suggests that families that received the intervention were less likely to reattend than control families if they first attended with a boy ($p<0.05$), but were more likely to reattend if they first came with a girl (difference not significant).

Table 5.9: OLS regression results examining the interaction of intervention and patient gender during initial non-urgent attendance on the probability of non-urgent reattendance..

Outcome: Any non-urgent reattendance (0=no, 1=yes)				
	Model 1		Model 2	
	Coef. (β)	SE	Coef. (β)	SE
Intervention (vs control)	-4.2**	(1.7)	-2.1	(1.6)
Patient gender at initial attendance (coded as 0 = male, 1= female)	-3.0*	(1.8)	-1.5	(1.6)
Intervention * patient gender at initial attendance	5.8**	(2.6)	3.4	(2.3)
Baseline variables included	*No*		*Yes*	
Constant	26.0***	(1.3)	17.0**	(7.2)
Sample size (number of families)	3,932		3,685	
Observations included in analysis (attendances)	5,168		4,831	
R-square value (R^2)	0.00		0.22	

Beta coefficients and standard errors (SE) are presented in percentage points. Standard errors are clustered at the family level. *Baseline variables* are all those listed in Table 4.7.

*** p<0.01 (significant at the 1% level),

** p<0.05 (significant at 5% level),

* p<0.1 (significant at the 10% level).

This subgroup analysis (Table 5.9) demonstrated that the educational bundle led to a 4.2 percentage point lower reattendance among families first attending with boys (p=0.02), but a 1.6 percentage point higher rate among families first attending with girls (p=0.08).

However, adjusting for the full set of covariates (Model 2 in Table 5.9) reduced this reduction to a 1.5 percentage point lower reattendance among families first attending with boys (p=0.19), and a 0.8 percentage point higher rate among families first attending with girls (p=0.23). Neither of these differences were statistically significant.

This 5.8 percentage point difference in intervention effects between the genders was itself statistically significant (p=0.02). Adjusting for the full set of covariates reduced this interaction effect to a nonsignificant 3.4 points (p=0.14). The full regression table of these results is included in *Appendix I*.

5.3.4 The impact of patient age on the effect of the intervention

Research question:

Are families that initially attend with a child aged 0–2 years old less likely to reattend PED or UCC with a non-urgent health condition following receipt of the educational bundle?

The second subgroup analysis was conducted to determine whether the educational bundle differentially affected families that initially attended with patients aged 0 to 2 years old compared to those that initially attended with patients aged 3 or 4 years old. This was a pre-specified interaction analysis. The aim of this analysis was to identify whether the education bundle had a different impact depending on patients' age at attendance.

The overall findings from this subgroup analysis are presented in Figure 5.9 and the regression analysis is summarised in Table 5.10.

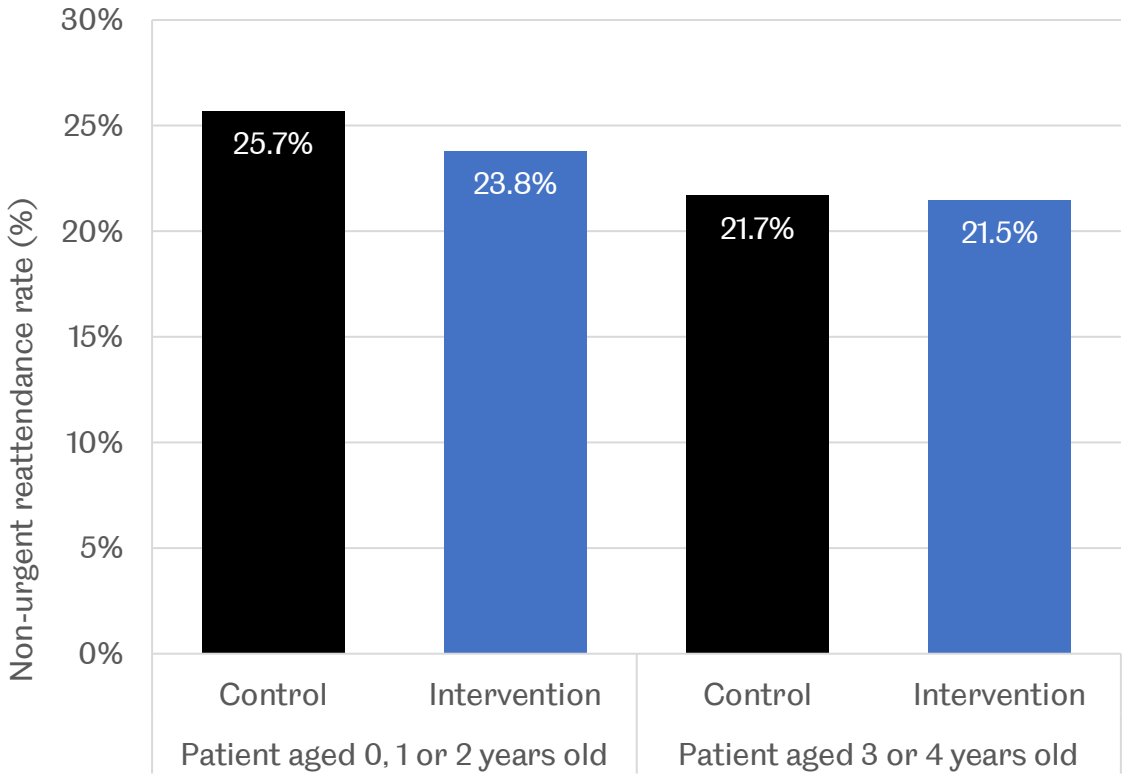


Figure 5.8: ***Non-urgent reattendance rate in the control and intervention groups, by patient age at initial attendance****. N = 5168 attendances (across 3932 families).*

Figure 5.9 demonstrates the overall results identified in Model 1 of the linear regression analysis presented in Table 5.10 (Model 1 shows the association between the response variable and the intervention variable only).

This result suggests that families that received the intervention were slightly less likely to reattend than control families if they first attended with a child aged 0 to 2 years old, but were slightly more likely to reattend if they first came with a child aged 3 or 4 years old. However, this difference was not statistically significant.

Table 5.10: OLS regression results examining the interaction of intervention and patient age during initial non-urgent attendance on the probability of non-urgent reattendance.

Outcome: Any non-urgent reattendance (0=no, 1=yes)				
	Model 1		Model 2	
	Coef. (β)	SE	Coef. (β)	SE
Intervention (vs control)	-1.9	(1.5)	-1.4	(1.4)
Patient over 2 at initial attendance (coded 0 = age 0–2, 1= age 3–4)	-4.0**	(1.9)	0.6	(2.6)
Intervention * age at initial attendance	1.7	(2.9)	3.6	(2.6)
Baseline variables included	*No*		*Yes*	
Constant	25.7***	(1.0)	16.3**	(7.2)
Sample size (number of families)	3,932		3,685	
Observations included in analysis (attendances)	5,168		4,831	
R-square value (R^2)	0.00		0.22	

Beta coefficients and standard errors (SE) are presented in percentage points. Standard errors are clustered at the family level. *Baseline variables* are all those listed in Table 4.7.

*** p<0.01 (significant at the 1% level),

** p<0.05 (significant at 5% level),

* p<0.1 (significant at the 10% level).

This subgroup analysis (Table 5.10) demonstrated that the intervention led to a 1.9 percentage point lower reattendance among families first attending with a child aged under 2 (p=0.21), and a 0.2 percentage point lower rate among families first attending with a child aged 3 or 4 years old (p=0.16). Neither of these differences were statistically significant.

However, adjusting for the full set of covariates (Model 2 in Table 5.10) reduced this reduction to a 1.4 percentage point lower reattendance among families first attending with a child aged under 2 (p=0.32), and a 2.2 percentage point higher rate among families first attending with a child aged 3 or 4 years old (p=0.22). Neither of these differences were statistically significant.

This 1.7 percentage point difference in intervention effects between the genders was not statistically significant (p=0.56). Adjusting for the full set of covariates reduced this interaction effect to non-significant 3.6 percentage points (p=0.17). The full regression table of these results is included in *Appendix I*.

5.4 Chapter summary

This chapter describes the results of the primary, secondary and subgroup analyses used to evaluate the effectiveness of the educational bundle in the RCT conducted across two hospital sites.

On average, families receiving the intervention were 1.5 percentage points less likely to reattend, but this difference was not statistically significant (p=0.25). Adjusting the analysis for identified co-variates reduced the identified difference to 0.6 percentage points (p=0.65).

The secondary analysis identified no unintended consequences. No statistically significant difference in repeat urgent attendance was identified between the intervention and control groups.

However, pre-specified interaction analysis found the intervention resulted in families initially attending with boys 4.2 points less likely to reattend (p=0.02), and girls 1.6 points more likely to reattend (p=0.08). Adjusting the analysis for the identified co-variates reduced this reduction to a 1.5 percentage point lower reattendance among families first attending with boys (p=0.19), and a 0.8 percentage point higher rate among families first attending with girls (p=0.23).

Interaction analysis of the effect of age of the child at initial attendance found no statistically significant difference between the intervention and control group.

Chapter 6:
Discussion

6.1 Thesis findings

This research project achieved the three key aims initially outlined in the introductory chapter (section 1.7):

1) The reasons for non-urgent attendance at PED as described in the published literature were identified.
2) A targeted intervention that aims to reduce non-urgent reattendance at PED was developed.
3) The effect of the targeted intervention on non-urgent reattendance at PED was evaluated using a randomised controlled trial (RCT).

Completion of a narrative review enabled a number of underlying reasons for non-urgent PED attendance to be identified from published articles. The literature sources were appraised for quality and judgement was made on the reliability of each identified factor. These were ranked in order to inform the development of the educational bundle.

A systematic review of previous studies that evaluated interventions that attempted to reduce non-urgent PED attendance provided useful learning and highlighted a number of gaps in previous intervention development. This reinforced the importance of the development of a theoretical framework and of involving parents and carers in the process of intervention development.

This evidence base, a theoretical framework and caregiver and stakeholder involvement were combined with an awareness of the population context and the application of

behavioural insights to develop the educational bundle. The effectiveness of the educational bundle was evaluated using an RCT study design.

6.1.1 RCT findings

The main focus of this research was to test the effect of targeted parental information (the educational bundle) on non-urgent paediatric emergency department reattendance.

The major findings from this RCT were as follows:

- Overall, the educational bundle did not have a detectable effect on *non-urgent* reattendances.
- The educational bundle did not have a detectable effect on *urgent* reattendance or *any* reattendance, and therefore does not appear to have resulted in unintended consequences.
- The educational bundle may have reduced the proportion of non-urgent reattendances for families that initially attended with male children (but not for those that initially attended with female children).
- The educational bundle did not have a detectable effect on non-urgent attendance of those that initially attended with younger children (aged 0 to 2) compared to those that attended with older children (aged 3 or 4).

6.1.2 Additional findings

In addition to the research questions addressed in section 6.2, a number of findings regarding overall attendance behaviour were noted from the primary analysis. These results

relate to explanatory variables included in the regression equation and are summarised below.

- Families with a history of frequent attendance ("frequent attenders") reattended PED and UCC more than those that had no history of frequent attendance.
- Older children reattended less than younger children.
- Families with a home address geographically closer to the hospital reattend more than those that live further away from the hospital.
- No significant effect of which hospital the family attended on reattendance was detected.
- No significant effect of deprivation quintile on reattendance was detected.

6.2 Addressing the research questions

The RCT was designed to answer three research questions. The results generated in an attempt to answer these questions are interpreted below.

6.2.1 Are families that receive the educational bundle less likely to reattend PED or UCC with a non-urgent health condition?

Although treatment families were 1.5 percentage points less likely to reattend, this difference was not statistically significant at the 5% significance level. Therefore, no statistically significant difference in the proportion of non-urgent reattendance was detected between the control and intervention groups. This suggests that, overall, the educational bundle did not have an effect on non-urgent reattendance. Further investigation regarding reasons for this may be required, but the wider literature provides a number of possibilities for the lack of a detectable effect.

It may be possible that the intervention was effective at reducing non-urgent reattendance for some families and had the opposite effect for others resulting in more non-urgent repeat attendances. Therefore, the calculation of the overall average effect size may mask the different outcomes for two distinct groups of families.

As discussed in Chapter 2, a key reason for non-urgent PED attendance is because there are perceived advantages to attending PED with non-urgent childhood illness (Rowe *et al*., 2015; Hendry *et al.*, 2005). Berry *et al.* (2008) describe how the PED environment is seen by some parents as being more attractive, supportive and child-friendly than alternative local

healthcare services. The postal delivery of the educational bundle following a non-urgent attendance may have the unintended effect of increasing the attractiveness of PED or UCC. For example, if families perceive having received a good service from the hospital department, the additional receipt of a supportive educational bundle following their initial attendance could be interpreted as an extension of a positive PED or UCC experience. This may reinforce the attractiveness of emergency or urgent care and result in an unintended consequence, i.e. some families become more likely to non-urgently reattend PED or UCC because the intervention increases the attractiveness of the hospital. Further evaluation of how the intervention was received by participants may shed light on this possibility (discussed in section 6.6.1).

Another consideration is whether the timeliness of the intervention was appropriate. In this study, delivery of the intervention in the days following initial attendance was considered a timely moment. Literature supports the finding that members of society appear to be more receptive to changes at moments that seem significant to them (Shum, 1998; Alter and Hershfield, 2014). However, it is worth considering whether providing the same intervention prior to a family, before a child becomes unwell (for example, in the first few months of a child's life), the initial non-urgent attendance may be prevented. This could result in an overall reduction in non-urgent attendance.

Caution should be taken in the applicability of these results beyond the population of families attending St Mary's Hospital and Northwick Park Hospital. These results are likely to be representative of these population groups, and may not apply to other populations outside of this study. In order to identify any difference in the effectiveness of interventions

in different areas, with different populations a similar study evaluating the effect of the intervention would be required.

6.2.1.1 Families were not less likely to reattend PED or UCC with an urgent health condition

It is reassuring to note that the educational bundle did not have a detectable difference on urgent reattendance or any reattendance. This latter result means that, with reasonable confidence, it can be concluded that the intervention did not have an adverse effect and cause families to end up making a greater number of urgent attendances. This may have occurred if the educational bundle sent to families in the intervention group caused them to have misplaced confidence in their ability to handle their child's health problem, resulting in delayed presentation to PED or UCC.

There is no evidence to suggest that the intervention resulted in delayed presentation or more urgent attendances. This suggests that the educational bundle was an appropriate safety-netting resource (section 2.6), and therefore is a safe resource that can be distributed to families in order to support identification of serious illness in children and aid self-care.

