

**RANDOMISED CONTROLLED TRIAL OF A MULTIMEDIA-  
BASED PARENTING INTERVENTION FOR THE  
PREVENTION OF BURN INJURIES IN PRE-SCHOOL  
CHILDREN**

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## SUMMARY

Childhood burn injuries are a leading cause of death and disability worldwide and a major public health concern. Children younger than five years of age are more at risk. Majority of burn incidents occur as accidents within the home. Poor parental burn hazard perception and knowledge of burns first aid have been reported. This PhD project aimed to determine whether a targeted preventative parenting intervention '*Toddler-safe*' improved parental burns safety and first aid knowledge and behaviour in the home, and reduced the risk of future childhood burns.

A systematic review of the literature was undertaken to assess the effectiveness of parenting interventions at preventing unintentional injuries in pre-school children. The review found that parenting interventions that provided home visitation, education, and free/discounted safety devices, delivered on a one-to-one basis, during the perinatal or early postnatal period, were associated with significantly fewer childhood injuries, and improvements in parental safety knowledge and practices. However, there was a lack of prevention intervention research specifically for burn injuries in children under the age of five. Findings from the systematic review informed the design and methodology of the *Toddler-Safe* study.

*Toddler-Safe* was conducted as a randomised controlled trial. One hundred and fifty six parents allocated to the intervention arm of the trial received an intervention consisting of a burns safety and first aid video, and an injury safety leaflet. An equal number of controls received only the injury safety leaflet. The study was evaluated using pre- and post-test questionnaires. Outcome measures included first aid knowledge and burns prevention, knowledge, attitude, and practices; and parent-reported or medically attended injuries.

Just over half of the study participants were available for follow-up at six months. Non-responders were found to be younger and from lower socioeconomic backgrounds. *Toddler-Safe* was not effective at improving parental burns prevention and first aid knowledge, attitudes, and practices at

follow-up. Burn injuries were reported in four children living with participating families. Participant attrition and omission of key knowledge and attitude topics from the intervention were major limitations of the study.

## **AUTHOR'S DECLARATION**

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

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## **LIST OF ABBREVIATIONS**

ADHD: Attention Deficit Hyperactivity Disorder  
BCIRPU: British Columbia Injury Research and Prevention Unit  
BCT: Behaviour Change Technique  
CAPIC: Collaboration for Accident Prevention and Injury Control  
CAPT: Child Accident Prevention Trust  
CI: Confidence Interval  
CONSORT: Consolidated Standards of Reporting Trials  
CRD: Centre for Reviews and Dissemination  
CSH: Controllable Safety Hazards  
DVD: Digital Versatile Disc  
ED: Emergency Department  
GCP: Good Clinical Practice  
GCSE: General Certificate of Secondary Education  
GP: General Practitioner  
HBM: Health Belief Model  
HOME: Home Observation for Measurement of the Environment  
ICC: Intraclass Correlation Coefficient  
IOBI: Injury Observatory for Britain and Ireland  
IRAS: Integrated Research Application System  
ISBI: International Society for Burn Injuries  
ITT: Intention-to-treat  
KAP: Knowledge, Attitudes, and Practices  
LMIC: Low and Middle-Income Countries  
LOCF: Last Observation Carried Forward  
MLU: Midwifery Led Unit  
MRC: Medical Research Council  
NHS: National Health Service  
NISCHR: National Institute for Social Care and Health Research  
NS-SEC: National Statistics Socio-economic Classification  
OR: Odds Ratio  
PICOS: Population, Intervention, Comparator, Outcomes, and Study design  
PPI: Patient and Public Involvement

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

R&D: Research and Development

RCT: Randomised Controlled Trial

REC: Research Ethics Committee

ROSPA: Royal Society for the Prevention of Accidents

RR: Risk Ratio

RTA: Road Traffic Accident

SCT: Social Cognitive Theory

SD: Standard Deviation

SLT: Social Learning Theory

SPSS: Statistical Package for the Social Sciences

STD: Sexually Transmitted Disease

TBSA: Total Body Surface Area

TMV: Thermostatic Mixing Valve

TPB: Theory of Planned Behaviour

TRA: Theory of Reasoned Action

TTM: Transtheoretical Model

UHW: University Hospital of Wales

UK: United Kingdom

UKCRN: UK Clinical Research Network

USA: United States of America

UV: Ultraviolet

WHO: World Health Organisation

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# CHAPTER ONE

## **CHAPTER ONE: INTRODUCTION**

### **1.1 BACKGROUND**

Burn injuries are a serious public health problem responsible for significant morbidity and mortality worldwide. They are the fourth leading cause of injury after road traffic accidents (RTAs), falls, and interpersonal violence (Peck, 2011). According to the World Health Organisation (WHO), approximately 11 million people globally required medical attention for burns and scalds in 2004 (WHO, 2008b). In the UK, as many as 250,000 people experience burn injuries every year – 175,000 of whom attend emergency departments (ED), and 13,000 are admitted to hospital (National Burn Care Review, 2001). Burn injuries are also responsible for over 300,000 deaths each year throughout the world (WHO, 2012). House fires, conflagrations, and clothing fires are responsible for the vast majority of all burn-related deaths (WHO, 2008c, WHO, 2012). Most of these incidents occur in low and middle-income countries with mortality rates approximately five times higher (4.5 deaths per 100,000 per year) when compared to high-income countries (1.0 death per 100,000 per year) (WHO, 2008b).

Non-fatal burns greatly outnumber fatal burns, and are a leading cause of morbidity, often with long-term physical, psychological and economic consequences (WHO, 2012). Burn injury survivors are often faced with lifelong challenges as they adjust to life following a burn that may cause significant scarring and long term health needs. These may include: depression, stress, stigmatisation, social segregation, unemployment, and even abandonment by family and friends (Peck, 2011). Burn survivors present an enormous economic burden on a country's healthcare system. In the United Kingdom (UK), burn care provision by burns and plastic surgery services is estimated to cost £140 million per year (Duncan and Dunn, 2009). In 2012, in Australia, it would have cost a total of AU\$71,056.02 (£36,944.11) to treat a single burns inpatient in the acute phase of burns management (Ahn and Maitz, 2012). In addition, burn

survivors require costly wound and scar treatment, rehabilitation, and psychological counselling which invariably adds to the cost of burn injury management.

Children are particularly at risk of suffering burn injuries. According to WHO, burns are an important contributor to the overall disease toll in children all over the world, especially in low and middle-income countries (WHO, 2008c). Over 50,000 children in the UK attend the ED every year for treatment of burns, with approximately 3,800 admitted to hospital for further treatment (Kemp et al., 2014); making childhood burns one of the most frequent paediatric injuries. It costs an average of £63,157.22 to manage a paediatric burns case from admission into burns services to first discharge (Pellatt et al., 2010).

Multiple studies have shown that children younger than five years of age have a higher burn injury rate than children of other ages (Mashreky et al., 2008, Edelman et al., 2010, WHO, 2008c, Brudvik et al., 2011, Wasiak et al., 2009, Hammig and Ogletree, 2006, Dokter et al., 2014). This age group accounts for approximately half the number of childhood burns cases seen in ED and burns units worldwide (Wasiak et al., 2009, Hansbrough and Hansbrough, 1999, WHO, 2008b). In addition, children within this age group are at an increased risk of dying from burn injuries (WHO, 2008a, WHO, 2008c). Their curiosity and impulsiveness, together with their limited ability to perceive and react promptly and properly to dangerous situations, makes young children more vulnerable to burn injury (Mashreky et al., 2010). Furthermore, burn injuries tend to be more severe in children than in adults. This is because children have much thinner skin and slower withdrawal reflexes than adults, therefore making them more susceptible to the detrimental effects of heat.

Inadequate supervision by parents and other caregivers further increases the risk of sustaining a burn in early childhood (Schnitzer et al., 2011). Parents and carers are oftentimes ill-prepared to deal with their child's curiosity and fail to appreciate the presence of potential hazards in

the home (Babul et al., 2007). Poor parental burns safety skills, including hazard perception, knowledge of burns prevention, and knowledge of appropriate burns first aid, have been reported (Davies et al., 2013, Tekin and Suskan, 2010, Cox et al., 2016). There is therefore an urgent need for preventative interventions aimed at reducing the risk of childhood burns by improving the burns prevention and first-aid knowledge and behaviour of parents and carers of young children.

## **1.2 STRUCTURE OF THE THESIS**

This doctoral thesis consists of eight chapters and examines the effectiveness of a parenting intervention (*Toddler-Safe*) at improving parent/carer burns safety and first aid knowledge and behaviour in the home, as well as reducing the risk of future burns in pre-school children. Chapter one sets the stage for the rest of the thesis by giving an overview of childhood burns, examining burns preventative strategies and behaviour change theories, and introducing the study's aims and objectives. Chapter two addresses the first objective of the study and presents a systematic review to establish whether interventions specifically targeting parents of pre-school children are effective at preventing childhood unintentional injuries or improving parental child safety knowledge and behaviour. The findings from this systematic review inform the design and methodology of the *Toddler-Safe* study. Chapter three gives an in-depth description of the *Toddler-Safe* study and the development of the study's parenting intervention. Chapter four describes the evaluation method chosen for the *Toddler-Safe* study, including steps taken in its validation and development. Chapter five outlines the study's methodology including the participant selection process, sample size calculations, and the process by which all the data collected will be analysed. The results of the *Toddler-Safe* study are presented in chapter six. Chapter seven presents a discussion which builds on and supports the results described in chapter six. Finally, a summary of the thesis findings, along with recommendations for future research are presented in chapter eight.