6.2.2 Are families that initially attend with a male child less likely to reattend PED or UCC with a non-urgent health condition following receipt of the educational bundle?

The first subgroup analysis explored whether the effectiveness of the educational bundle at reducing non-urgent reattendance affected families that initially attended with a male child compared to a female child.

Regression analysis indicated that the intervention made families attending initially with male patients 4.2 percentage points less likely to reattend ($p<0.05$), but made families attending with girls 1.6 percentage points more likely to reattend (although this difference was not statistically significant). Once the full list of baseline variables (covariates) was included in the analysis, no statistically significant interaction was detected between the intervention group and either gender. The results from the regression analysis suggest that the educational bundle may have reduced the proportion of non-urgent reattendances for families that initially attended with male children (but not for those that initially attended with female children).

As demonstrated in Figure 6.1, when comparing the control groups for families that initially attended with a male child (column A) to those that initially attended with a female child (column C), the non-urgent reattendance is higher for the male patient group than the female patient group (26.0% versus 23.0%).

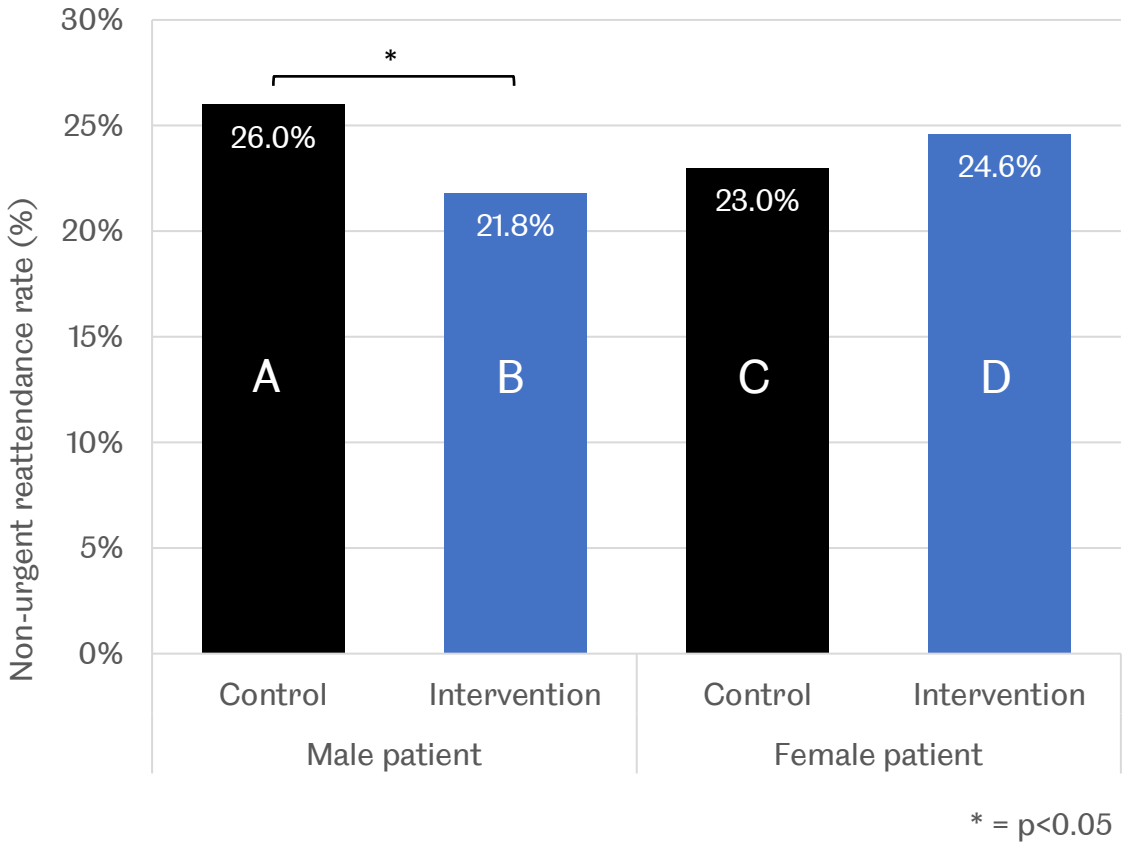


Figure 6.1: ***Non-urgent reattendance rate in the control and intervention groups, by patient gender at initial attendance.*** *N = 5168 attendances (across 3932 families) – analysis not including baseline variables.*

This may indicate that overall male children generally have a higher baseline proportion of non-urgent attendance at emergency and urgent care services.

Previously published studies have confirmed that male children are more frequent attenders at hospital EDs; however, this higher rate of attendance has been attributed to a higher rate of injuries in male children compared to female children (Gofin *et al.*, 1989; Yates *et al.*, 2006). Studies have concluded that boys are more likely to injure themselves accidentally in childhood than girls, and this is because male children demonstrate more risk-taking behaviour than female children (Morrongiello and Rennie, 1998).

In this study the gender difference cannot be attributed to differences in the incidence of injuries. This is because attendances due to injury were not classified as a "non-urgent attendance" and were therefore excluded from the trial and analysis. This means this attendance rate is only attributable to non-urgent medical (i.e. non-injury-related) presentations.

Studies have previously provided evidence to state that males are more likely to suffer with ill health in childhood compared to their female counterparts (Van den Bosch *et al.*, 1992; Hon and Nelson, 2006) and male children are more likely to be hospitalised than female children (Berg-Kelly, 2007; Rajmil *et al.*, 2007). However, there are limited studies specifically describing the PED attendance behaviour of boys compared to girls. Singhi *et al.* (2004) identified that at two hospitals in India, male patients had three times the number of PED attendances that female patients did. They surmised that this difference may be related to the biological vulnerability of males to infection, but a more likely reason was the premium attached to male children in Indian society, leading to preferential medical referral (Singhi *et al.*, 2004).

The gender differences noted in this North West London study might be related to differing attitudes to illness severity risk among parents of boys and girls for which there is some evidence (Pogrebna *et al.*, 2018). Further exploration of underlying attitudes with regards to childhood illness severity, risk and gender in the St Mary's Hospital and Northwick Park Hospital population would be required before drawing any assumptions from this data.

6.2.3 Are families that initially attend with a child aged 0–2 years old less likely to reattend PED or UCC with a non-urgent health condition following receipt of the educational bundle?

As discussed in sections 1.2.2 and 3.6.3.1 of this thesis, younger children are more likely to attend emergency and urgent care services for non-urgent medical conditions (Gill *et al.*, 2013; McHale *et al.*, 2013; Mann and Tempest, 2014; Ruzangi *et al.*, 2020). Therefore, this study explored whether the educational bundle would be more likely to influence families with younger children (aged 0 to 2 years old) compared to those aged 3 or 4 years old.

The second subgroup analysis explored whether the effectiveness of the educational bundle at reducing non-urgent reattendance affected families that initially attended with a child aged 0–2 years compared to a child aged 3 or 4 years old.

Regression analysis indicated that the intervention made families attending initially with patients aged between 0 and 2 years old 1.9 percentage points less likely to reattend, but made families initially attending with parents aged 3 or 4 years old 0.2 percentage points less likely to reattend. Neither of these differences were statistically significant, and adjusting for the full set of baseline variables further reduced the non-significant differences.

If a difference had been detected, this would have provided potential evidence for targeting the intervention at families with children in the first 3 years of life, as opposed to those with children aged up to 5 years old.

6.3 Additional findings regarding attendance behaviour

Interpretation of the most relevant additional findings regarding attendance behaviour is summarised below.

6.3.1 "Frequent attenders" reattended more

Data summarising the number of non-urgent attendances made by individual families in the 3 years before the start of the trial (from 1st October 2014 to 30th September 2017) was included as a baseline variable in the analytical strategy. This meant the relationship between number of non-urgent attendances in the preceding 3 years and whether or not the family made a non-urgent reattendance during the trial could be measured.

Those families that attended 4 or more times in the previous 3 years were considered "frequent attenders". This definition was based on a previous published definition identified from a scoping review of frequent ED attendance by Krieg *et al.* (2016).

The linear regression analysis identified that compared to a family that made 0 non-urgent attendances in the three years before the trial (68% of families), families that made 4+ non-urgent attendances in that period (6% of families) were 19.6 percentage points more likely to make a non-urgent reattendance during the trial ($p<0.001$). In addition, families that made between 1 and 3 non-urgent attendances in the three years before the trial were 7.0 percentage points more likely to make a non-urgent reattendance during the trial.

There is a precedent for this finding. Studies exploring predictors of ED frequent attendance have identified that a past history of frequent ED attendance indicates that adults are more likely to reattend ED in future (Andrén and Rosenqvist, 1987; Okuyemi and Frey, 2001).

However, other studies have attributed this predictive history of past attendance to clinical presentations, including substance misuse (Doupe *et al.*, 2012) and asthma exacerbations (Griswold *et al.*, 2005).

Although work to explore categorise children's frequent attendance has been undertaken in England (Blair *et al.*, 2018; Greenfield *et al.*, 2020), there is currently a gap in published evidence suggesting families that have frequently attended PED in the past are more likely to reattend in future.

6.3.2 Families with a home address geographically closer to the hospital reattend more

The distance between the hospital families attended, and the home address recorded on the patient record of the child that made the initial attendance, was calculated for all families enrolled in the study. This distance was included as an explanatory variable in the primary analysis.

Results from this analysis demonstrated that families were 1.1 percentage points less likely to reattend for each 1-mile increase in distance from the family home to the hospital ($p<0.01$). For example, families that had a home address postcode 3 miles from the hospital they attended (St Mary's or Northwick Park) had a non-urgent reattendance that was 1.1% lower than those that had a home address postcode 2 miles from the same hospital.

This is consistent with the published literature which suggests that non-urgent attenders in one English study were more likely to live close to the hospital (Prince and Worth, 1992).

Another study evaluating all types of childhood attendance at emergency and urgent care identified that for each additional kilometre of distance from a hospital, predicted child attendances fell by 2.2% ($p<0.001$) (Rudge *et al.*, 2013).

The reduced likelihood of non-urgent attendance associated with a greater distance from the hospital may be explained by the additional costs of time and transport to reach the hospital, especially if these health problems could be managed by a primary or community care location situated closer to families' homes. This explanation would be consistent with the behavioural science literature that suggests that specific actions are more likely to happen if you make them easier to carry out (as discussed in section 3.7.6.1) (Service et al., 2014).

Previous studies confirm that distance from hospital is likely to dissuade non-urgent presentations but is unlikely to affect attendance for more serious health concerns. A study of injuries in children in Wales showed that there was a significant decrease with distance in injury presentations generally, but in fractures the distance effect was not significant, suggesting that less severe attendances will be more sensitive to distance (Lyons *et al.*, 1995). Similarly, a Canadian study looking at adult attendance behaviour showed that there was a significant decrease associated with increased distance for less urgent cases, but not for more urgent ones (Béland *et al.*, 1998).

6.3.3 No significant effect of deprivation quintile on reattendance

The postcode from home address recorded on the patient record of the child that made the initial attendance was used to identify the Index of Multiple Deprivation (IMD) quintile for each family enrolled in the study. This IMD quintile variable was included in the primary analysis.

Families were no more likely to reattend depending on whether they lived in more or less deprived areas (p=0.79). There was no statistically significant difference.

There is a wealth of literature that does not support this finding. Published literature provides evidence that deprivation is significantly associated with increased likelihood of attendance (and frequent attendance) of families at emergency or urgent care services minor and moderate injury and illness (Beattie *et al.*, 2001). This includes children of all ages (Rudge *et al.*, 2013), but particularly those under the age of 5 years old (Flanagan and Stewart, 2014). International studies from Australia and the USA also support this finding (Lhila and Simon, 2010; Parry *et al.*, 2016).

A potential reason why no difference was detected in this study was that the participants included only those families that made a non-urgent attendance with a child. Many of the above-referenced studies include all types of childhood attendance at EDs. For example, additional studies have demonstrated that living in an area of high deprivation is predictive of an increased risk of PED attendance for injuries (Reading *et al.*, 1999; Yates *et al.*, 2006). The research presented in this thesis excludes injury presentations.

Studies supporting mixed findings with regards to the relationship between deprivation and non-urgent attendance also exist. For example, McHale *et al.*'s (2013) study found the inverse relationship after adjusting the statistical model used for covariates. This suggests that low deprivation was associated with an increased risk of non-urgent attendance (McHale *et al.*, 2013).

This may be explained by greater access to ED among more affluent individuals (for example, through increased availability of transport), and smaller family sizes which allow greater focus on individual children and increased concern over non-urgent conditions (Hendry *et al.*, 2005; Rudge *et al.*, 2013).

The lack of a detectable result regarding deprivation overall in this study may be due to the similar behaviour being demonstrated by two distinct groups. For example, families from more deprived areas may have a higher risk of non-urgent attendance, and those from a less deprived area may also have a high risk of non-urgent attendance due to the mechanism discussed above.

6.4 Use of the MRC Framework

A key strength of this research was the adoption of the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008). The use of this framework enabled the development a theory- and evidence-based intervention; to specify a proposed causal pathway to modify family behaviour; to test and refine the intervention delivery system; and to design a randomised evaluation of the intervention. However, a challenge

during this work was ensuring there was sufficient time and resources available to apply the MRC Framework and benefit from the iterative development process and from testing study-related procedures. For example, it took several months longer than anticipated to complete the intervention development and obtain ethical approval for this research study.

This thesis demonstrates how the framework can be operationalised for an intervention attempting to reduce non-urgent PED attendance by explicitly mapping the activities, development, and testing to the stages of the 2008 MRC Framework (see section 1.6).

It is important to acknowledge that due to time and resource limitations, this *MD (Res)* project was comprised of steps 1.1 to 3.1 (inclusive). Steps 3.2 to 4.2, summarised in Table 6.1, were beyond the scope of this study's funding and requirements and will therefore be completed outside of this *MD (Res)* as an additional project.

Table 6.1: ***Section 3.2, 3.3, 4.1 and 4.2 of the MRC Framework*** *– Extracted from Table 1.2.*

3	**Evaluating a complex intervention**		
3.2	Understanding change processes	i.	Further work following on from the trial to conduct an implementation and process evaluation of the trial and evaluation to understand the trial results is ongoing.
3.3	Assessing cost-effectiveness	i.	Estimation of the cost-effectiveness of the intervention was not conducted as part of this MD thesis. It is anticipated that this will be incorporated into the follow-up implementation and process evaluation.
4	**Implementation and beyond**		
4.1	Dissemination	i.	Peer review publications, conference presentations, public engagement activities, availability of tools used to develop and deliver intervention
4.2	Surveillance, monitoring, and long-term outcomes	i.	Process and outcome data may inform additional pragmatic trials. It is anticipated that this research will inform additional work at both hospital sites, and across North West London.

This work has confirmed that sufficient time and resources are required to apply the MRC Framework, benefit from the iterative development process and from the testing of study-related procedures. Although a large volume of work was completed as part of this project, further work to understand why the educational bundle had no overall detectable effect is still required.

The MRC Framework guidance highlights how process evaluation is an essential part of designing and testing complex interventions (Craig *et al.*, 2008). To put it simply, RCTs are able to identify 'what works'; and implementation and process evaluations (IPEs) provide an explanation for how and why it works (or, in the case of null impact, why an intervention appears not to have worked). A plan for this IPE is discussed in section 6.6.1.

6.5 Strengths, limitations and scope for future research

Despite the use of a theoretical framework (the MRC Framework discussed in section 6.4), the educational bundle was not identified to have the intended effect on non-urgent reattendance. This may be due to limitations in the development of theory or trial design.

This section identifies a number of strengths and limitations. An awareness of both elucidates the need for future research on this topic and provides recommendations for future work.

6.5.1 Theoretical foundations

An important criticism of this research project is the lack of specific evaluation of the theorised causal mechanism described in section 3.4.3. A combination of an appreciation of health literacy literature and the theory of personal control and perceived threat proposed by Kai (1996) was used to propose a causal model. This included the relevant determinants described in section 3.4.2.

Although a causal modelling approach was informed by relevant theory, this project did not evaluate the components of this causal model. For example, the theorised mechanism assumes that increased health literacy increases personal control, decreases perceived threat and overall decreases parental worry. This study did not measure participants' health literacy, personal control, perceived threat or parental worry. Therefore, no evidence was produced to validate this theorised causal mechanism.

This would have been challenging during the RCT as participants were not approached directly by the trial team, and enrolment was a passive process undertaken through an assessment of electronic patient records. Evaluation of health literacy, personal control and

parental worry would require follow-up interviews with research trial participants. Unfortunately, contact with trial participants was considered disproportionate to the educational bundle intervention and may have therefore influenced the trial outcome. It was therefore agreed by the multi-disciplinary steering group that provide input into the trial design, that assessment of the steps of the theorised causal mechanism would be assessed as part of the implementation and process evaluation (described in section 6.5.1).

This thesis focuses specifically on the application of behavioural insights through nudges, and their potential to improve health outcomes by targeting the automatic system for processing information and decision-making (System 1) (Marteau *et al.*, 2011; Perry *et al.*, 2015). As discussed in section 2.7.1, there is evidence to suggest that the effect of the behavioural nudges described can be further enhanced by combining several nudges (Taylor *et al.*, 2013; Backman *et al.*, 2015). This was the rationale for incorporating multiple nudges into the design of the educational bundle. However, this could be interpreted as a "kitchen sink approach".[12] The logic underpinning this approach is that by including all mechanisms or tools that may be effective, the likelihood of an intervention being effective is increased.

A criticism to this approach is that through the use of multiple nudges in an intervention, it becomes impossible to identify which of the included nudges are most effective at influencing the targeted behaviour (Hummel and Maedche, 2019).

[12] The term "kitchen sink approach" is an allusion to the expression "everything but the kitchen sink". It refers to everything that can be conceived of. In this case, it means every imaginable feature has been included.

Although a combination of nudges may increase the likelihood that the intervention will change behaviour, this makes the reason why unclear and may result in incorrect inferences about what caused the behaviour change. This in turn may lead to the adoption of ineffective future nudges at a future date (Hauser *et al.*, 2018).

An alternative approach would be to test multiple different interventions that each use a different specific nudge on multiple different groups (Ludwig *et al.*, 2011). For example, one intervention may include no additional nudges, one could include a hand-signed letter from a clinician (messenger effect), and one could include a personalised intervention. However, this would require a sufficiently powered study to detect the difference between a range of intervention groups.

Further criticism to the kitchen sink approach is argued by researchers that recommend that nudges are selected and designed specifically for the target population, problem, and context. By ensuring the greatest relevance, the potential intervention effectiveness is increased (Rycroft-Malone, 2015; Hauser *et al.*, 2018). Hauser *et al.* (2018) assert that efforts to change behaviour (to nudge people) can be informed by careful consideration of the psychology of the underlying population, understanding people's underlying (conscious or unconscious) beliefs in order to ensure that any nudge will actually shift their current beliefs. In order to mitigate this potential weakness, future work that draws upon behavioural insights should consider the merits of this approach.

6.5.2 Trial design

This was a research study conducted at pace. The task set by funders and research group collaborators was ambitious, and this required a large body of work to be completed by the author and a supportive team within a 24-month period. Despite these challenges, the research was successfully completed in the timeframe set by the research funder. It is hoped that the novel intervention is a useful resource for families, and the research findings contribute to the existing literature on this topic.

One criticism of the rapid development approach taken during the design of this research study is that particular areas of work were not pursued in great depth. For example, although qualitative research was undertaken to inform the design of the educational bundle (discussed in section 3.5), this exploration was limited to 8 parents or carers and 12 healthcare professionals. Additional capacity and time would have allowed this work to be extended, and allowed a greater number of participants to be interviewed in greater depth. For example, a 'grounded theory' approach could have been used to gather, synthesise, analyse, and conceptualise this qualitative data. A grounded theory approach provides the opportunity to iteratively adapt concepts until conciliation is reached between researchers and the participants (Noble and Mitchell, 2016).

6.5.2.1 Sample size

It should be recognised that the study design and test combination was underpowered for detecting the hypothetical effect size of interest. In section 4.4.6, the minimum clinically significant effect size was stated to be a 10% reduction in non-urgent reattendance, and the sample size calculations aimed to detect an effect size less than this. Although the analytical strategy used for this study was appropriate, the resulting sample size following participant enrolment was small. Therefore, the analysis was less likely to detect a statistically significant effect size.

The main reasons for the sample size being smaller than expected is due to the effect of the "clinical judgement" step described in section 4.4.2.2, and additional inclusion criteria added to the list in section 4.4.2.1 prior to study commencement meaning that a lower proportion of attendances were considered non-urgent. These more stringent criteria were a requirement of the study's ethical approval. More specific criteria ensured that all families enrolled were agreed by the multi-disciplinary steering group as non-urgent attendances, and families that received an instruction to attend PED or UCC by another healthcare professional were not incorrectly enrolled into the trial.

It should be noted that in many ways this was a well-designed study, which resulted in having a sample size that was smaller than expected (although still 5168 non-urgent PED and UCC attendances between October 2017 to September 2018). The smaller sample size means that the results should be interpreted with caution (Hackshaw, 2008). In the context of this study, it means that strong conclusions cannot be drawn from the results, but any findings are still relevant. The findings from this research can still contribute to the

published literature in this topic area, and inform any larger confirmatory studies that look to determine the effect of similar types of intervention.

6.5.2.2 Randomised controlled trial study design

One of the main strengths of this study was the randomised controlled trial (RCT) design. The trial design, analysis plan and outcome measures were all pre-specified on the ISRCTN registry (IRSCTN, 2017). The prospective RCT design ensured control over confounding variables through the random assignment of subjects to either the intervention or control group. The process of randomisation provides greater confidence in the identification of real associations between the educational bundle and non-urgent reattendance outcome (Campbell and Stanley, 1963).

The study was further strengthened by the inclusion of a large set of covariates known to be predictive of ED attendances, including families' own ED attendance history over the 3 years preceding the trial.

One weakness in the allocation procedure was that the clinician responsible for the identification cases, application of inclusion criteria and clinical judgement regarding whether the family should be included was the lead researcher (and the author of this thesis). Although rigorous methodology was applied to the identification and group allocation step (including the randomisation protocol), there is a risk of bias during the clinical judgement step. Ideally, the detailed review of patient records and the clinical judgement regarding whether a family should be enrolled in the study should have been carried out by a clinician not involved in the enrolment and group allocation of participants.

However, due to resource limitations this trial was reliant on a single clinician that also led this research project. To mitigate this risk in future trials, projects should be resourced to ensure identification and group allocation are undertaken by separate researchers.

The lead researcher was aware of the family allocation at the time of intervention delivery, but all further follow-up of the objective measure of non-urgent attendance was undertaken through anonymised records. These anonymised records grouped by an anonymised Family ID were reviewed by the outcome assessor and data analyst team. The outcome assessor and data analyst did not have access to any patient identifiable data. This ensured that the research team members responsible for data analysis would be blinded to intervention or control group allocation, and prevented investigator bias.

6.5.2.3 Participants grouped at the family level

Section 4.4.8.1 described the process for generating a family identifier, to ensure that individual patients that met the inclusion criteria were grouped by family.

The strength of this method is that it would prevent children from the same family or household being allocated to different intervention groups during the research trial in the majority of cases. However, there are a number of limitations associated with this approach. For example, if a hypothetical postcode (such as ABC123) denoted a large apartment building, and if the surname was relatively common, there was a risk that unrelated individuals may be classified as belonging to the same family. Another weakness of this method was that it did not allow identification of family members with different surnames or different addresses. This could have been the situation for step-siblings that have different surnames, or siblings that spend time living with separated parents or other family

members at different addresses. The method is reliant on the quality of the data recorded in the hospital's electronic record.

As the participants in this research trial were clustered at the family level, this meant the family characteristics were based on the child that made the initial attendance. It meant that if the family's repeat attendance was made by a different family member, the characteristics of the second child would not be identified and evaluated through the analytical strategy used in this study. This is why the results discussed in section 6.2.2 and section 6.2.3 are only interpreted based on the gender and age of the child that made the initial attendance.

6.5.3 Patient and public involvement

A key strength of this study was the involvement of parents and carers with experience of managing unwell children in the design of the intervention and research. This patient and public involvement (PPI) activity recognised that people with lived experiences can contribute additional expertise and give valuable, novel insights to research. PPI ensured the design of relevant, participant-friendly, ethically sound research.

In 2015–16 when this research project was conceived, co-production (referred to as or co-design) in academic research was still relatively novel, and resources or guidance existed on how best to undertake co-design with patients and members of the public.

However, since 2017 there has been a great deal of interest and work in this field. At the time of writing, a wealth of co-design frameworks to support participant-led co-production

in health research now exists (Greenhalgh *et al.*, 2019; Slattery, Saeri and Bragge, 2020). For example, *Guidance on co-producing a research project* (INVOLVE, NIHR, 2018) aims to provide clarity through five key principles and features of co-production.

Although many of the key principles of the INVOLVE, NIHR (2018) guidance document were embraced in the PPI work that informed intervention and trial design in this project (such as "reciprocity" and "respecting and valuing the knowledge of all those working together on the research"), this was iterative and informal and not matched to an evidence-based framework. Future research in this area could be strengthened with the inclusion of established co-production principles from the moment a research idea is conceived.

The PPI described in section 3.5.1 relied on volunteers from the local community to give up their time and share information regarding their experience of non-urgent PED attendance. The volunteers were not provided with an incentive or compensated for the time that they gave to the project.

It is understood that patients and the public engage with research for a variety of reasons including: interest in a healthcare topic, often driven by personal experience of a disease or of the health service; altruistic motivations to contribute to a better healthcare system through research; and a desire to influence and reflect patient perspectives in research (Bagley *et al.*, 2016). However, one of the challenges associated with PPI being provided by volunteers is that those involved may not be representative of the target population. For example, the volunteers in this research study were likely to be more engaged with healthcare services than others within population that are more likely to reattend PED with non-urgent health conditions.

The challenge of recruitment of PPI volunteers representative of a target population is recognised across all areas of medical research (Lander, Langhof and Dierks, 2019). In order to improve representativeness of the PPI volunteers involved in this project, additional resource could have been spent at engaging the target population and providing opportunities for community outreach activities.

A key example of a limitation of the final intervention design is that it was only available in the English language and required a minimum reading age of 12 years old. This was acceptable to the PPI volunteers that were members of the project steering group, but this may not have been appropriate for the wider population. Feedback from the trial highlighted that many residents of the hospital catchment areas may not speak English as a first language, and therefore the resources delivered to families may not have been as accessible as was intended.

6.5.4 Location of the intervention

A potential criticism of the designed intervention was that it was delivered from a hospital environment. Although the content of the intervention referred to alternative care services (such as pharmacy, NHS 111 and primary care), the intervention was delivered from PED or UCC and signed by a clinician from the same location. This may run the risk of unintentionally increasing the attractiveness of the hospital, and increases non-urgent reattendance (as discussed in section 6.2).

This research study was required to be undertaken from within a hospital emergency or urgent care setting, and therefore the messenger was identified as the clinical team within the hospital. By changing the messenger to a healthcare service that families were being encouraged to attend instead, the intervention may become less "hospital-centric" and instead increased the attractiveness of the community or primary care. For example, the personalised letter could be signed by the child's GP, or a local pharmacist. It could include information more relevant to the community care location that the intervention was sent from.

There is a precedent for effective primary care-based interventions to reduce non-urgent PED attendance. In Racine *et al.*'s (2009) study the intervention (delivered by a primary care provider 72 hours following the initial visit) resulted in a 3% (statistically significant) reduction in the number of visits to PED by subjects in the intervention groups 12 months after the index PED visit, albeit in a USA setting.

If there had been additional flexibility in the study timetable and the study requirements, attempts could have been made to amend the project specification in order to mitigate this impact of delivering an intervention from within of the hospital setting (for example, having the educational bundle owned by and delivered from primary or community care instead of PED and UCC).

A future hypothesis that could be explored is whether a similar intervention that was based in a community or primary care location, with a community healthcare professional as the messenger, would be more effective at reducing non-urgent PED reattendance.

6.5.4.1 Locality specific issues

As discussed in section 3.6.2 the structure of the emergency and urgent care departments differed between the two hospital sites. In order to better understand these differences, observations of the patient journey at St Mary's and Northwick Park Hospital were undertaken. The patient journey of each site is summarised in a process diagram in *Appendix E.*

In addition to differences in the structure of the health systems within hospital, there are also differences in the structure of the health systems covering the hospital catchment areas. St Mary's Hospital is a tertiary referral centre located in Central London. Specialist paediatricians and paediatric teams are located on site. Although Northwick Park hospital is a major hospital with extensive facilities, it does not offer the same level of specialist expertise and therefore members of the public may perceive both hospitals differently. The referral pathway for both hospitals emergency and urgent care pathway is different, and both hospitals are aligned in different ways to the local healthcare system. Integrated care pathways (linking primary and secondary care) exist within St Mary's Hospital that are not present within Northwick Park Hospital.

In addition to these differences, there are other locality specific issues that suggests a large degree of heterogeneity between the hospital sites and respective healthcare systems. It is important to consider this heterogeneity when interpreting the trial results, as the effect of the intervention may have been influenced by the healthcare system context and been more or less effective depending on external factors. Both NHS sites and the related systems are not directly comparable.