### **1.3 CHAPTER OVERVIEW**

This chapter reviews the scientific literature regarding childhood burn injuries focussing primarily on three themes: epidemiology, characteristics, and prevention. Section 1.4 outlines the methodology of the literature review highlighting the search criteria for identification of relevant studies. This is followed by a brief discussion on the classification of burns based on depth and extent of injury (sections 1.5 and 1.6). Section 1.7 addresses the pathophysiology of burns while section 1.8 focuses on the types of burns based on aetiology, highlighting the various agents and mechanisms of injury in children. This is followed by a detailed description of the epidemiology of childhood burns (section 1.9), specifically describing incidence and mortality, gender and age distribution, seasonal variation, place of occurrence, and the risk factors for childhood burn injury. Section 1.10 briefly describes intentional childhood burns while section 1.11 discusses the pre-hospital management of burn injuries highlighting its importance, current recommendations, and examples of inappropriate first aid treatments. This is followed by a description of childhood burns prevention strategies (section 1.12), describing passive and active prevention measures. Section 1.13 describes in detail how behaviour change theories and models can be used to design interventions capable of modifying health behaviour. Section 1.14 follows up on the previous section and describes how health education can be used as a strategy for changing health behaviour. Sections 1.15 to 1.17 describe the rationale for undertaking this childhood burns prevention research study, the aims and objectives of the PhD project, as well as the hypothesis for the study. Finally, chapter one concludes with a brief summary of all the key points raised in chapter (section 1.18).

## **1.4 METHODOLOGY OF THE LITERATURE REVIEW**

### **1.4.1 Search methods for identification of studies**

In order to establish the extent of the relevant literature relating to childhood burns prevention, an initial ‘scoping search’ was conducted by the author of this PhD thesis before the final search was conducted. A search strategy was designed comprising of electronic database searches and searches of other key resources. The search for relevant literature was limited to a date range of January 1970 to December 2016. Articles published prior to January 1970 were excluded from the literature search. This was because the key milestones in burns safety and prevention, such as the widespread use of battery-powered home smoke alarms (Milke, 2010, Public/Private Fire Safety Council, 2006) and the use of flame retardant children’s sleepwear and home furniture (Shaw, 2010, Liao and Rossignol, 2000), were achieved in the 1970s. The literature review would therefore have greater relevance in present day society. Publication search was also limited to studies published in English or with English language versions or abstracts. All references to publications accessed were stored on an electronic reference management software (EndNote X7; Thomson Reuters, Philadelphia, Pennsylvania).

### **1.4.2 Electronic database searches**

The following electronic databases were searched to identify relevant publications;

- MEDLINE
- SCOPUS
- CINAHL
- EMBASE
- PsycINFO
- Web of Science

In order to access the maximum amount of literature around childhood burns prevention, the following broad keywords were used for the search: ‘burns’, ‘child’, ‘prevention’, and ‘first aid’.

### **1.4.3 Extending the search strategy**

Other sources of information included the reference lists of relevant papers and the web pages of injury prevention organisations such as, The Royal Society for the Prevention of Accidents (ROSPA), and Child Accident Prevention Trust (CAPT). Google and Google Scholar were used to identify grey literature.

## **1.5 CLASSIFICATION OF BURNS**

A burn is defined as a traumatic injury to the skin or other organic tissue caused by thermal or other acute exposures (WHO, 2008c). Burns occur when some or all of the different layers of cells in the skin are destroyed by hot liquids, hot solids, flames, radiation, electricity, friction, or contact with chemicals (WHO, 2012). The extent and depth of a burn injury is related to the temperature of the burning agent, the duration of contact, and the thickness of the skin.

Burns can be classified, based on the depth of tissue injury in the zone of maximum necrosis, into superficial/epidermal, partial-thickness, and full-thickness/deep burns (Coovadia and Wittenberg, 2007, Evers et al., 2010) (Table 1.1). These used to be formally classified as first degree, second degree, and third degree burns respectively. Burns extending through the entire skin and involving underlying fascia, muscle, tendons, or bone are often considered fourth-degree burns. Burn injury is a dynamic process and the depth of a burn wound could evolve over time, especially with partial thickness burns (Evers et al., 2010). According to Evers et al. (2010), burn wounds that start as superficial partial or deep partial could progress to deep partial or full thickness burns over a period of about 3 days after injury.

In superficial burns only the epidermis is involved with redness, slight swelling and pain. These burns generally heal in a few days without any scarring. Partial-thickness burns involve the epidermis and portions of the dermis. They are subdivided into superficial partial-thickness burns and deep partial-thickness burns. Superficial partial-thickness burns are characterised by redness of the skin, pain, and thin-walled blisters. These burns generally heal in 10 to 20 days without functional impairment or scarring (Evers et al., 2010, Rice and Orgill, 2012). Deep partial-thickness burns on the other hand, extend into the deeper dermis and cause damage to hair follicles, nerve endings, and glandular tissue. Healing takes between 25 to 60 days with pigmentary changes, scarring and contracture (Evers et al., 2010). Full thickness burns involve all the layers of the skin and a variable amount of underlying subcutaneous tissue. Clinically the skin appearance may vary from waxy white to leathery grey to charred black. Sensation is absent. Complete spontaneous healing is not possible in full thickness burns and most require skin grafting (Coovadia and Wittenberg, 2007, Greaves et al., 1997, Rice and Orgill, 2012, Burgdorf et al., 2009, Glasgow and Graham, 1997). Without surgery, full thickness burns heal by wound contracture with epithelialisation around the wound edges (Rice and Orgill, 2014).



**Table 1.1: Description of the clinical characteristics of burn wounds of various depths**

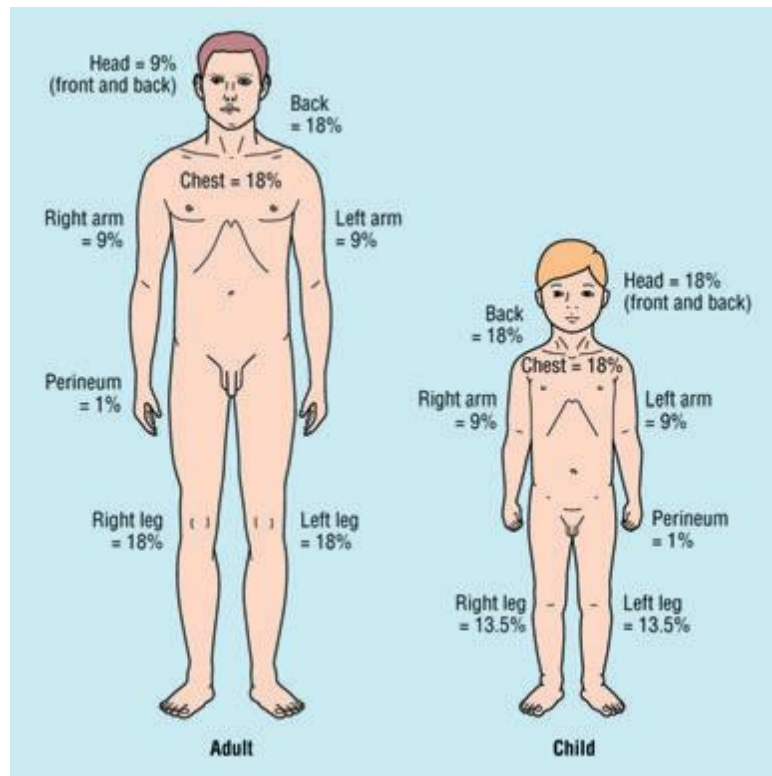
<i>Depth</i>	<i>Layer of skin involved</i>	<i>Appearance</i>	<i>Pain</i>	<i>Healing time</i>
<i>Superficial</i>	<i>Epidermis only</i>	<i>Pink to red, moist, no blisters</i>	<i>Moderate-Severe</i>	<i>3 – 7 days</i>
<i>Superficial partial</i>	<i>Superficial (papillary) dermis</i>	<i>Blisters, redness, moist, intact epidermal appendages, blanches on pressure</i>	<i>Severe</i>	<i>1 – 3 weeks, long term pigment changes may occur</i>
<i>Deep partial</i>	<i>Deeper layer (reticular) dermis</i>	<i>Dry, white, non-blanching, loss of all epidermal appendages</i>	<i>Minimal</i>	<i>3 – 6 weeks, with scars</i>
<i>Full thickness</i>	<i>Full thickness of skin and into the subcutaneous fat or deeper</i>	<i>Leathery, dry, white or red with thrombosed vessels</i>	<i>No</i>	<i>Does not heal by primary intention, requires skin graft</i>

*Source: Adapted from Evers et al (2010) 'The Biology of Burn Injury' (Evers et al., 2010)*

### **1.6 BURN WOUND EXTENT**

The extent of a burn injury is normally estimated using the percentage of the total body surface area (TBSA) affected by the burn. Superficial burns are not included in TBSA assessment (Rice and Orgill, 2014). The Wallace rule of nines (Figure 1.1) is used for rapid estimation of burn extent in emergency situations, however it is not accurate for children younger than 15 years of age or for obese people (Burns Management Guidelines, 2012a).

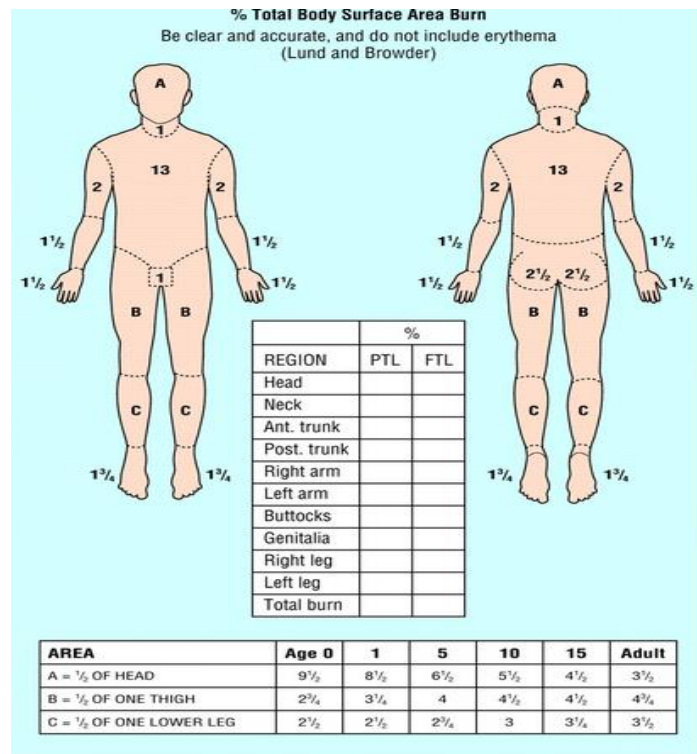
**Figure 1.1: Evaluation of burn wound extent using Wallace's rule of nine**



*Source: Evers et al (2010) 'The Biology of Burn Injury'*

In children and infants, the surface area of the head and neck relative to the surface area of the limbs is larger than in adults, hence, the “Rule of Nines” chart is inappropriate for TBSA estimation (Hansbrough and Hansbrough, 1999). The Lund-Browder chart (Figure 1.2) is used instead as it takes into account the relative percentage of body surface area affected by growth, thereby offering a more accurate estimation of TBSA in adults and children (Rice and Orgill, 2014).

**Figure 1.2: Evaluation of burn wound extent using the Lund-Browder chart**



Source: (Forensic medicine for medical students, 2015) 'Burn area'

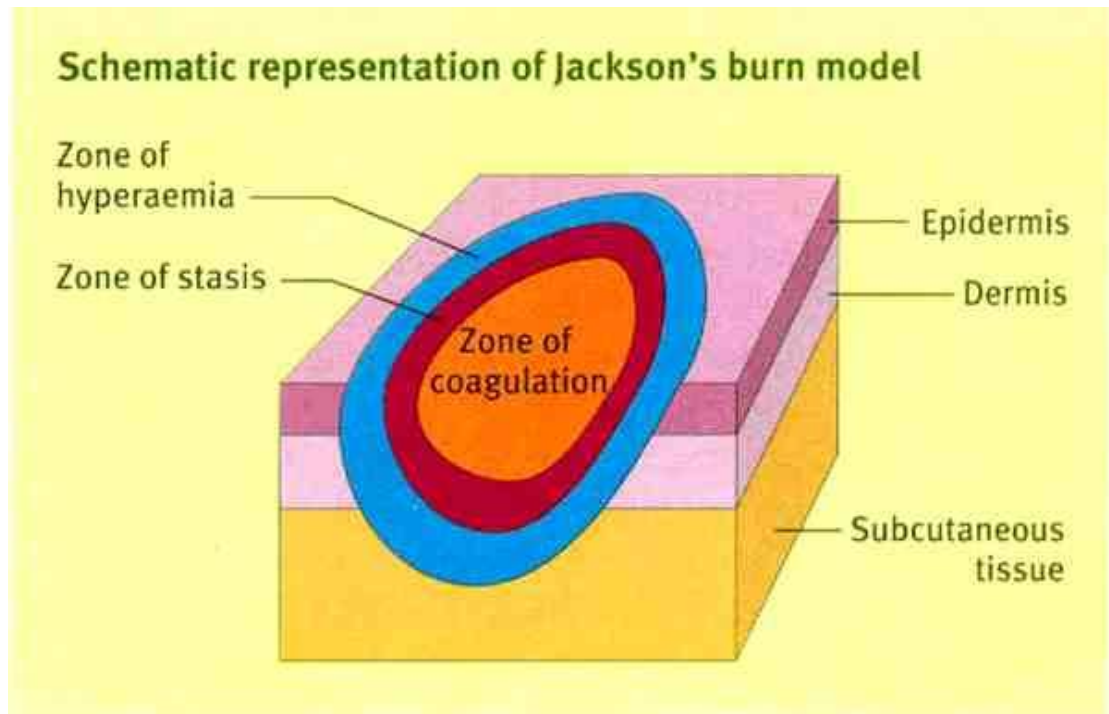
### 1.7 PATHOPHYSIOLOGY OF BURNS

Burn injuries produce a complex physiologic response in the skin and adjacent tissues. An understanding of this response is important for effective management of burn injuries. As temperature rises, the proteins in the skin become denatured leading to loss of their plasma membrane integrity (Evers et al., 2010). After the burn, necrosis occurs at the centre of the injury and becomes progressively less severe at the periphery (Keck et al., 2009). Jackson's burn model of 1953 (see figure 1.3) describes the three zones of burn injury. The zone of coagulation is located at the centre of the wound and represents the area of severe damage characterised by irreversible tissue loss from protein coagulation. Surrounding this zone is an intermediate region of indeterminate prognosis called the zone of stasis. This zone comprises of less damaged tissue, decreased tissue perfusion, capillary vasoconstriction and ischaemia. The tissue in this zone is

potentially salvageable. The zone of hyperaemia is the outermost zone characterised by viable cells and vasodilatation mediated by local inflammatory mediators. There is usually complete recovery in the tissue within this zone unless complicated by severe sepsis or prolonged hypoperfusion (Hettiaratchy and Dziewulski, 2004a, Keck et al., 2009, Evers et al., 2010, Burns Management Guidelines, 2012b).

Tissue loss in burn injury is rapidly followed by activation of toxic inflammatory mediators such as cytokines (Hettiaratchy and Dziewulski, 2004a). These inflammatory mediators cause further damage to the skin and endothelial cells leading to ischaemic tissue necrosis (Keck et al., 2009). In addition, complement activation and intravascular stimulation of neutrophils occur, resulting in the production of cytotoxic oxygen free radicals. Toxic by-products of xanthine oxidase, produced due to increased histamine activity, further causes damage to dermal structures (Keck et al., 2009). Cold water treatment initiated immediately after a burn injury has been shown to reduce the release of these inflammatory mediators (Cuttle et al., 2009b). Cooling using cold water promotes re-epithelialization thereby increasing the rate of wound healing post injury (Brown et al., 2014, Sawada et al., 1997).

**Figure 1.3: Jackson's Burn Model showing zones of burn injury**

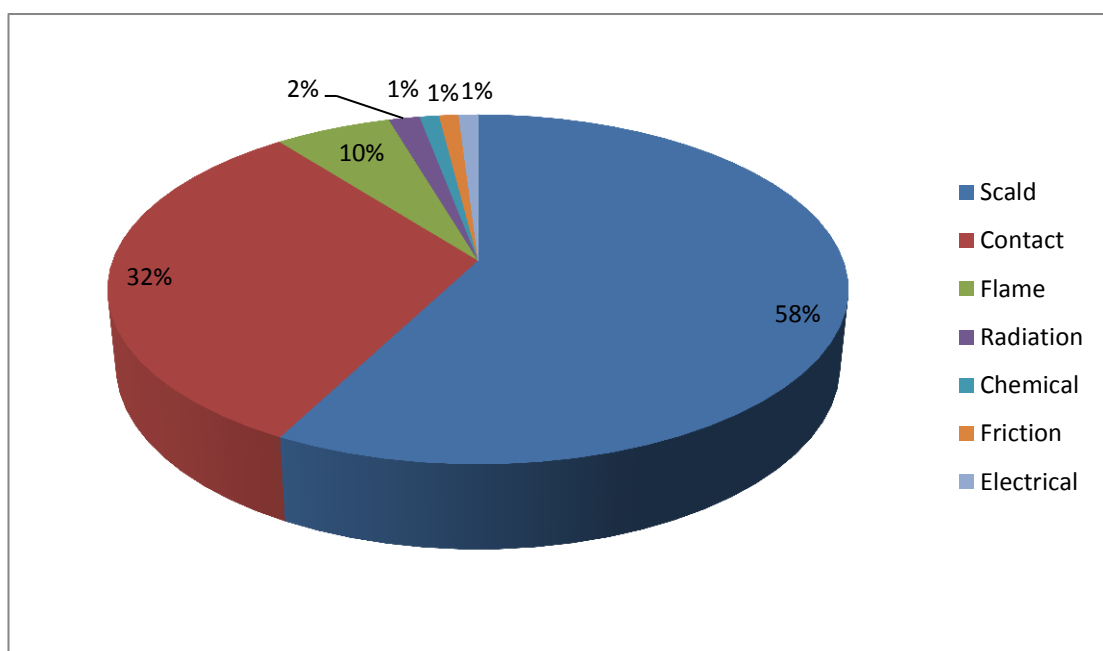


*Source: Burns Management Guidelines (2012b) 'Burns Assessment: Burn Pathophysiology'*

### **1.8 TYPES OF BURN INJURY**

Burns can be classified into seven types based on aetiology as can be seen in Figure 1.4. Each type of burn is associated with a number of agents and different mechanisms of injury. There is a complex relationship between the characteristics of the child, the agent (heat source), mechanism (how the child comes into contact with the agent), and the environment (where the event occurs) that contribute to the severity of childhood burns (Kemp et al., 2014).

**Figure 1.4: Paediatric burn types**



*Source: 'Patterns of burns and scalds in children' (Kemp et al., 2014)*

**Scalds:** A scald occurs when the skin is exposed to hot liquids or steam. Approximately 60% of all burns in children are caused by scalds, with hot beverages (tea and coffee) being the most frequent agent (Kemp et al., 2014, Dokter et al., 2014, Hutchings et al., 2010, Stockton et al., 2015). Other common agents are hot water, steam, and hot food items such as soups, cooking oils, and hot noodles in soup (Kemp et al., 2014, Kai-Yang et al., 2008, Fukunishi et al., 2000). Scalds typically occur in the home environment (Goldman et al., 2006, Carlsson et al., 2006, Kemp et al., 2014, Verey et al.). The mechanism of a scald injury varies with the age and developmental stage of the child. Younger children are more likely to pull hot beverages or containers of hot water down onto themselves from high surfaces such as a kitchen counter or table, while older children suffer scalds as a result of spills during food preparation (Kemp et al., 2014, Drago, 2005). Due to these mechanisms of injury, scalds frequently affect the upper parts of the body – the head/neck, upper torso, and upper limbs (Drago, 2005).