6.5.5 Targeting a specific population

Another limitation of the research design was that the study targeted all non-urgent attendances under the age of 5 years old. Although targeted at families attending non-urgently with children in a specific age group, this may be considered a broad target for this intervention. Further in-depth work into the specific type of non-urgent attenders within this group during study conception could have led to an approach that was more targeted, and potentially more likely to be effective.

For example, future research could consider the findings related to frequent attenders (section 6.3.1), and develop a targeted approach specifically aimed at frequent attenders.

The population of families that make non-urgent attendances at Northwick Park Hospital UCC are likely to be different to the population of families that make non-urgent attendances at St Mary's Hospital PED. The intervention did not take into account a wider appreciation of population demographics specific to both hospital populations (for example, the influence of ethnicity and culture).

London has an incredibly diverse population, and the reason some parents are more likely to attend hospital with unwell children may be because of different cultural expectations (Daniels *et al.*, 2018). For example, in 2018, 36% of Londoners were not UK nationals but came from over 50 different countries (Migration Observatory, 2019). The diversity in culture means there is also diversity in attitudes and behaviours around healthcare (Coleman and Testa, 2008). For example, published research has highlighted the differences

in family support structures in families of different ethnic origin (Bhopal, 2000). The ethnic diversity of the targeted population, and the related differences in family support structures may have impacted on health-seeking behaviours. Future interventions may be better placed when designed in collaboration with specific groups, to provide more tailored advice that is relevant to a variety of family support structures.

Given the population demographics of those living in the boroughs where the hospital sites in this study were located, it may be that there are more non-urgent attendances from some cultures than others, due to these differing healthcare expectations. For example, the population surrounding Northwick Park Hospital includes a high proportion of people with a Polish background, and also a high proportion with an Indian background. A key weakness of the educational bundle designed as part of this study was that it did not attempt to target specific cultures that may be responsible for a higher proportion of non-urgent hospital attendances.

This was in part due to the lack of available data regarding country of origin, ethnicity or culture in the hospital data sets used within this study. Unfortunately, ethnicity and country of origin data were not consistently available in the routinely collected hospital data during the trial period, nor in the three years preceding the trial at either hospital. This challenge is not specific to this research project. Although ethnicity data collection has been proven to be important in healthcare, but despite several government initiatives ethnicity data in healthcare records remains incomplete and mostly unvalidated in the UK (Iqbal *et al.*, 2012). The lack of ethnicity and country of original data mean that the identified characteristics of those that made non-urgent attendances was limited to those included in the data available

(this was presented in section 3.6.3.1). Future work should aim to ascertain these population characteristics prior to intervention development.

Another weakness of the intervention in the context of diverse population groups that are likely to be attending both hospitals, is that the intervention was only distributed in the English language. Local data suggested that over 15 different languages were spoken by individuals in the area surrounding Northwick Park Hospital. Unfortunately, sufficient resource for the translation of resources was not available, and hospital data did not consistently identify the primary language spoken by families attending PED or UCC.

The intervention was targeted at those with a reading age of 12 years old, and only available in English. This meant that recipients whose first language was not English may have been less likely to review and use the educational bundle.

This criticism is particularly pertinent when considering a study from the USA that suggests patients with a lower English language proficiency are more likely to reattend for emergency and urgent care (Ngai *et al.*, 2016). Future work in this area should align with the recommendations provided by Neill *et al.* (2015) and translate resources into a language accessible for the target audience.

6.5.6 Outcome data

The ability to measure re-attendance using objective hospital attendance data is a major strength of this trial. Reduced bias is associated with use of objective outcome measures,

compared to subjective measurements that may be prone to observer bias (Moustgaard *et al.*, 2014).

A limitation of this study was the lack of data on families' interactions with other healthcare providers during the trial period; this means we are not able to assess whether the intervention caused any change in the use of other healthcare facilities (including, for example, the NHS 111 phone service, GP practices or PED at other hospitals). Outcome data was only available for the two research sites, and therefore interpretation is limited to attendance activity at Northwick Park and St Mary's Hospital.

Additional data that was not recorded in the hospital data sets was related to birth order or number of siblings in the family. It would have been useful to ascertain whether families were attending with a first child, or if families had previous cared for multiple older siblings. Studies suggest that the more experience parents or carers have in caring for children, the less likely they are to non-urgently attend at PED (Costet Wong *et al*., 2015; Graham *et al*., 2010).

If this data had been available for this study, another research question could have explored whether the intervention was more effective for first-time parents compared to other families or vice versa. When receiving the intervention materials, parents with lower levels of risk aversion may feel more confident in following the advice in the education materials, while parents who are more risk averse may still prefer the perceived safe option of taking their child to the PED.

Further research in this area would benefit from the evaluation of integrated data that summarises a child or family's use of health and social care services across the system, and is not limited to specific secondary care locations. The recent development of a whole systems integrated care (WSIC) data set in North West London would allow this analysis to be done in the future (North-West London CCG, 2019).

6.5.6.1 Period of participant follow-up

A key limitation of the research trail was the length of time allocated to follow-up trial participants. Participant families that were enrolled into the trial within the final month of recruitment had three months in which to reattend and their reattendance be included in the data collection. Unfortunately, the three-month follow-up period was unavoidable due to the limitations of the research grant.

Ideally the period of participant follow-up should have been 12 months. The number of non-urgent attendances varies between seasons (typically lower in the summer months and higher in the winter) (Hendry *et al.*, 2005). 12 months of follow-up would have included the following Autumn and Winter for around half the participant cohort and increasing the period of time in which participant families could reattend subsequently increasing the statistical power of the research trial.

6.5.7 Analytical strategy

This trial used an 'intention-to-treat' analysis. Intention-to-treat (ITT) analysis refers to the method for analysing results in a prospective randomised study in which all participants that are randomised are included in the statistical analysis, and they are analysed according to

the intervention group that they were originally assigned, regardless of what intervention or treatment they received during the trial.

ITT analysis has become the 'gold standard' for analysing the results of randomised controlled trials. This is because it allows conclusions to be drawn regarding the effectiveness of a specific intervention in real life (as opposed to an experimental setting). The advantage of the ITT method for this research study was that the findings are more likely to be representative of the true effect of the educational bundle in the target population.

The statistical analysis for this research was conducted using multiple linear regression. As addressed in section 4.5, either linear regression or logistic regression methods can both be used for hypothesis testing of binary dependent variables (Hellevik, 2009). However, the use of linear or logistic regression methods for a dichotomous outcome measure has been debated in the literature (Localio *et al.*, 2007).

Medical researchers typical use logistic regression in the hypothesis testing of binary outcomes. This is because, unlike logistic regression, linear regression assumes proportionate sampling on the dependent variable. This can make linear regression more prone to potential selection bias, and less generalisable (e.g. to a different region or country where the baseline prevalence is different) (Allison, 2012). In terms of this research project, it is unlikely that use of binary logistic regression would have made a difference to the primary unadjusted analysis. However, it is traditionally considered a better method and

would have generated a more consistent approach when adjusting for covariates and examining the effects of covariates on reattendance.

Linear regression was the chosen method in this study because the results generated have an intuitively meaningful interpretation. This provides results that are easier to communicate to broader audiences without compromising on robust methods of statistical analysis. However, this analytical strategy could have been strengthened through consultation with professional statisticians embedded within a University Clinical Trials Research Unit. Future work should consider the robust methods of statistical analysis available and utilise analytical support at the trial design stage.

6.5.8 Influences on behaviour external to the intervention

As discussed in the introductory chapter of this thesis (section 1.3.1), the underlying causes of non-urgent attendance are complex and influenced by both behavioural and structural factors. This list of external factors likely to influence families' health-seeking behavioural is extensive. A number of key factors are discussed below.

Families may be influenced by a wide range of internet sources of advice. For example, the NHS website (www.nhs.uk), which received 538 million visits in 2015 and accounts for a quarter of all health-related web traffic in the UK (NHS, 2017a), provides health information through articles and videos. For example, a parent who searches "fever" on the NHS website can access text and video resources describing the causes of high temperature, guidelines on when to seek medical advice, methods of treatment, and advice on when fever may indicate serious illness (NHS, 2016b). Other popular informal services are the

forums Mumsnet (2017b) and Netmums (2017). Both websites offer parenting advice, including information about child health, and combined receive over 1 billion views per year (Mumsnet, 2017a). How and when these resources are used by parents and their effectiveness remain a relatively under-researched area. These online sources external to the intervention may have influenced family behaviour and attitudes to the educational bundle.

Mainstream media, social media and public health campaigns can all influence health behaviour (Laranjo *et al.*, 2014). Reports in the media of young children developing severe illness following common symptoms (e.g. severe sepsis following a fever, or a cough that worsened and required admission to hospital) may encourage families to have a risk-averse attitude towards childhood illness. This may be perpetuated by media and social media publicity regarding perceived medical disasters and potential medical negligence. Public health campaigns may also have unintended consequences on healthcare systems. For example, campaigns to encourage vaccination or identify sepsis early may inadvertently increase fear around childhood illness such as meningitis. This makes the risk of childhood illness more pertinent to families and increases concern when a child becomes unwell.

Families that have previous used healthcare services for their children may be influenced by their prior experience. As described in section 2.3.34, a positive past experience in PED can also encourage parents to reattend in the future (Berry *et al.*, 2008). The same is true for experience of other healthcare services, with a negative experience of one provider likely to dissuade a repeat attendance (Rowe *et al.*, 2005).

The health and wellbeing of the parents or caregivers may also influence PED attendance behaviour. For example, evidence suggests that caregivers with mental health diagnoses or other underlying medical conditions are more likely to choose to attend PED with a non-urgent health condition (O'Cathain *et al.*, 2008; Adamson *et al.*, 2009).

It should be acknowledged that the impact of interventions such as those described in this thesis may only be part of the complex solution required for this multifaceted health policy challenge.

6.5.9 Quality Improvement methodology

The concept of improvement science has emerged in the last decade to provide a framework for research focused on healthcare improvement (Reed and Bell, 2013). There is no single definition of quality improvement (QI). However, a number of definitions describe it as a systematic approach that uses specific techniques to improve quality. The key elements to QI programmes are the combination of a 'change' (improvement) and a 'method' (an approach with appropriate tools), while paying attention to the context, in order to achieve better outcomes (The Health Foundation, 2013).

It can be argued that the research study presented in this thesis was a QI programme. For example, the study design included a literature review, scoping of the issue, identification of stakeholders and an element of co-production. However, the research trial design was limited to a controlled trial focusing on incorporating a single "nudge" to improve healthcare outcomes.

On reflection, by recognising and employing a robust QI methodology to design and test an intervention in the described context may have led to a more successful outcome. This could have been achieved through the incorporation of continuous data harvesting and regular adjustments to implementation (through plan, do, study, act cycles); more appropriate time series analyses and wider community involvement and engagement (Taylor *et al.*, 2014). It is worth noting that QI methodology has been used to successfully undertake the 'Itchy Sneezy Wheezy' project in Northwest London (Warner and Spitters, 2017).

An adaptable approach for this study may have enabled more aspects of the literature review findings (Chapter 2) to be put into practice. For example, Racine *et al.*'s (2009) study (see section 2.4) described an intervention delivered by a designated primary care provider 72 hours following the participants' non-urgent ED visit. This intervention resulted in a significant reduction in the number of visits to PED by subjects in the intervention group 12 months after the index PED visit. Due to the inflexibility of this study, and design limited to PED these literature review findings were not put into practice.

Adoption of QI methodology may have ensured flexibility in the intervention design and location which may have proved more effective than the intervention presented within this thesis.

6.6 Next steps

The MRC Framework guidance highlights how process evaluation is an essential part of designing and testing complex interventions (Craig *et al.*, 2008). Key next steps of this work include the design and pilot of an IPE of this research trial.

6.6.1 Implementation and process evaluation (IPE)

An IPE will be conducted following the conclusion of this *MD (Res)* research project. The IPE has been designed to complement the evaluation of effectiveness and to focus on the identification of causal mechanisms and key moderating factors. The theorised causal mechanisms described in section 3.4.3 will provide greater understanding of what active ingredients may be bringing about changes to individuals' behaviour. This is essential for future research programme iterations, and any potential health policy development.

The IPE will utilise a qualitative approach that includes a sample of research participants from the trial described in this thesis. The IPE will involve conducting in-depth semi-structured interview with the parents or carers of the children that made the initial attendances. If possible, the interviews will be conducted in the participant's home, and be accompanied by observations of the home environment and evidence of the educational bundle intervention (e.g. fridge magnet). These data will be analysed using qualitative techniques to create an in-depth understanding of how the intervention was experienced and implemented by the families.

6.6.1.1 Semi-structured interviews

In depth semi-structured interviews will be conducted with the parent or carer of the child under 5 from the family recruited into the trial (this will count as one family). The interviews will be conducted at one time point to explore the experience of the intervention. Semi-structured interviews allow for conversation focus but also the flexibility to divert off topic should new themes arise (Jamshed, 2014). The interview will maintain flexibility for more than one parent or carer from the same family to participate if they wish to do so.

6.6.1.2 Observations

As far as it is practically possible, home observations will be conducted in conjunction with interviews. The aim of the observations is to look for evidence of intervention implementation by families and to contextualise the implementation environment. Observations have been used in healthcare research in contexts such as intensive care units and EDs in order to understand facilitators and barriers to processes and decision-making (Carthey, 2003). It is not feasible to conduct observations in the home during the decision-making process when a child is unwell; however, understanding the context and everyday frictions or constraints to accessing tools aimed at improving informed decision-making will contribute to our understanding of how and where the intervention could be improved. This work will be led by colleagues at Imperial College Healthcare NHS Trust, and supported by collaborators from BIT.

6.6.1.3 Future work

Section 3.3 of the MRC Framework (Table 6.1) recommends cost-effectiveness analysis of any complex intervention. However, as no overall effect of the educational bundle was detected in this trial, a health economic analysis to demonstrate cost-effectiveness is not currently indicated. If future studies identify that the educational bundle, or a similar intervention, have a significant effect on non-urgent PED reattendance, a dedicated cost-effectiveness analysis should be considered.

The financial implications of the intervention should be considered within an economic analysis, including reference to both direct and indirect costs of delivering the intervention. Direct costs represent the resources consumed by delivery of the intervention and associated events. This will be dependent on the mode of delivery, but in the context of this trial the following direct costs were incurred: design and printing of educational bundle, resourcing of a clinician to evaluate whether PED attendances were non-urgent or urgent and postal delivery costs. Indirect costs include those that are tangible (e.g. the productivity losses of resourcing a clinician to review case records) and those that are less tangible (e.g. the unintended economic harms caused by the intervention resulting in delayed treatment, or self-care activity that was not required).