Contact burns: Contact burns occur when the skin comes into contact with hot objects. They are the second most commonly occurring burn type in young children accounting for about 32% of all childhood burns (Kemp et al., 2014, Hansbrough and Hansbrough, 1999, Verey et al., 2014). Most contact burns occur in the home environment and common agents include hot domestic irons, oven doors, hot water bottles, radiators and light bulbs (Kemp et al., 2014, Batchelor et al., 1994, Goltsman et al., 2015). Recent studies have also reported an increase in the number of contact burns in children caused by hair straightening devices (Mehta et al., 2008, Wilson Jones et al., 2008, Foong et al., 2010, Sarginson et al., 2013). The most common mechanism of injury involves the child touching the hot item, with the hands being the most commonly affected body part (Drago, 2005, Batchelor et al., 1994, Kemp et al., 2014).

Flame burns: Flame burns occur as a consequence of direct contact with open fires and are more commonly seen in low-income countries where outdoor cooking fires are used. In rural parts of Africa, more than half of all paediatric burn incidents are due to open flames with kerosene stove explosions as the most frequent agent (Albertyn et al., 2006). Children with epilepsy are particularly at risk, and there have been reported incidents of children falling into open fires during convulsive episodes (Albertyn et al., 2006, WHO, 2012). In high income countries, flame burns (excluding house fires) make up between 2% to 13% of all paediatric burn types seen in the ED (Kemp et al., 2014, Alnababtah et al., 2011, Delgado et al., 2002, Verey et al., 2014). Flame burn agents can be subdivided into indoor and outdoor agents. The most common indoor flame source is the fireplace while outdoor flame sources include barbeques and bonfires (Vermaak et al., 2012, Goldman et al., 2006). Older children have a higher incidence of outdoor flame burns (Stockton et al., 2015, Shah et al., 2011). The most common mechanism of injury involves the child touching the flames (Kemp et al., 2014), therefore, as with contact burns, the most commonly affected body parts are the hands (Kemp et al., 2014). Flame burns such as those resulting from house fires, are also associated with inhalational injury and other concomitant trauma (Hettiaratchy and Dziewulski, 2004a).

Chemical burns: Chemical burns make up between 0.5% and 2% of all burns seen in children (El-Badawy and Mabrouk, 1998, Kemp et al., 2014, Reed and Pomerantz, 2005, Iregbulem and Nnabuko, 1993, Verey et al., 2014) and occur when the skin comes into contact with corrosive substances such as acids and alkalis. Acids produce a coagulative necrosis which limits the depth and penetration of the burn while alkalis produce liquefactive necrosis causing deeper and more significant burns (Reed and Pomerantz, 2005). Everyday household cleaning products and aerosols are the most common agents (D’Cruz et al., 2015). Burn incidents are normally due to accidental splashes or when a child spills or pulls down the chemicals on themselves (Kemp et al., 2014). As a result of this mechanism of injury, chemical burns are normally widely distributed over the body.

Electrical burns: Electrical burns occur when electricity travels through the body creating entry and exit points. Young children get burned when they are exposed to faulty household equipment or frayed electrical cords. Electrical burns are not very common and account for between 1% and 2% of all paediatric burns seen in the ED (Kemp et al., 2014, Reed and Pomerantz, 2005). The most common mechanisms of injury involve the child touching exposed electrical cables with the hands or placing household plugs in the mouth (Reed and Pomerantz, 2005, D’Souza et al., 2009).

Radiation: Injury occurs when the skin is damaged due to exposure to ionizing radiation. The most common type of radiation burn is sunburn (Rice and Orgill, 2014). Radiation burns make up approximately 1% to 2% of paediatric burns seen in the ED and burns units (Kemp et al., 2014). Most cases are due to ultraviolet (UV) radiation but there have also been reported cases of radiation burns from microwave ovens (Alexander et al., 1987). Excessive exposure to ultraviolet radiation in childhood has been linked to the development of skin cancers in later life (Bandi et al., 2010).

Friction burns: Friction burns occur due to a combination of mechanical abrasion and heat generated by friction. They account for about 1% of all paediatric burns seen at the ED (Jeremijenko et al., 2009, Verey et al.,



2014). Currently, many of the friction burns in children occur as a result of contact with exercise treadmills (Attalla et al., 1991, Kemp et al., 2014, Juang et al., 2011, Davidson and Eadie, 2009, Goltsman et al., 2016b). The most common mechanism of injury involves the child touching the treadmill's moving belt while it is being used by an adult (Jeremijenko et al., 2009, Juang et al., 2011). Treadmill friction burns have been reported to occur mainly on the hands (Davidson and Eadie, 2009, Juang et al., 2011, Attalla et al., 1991, Jeremijenko et al., 2009, Kemp et al., 2014).

## **1.9 EPIDEMIOLOGY OF CHILDHOOD BURNS**

### **1.9.1 Incidence of burns in children**

Burns are currently the fifth most common cause of non-fatal childhood injury behind intracranial injury, open wounds, poisoning, and forearm fractures (WHO, 2008b). The actual number of children who suffer burn injuries throughout the world each year is unknown. However, a literature review (Burd and Yeun, 2005) estimated that about half a million children worldwide are hospitalised every year with a burn or scald - the majority occurring in the low and middle-income countries of Africa and Asia. The epidemiological data used in deriving this estimate was largely drawn from in-patient reports which capture serious burn injuries treated in hospital. Many other publications reporting on child burn injuries have relied on in-hospital admissions data. This could present a significant problem when attempting to measure the true incidence of childhood burn injuries in a population, as children with minor injuries are less likely to be taken to hospital, thereby seriously underestimating the problem. A recent UK study (Emond et al., 2016) reported that only 24% of pre-school children with domestic burn injuries attended hospital. Furthermore, the hospital recording systems in some countries are not very efficient at recording and collating information, meaning that some medically attended paediatric burn incidents are unreported. This suggests that burns in children occur more frequently than reported in hospital figures.

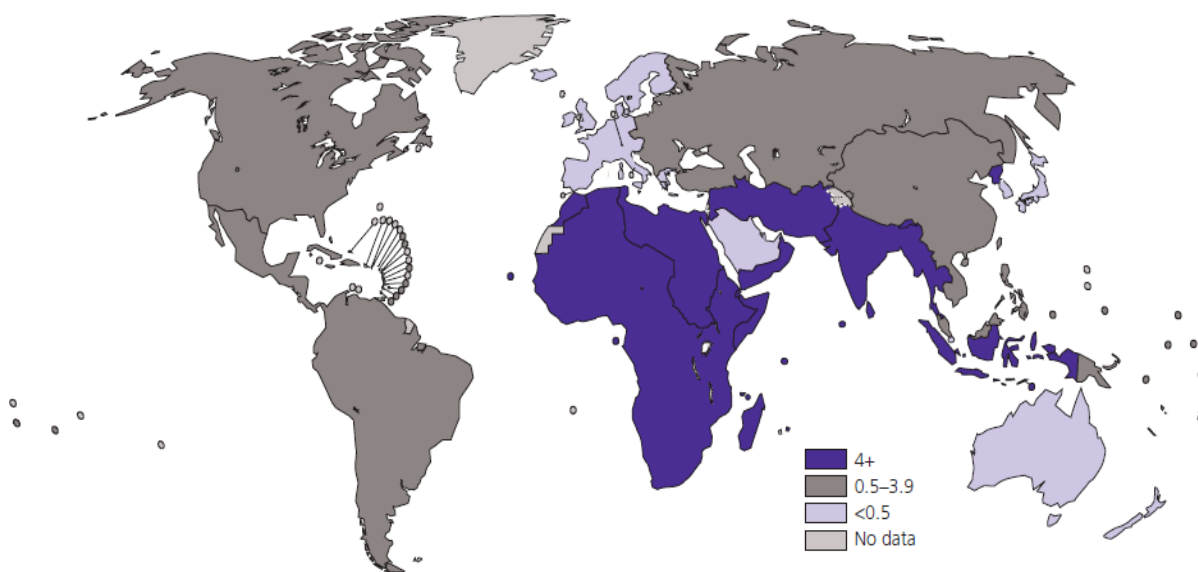
According to Burd and Yeun (2005), the highest incidence of hospitalised paediatric burn patients is in Africa and the lowest is in the Americas. Europe, the Middle East, and Asia show similar figures, but owing to the considerably large population of Asia, the continent bears over half of the world's paediatric burn population. This is not surprising as the risk of children suffering from burn injuries is much higher in low and middle-income countries (LMIC) compared to that in high-income countries (HIC). This is mainly due to hugely different exposure risks experienced by children in LMIC and HIC. In LMIC, the use of open flames and carbon-based fuels for cooking and lighting is very common. Children are exposed to these risks and suffer burn injuries as a result. This, coupled with the lack of burn prevention programmes and poor access to and inconsistent quality of healthcare given to burn victims, contributes immensely to the high burn incidence rates seen in LMIC (Mock, 2007). It therefore, may not be appropriate to make comparisons between burn injury rates in LMIC and HIC due to these exposure risks.

A large population-based survey conducted in Bangladesh for instance, showed an annual non-fatal paediatric burn incidence of 288.1 per 100,000 children per year (Mashreky et al., 2008). In the United States of America (USA), it was estimated that there were 429,187 hospital reported cases of non-fatal paediatric burn injuries in 2011, amounting to a crude annual incidence rate of 138 per 100,000 population (CDC, 2013). In Ireland, the reported average annual hospital admission rate for paediatric burns in 2001 was approximately 100 per 100,000 per year (Scallan et al., 2001), while in Israel the annual hospitalisation rate was 74 per 100,000 children in 2006 (Goldman et al., 2006). Much lower figures have been reported in smaller countries such as Kuwait and Hong-Kong which had paediatric burn incidence rates of 17.5 and 3.4 per 100,000 population respectively (Sharma et al., 2006, Tse et al., 2006).

### **1.9.2 Mortality from childhood burns**

Burns are the third most frequent cause of childhood injury resulting in death behind motor vehicle accidents and drowning (Toon et al., 2011). Globally, nearly 96,000 children were estimated to have died as a result of a fire-related burn in 2004 (WHO, 2008b). According to WHO, the annual global death rate for childhood burns approximates 3.9 per 100,000 population (WHO, 2008c). These burn-related deaths show great socio-economic and regional variability as can be seen in Figure 1.5. The mortality rates in low and middle-income countries are almost eleven times higher than those in high-income countries, 4.3 per 100,000 compared to 0.4 per 100,000. The Americas and the high-income countries of Europe and the Western Pacific have the lowest burn-related death rates in the world while the poor regions of Africa and South-East Asia account for the highest mortality rates (WHO, 2008c). Factors contributing to this wide variation in mortality between regions include poverty; poor access to, and quality of healthcare following a burn; mass illiteracy; poor quality of housing; the use of carbon-based fuels for heating and lighting; and the loss of social safety networks in countries undergoing economic and political transition (WHO, 2008a, Albertyn et al., 2006). In high-income countries, the single most important determinant of child mortality from burns is smoke inhalation from house fires or other conflagrations (WHO, 2008c).

**Figure 1.5: Mortality rates due to fire-related burns per 100,000 children**



Africa	Americas		South-East Asia	Europe		Eastern Mediterranean		Western Pacific	
LMIC	HIC	LMIC	LMIC	HIC	LMIC	HIC	LMIC	HIC	LMIC
8.7	0.7	0.6	6.1	0.2	1.1	0.4	4.7	0.3	0.6

<sup>a</sup> These data refer to those under 20 years of age.  
HIC = High-income countries; LMIC = low-income and middle-income countries.

Source: WHO (2008) *The Global Burden of Disease: 2004 Update*

### 1.9.3 Gender distribution

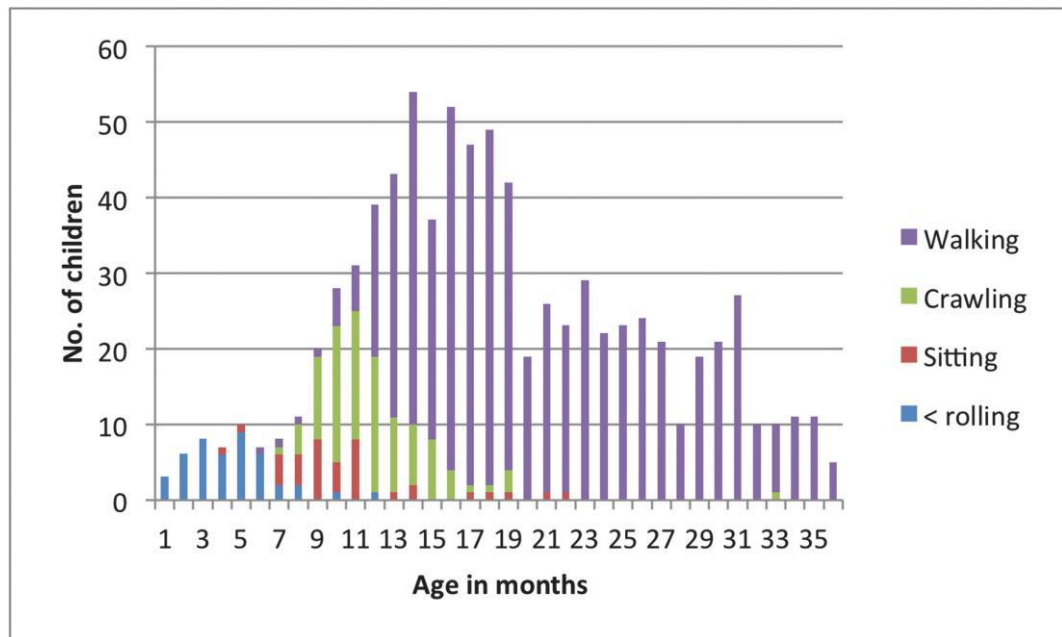
Boys are reported to have a higher incidence of burn injuries than girls. A recent prospective population-based study by Emond et al (2016), found that boys less than two years of age were more likely to sustain burns than girls of the same age group. A recent UK retrospective matched cohort study by Hutchings et al. (2010), reported that 58% of all childhood burn admissions were male. Similar patterns of male predominance have been reported in USA - 60% (Edelman et al., 2010), Australia - 58% (Abeyasundara et al., 2011), Sweden - 64% (Carlsson et al., 2006), France - 61.6% (Mercier and Blond, 1996), Turkey - 60% (Balseven-Odabası et al., 2009), Norway - 56% (Brudvik et al., 2011), China - 58% (Tse et al., 2006), India - 60% (Ganesamoni et al., 2010), Iran - 62% (Torabian and Saba, 2009), Nigeria - 58% (Okoro et al., 2009), and Egypt - 53.7% (El-Badawy

and Mabrouk, 1998). This male predominance is seen in most other injury types and may be attributable to gender differences in exploratory and risk-taking behaviour (Kai-Yang et al., 2008, Towner and Mytton, 2009), and a higher incidence of misbehaviour-related injuries in boys (Morrongiello et al., 2006).

#### **1.9.4 Age distribution of burns in children**

Children of all ages are vulnerable to burn injuries. However, most epidemiological studies have reported the highest incidence in children younger than five years of age (Parbhoo et al., 2010, Mukerji et al., 2001, Nasser et al., 2009, Edelman et al., 2010, Mashreky et al., 2008, Brudvik et al., 2011, Dokter et al., 2014). Within this group, toddlers aged between 13 and 17 months have the highest incidence rates and account for the majority of childhood burns cases seen at ED and burns units (Fukunishi et al., 2000, Balseven-Odabası et al., 2009, Carlsson et al., 2006, Goldman et al., 2006, WHO, 2008c). A recent multicentre analysis (Figure 1.6) analysed the monthly age bands of 1215 children admitted for unintentional burn injuries in the UK and Ireland and demonstrated a mean age of 17 months with a peak prevalence at around 13 months of age (Kemp et al., 2014). A sharp increase in prevalence was noticed at nine months of age corresponding to the onset of independent mobility in infants (Kemp et al., 2014). Children older than five years are also susceptible to burns. Older children are eager to engage in new activities and are more likely to get injured while experimenting with open flames, lighters, and fireworks (WHO, 2008a).

**Figure 1.6: Age and developmental milestone of children younger than 36 months of age with burns and scalds**



Source: 'Patterns of burns and scalds in children' Kemp et al.(2014)

### 1.9.5 Risk factors for burns in children

Burns are an important cause of morbidity and mortality particularly in children younger than five years of age. To prevent childhood burns, a thorough understanding of the risk factors associated with these injuries is required. Numerous risk factors have been identified and relate to factors within the child, the family, and the social and physical environment. These include multiparity, male gender, low socio-economic status, low educational level of the primary caregiver, and immigrant status (Fukunishi et al., 2000, Quayle et al., 2000, WHO, 2012, Morrongiello and Schwebel, 2008, Kendrick et al., 2012, Petridou et al., 1998, Goltsman et al., 2016a). Families at greater risk are those living on subsistence income or being cared for by an unsupported, single parent who tends to be young and inexperienced (Glasgow and Graham, 1997). Additional risk factors include: the presence of a pre-existing impairment in the child such as blindness or epilepsy; history of burn injury in a sibling; overcrowding; having a smoker in the household; alcohol abuse; birth order (children who are not the first born carry a higher risk); lack of access to water supply; and

behavioural difficulties such as attention deficit hyperactivity disorder (ADHD) (Badger et al., 2008, Jagannath et al., 2011, Holland, 2006, Ghanizadeh, 2008, Forjuoh et al., 1995b, Werneck and Reichenheim, 1997, Delgado et al., 2002, WHO, 2008a). Lapses in the supervision of children by their parents has also been reported as an important risk factor for repeat burns (Forjuoh, 2006).

### **1.9.6 Seasonal variation**

A number of studies have reported seasonal variations in unintentional childhood burns, with most reporting a higher incidence during the cold winter months compared to the warmer months (Abeyasundara et al., 2011, Van Niekerk et al., 2004, Goldman et al., 2006, El-Badawy and Mabrouk, 1998, Mukerji et al., 2001, Mashreky et al., 2008, Hemeda et al., 2003). In Sub-Saharan Africa, an increased incidence of burns has been observed during the Harmattan season which is the cold dry period between October and February (Mabogunje et al., 1987, Albertyn et al., 2006, Iregbulem and Nnabuko, 1993). This predominance of burns occurring during the cooler months may be related to the increased use of heating devices and hot liquids to counteract the effects of the cold weather. A few studies have; however, reported an increased incidence of burns during the summer months, with a peak in the month of July (Shah et al., 2011, Quayle et al., 2000, Hammig and Ogletree, 2006). This period oftentimes correlates with the start of school holidays.

### **1.9.7 Place of occurrence**

The majority of childhood burn injuries occur as accidents in the home environment (El-Badawy and Mabrouk, 1998, Fukunishi et al., 2000, Ansari-Lari and Askarian, 2003, Goldman et al., 2006, Ryan et al., 1992, Mukerji et al., 2001, Mercier and Blond, 1996, Petridou et al., 1998, Sakallioğlu et al., 2007, Forjuoh et al., 1995a). The kitchen has been reported as the most frequent site within the home where burns occur, with the majority of incidents occurring at mealtimes and during food preparation by parents (Mashreky et al., 2009, Khandarmaa et al., 2012, Mukerji et al.,

2001, El-Badawy and Mabrouk, 1998, Drago, 2005, Rossi et al., 1998, Petridou et al., 1998, Mercier and Blond, 1996, Hammig and Ogletree, 2006). Other frequent sites within the home where burn accidents have been reported include the bathroom (Fukunishi et al., 2000) and living room (Brudvik et al., 2011).