Dissemination of the findings from this research is ongoing. The results have been shared through conference presentations, and are currently under review for publication in a peer-reviewed journal.

Future work may include surveillance and monitoring of long-term outcomes if this educational bundle is adopted by other organisations beyond those included in this initial research trial.

6.7 Implications of this research during the COVID-19 pandemic

This research shed an important light on an issue that remained relevant up until the end of 2019 (15 months after the conclusion of the trial described in this thesis). The pattern of rising non-urgent PED attendance in young children was seen in the published national statistics at the start of the year 2020 (NHS England, 2020).

As addressed in section 1.12, healthcare service use in England began to shift following the identification of the first confirmed cases of COVID-19 in England in January 2020 (Lillie *et al.*, 2020). In response to a global pandemic the NHS has changed radically in many ways, and the effects of COVID-19 are likely to impact on the health and social care landscape for many years to come (Isba *et al.*, 2020).

Of most relevance to this study is the drop in the overall number of attendances to all EDs in England (for adults and children). The number of attendances at both major and minor EDs (including UCCs) fell sharply in March and April 2020. Compared to the previous year, the overall number of attendances for major EDs fell by 26% in March and 48% in April 2020. For minor EDs the difference was greater with a reduction of 35% in March and 71% in April 2020 (Kelly and Firth, 2020). An English study specifically reviewed the number of PED attendances of children at two hospitals in February and March 2020. Compared to the

previous year, this identified a drop of up to 5.6% in February, and reduction of 33.8% in March 2020 (Isba *et al.*, 2020).

Possible reasons for these findings may be that patients with less severe conditions seeking or being directed towards care outside acute settings or families are choosing to go without medical help (Isba *et al.*, 2020). Other studies continue to evaluate the effects of COVID-19 on urgent and non-urgent attendance of children at emergency departments (McDonnell *et al.*, 2020).

Scaramuzza *et al.*, (2020) have published paediatric attendance data from Italy which is consistent with the English findings. They suggest the effect of COVID-19 has demonstrated the potential impact of disincentivizing non-urgent attendances at PED and suggest that an increase in healthcare education for families, the expansion of primary care and increased alternative healthcare services may maintain the current reduction in PED demand (Scaramuzza *et al.*, 2020).

In May 2020, the Royal College of Emergency Medicine (RCEM) provided a position statement that makes recommendations about how care in emergency departments in the UK needs to be transformed (RCEM, 2020). This report states that “Emergency Departments must not become crowded ever again” and suggests steps that will reduce crowding and improve safety.

Educational materials, that support families to self-care and pursue alternatives to PED attendance have a role in reducing overcrowding and preventing increased demand on

hospital services. Although the future of society and the health and social care sector remains uncertain, support to families caring for unwell children remains a key priority. Although, non-urgent hospital attendance is unlikely to be an acute issue in the coming months. The identification of children suffering with serious illness and ensuring that families seek appropriate healthcare is more important than ever.

6.8 Recommendations

Recommendations from this work can be split into practical recommendations for use in healthcare settings and recommendations for future research activities.

6.8.1 Recommendations for practice

Although the educational bundle did not have the hypothesised effect on non-urgent PED reattendance, it was praised by parents and carers involved in the development process. Provided this feedback is emulated by wider parent and carer population of North West London, the intervention is likely to be an effective tool that can be used to support families in the identification of serious illness in children, and provide additional information regarding self-care.

Families are likely to have several touchpoints with the health and social care system prior to the birth of a child, and during a child's early years. Exploration of other avenues for the delivery of this intervention may have wider health and social care benefits. For example, the intervention could be made available in GP waiting rooms, through health visitors, at antenatal classes or provided by local pharmacies.

This work has highlighted the importance of working with parents and carers to develop interventions. Co-design or co-production appears essential to improving the health and social care for citizens, and all future research and quality improvement work should include PPI wherever possible.

In a world that is adapting to the presence of COVID-19, increased physical distancing measures and restructured health services, accessible health information to support self-care becomes increasingly important. Wider availability of the educational bundle (specifically the information booklet and the factsheet) may provide reassurance and helpful signposting to services for families caring for unwell children.

6.8.2 Recommendations for research

In view of the key findings from this research project, further exploration is required to try and identify:

- whether the educational bundle influenced parents and carers as hypothesised in the causal mechanism informed by relevant theory;
- whether there is any underlying reason for differences in attendance behaviour and the effectiveness of the intervention based on patient gender;
- further information regarding the characteristics of 'frequent attenders' at PED and UCC; and
- how the intervention was received and experienced by families, including any possible unintended effects.

Some of the above may be identified through the IPE planned as a follow-up of this research project (section 6.6.1)

Additional recommendations for future research include the following:

- The effectiveness of the educational bundle (or similar interventions) when delivered by primary or community care professionals should be assessed. An intervention delivered by a primary care setting may be more likely to influence PED attendance compared to an intervention owned and delivered by PED. Repeat of a similar study through integrated GP hubs, or groups of primary care practice would generate useful findings that would inform the effectiveness of the educational bundle at reducing non-urgent PED reattendance.

- Future work should include the adoption of QI methodology to explore this issue. This would ensure the project is adaptable and would acknowledge the complex and multifaceted issue of non-urgent PED reattendance.

- Future work in this area could target more specific populations. For example, families that are already known to frequently attend PED or UCC.

- For interventions to be accessible, all resources delivered to families should be available in multiple languages.

- Research identifying the effect of interventions on use of healthcare services should not be limited to the use of secondary care data sets. The availability of whole systems integrated care dashboards provides an opportunity for integrated data to be used for healthcare and research purposes.

- Any research that assesses the effectiveness of behavioural nudges should consider a focus on specific nudges, and identify how different specific nudges could be compared.

- Research trials should identify sufficient resource in order to run a trial that includes the required number of research participants. Resource and project planning should be informed by the trial power and sample size calculations.
- To reduce the potential of bias, any RCTs in this area should resource the project to ensure that the participant identification and group allocation steps are undertaken by separate researchers.

- Further research should incorporate the key principles of co-design and co-production outlined by INVOLVE, NIHR (2018).

6.9 Concluding statement

This thesis identified the factors that influence a family's decision to attend PED with a non-urgent health concern, and evaluated evidence regarding interventions that had attempted to reduce non-urgent reattendance at PED. Available evidence was not explicit in the theoretical basis for these interventions, and there were few examples of rigorous evaluation in an English context.

This project demonstrates how the MRC Framework for "Developing and evaluating complex interventions" (Craig *et al.*, 2008) can be operationalised to develop a theory- and evidence-based intervention to reduce non-urgent PED reattendance, and design a robust evaluation to assess intervention effectiveness.

The application of nudge theory to the intervention design process provided novel components that have been proven to influence individual behaviour in healthcare

contexts. Caregiver and healthcare professional feedback provided valuable input to the intervention development process, which was combined with an understanding of the population context and the evidence base to produce an educational bundle underpinned by a theoretical framework.

A multicentre, two-armed RCT with balanced randomisation (1:1) did not detect a statistically significant difference in the proportion of non-urgent PED or UCC reattendance between families that received the educational bundle and those that did not. However, a potential difference in the effectiveness of the intervention between families that attended with a male child and those that attended with a female child was identified. The causal mechanism for the educational bundle, and reasons for the trial findings, require further exploration and should be informed by an IPE involving participants from this research study.

There may be merit in an approach in which the educational bundle is delivered from primary or community care settings, and future work should look to replicate this study outside of a hospital setting.

Despite use of the MRC Framework, the targeted parental information provided as part of the final intervention did not have the intended effect. Although no effect was detected, an informative and evidence-based intervention was successfully developed in collaboration with caregivers and healthcare professionals. This educational bundle provides self-care guidance and safety-netting advice to families caring for young children, and will continue to have utility beyond this research project.

This thesis demonstrates the utility of the MRC Framework, patient and public involvement and the application of behavioural insights in response to a healthcare system challenge.

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Appendices

Appendix A:

Why do children attend PED with non-urgent health conditions? - Search Strategies

MEDLINE (via Ovid) Search strategy

1. exp Parents/ or exp Caregivers/ or exp Family/ or parent*.tw. or carer*.tw. or caregiv*.tw. or famil*.tw.
2. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
3. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
4. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
5. 1 and 2 and 3 and 4

[475 references returned]

EMBASE (via Ovid) Search strategy

1. exp Parents/ or exp Caregivers/ or exp Family/ or parent*.tw. or carer*.tw. or caregiv*.tw. or famil*.tw.
2. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
3. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
4. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
5. 1 and 2 and 3 and 4

[1249 references returned]

CINAHL (via EBSCO) Search strategy

S1. (MH "Parents+") OR (MH "Family+") OR TI Parent* OR AB Parent* OR TI Carer* OR AB Carer* OR TI Caregiv* OR AB Caregiv* OR TI Famil* OR AB Famil*

S2. (MH "Child+") OR (MH "Infant+") OR (MH "Adolescence+") OR (MH "Hospitals, Pediatric") OR (MH "Pediatric Units+") OR TI Child* OR AB Child* OR TI Infant* OR AB Infant* OR TI Adolescen* OR AB Adolescen* OR TI Pediatri* OR AB Pediatri* OR TI Paediatri* OR AB Paediatri*

S3. TI Non-urgent* OR AB Non-urgent* OR TI Unnecessar* OR AB Unnecessar* OR TI Inappropriat* OR AB Inappropriat* OR TI (Minor N2 (Illness* or Ailment* or Health*))

OR AB (Minor N2 (Illness* or Ailment* or Health*)) OR TI Non-emergenc* OR AB Non-emergenc* OR TI Non-critical* OR AB Non-critical*

S4. (MH "Emergency Service+") OR (MH "Emergency Care+") OR (MH "Emergency Medicine") OR TI Emergenc* OR AB Emergenc* OR TI ("Accident and Emergenc*") OR AB ("Accident and Emergenc*") OR TI A&E OR AB A&E OR TI “ED” OR AB “ED” OR TI PED OR AB PED OR TI (Attend* N2 (“ED” or A&E or PED)) OR AB (Attend* N2 (“ED” or A&E or PED)) OR TI (Utili* N2 (“ED” or A&E or PED)) OR AB (Utili* N2 (“ED” or A&E or PED))

S5. S1 AND S2 AND S3 AND S4

[257 references returned]

PsycInfo (via Ovid) Search strategy

1. exp Parents/ or exp Caregivers/ or exp Family/ or parent*.tw. or carer*.tw. or caregiv*.tw. or famil*.tw.
2. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
3. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
4. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
5. 1 and 2 and 3 and 4

[99 references returned]

OpenGrey Search strategy

Note: Each numbered search line refers to a separate search. All individual search results were combined to give the final total number of references.

1. Parent* AND emergenc*
2. Carer* AND emergenc*
3. Caregiv* AND emergenc*
4. Child* AND emergenc*
5. Pediatric* AND emergenc*
6. Paediatric* AND emergenc*
7. Parent* AND non-urgent*
8. Carer* AND non-urgent*
9. Caregiv* AND non-urgent*
10. Child* AND non-urgent*
11. Pediatric* AND non-urgent*
12. Paediatric* AND non-urgent*
13. Parent* AND minor illness

14. Carer* AND minor illness
15. Caregiv* AND minor illness
16. Child* AND minor illness
17. Pediatric* AND minor illness
18. Paediatric* AND minor illness

[279 Grey literature references returned]

Appendix B:

Adapted CASP and JBI checklist

Reviewer: _____

Date: _____

Study: _____

Checklist questions	Yes	No	Not applicable	Unclear
Was there a clear statement of the aims?				
Is a qualitative methodology appropriate?				
Was the research design appropriate to address the research aims?				
Was the recruitment strategy/sampling appropriate to the aims of the research?				
Was the data collected in a way that addressed the research issue?				
Has the relationship between researcher and participant been adequately considered?				
Have ethical issues been taken into consideration?				
Was the data analysis sufficiently rigorous?				
Is there a clear statement of findings?				
Do the conclusions drawn in the research report flow form the analysis or interpretation of the data?				

Quality (circle): High Moderate Low

Rationale and comment:

_____

_____

_____

Appendix C:

What interventions have successfully reduced non-urgent PED attendances, compared to usual PED care, using an RCT study design? - Search Strategies

MEDLINE (via Ovid) Search strategy

6. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
7. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
8. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
9. exp Randomized Controlled Trial/ or exp Random Allocation/ or exp Clinical Trial/ or Random* allocate*.tw. or (allocate* adj2 random*).tw
10. 1 and 2 and 3 and 4

[105 references returned]

EMBASE (via Ovid) Search strategy

1. exp Child/ or exp Infant/ or exp Adolescent/ or exp Pediatrics/ or child*.tw. or infant*.tw. or adolescen*.tw. or pediatri*.tw. or paediatri*.tw.
2. (non-urgent* or unnecessar* or inappropriat* or (Minor adj2 (illness* or ailment* or health*)) or non-emergenc* or non-critical*).tw.
3. exp Emergency Service, Hospital/ or exp Emergency Medical Services/ or exp Hospitals/ or emergenc*.tw. or (accident and emergenc*).tw. or A&E.tw. or ED.tw. or PED.tw. or (attend* adj2 (ED or A&E or PED)).tw. or (utili* adj2 (ED or A&E or PED)).tw.
4. exp Randomized Controlled Trial/ or exp Random Allocation/ or exp Clinical Trial/ or Random* allocate*.tw. or (allocate* adj2 random*).tw
5. 1 and 2 and 3 and 4

[278 references returned]

CINAHL (via EBSCO) Search strategy

S6. (MH "Child+") OR (MH “Infant+") OR (MH "Adolescence+") OR (MH "Hospitals, Pediatric") OR (MH "Pediatric Units+") OR TI Child* OR AB Child* OR TI Infant* OR AB Infant* OR TI Adolescen* OR AB Adolescen* OR TI Pediatri* OR AB Pediatri* OR TI Paediatri* OR AB Paediatri*

S7. TI Non-urgent* OR AB Non-urgent* OR TI Unnecessar* OR AB Unnecessar* OR TI Inappropriat* OR AB Inappropriat* OR TI (Minor N2 (Illness* or Ailment* or Health*)) OR AB (Minor N2 (Illness* or Ailment* or Health*)) OR TI Non-emergenc* OR AB Non-emergenc* OR TI Non-critical* OR AB Non-critical*

S8. (MH "Emergency Service+") OR (MH "Emergency Care+") OR (MH "Emergency Medicine") OR TI Emergenc* OR AB Emergenc* OR TI ("Accident and Emergenc*") OR AB ("Accident and Emergenc*") OR TI A&E OR AB A&E OR TI “ED” OR AB “ED” OR TI PED OR AB PED OR TI (Attend* N2 (“ED” or A&E or PED)) OR AB (Attend* N2 (“ED” or A&E or PED)) OR TI (Utili* N2 (“ED” or A&E or PED)) OR AB (Utili* N2 (“ED” or A&E or PED))

S9. (MH "Randomized Controlled Trials+") OR (MH "Random Assignment") OR (MH "Clinical Trials+") OR TI (random*) OR AB (random*)

S10. S1 AND S2 AND S3 AND S4

[79 references returned]

Appendix D:

Example Data Extraction Form

Chande (1996)

General Information	
First author:	Chande, VT
Year of publication:	1996
Publication type;	Peer-reviewed journal article
Country of study:	USA
Funding source of study:	Clinical research initiation grant from Rainbow Babies and Children's Hospital, Cleveland, Ohio.
Any potential conflict of interest from funding source?	None identified.