### **1.10 CHILDHOOD BURNS FROM MALTREATMENT**

Most childhood burn injuries are unintentional in nature. A significant few however, are due to maltreatment. Child maltreatment in this regard includes neglect (from inadequate supervision), and physical abuse. Some intentional burns occur because of specific social habits and beliefs. For instance, in Vietnam, ‘coining’ or ‘coin rubbing’ is practiced as a remedy for treating minor ailments. This involves the application of hot oil on the back and chest, and the use of a coin to vigorously rub against the body (Al-Qattan and Al-Zahrani, 2009). In parts of West Africa, there have been reports of ‘therapeutic’ burns inflicted on children as a form of treatment for convulsive attacks (Forjuoh, 1995).

Burns due to neglect greatly outnumber those due to physical abuse by as much as 9:1 (Maguire et al., 2014). Burns from physical abuse account for an estimated 1% to 25% of all childhood burns presenting at ED and burns units (Chester et al., 2006, Maguire et al., 2008). These burns are generally more severe, require longer hospital stays and demand greater resources in their treatment (Andronicus et al., 1998). The morbidity accompanying this form of injury as well as the element of premeditation seen in some cases, makes burns due to physical abuse a major cause for concern (Hobbs, 1986).

Distinguishing between unintentional and intentional burns in children is often challenging even for experienced healthcare practitioners. The injury pattern of intentional burns can sometimes be clear, as in the case of cigarette burns and immersion incidents (Maguire et al., 2008). However, the clinical features of some intentional burns can mimic those of



unintentional burns, thus requiring further assessments to arrive at a definite diagnosis. In addition, suspected cases of intentional burns could have previous notifications to child protection agencies for abuse or neglect (Andronicus et al., 1998). Detecting burns from physical abuse is therefore of paramount importance. The risk of reoccurrence is high and up to 30% of children who suffer repeated abuse or neglect will be fatally injured (Hettiaratchy and Dziewulski, 2004a). Furthermore, any infant or toddler (aged less than three years old) who has sustained a burn injury is at significantly greater risk of neglect or abuse or becoming 'a child in need' by their sixth birthday (James-Ellison et al., 2009).

### **1.11 PRE-HOSPITAL MANAGEMENT OF BURNS**

Burns are normally more severe in children than in adults. This is because a child's skin is thinner and more sensitive to heat and will burn more quickly when it comes into contact with a heat source. It takes about a second for hot liquid heated to 71 degrees centigrade to cause a burn on adult skin. Approximately half this time is required to cause a burn on the skin of a child under five years of age (Reed and Pomerantz, 2005).

Initial first aid plays an important role in burn outcome. It has been shown to reduce the pain and severity of burns and the need for skin grafting and other expensive burns treatment (Nguyen et al., 2002, Wright et al., 2015, Fadeyibi et al., 2015). Prompt and appropriate first aid aims to stop the burning process, to cool and cover the burn, and to provide pain relief (Hudspith and Rayatt, 2004, Baartmans et al., 2016). Current recommendations involve application of cool running water at a temperature of between 5° to 25° Celsius for 10 to 30 minutes within three hours of injury, covering with polyvinyl chloride film (cling film), and providing analgesia (Allison and Porter, 2004, Holland, 2006, Sawada et al., 1997, Glasgow and Graham, 1997, Cuttle and Kimble, 2010). Cold water treatment halts progression of the burn by decreasing the histological depth of damage and minimising wound ischemia (Cuttle and Kimble, 2010). It removes any noxious agents, provides pain relief, and reduces oedema by

stabilizing mast cells; thereby, reducing the release of histamines (Hudspith and Rayatt, 2004, Cuttle et al., 2009a). Cooling has been shown to increase the rate of wound healing by promoting the rapid growth of epithelial cells (Sawada et al., 1997, Ofeigsson et al., 1968). Excessive cooling should however, be avoided as this could induce hypothermia in a young child (Hudspith and Rayatt, 2004). Ice or iced water should never be used for cooling as intense vasoconstriction can lead to progression of the burn (Hudspith and Rayatt, 2004). Alternative treatments such as Aloe Vera and hydrogels have been reported in the literature but both treatments do not appear to convey any beneficial effects on burn wounds (Cuttle and Kimble, 2010). Covering the burn after cooling prevents infection and aids wound healing. Cling film is ideal for covering burns as it is pliable, non-adherent, sterile (as long as the first few centimetres are discarded), transparent (for wound inspection), and available in most households (Hudspith and Rayatt, 2004, Jevon and Cooper, 2007). A parent's knowledge of burns first aid is therefore important.

Previous studies have shown that burns first aid administered in the home to children is suboptimal (Cuttle et al., 2009a, Ofeigsson et al., 1968, Tekin and Suskan, 2010, Conrad and Beattie, 1996, Davies et al., 2013, Graham et al., 2012, McCormack et al., 2003). Parental knowledge of first aid has equally been reported as poor with less than 32% of parents demonstrating adequate burns first aid knowledge (Davies et al., 2013, Cronin et al., 1996, Tekin and Suskan, 2010). A recent UK study showed that 25% of children with a burn or scald received no first aid prior to attendance at the ED, and in 75% of those who did receive some first aid, it was reported to be suboptimal (Kemp et al., in press). Similar findings were also reported in an Indian survey which showed that only 22.8% of paediatric patients had received appropriate first aid for their burns (Ghosh and Bharat, 2000). Davies et al. (2013), reported that in 6% of children who had sustained a burn, inappropriate and potentially harmful treatments such as raw eggs, petroleum jelly (Vaseline), toothpaste, ice, or butter, were used for first aid. Other inappropriate agents that have been reportedly used for burns first aid include; yoghurt, tomato paste, pap (maize porridge), frozen

peas, and sliced potatoes (Karaoz, 2010, Fadeyibi et al., 2015, Deave et al., 2013).

### **1.12 CHILDHOOD BURNS PREVENTION STRATEGIES**

Great strides have been achieved in recent years to reduce the morbidity and mortality associated with childhood burns. The development of advanced tissue-engineered biomaterials, along with modern surgical and burn-wound management approaches have been shown to substantially shorten hospital stay, improve wound healing, and decrease the severity of hypertrophic scars in paediatric burn victims (Atiyeh et al., 2005). However, burn injury management and rehabilitation represents a huge financial burden on individuals and health systems; therefore, prevention remains the most cost-effective management strategy for burns in children.

Most childhood burns are preventable. As with burns first aid, parental knowledge of childhood burns prevention is poor (Cox et al., 2016). The majority of childhood burns occur in circumstances with predictable patterns, therefore, offering an opportunity for intervention. Efforts to prevent burn injuries in children (and injuries in general) fall under two broad approaches - passive (structural) and active (behavioural) measures. Both approaches have advantages and disadvantages (see sub-sections below). In order to successfully prevent burns in children, the approach chosen should be based on sound knowledge of the burn aetiology and must take into account geographical variations and socioeconomic differences in burn epidemiology (Liao and Rossignol, 2000). Prevention strategies should also address the hazards for specific burn injuries, education for at-risk populations, and training of communities in secondary prevention by promoting first aid (Mock et al., 2008). Approaches that combine a range of prevention measures have been reported to be more effective at preventing burns in children (WHO, 2008a).

### **1.12.1 Passive measures**

Passive prevention measures are those that rely on changing products or environments to make them safer for all (Gielen and Sleet, 2003). They do not require the active participation of the individual. These measures typically include: legislation (such as the compulsory fitting of smoke alarms and sprinklers in commercial buildings); product modification (such as the use of kettles with short or curly flex); and environmental redesign (such as the use of thermostatic mixer valves to reduce bath hot tap water) (Hettiaratchy and Dziewulski, 2004b, Kendrick et al., 2011, Towner and Mytton, 2009). As it does not rely on a change in individuals' actions, passive measures have the potential to be very effective. A recent UK study found that households with thermostatic mixing valves (TMVs) installed, had safer bath hot water temperatures over a twelve month period and a lower risk of child scald injury (Kendrick et al., 2011). Another epidemiological study in the USA found that a state-wide regulation of household hot water temperatures contributed to a significant decline in tap water scalds in toddlers over a twenty year period (Hammig and Ogletree, 2006). However, in order to be effective, passive measures such as legislation, need to be applied consistently and enforced rigorously (Towner and Mytton, 2009). Furthermore, legislation can take a long time to be approved and further time to demonstrate an effect (Hettiaratchy and Dziewulski, 2004b).

### **1.12.2 Active measures**

Active prevention measures are those that require the consistent active participation of an individual or caregiver to bring about a change in behaviour (Ytterstad et al., 1998, Liao and Rossignol, 2000). They are necessary to mitigate the severity of burn injuries as well as prevent burns for which passive approaches are unavailable or have not been implemented (Liao and Rossignol, 2000). According to Gielen and Sleet (2003), it is rarely feasible to achieve injury reduction without some form of behaviour change. Active individual effort is sometimes required even for passive measures. For instance, a passive measure such as the fitting of smoke

alarms in residential buildings, still requires the active participation of the homeowner to physically install the smoke alarm and change the batteries when they run out. In relation to childhood injury prevention, injury control must entail some degree of behaviour change, requiring the establishment and maintenance of appropriate safety behaviour by parents, carers, and policy makers (Krasnegor et al., 1986). Active childhood burns prevention measures are primarily propagated through health educational programmes targeting specific burn aetiologies or populations at risk. An example is “The Children Safe at Home Project” (Cagle et al., 2006) which was a scald prevention programme targeting parents of young children resident in an area that accounted for the majority of scald injuries.

### **1.13 BEHAVIOUR CHANGE THEORY AND CHILDHOOD INJURY PREVENTION**

The main outcome of active prevention measures in public health practice is a change in people’s health-related behaviour. Health behaviour can be defined as “a combination of knowledge, practices, and attitudes that together contribute to motivate the actions we take regarding health.” (Farlex Partner Medical Dictionary, 2012). Currently, there is overwhelming evidence to show that modifying health behaviour can have a major impact on some of the greatest causes of mortality and morbidity, including childhood unintentional injury (NICE, 2010, NICE, 2007, NICE, 2014). Actions to modify health behaviour can be delivered at individual or community levels using a variety of methods and techniques (NICE, 2007). These methods are drawn from the fields of social and behavioural sciences and fall under the umbrella of behaviour change interventions.