Study Characteristics	
Aim/objectives of the study:	To test the hypothesis that educating parents about use of their primary care provider and providing information about common paediatric illnesses will reduce visits to the paediatric emergency department (PED).
Study design:	RCT
Recruitment procedures:	Eligible families were approached for the study by a single researcher after they had been evaluated by a physician, but before they were discharged from PED.
Allocation procedures:	Families were randomly assigned (randomisation generated by a table of random numbers) to the control or intervention group.
Study inclusion and exclusion criteria:	*Inclusion*: English-speaking families, with telephone in their home. *Exclusion*: Did not consent to study. Urgent PED attendance.

Participant Characteristics	
Brief description of participants included:	Parents or guardians of children with minor illnesses who sought care in the PED at University Hospitals of Cleveland, Ohio.
Number assigned to each group (during intervention period):	Intervention group: 69 participants Control group: 61 participants
Average age (mean):	Intervention group: 39 months (3 years, and 3 months old) Control group: 63 months (5 years and 3 months old)
Gender:	Intervention group: 28 (41%) females Control group: 25 (41%) females

Health insurance status:	Intervention group: 67% medical assistance, 26% commercial insurance, 7% no insurance (or unknown) Control group: 61% medical assistance, 31% commercial insurance, 8% no insurance (or unknown)

Intervention Characteristics	
Description of intervention:	Participants in the intervention group were provided with a sixth-grade reading level booklet on common childhood medical problems and watched a 10 min video. Intervention covered information on the role of primary care, temperature, asthma, diarrhoea, cold and chicken pox management and how to comfort a crying baby and child safety. Note: only 48 subjects in the intervention group watched the video.
Location of intervention delivery:	Intervention was delivered in ED
Duration of intervention:	Start date: September 1993 Stop date: October 1994 Intervention duration: 14 months

Comparator Characteristics	
Description of comparator:	The control group received the standard PED discharge instructions.
Duration of comparator:	Start date: September 1993 Stop date: October 1994 Intervention duration: 14 months

Outcome Measures	
List any outcomes identified:	Total number of PED visits during a 6-month period. The number of visits to the PED for minor illness during a 6-month period.
How does the study define non-urgent reattendance?	Attendance based on triage nurses' evaluation..
Number of participants included in analysis:	68 participants.
Number of withdrawals, exclusions, lost to follow-up:	62 participants.
Type of analysis used in study:	N/A
Time points of outcome measurements:	6 months after delivery of intervention.
Statistical techniques used	Data were analysed by the Chi-squared analysis and Student's *t* test.

Setting

Setting in which the intervention is delivered:	Paediatric emergency department of an urban university hospital .

Results	
Primary outcome measure: (Results and statistical analysis)	No statistical difference in the number of participants in the intervention group who returned to PED with minor illness and those in the control group (p=0.46). No significant difference (p≥0.99) in the number returning to PED after watching the videotape and those who did not.
Secondary outcome measure(s):	N/A
Adverse events:	Not stated.

Appendix E:

The patient journey at St. Mary's Hospital and Northwick Park Hospital

In order to develop a suitable research study, an understanding of how parents' with unwell children proceed through the hospital system at St. Mary's and Northwick Park was required. This understanding was developed through observational sessions and interviews with staff at both hospital sites. The representation of the patient journeys at both sites are grouped into three phases and shown in Figure E.1 (St. Mary's) and Figure E.2 (Northwick Park).

Phase A - Arrival

As you will see from the flowcharts describing the patient journeys (Figure E.1 and Figure E.2), paediatric patients enter the emergency and urgent care pathway by arriving via ambulance, self-referring to the departments or by being referred by their GP or NHS 111. Our report focuses on non-urgent attendances excluding those that arrive by ambulance or are referred by another healthcare professional. However, for completeness we include these in our overview of the pathway.

Phase B – Initial assessment and service allocation

Families that self-refer initially register at a reception desk and then wait to be assessed by a healthcare professional. At St Mary's this encounter with a professional is called 'paediatric triage' – all children that present see a specialist paediatric nurse. This nurse assesses the severity of the child's illness and decides whether they should stay in PED or be sent to UCC. This decision is made based on certain exclusion criteria.

At Northwick Park this initial encounter with a professional is called 'streaming' – all children see an emergency nurse practitioner (ENP) who has no specialist paediatric training. The ENP decides whether they should stay in UCC or be sent to PED. Once the child has been allocated to either UCC or PED the processes are largely similar between the hospital sites.

Phase C – Medical assessment and decision to admit

In PED, depending on the severity of the child's illness, they are allocated a bed or remain in the waiting room. Once they have been reviewed by a doctor and received any required tests or treatment (medical assessment), they are either admitted, observed for more time or discharged from PED. In UCC, they wait to be seen by a GP or primary care paediatrician. After their medical assessment, they are either discharged or, if they require hospital-level care, they are referred to PED for further management by hospital specialists.

Figure E.1: The patient journey at St Mary's Hospital PED and UCC
Note: the key illustrates the parts of the pathway that belong to each service (either UCC or PED).

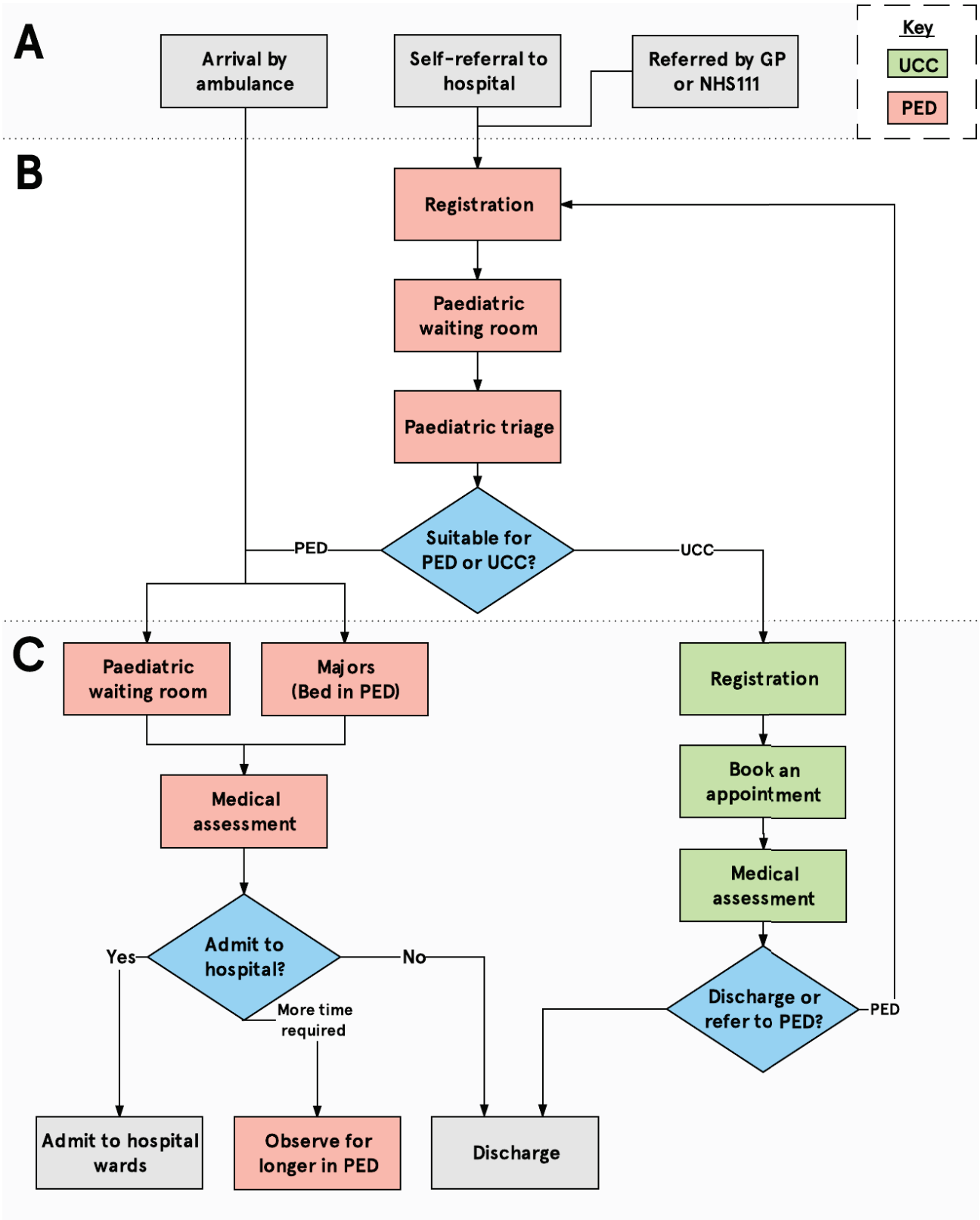
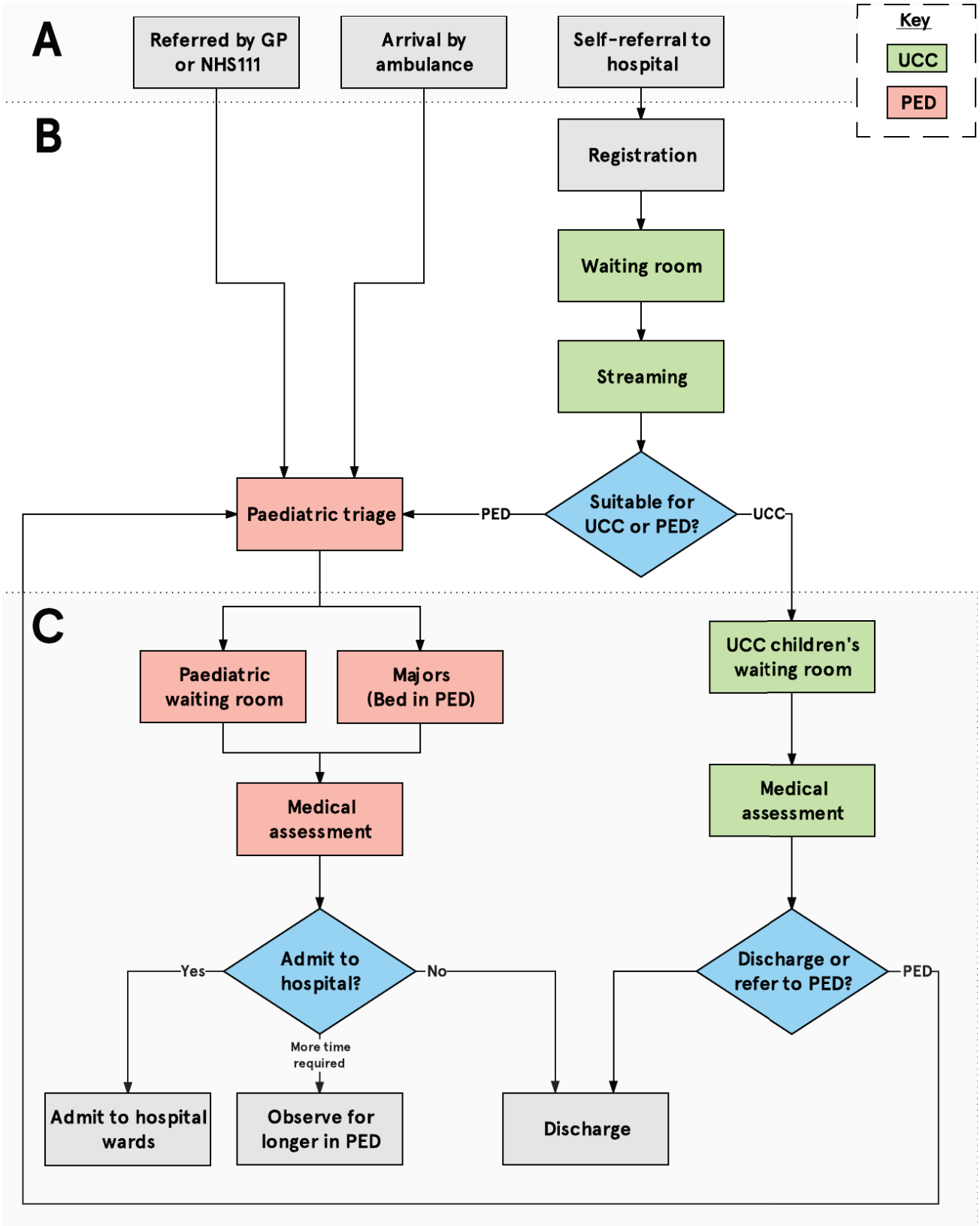


Figure E.2: The patient journey at Northwick Park Hospital PED and UCC
Note: the key illustrates the parts of the pathway that belong to each service (either UCC or PED).



Appendix F:

Educational Bundle – St Mary's Hospital PED Cover Letter

Imperial College Healthcare NHS
NHS Trust

Connecting Care for Children (CC4C)
Imperial College Healthcare NHS Trust
The Bays Building
St Mary's Hospital
South Wharf Road
W2 1NY

Email: benholden@nhs.net

Date: 01/06/17

To the parent or carer of Benjamin,

According to our records, your child recently attended St Mary's Hospital Paediatric Emergency Department. We hope they are feeling better now. We are sending you some material to help you manage your child's health the next time they are ill.

Please take a look at the following:



1) An **information booklet** called '*How to help your unwell child'*. This will:
- help you work out whether your child has a serious illness;
- advise you on how to manage common childhood illnesses;
- tell you who to contact when your child is ill.



2) A **factsheet** - *'Is it serious? Look, Listen, Touch, Check'.* Please stick this on your fridge using the enclosed magnet or somewhere in your home where it's easy to see. If you have a smartphone, you can also take a photo of the leaflet so you can look at it when you need to.