#### **1.13.1 Behaviour change interventions**

Behaviour change interventions are coordinated sets of techniques, used together, which aim to change the health behaviours of individuals, communities or whole populations (NICE, 2014). There is evidence to suggest that behaviour change interventions are effective at modifying human behaviour (Hobbs et al., 2013). The success of behaviour change

interventions relies on a thorough understanding of the determinants of the specified behaviours as well as an understanding of behaviour change theories and models, and the ability to properly apply them in practice (Glanz et al., 2008). According to Glanz et al (2008), a theory can be defined as “a set of interrelated concepts, definitions, and propositions that present a systematic view of events or situations by specifying relations among variables, in order to explain and predict the events or situations”. Models on the other hand, are said to draw on a number of theories in order to understand a specific problem (Glanz et al., 2008). Behaviour change theories and models are therefore, necessary to inform the design and development of interventions aimed at changing behaviour. They are also important tools for use in understanding behaviour and facilitating change in people whose behaviours put them (or people under their care) at risk.

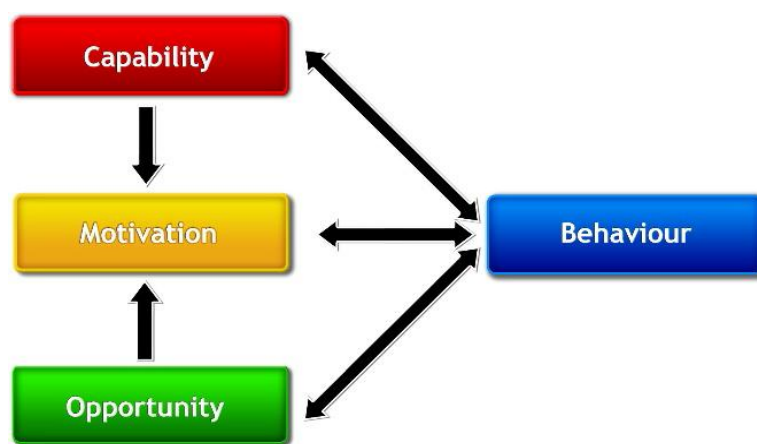
For any change in behaviour to occur, Michie et al (2011) proposed a ‘behavioural system’ known as the COM-B model of behaviour (see Figure 1.7). In this system, three essential conditions or components must be fulfilled before a desired behaviour can be performed. These conditions are:

1. **Capability:** The individual’s psychological and physical capacity to engage in the activity concerned, including having the necessary knowledge and skills
2. **Opportunity:** All the factors that lie outside the individual that make the behaviour possible or prompt it
3. **Motivation:** All the processes that direct behaviour

In other words, an individual will only be able to perform a desired behaviour if that individual has the capability (C) to perform the behaviour, has the right opportunity (O) to perform the behaviour, as well as the motivation (M) to perform the behaviour. Each of these essential components interacts with the others to generate behaviour that in turn influences all the three components in the system (Michie et al., 2011). The COM-B model has been widely used in a number of contexts. Successful

clinical applications include: medication adherence (Jackson et al., 2014), hearing-aid use (Barker et al., 2016), and child health assessment (Alexander et al., 2014). The COM-B model provides a solid basis for the design and development of interventions aimed at modifying human health behaviour, and would therefore be an ideal model to base the *Toddler-Safe* study on.

**Figure 1.7: The COM-B model of behaviour**



*Source: 'The behaviour change wheel: A new method for characterising and designing behaviour change interventions' (Michie et al., 2011)*

Glanz et al (2008) stated that “The best theory is informed by practice; the best practice should be grounded in theory.” There is however, currently a debate over the importance of theory in the development of health behaviour interventions. It is unclear how these theories translate into practice. A number of systematic reviews have suggested that interventions developed with the use of behaviour change theories are more effective than interventions that are not based on theory (Avery et al., 2013, Protogerou and Johnson, 2014, Webb et al., 2010). These findings have been disputed in other reviews (Mehtälä et al., 2014, Portnoy et al., 2014) suggesting that interventions with theoretical underpinnings are less effective. This lack of consensus over the importance of theory in developing health behaviour

interventions was assessed in a recent review (Prestwich et al., 2015), which found mixed evidence regarding the association between the use of theory to develop interventions and the resultant change in health behaviour.

### **1.13.2 Applying behaviour change theory to injury prevention research**

The application of behaviour change theory in injury prevention research has, until recently, been very unpopular and lagged behind other approaches (Gielen and Sleet, 2003). As a consequence, several prevention interventions have been unsuccessful at modifying injury-related behaviours, in part, because they did not take into account the determinants of the specified behaviours, and they failed to properly apply behaviour change theory to their development (Gielen and Sleet, 2003). There has been a lack of clarity as to what extent behaviour change theories have been applied as the basis for developing injury prevention interventions. A systematic review assessing the use of different theories and models (Trifiletti et al., 2005), found only a few scholarly applications of the most commonly used theories in unintentional injury prevention research. Recommendations for more theory-based health behaviour interventions in the field of injury prevention have been made (DiGiuseppi and Roberts, 2000, Thompson et al., 2002).

A multitude of theories and models have been used by behaviour change interventionists in health behaviour research. Table 1.2 shows the most commonly used theories and models in health education and health promotion. These include: Health Belief Model, Theory of Reasoned Action or Theory of Planned Behaviour, Stages of Change or Transtheoretical Model, Social Learning Theory, Social Cognitive Theory, PRECEDE-PROCEED Model, Community Organization Theory, Diffusion of Innovation Theory, Social Marketing, Social Support and Social Networks, Patient-Provider Communication, Stress and Coping, and Ecological Models/Social Ecology (Glanz et al., 2008). In relation to this PhD project, the theories and models most frequently used in unintentional injury prevention research include: PRECEDE PROCEED Model, Theory of



Reasoned Action/Theory of Planned Behaviour, Social Learning Theory/Social Cognitive Theory, the Stages of Change or Transtheoretical Model, and Health Belief Model (Trifiletti et al., 2005, Gielen and Sleet, 2003).

**Table 1.2: Most commonly used health behaviour theories and models**

<b>Most commonly used health behaviour theories and models</b>	<b>Health behaviour theories and models most commonly used in unintentional injury prevention</b>
Health Belief Model	PRECEDE PROCEED Model
Theory of Reasoned Action/Theory of Planned Behaviour	Theory of Reasoned Action/Theory of Planned Behaviour
Stages of Change/Transtheoretical Model	Social Learning Theory
Social Learning Theory	Social Cognitive Theory
Social Cognitive Theory	Stages of Change/Transtheoretical Model
PRECEDE PROCEED Model	Health Belief Model
Community Organization Theory	
Diffusion of Innovation Theory	
Social Marketing	
Social Support and Social Networks	
Patient-Provider Communication	
Stress and Coping	
Ecological Models/Social Ecology	

**The PRECEDE-PROCEED Model:** This is a widely used planning model which provides a structure for applying theories and concepts systematically for planning and evaluating health behaviour change programmes (Gielen et al., 2008). This model addresses health within the context of the community and emphasises active community participation in selecting priority behaviours to be addressed (Green and Kreuter, 1999). As its name suggests, the model has two distinct parts – PRECEDE, which was developed in the 1970s and stands for Predisposing, Reinforcing, and

Enabling Constructs in Educational/Environmental Diagnosis and Evaluation, and PROCEED which was added to the framework in 1991 and stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (Glanz et al., 2008). A review by Trifiletti et al (2005) reported that the PRECEDE-PROCEED model was the most frequently cited theory of behaviour change used for injury topics. The search strategy for this review was, however, not exhaustive or inclusive of all databases, and may have limited articles reporting other theories.

**The Theory of Reasoned Action (TRA) and the Theory of Planned Behaviour (TPB):** TRA and TPB are closely associated and are normally described together. TRA was formulated towards the end of the 1960s and characterises behaviour as a function of behavioural intention, subjective norms, and attitudes (Fishbein and Ajzen, 1977). TRA states that “people’s intention to perform a behaviour predicts their actual behaviour” (Gielen and Sleet, 2003). Behaviour is dependent on an individual’s attitudes and subjective norms (Taylor et al., 2006). An individual will therefore, be unlikely to perform a recommended behaviour if he or she is not motivated or lacks the intent to do so. TPB is a modified version of TRA. It contains an additional construct: perceived control over performance of the behaviour, which takes into account situations where an individual may not have complete control over a behaviour (Montano and Kasprzyk, 2015). TRA and TPB have been shown to be very effective at predicting changes in knowledge, attitudes and/or behaviour (Taylor et al., 2006). More recently, the use of an Integrated Behavioural Model (IBM) that draws from both TRA and TPB, as well as from other dominant theories has been proposed (Montano and Kasprzyk, 2015).

**Social Learning Theory (SLT)/Social Cognitive Theory (SCT):** The SLT states that “learning is a cognitive process that takes place in a social context and can occur purely through observation or direct instruction, even in the absence of motor reproduction or direct reinforcement” (Bandura and Walters, 1977). Elements of cognitive psychology were added to SLT to better understand human information

processing, and was subsequently renamed Social Cognitive Theory (SCT) (Bandura, 1988). The SCT states that “human behaviour is the product of the dynamic interplay of personal, behavioural, and environmental influences.” (McAlister et al., 2008). Modelling is a key component of the SCT. Bandura (1988) refers to modelling as “the first step in developing competencies.” Bandura and several other behavioural scientists have shown that models are imitated most frequently when observers perceive the models as similar to themselves – a method known as peer modelling (Bandura, 1988, Krouse, 2001, Brody and Stoneman, 1981). Applications of SCT in peer modelling have traditionally been designed using videotapes and other media sources (video modelling), however, more recent applications have been developed utilising current technologies such as interactive internet-based tools (McAlister et al., 2008). Interventions based on SCT have been shown to achieve small to moderate effects on health behaviours (Prestwich et al., 2015). With regards to child injury prevention, effective applications of SLT and SCT include: parental education on correct child restraint use (Tessier, 2010, Swartz et al., 2013); home safety (Hendrickson, 2005); home supervision (Morrongiello et al., 2013); and home visitation (Fergusson et al., 2005).