You know better than anyone what your child is usually like. If you are really worried about them, get medical help as soon as possible:

- **during the day from Monday to Friday** – call your child's GP practice
  - *GPs often prioritise seeing unwell children*.
- **during evenings and weekends when the GP is closed** – call NHS 111
- **If the situation is urgent** – go to a walk-in centre or, in an emergency, go to the nearest emergency department.

Yours sincerely,

Dr Ben Holden
St Mary's Hospital Paediatric Department,
Imperial College Healthcare NHS Trust

IRAS ID: 229748

Appendix F continued:

Educational Bundle – Northwick Park Hospital UCC Cover Letter

Northwick Park Hospital Urgent Care Centre
Greenbrook Healthcare
Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ

Email: benholden@nhs.net

Date: 01/06/17

To the parent or carer of [redacted]

According to our records, your child recently attended Northwick Park Hospital Urgent Care Centre. We hope they are feeling better now. We are sending you some material to help you manage your child's health the next time they are ill.

Please take a look at the following:



1) An **information booklet** called '*How to help your unwell child*'. This will:
- help you work out whether your child has a serious illness;
- advise you on how to manage common childhood illnesses;
- tell you who to contact when your child is ill.



2) A **factsheet** - *'Is it serious? Look, Listen, Touch, Check'*. Please stick this on your fridge using the enclosed magnet or somewhere in your home where it's easy to see. If you have a smartphone, you can also take a photo of the factsheet so that you can look at it when you need to.

You know better than anyone what your child is usually like. If you are really worried about them, get medical help as soon as possible:

- **during the day from Monday to Friday** – call your child's GP practice
  - *GPs often prioritise seeing unwell children*.
- **during evenings and weekends when the GP is closed** – call NHS 111
- **If the situation is urgent** – go to a walk-in centre or, in an emergency, go to the nearest emergency department.

Yours sincerely,

Dr Ben Holden
Northwick Park Hospital Urgent Care Centre,
Greenbrook Healthcare

IRAS ID: 229748

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (front cover)

NHS

How to help your unwell child

For parents and carers of children under five years old



Is it serious?
Go to page 1

It's not serious, what should I do?

Coughs and colds Page 2
Diarrhoea and vomiting Page 4
Fever (high temperature) Page 6
Ear problems Page 8
Rashes and dry skin Page 10
First aid kit Back cover

IRAS ID: 229748

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (inside cover)

Young children often get sick - it is part of growing up.

It can be stressful for parents and carers when a child is not well. Often, the illness is not serious, and the child can be treated safely at home, or with support from a GP, pharmacist, or health visitor.

This booklet has been designed by a team of paediatricians to help you care for your sick child. It will help you identify when an illness is minor, and when it is serious. We recommend treating minor illnesses at home, where the child will be most comfortable.

If you are worried about your child's health, or think there might be a serious problem, trust your instincts and call the non-emergency NHS phone number 111 for advice.

My child's GP is

.....

Address.....

.....

.....

.....

Phone

.....

Our local pharmacy is

.....

Address.....

.....

.....

.....

Phone

.....

To find out the location of your local GP or pharmacy, go to the NHS Choices website - www.nhs.uk

This booklet is being distributed by the Connecting Care for Children (CC4C) team - **www.cc4c.imperial.nhs.uk**

If you have any questions or feedback about this booklet, please contact: **benholden@nhs.net**

NHS choices www.nhs.uk

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 1)

Is it serious? Look, Listen, Touch, Check

NHS

Go straight to the emergency department (A&E) or call 999 if your child:

- looks mottled, bluish or pale
- is very lethargic or difficult to wake
- feels abnormally cold to touch
- is breathing much faster than normal
- has a rash that does not fade when you press it
- has a fit or convulsion

Call NHS 111 to get urgent medical advice if your child:



- ☐ is finding it hard to get their breath and is sucking their stomach in under their ribs
- ☐ has bright green, bloody or black vomit
- ☐ has not drunk anything for more than eight hours (when awake)
- ☐ has eyes that look 'sunken'
- ☐ is quiet and lacking energy, even when their temperature is normal



- ☐ makes a throaty noise while breathing
- ☐ is making 'grunting' noises with every breath
- ☐ can't say more than a few words at once (for older children who normally talk)
- ☐ has obvious 'pauses' in their breathing
- ☐ is crying constantly and you can't comfort or distract them, or the cry doesn't sound like their normal cry



- ☐ is under 8 weeks old and doesn't want to feed
- ☐ has not had a wet nappy or had a wee for 12 hours
- ☐ is under 2 years old and has a bulging soft spot (fontanelle) on their head
- ☐ is floppy
- ☐ is hard to wake up, or appears confused



- ☐ is under 3 months old and has a high temperature of 38ºC or above
- ☐ is over 3 months old and has a high temperature of 38ºC or above that doesn't come down 15 - 30 minutes after paracetamol or ibuprofen
- ☐ is between 3 and 9 months old and has a high temperature of 39ºC or above
- ☐ is any age and has a low temperature below 36 ºC when checked three times in a 10-minute period

If you don't see any of these signs, use this booklet for advice on the most common childhood illnesses:

Coughs and colds: **Page 2** Diarrhoea and vomiting: **Page 4**
Fever (high temperature): **Page 6** Ear problems: **Page 8** Rashes: **Page 10**

1

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 2)

Coughs and colds

1 What do I see?

My child keeps coughing and sneezing, sometimes has a high temperature (above 38ºC) and seems generally unwell.



2 What is it likely to be?

Catching a cough or cold is very common, especially if they are in close contact with other children (e.g. starting nursery or playgroup).

3 What should I do now?

Give your child lots to drink. Speak to your pharmacist about children's paracetamol and other medicines that might help.

4 What else do I need to know?

Most colds get better within 5 - 7 days. If symptoms last for more than 10 days or your child is coughing up yellow stuff, they may have an infection. If this happens, contact your GP.

2

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 3)

Coughs and colds

Things you can do at home to help:

- Give your child lots to drink - water is best.
- Try children's paracetamol or ibuprofen (not aspirin).
- Talk to your pharmacist about medications that might help, but remember that coughing is normal and is the body's way of keeping the lungs clear.
- Saline nose drops can help loosen dried snot (mucus) and relieve a stuffy nose. Ask your pharmacist, GP or health visitor about these.

See your GP or call NHS 111 if:

- Your baby is under three months and has a temperature of 38ºC or more.
- Your child has a fever with a rash.
- Your child is finding it hard to breathe.
- Your child's fever goes away for a day or more, but then returns.

Call 999 or go to the emergency department if:

- Your child is not waking up or interacting.
- Your child is breathing much faster than normal.
- Your child's condition suddenly gets much worse very quickly.

3

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 4)

Diarrhoea and vomiting

1

What do I see?

My child keeps being sick (vomiting) and having more frequent, loose, watery poo (diarrhoea).



2

What is it likely to be?

Diarrhoea and vomiting are very common. They are normally caused by a virus and last several days.

3

What should I do now?

It is important to make sure your child does not get dehydrated (lose more fluid than they take in).
You can give them rehydration powder (sometimes called 'oral rehydration salt') mixed with water to help keep them hydrated.
Get your child to drink slowly (drinking too fast may make them vomit).

4

What else do I need to know?

If your child is weeing at least twice a day, this is a good sign they are not dehydrated.

Diarrhoea and vomiting can last several days, but the symptoms should gradually improve by themselves. Vomiting often stops first, diarrhoea might carry on for longer. For further information, turn to page 12.

4

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 5)

Diarrhoea and vomiting

Things you can do at home to help:

- Give your child regular small drinks of fluid.
- Try to give your child 5 or 10 ml of rehydration powder mixed with water (see instructions on the back of the packet) every 5 minutes.
- Don't make your child eat if they don't want to. The important thing is that they keep drinking.
- If your child has a temperature or tummy ache, give them children's paracetamol or ibuprofen.

See your GP or call NHS 111 if:

- Your child is vomiting so much they can't keep anything down.
- Your child has cold hands or feet.
- Your child has not had a wet nappy or a wee in the last 12 hours.
- Your child has bright green or black vomit, or blood in their vomit or poo.

Call 999 or go to the emergency department if:

- Your child is not waking up or interacting.
- Your child has a temperature of 38°C or more and diarrhoea or vomiting.
- Your child has severe abdominal (tummy) pain or is breathing rapidly.

5

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 6)

Fever (high temperature)

Temperature over 38°C means a fever

1 What do I see?

My toddler is hot and grumpy. Their temperature is more than 38°C.



2 What is it likely to be?

Fevers are common in young children, and are the body's natural response to infection. A fever can usually be left to get better on its own as long as your child is drinking enough and is otherwise well.

3 What should I do now?

Give them children's paracetamol or ibuprofen to bring down the fever. Make sure they are drinking regularly so that they do not get too dry (dehydrated). Look out for the more serious signs of fever (see page 7).

4 What else do I need to know?

Your child's urine should be pale yellow - if it is darker, your child may need to drink more fluids. For further information on fever and to see a urine colour chart, turn to page 13.

6

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 7)

Fever (high temperature)

Things you can do at home to help:

- Give your child lots to drink - water is best.
- Try children's paracetamol or ibuprofen (not aspirin).
- Remove extra clothes. One layer of clothing should be left on. Do **not** use cold water or cold towels on the face or body.

See your GP or call NHS 111 if:

- Your baby is under three months and has a temperature of 38ºC or above.
- Your baby is three to nine months old and has a temperature of 39ºC or above.
- Your child has a fever with a rash or other symptoms in addition to fever.
- Your child has a temperature of 38ºC or more, but cold feet and hands.
- Your child has a high temperature that doesn't come down 15 - 30 minutes after paracetamol or ibuprofen.
- Your child is over three months old and has a temperature of 38ºC or above for more than 5 days.
- Your child has recently travelled overseas, especially if outside of Europe.

Call 999 or go to the emergency department if:

- Your child is not waking up or interacting, or your child has become floppy.
- Your child has a convulsion or fit with the fever, or has rapid breathing.
- Your child has a rash that does not fade when you press it.
- Your child looks bluish or pale, or feels abnormally cold to touch.

7

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 8)

Ear problems

1 What do I see?

My toddler is tearful and keeps holding their ear.



2 What is it likely to be?

Ear aches are often caused by ear infections. These are common in babies and toddlers. They often follow a cold and can sometimes cause a high temperature.

3 What should I do now?

Most ear infections get better by themselves over several days. Try giving children's paracetamol or ibuprofen for the pain.

If there is no improvement with painkillers, or they still have a high temperature after 2 days, or you notice fluid coming from the ear, then speak to your child's GP.

4 What else do I need to know?

Although most ear infections settle down without any serious effects, there can be mild hearing loss for a short time (2 - 3 weeks).
If this lasts longer than 3 weeks arrange to see your child's GP.

8

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 9)

Ear problems

Things you can do at home to help:

- Give your child lots to drink - fluid is important when they have an infection.
- Try children's paracetamol or ibuprofen (not aspirin).
- Comfort your child regularly.
- Do **not** put oil or cotton buds into your child's ears as this can damage the ear and make infections worse.

See your GP or call NHS 111 if:

- Your child has ear problems and a temperature of 38ºC or above for more than two days.
- You notice fluid coming out of your child's ear.
- Your child has a temperature of 38ºC or more that doesn't come down 15 - 30 minutes after paracetamol or ibuprofen.
- Your child seems in a lot of pain despite painkillers (paracetamol and ibuprofen).

9

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 10)

Rashes and dry skin

1 What do I see?

Your baby's skin may be flaky and dry, or they have a rash.



2 What is it likely to be?

Dry skin and rashes are normal and usually nothing to worry about. They are very common in newborn babies.

3 What should I do now?

Avoid using soap or any other products on your baby's skin. Wash your baby in clean water. If your baby is well but has a rash you are worried about, contact your GP or health visitor.

Think about meningitis or sepsis

The glass test is a really useful way of spotting suspected meningitis. If your child has a lot of red or purple spots, press the side of a clear drinking glass firmly against the rash (spots).





Call 999 or go to the emergency department if you can still see the spots through the glass see a doctor immediately. If you cannot get help straight away, go to an emergency department (A&E).

If the spots under the glass have almost disappeared then it is unlikely to be meningitis. If you are still worried contact NHS 111 or your GP. Please note, you can have meningitis without a rash.

10

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 11)

Nappy rash

1 What do I see?

My baby has a red, sore rash around the nappy area and is uncomfortable and crying a lot.



2 What is it likely to be?

Nappy rash, which is very common and can affect lots of babies. It is usually caused when your baby's skin comes into contact with wee and poo that collect in their nappy.

3 What should I do now?

Most nappy rashes can be treated with a simple skincare routine and by using a barrier cream that you can get from a pharmacist.

4 What else do I need to know?

Nappy rash causes your baby's skin to become sore. The skin in this area may be covered in red spots or blotches. You might need to change their nappy more often.

11

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 12)

Further information: Diarrhoea and vomiting



You can buy rehydration powder (sometimes called 'oral rehydration salt') at the supermarket or pharmacy.

Keep it in your first aid kit at home.

When your child wants to eat again, start with plain foods e.g. dry crackers, toast or plain rice. **Avoid** fatty foods and dairy products. Remember to keep drinking slowly.

Vomiting usually lasts for **1 - 2 days**, while diarrhoea can last for about **5 - 7 days**. If your child's symptoms last longer than this, or if they are showing signs of dehydration, speak to your GP.

Your child may be dehydrated if they have:

- sunken eyes
- in young babies, a sunken soft spot (fontanelle) on their head
- few or no tears when they cry, a dry mouth or fewer wet nappies
- dark yellow urine

If your child is dehydrated, give them fluid.
Water mixed with rehydration powder is a great way to rehydrate children.

12

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (page 13)

Further information: Fever (high temperature)



A good type of thermometer to use at home is a **digital underarm thermometer**. For children under five years old, the armpit is the best place to measure their temperature.

A high temperature on its own is not worrying, but be sure to look out for other signs of illness.

Paracetamol – can be given to children for pain or fever. Check you have the right product, dose and strength for your child's age by reading the packaging carefully.

Ibuprofen – can be given to babies and children aged three months and over who weigh more than 5 kilograms (kg). Read the packaging carefully. Do not use ibuprofen if your child has asthma, unless advised by your GP.

Aspirin - not suitable for children under 16

What colour is your child's wee (urine)?

They are drinking enough fluid (adequately hydrated).



They might need to drink more fluid.



They need to drink more fluid (probably dehydrated).

13

Appendix F continued:

Educational Bundle – '*How to help your unwell child*' information booklet (back page)

First aid kit

Top tip: Keep a small supply of useful medicines in a first aid kit at home. You can buy these at your local pharmacy.



Make sure you have an **age-appropriate painkiller**, such as **paracetamol** or **ibuprofen**. For younger children you will also need a special dosing syringe from the pharmacy. Always follow the dosage instructions on the label.



Digital thermometers – these are quick to use, accurate and can be used under the armpit (always use the thermometer under the armpit with children under five). Hold your child's arm against his or her body and leave the thermometer in place for the time stated in the manufacturer's instructions.



Oral rehydration powder (rehydration salts). If a child is vomiting or has diarrhoea they can become dehydrated. Rehydration powder (mixed with water) replaces the salts and water that are lost, and reduces the effect of dehydration.



Antiseptic cream or spray can be applied to cuts, grazes or minor burns after cleaning to help prevent infection.

Barrier cream for dry skin.

Calamine lotion - this can help to soothe itching, irritated skin, rashes (including chickenpox) and sunburn.



Antiseptic wipes are a handy way to clean cuts and grazes and help prevent infection. To use them, take a fresh wipe and clean the wound, gently working away from the centre of the wound to remove dirt and germs.



Sticking plasters, adhesive tape and small bandages. These protect minor cuts and grazes from further harm and help them heal quicker.

14

Appendix F continued:

Educational Bundle – '*Is it serious? Look, Listen, Touch , Check*' factsheet

Is it serious? Look, Listen, Touch, Check

NHS

Go straight to the emergency department (A&E) or call 999 if your child:

- looks mottled, bluish or pale
- is very lethargic or difficult to wake
- feels abnormally cold to touch
- is breathing much faster than normal
- has a rash that does not fade when you press it
- has a fit or convulsion

Call NHS 111 to get urgent medical advice if your child:



LOOK

- ☐ is finding it hard to get their breath and is sucking their stomach in under their ribs
- ☐ has bright green, bloody or black vomit
- ☐ has not drunk anything for more than eight hours (when awake)
- ☐ has eyes that look 'sunken'
- ☐ is quiet and lacking energy, even when their temperature is normal



LISTEN

- ☐ makes a throaty noise while breathing
- ☐ is making 'grunting' noises with every breath
- ☐ can't say more than a few words at once (for older children who normally talk)
- ☐ has obvious 'pauses' in their breathing
- ☐ is crying constantly and you can't comfort or distract them, or the cry doesn't sound like their normal cry



TOUCH

- ☐ is under 8 weeks old and doesn't want to feed
- ☐ has not had a wet nappy or had a wee for 12 hours
- ☐ is under 2 years old and has a bulging soft spot (fontanelle) on their head
- ☐ is floppy
- ☐ is hard to wake up, or appears confused



CHECK

- ☐ is under 3 months old and has a high temperature of 38ºC or above
- ☐ is over 3 months old and has a high temperature of 38ºC or above that doesn't come down 15 - 30 minutes after paracetamol or ibuprofen
- ☐ is between 3 and 9 months old and has a high temperature of 39ºC or above
- ☐ is any age and has a low temperature below 36 ºC when checked three times in a 10-minute period

If you don't see any of these, look at the 'How to help your unwell child' booklet

Coughs and colds: **Page 2** Diarrhoea and vomiting: **Page 4**
Fever (high temperature): **Page 6** Ear problems: **Page 8** Rashes: **Page 10**

IRAS ID: 229748

Appendix F continued:

Educational Bundle – NHS 111 fridge magnet



Example of how the fridge magnet may be used in combination with the factsheet:



Appendix G:

Trial Randomisation Protocol

Randomisation protocol	
Step	**Procedure**
1	Extract a tranche of 2-3 days of attendance data with three variables: (i) **date** of attendance (ii) attendee's **last name** (iii) attendee's **full postcode**
2	Open the tranche in Excel
3	Add five columns: (i) **name_pc** = Combine last name and postcode variables into a single variable using the function "(B2&" "&C2)", where B2 is the cell with the last name, and C2 is the cell with the postcode (ii) **id** = a sequential count for each row (iii) **day** = indicating the day of the trial. This starts as 1 on the first trial day (Oct 9) and is updated sequentially (e.g. December 1 should be day 53) (iv) **family ID** = a unique ID for each family, where families are identified by a combination of the patient post code and last name (v) **condition** = a randomly generated variable where 0 = control and 1 = intervention
4	Remove duplicate families by following this procedure: (i) Highlight the cells in the **name_pc** column (ii) On the HOME tab in Excel, click CONDITIONAL FORMATTING --> Highlight cells rules --> Duplicate values (iii) In the Duplicate values window, specify a rule that duplicate values be filled in with some colour. (iv) Working from the bottom-up, delete the duplicates (v) Now that you know there are no duplicate families in the data, clear the conditional formatting (CONDITIONAL FORMATTING--> Clear rules --> Clear rules from entire sheet) (vi) Create a sequential family ID variable for each row because each row now identifies a unique family
5	Assign people to intervention or control. In the "condition" column, put "=RANDBETWEEN(0,1)" for all the rows with data in them. Lock the randomly generated values by highlighting them, copying them, then right click and select Paste Special --> Paste Values --> Ok.
6	After completing this procedure, copy the data into a master excel file which lists all families identified to date.

Appendix H:

Details of clinician judgement regarding trial participant exclusion

As discussed in Section 4.4.2.2 of this thesis, as an additional safeguard to protect against inappropriate delivery of the intervention to families that should not receive the intervention, the clinical records were reviewed by a medical professional.

After application of the inclusion and exclusion criteria to the dataset, the remaining attendances were reviewed by a clinician prior to enrolment. The records were reviewed to ensure accurate data coding (ensuring attendances were correctly defined as non-urgent) and to identify any other reasons why the targeted intervention may be inappropriate (for example, safeguarding concerns regarding the child, or deterioration of health condition and a resulting hospital admission).

This was a requirement for the ethical approval of the study.

A summary of the reasons for exclusion of attendances following clinical review of the electronic records at each hospital site is detailed below in Table H.1 and Table H.2.

Appendix H continued:

Details of clinician judgement regarding trial participant exclusion

Table H.1: *Summary of number of attendances excluded at clinical judgement step during research trial at St Mary's Hospital PED.*

Reason for attendance not being considered appropriate	Number of attendances excluded (percentage of total)
Directly referred to ED by healthcare professional	141 (16.8%)
Patient received prescription	361 (42.9%)
Attendance for an 'injury' (incorrect data coding)	8 (1.0%)
Medication administered during UCC attendance	24 (2.9%)
Did not wait for clinical assessment	63 (7.5%)
Attended seeking assistance for allergic reaction	24 (2.9%)
Serious presentation requiring specialist Paediatric input	110 (13.1%)
Patient had a safeguarding alert	16 (1.9%)
Admitted to hospital soon after attendance	63 (7.5%)
Booked for hospital follow-up of condition	24 (2.5%)
Total:	**841 attendances**

Appendix H continued:

Details of clinician judgement regarding trial participant exclusion

Table H.2: *Summary of number of attendances excluded at clinical judgement step during research trial at Northwick Park Hospital UCC.*

Reason for attendance not being considered appropriate	Number of attendances excluded (percentage of total)
Arrived via ambulance (incorrect data coding)	12 (1.3%)
Patient received prescription (incorrect data coding)	213 (22.3%)
Attendance for an 'injury' (incorrect data coding)	59 (6.2%)
Medication administered during UCC attendance	283 (29.6%)
Did not wait for clinical assessment	24 (2.5%)
Attended seeking assistance for allergic reaction	165 (17.2%)
Serious presentation requiring specialist Paediatric input	177 (18.5%)
Patient had a safeguarding alert	24 (2.5%)
Total:	**957 attendances**

Appendix I:

OLS regression results for the research trial that evaluated the impact of the intervention on non-urgent PED reattendance

Table I.1: *OLS regression results showing the predictors of non-urgent reattendance following an initial non-urgent attendance.*

Model 1: No control variables

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-1.5	1.3	-4.0	1.0	1.154	0.249
(Constant)	24.6**	0.9	22.8	26.4	27.333	0.000

Sample size: 3,932 families
Observations: 5,168 attendances

Model 2: Control variables included

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-0.6	1.2	-3.0	1.8	0.484	0.649
Age of patient at initial attendance (0-4)	-2.3***	0.4	-3.1	-1.5	5.750	0.000
Female (vs. male) patient at initial attendance	0.2	1.2	-2.2	2.6	0.167	0.868
St Mary's (vs Northwick Park)	-0.4	1.5	-3.3	2.5	0.267	0.710
Miles between patient home and hospital	-1.1***	0.4	-1.9	-0.3	2.750	0.006
Index of multiple deprivation (1-5)	0.1	0.5	-0.9	1.1	0.200	0.791
Ease of getting GP appointment	-0.1	0.1	-0.3	0.1	1.000	0.317
Nonurgent attendances 2014-17 (pre-trial)						
0 (base)	-	-	-	-	-	-
1-3	7.0***	1.4	4.3	9.7	5.000	0.000
4+	19.6***	2.4	14.9	24.3	8.167	0.000
(Constant)	16.5**	7.2	2.4	30.6	2.292	0.022

Note: R^2 adjusted = 0.21

Sample size: 3,685 families
Observations: 4,831 attendances

The analysis controls for month of attendance but this is omitted from table for brevity.
The full list of control variables can be found in **Table 4.6**.
*** p<0.01 (significant at the 1% level),
** p<0.05 (significant at 5% level),
* p<0.1 (significant at the 10% level).

Appendix I continued:

OLS regression results for the research trial that evaluated the impact of the intervention on non-urgent PED reattendance

Table I.2: *OLS regression results showing the predictors of any reattendance (urgent or non-urgent) following an initial non-urgent attendance.*

Model 1: No control variables

Outcome: Any reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-1.8	1.3	-4.3	0.7	1.385	0.166
(Constant)	44.6**	1.0	42.6	46.6	44.600	0.000

Sample size: 3,932 families
Observations: 6,988 attendances

Model 2: Control variables included

Outcome: Any reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-0.5	1.2	-2.9	1.9	0.417	0.677
---------- ***Control variables included in analysis*** ----------						
(Constant)	16.4**	8.1	0.5	32.3	2.025	0.043

Note: R^2 adjusted = 0.25

Sample size: 3,685 families
Observations: 6,556 attendances

The analysis controls for all additional explanatory variables are omitted from the table for brevity.
The full list of control variables can be found in **Table 4.6**.
*** p<0.01 (significant at the 1% level),
** p<0.05 (significant at 5% level),
* p<0.1 (significant at the 10% level).

Appendix I continued:

OLS regression results for the research trial that evaluated the impact of the intervention on non-urgent PED reattendance

Table I.3: *OLS regression results showing the predictors of urgent reattendance following an initial non-urgent attendance.*

Model 1: No control variables

Outcome: Urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-1.5	1.3	-4.0	1.0	1.154	0.249
(Constant)	32.4***	1.0	30.4	34.4	32.400	0.000

Sample size: 3,932 families
Observations: 5,752 attendances

Model 2: Control variables included

Outcome: Urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-0.4	1.2	-2.8	2.0	0.333	0.739
---------- ***Control variables included in analysis*** ----------						
(Constant)	5.9	7.7	-9.2	21.0	0.766	0.444

Note: R^2 adjusted = 0.27

Sample size: 3,685 families
Observations: 5,397 attendances

The analysis controls for all additional explanatory variables are omitted from the table for brevity.
The full list of control variables can be found in **Table 4.6**.
*** p<0.01 (significant at the 1% level),
** p<0.05 (significant at 5% level),
* p<0.1 (significant at the 10% level).

Appendix I continued:

OLS regression results for the research trial that evaluated the impact of the intervention on non-urgent PED reattendance

Table I.4: *OLS regression results showing the predictors of non-urgent reattendance following an initial non-urgent attendance - subgroup analyses of the interaction with the patient gender variable.*

Model 1: No control variables

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-4.2**	1.7	-7.5	-0.9	2.471	0.015
Patient gender at initial attendance (coded as 0 = male, 1= female)	-3.0*	1.8	-6.5	0.5	1.667	0.096
Intervention * patient gender at initial attendance	5.8**	2.6	0.8	10.8	2.275	0.023
(Constant)	26.0***	1.3	23.5	28.5	20.000	0.000

Sample size: 3,932 families
Observations: 5,168 attendances

Model 2: Control variables included

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-2.1	1.6	-5.2	1.0	1.313	0.189
Patient gender at initial attendance (coded as 0 = male, 1= female)	-1.5	1.6	-4.6	1.6	0.938	0.349
Intervention * patient gender at initial attendance	3.4	2.3	-1.1	7.9	1.478	0.139
---------- ***Control variables included in analysis*** ----------						
(Constant)	17.0**	7.2	2.9	31.1	2.361	0.018

Note: R^2 adjusted = 0.22

Sample size: 3,685 families
Observations: 4,831 attendances

The analysis controls for all additional explanatory variables are omitted from the table for brevity.
The full list of control variables can be found in **Table 4.6**.
*** p<0.01 (significant at the 1% level),
** p<0.05 (significant at 5% level),
* p<0.1 (significant at the 10% level).

Appendix I continued:

OLS regression results for the research trial that evaluated the impact of the intervention on non-urgent PED reattendance

Table I.5: *OLS regression results showing the predictors of non-urgent reattendance following an initial non-urgent attendance - subgroup analyses of the interaction with the patient age variable.*

Model 1: No control variables

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-1.9	1.5	-4.8	1.0	1.267	0.205
Patient over 2 at initial attendance (coded 0 = age 0-2, 1= age 3-4)	-4.0**	1.9	-7.7	-0.3	2.105	0.035
Intervention * age at initial attendance	1.7	2.9	-4.0	7.4	0.586	0.558
(Constant)	25.7***	1.0	23.7	27.7	25.700	0.000

Sample size: 3,932 families
Observations: 5,168 attendances

Model 2: Control variables included

Outcome: Any non-urgent reattendance (0=no, 1=yes)

Variable	Coefficient (β)	SE	95% Confidence intervals for β Lower	Upper	*t* statistic	P value
Intervention (vs. control)	-1.4	1.4	-4.1	1.3	1.000	0.317
Patient over 2 at initial attendance (coded 0 = age 0-2, 1= age 3-4)	0.6	2.6	-4.5	5.7	0.231	0.818
Intervention * age at initial attendance	3.6	2.6	-1.5	8.7	1.385	0.166
---------- ***Control variables included in analysis*** ----------						
(Constant)	16.3**	7.2	2.2	30.4	2.264	0.024

Note: R^2 adjusted = 0.22

Sample size: 3,685 families
Observations: 4,831 attendances

The analysis controls for all additional explanatory variables are omitted from the table for brevity.
The full list of control variables can be found in **Table 4.6**.
*** p<0.01 (significant at the 1% level),
** p<0.05 (significant at 5% level),
* p<0.1 (significant at the 10% level).