**The Stages of Change or Transtheoretical Model (TTM):** TTM is a relatively new model and proposes behaviour change as a process that unfolds over time, with progress through a series of six consecutive stages: 1. Precontemplation (not thinking about changing); 2. Contemplative (aware and thinking about changing); 3. Preparation (taking steps necessary for changing); 4. Action (making the change for a short period of time); 5. Maintenance (maintaining the change for 6 months or longer), and 6. Termination (no temptation to relapse and 100% confidence) (Prochaska and DiClemente, 1984). Applications of TTM-tailored interventions have demonstrated remarkable successes in smoking cessation and multiple health-risk behaviour change programmes (Glanz et al., 2008).

**The Health Belief Model (HBM):** The health belief model was developed in the 1950s and states that “preventive behaviours are a function

of people's beliefs about their susceptibility to the health problem, the severity of the health problem, and the benefits versus costs of adopting the preventive behaviour, as well as whether people experience a cue to action" (Gielen and Sleet, 2003). HBM consists of four key constructs – perceived susceptibility, perceived severity, perceived benefits, and perceived barriers (Janz and Becker, 1984). Perceived susceptibility is central to HBM as it is linked to a person's readiness to take action (Rosenstock et al., 1988). Cues or triggers, which could be internal (e.g. symptoms of ill health) or external (e.g. mass media campaigns) are necessary for prompting engagement in health-promoting behaviour (Glanz et al., 2008, Janz and Becker, 1984). HBM is most suited to predicting patterns of behaviour, however the available meta-analytical evidence concludes that it has a relatively weak predictive power, capable of predicting only around 10% of behavioural variance (Taylor et al., 2006, Harrison et al., 1992). Effective applications of HBM in child injury prevention include: parental education on home safety (Hendrickson, 2005, Posner et al., 2004), and home supervision (Morrongiello et al., 2013).

#### **1.14 HEALTH EDUCATION AND BEHAVIOUR CHANGE**

There have been numerous definitions of health education over the years, however the definitions by Simonds (1976) and the WHO (2015) encapsulate all the key concepts of health education. According to Simonds, health education is aimed at "bringing about behavioural changes in individuals, groups, and larger populations from behaviours that are presumed to be detrimental to health, to behaviours that are conducive to present and future health." (Simonds, 1976). The WHO defines health education as "any combination of learning experiences designed to help individuals and communities improve their health, by increasing their knowledge or influencing their attitudes" (WHO, 2015). Both definitions emphasize the use of strategies at both individual and community levels in order to improve health behaviour, as well as the notion that health can be improved by improving knowledge and attitudes.

To be effective, health education must first reach the population of interest, then change knowledge and attitudes, and finally change behaviour (Colver et al., 1982). Changing the way an individual behaves can be challenging, and experts have recommended that interventions on social and behavioural factors related to health should link five main levels of influence: 1. The individual, 2. Interpersonal factors, 3. Institutional or organisational factors, 4. Community factors, and 5. Public policy factors (McLeroy et al., 1988). Generally, health education can be carried out anywhere, however the particular setting for education has to be one that is ideal for targeting the population of interest. Glanz et al (2008) outlined seven major settings particularly relevant to present-day health education. These are: 1. Schools, 2. Communities, 3. Worksites, 4 Health care settings, 5. Homes, 6. The consumer marketplace, and 7. The communications environment. In addition, the health and social characteristics of the population of interest need to be taken into account when designing health education interventions (Glanz et al., 2008).

#### **1.14.1 Health education and childhood burns prevention**

Various educational interventions aimed at preventing unintentional injuries in young children have normally targeted parents or caregivers (Powell et al., 2000, Altman et al., 2011, Turcotte and Babul-Wellar, 2011). The primary reason for this is because young children (who are predominantly under the care of an adult) do not possess the cognitive ability to interpret prevention messages. Older children can, and prevention interventions focussed on this group are normally targeted at the children themselves via school-based educational programmes (Orton et al., 2012, Orton et al., 2016). In addition, interventions aimed at parents and carers have been shown to not only encourage safer habits, but also lead to environmental changes in the home if the parents/carers are given the appropriate education (Harré and Coveney, 2000).

Education is the primary means through which active prevention measures are propagated. It is an important strategy for preventing burn

injuries in young children. Multi-pronged approaches incorporating both active and passive elements, such as the “Hot Water Burns Like Fire” campaign (Smith et al., 2002), have been shown to have the most far-reaching effects in reducing the incidence of childhood burns (WHO, 2008c). In spite of this, reshaping the behaviours of parents and caregivers of young children at risk of burn injuries through education is of paramount importance because there are limited passive burn prevention measures available. There is evidence in the literature supporting the use of educational programmes in improving burns safety behaviour and reducing childhood burn injury incidence and severity. Successful educational campaigns have been reported in the UK (Carman et al., 2006), Sweden (Carlsson et al., 2011), USA (Cagle et al., 2006, Bablouzian et al., 1997, Bass et al., 1991), Canada (Turcotte and Babul-Wellar, 2011, Babul et al., 2007), Israel (Peleg et al., 2005), India (Jetten et al., 2011), Australia (Livingston et al., 2006) and New Zealand (Skinner et al., 2004).

#### **1.14.2 Strategies for enhancing health educational messages**

In developing any health educational messages, it is important to develop a communication strategy designed to enhance the relevance of the information presented to the intended recipients. In other words, health education messages need to be adapted to the specific needs and interests of the intended recipients. This is usually done by messaging strategies known as ‘tailoring’ and ‘targeting’. Tailored health communication customises the source, message and channel of a given communication to a given individual, and by so doing, maximizes the relevance of the communication to that individual (Kreuter and Wray, 2003). Message tailoring has its theoretical underpinnings in the Elaboration Likelihood Model (Cacioppo and Petty, 1984), which states that the more personally relevant messages are, the more likely they are to be processed cognitively, remembered, and used. It discredits the ‘one-size-fits-all’ approach used for many traditional health education materials. Targeted communication on the other hand, refers to messages that are intended to reach a population subgroup based on characteristics shared by members of that group (Kreuter and Wray, 2003).

The practice of message tailoring and targeting has been widely used in enhancing health educational messages in various clinical contexts. This is particularly true in unintentional injury prevention research where a number of studies have demonstrated the superiority of tailored and targeted health messages at promoting behaviour change and preventing childhood injury, when compared with generic health messages (Nansel et al., 2008, Schwarz et al., 1993, Harré and Coveney, 2000, Ytterstad et al., 1998, Kreuter and Holt, 2001).

Using the above principles, an educational intervention aimed at preventing burn injuries in young children can be developed with an understanding of the target recipients. Young children are entirely dependent on their parents and caregivers for their sustenance and safety. Therefore, in developing an educational programme aimed at preventing burns in young children, it is essential to target parents and caregivers of these children rather than the children themselves. Young children do not possess the cognitive ability to interpret prevention messages and are predominantly under the care of an adult. However, some researchers believe that inculcating preventative messages early into children can provide a long term application of safety behaviour (Bruce and McGrath, 2005). Parents are also reported to be more receptive to educational messages during the early part of their child's lives (Benjes et al., 2004). Delivering tailored educational messages to parents and carers of young children during this time period, can therefore, potentially increase awareness of the risks of childhood burns and bring about behaviour change. Tailored educational messages aimed at parents and carers of young children should be 'personalised' for this group and the content matched to their needs.

### **1.14.3 Parenting programmes and interventions**

Parenting programmes can be defined as formal interventions designed to facilitate parent-child interactions and to equip parents with the necessary skills to carry out their parenting role (McDaniel et al., 2010).

These programmes are often intensive courses of a series of interventions delivered to parents over several weeks. They have been increasingly recognised as having the potential to improve the health and well-being of both parents and children (Mytton et al., 2014b), and have consequently become a core component of child and family policy in the UK (Mytton et al., 2014a).

Parenting programmes can be delivered either on a one-to-one or group basis, and can be offered in a variety of settings including the home, hospital, and in the community. Recent systematic reviews have demonstrated the effectiveness of parenting programmes in improving a range of psychosocial and developmental outcomes in mothers and their children (Coren et al., 2003), improving parenting in families at risk of abuse and neglect (Barlow et al., 2007), and reducing or preventing substance use in children (Petrie et al., 2007). There is also evidence to suggest that parenting programmes are effective at preventing childhood unintentional injuries (Kendrick et al., 2013). A few examples of parenting programmes that have been developed and evaluated include SafeCare (NSPCC, 2015), the Incredible Years Programme (Marcynyszyn et al., 2011), Triple P (Positive Parenting Programme) (Sanders et al., 2014), and the Nurse-Family Partnership (Olds, 2006). All four programmes have strong evidence base supporting improved child outcomes, including injury prevention, and long term cost effectiveness.

The Individual components of parenting programmes can be used effectively to improve parent and child health outcomes. Effective applications of individual interventions in child unintentional injury prevention research include: home visitation (Armstrong et al., 2000, King et al., 2001); parental education and skill development (Swartz et al., 2013, Shields et al., 2013, Reich et al., 2011); and provision of safety equipment (Kendrick et al., 2011, Keay et al., 2012).



#### **1.14.4 Delivering health educational messages**

Understanding how best to convey health educational messages to intended recipients is particularly important when developing an educational intervention aimed at modifying health behaviour. An approach which is cost-effective and addresses issues of literacy and comprehension is more likely to be understood, retained in memory, and subsequently lead to behaviour change. Common modes of delivery for health educational interventions include: print-based materials (educational brochures, leaflets and posters); use of mass media or other multimedia-based communication; and face-to-face interactions at home or other designated locations (WHO, 2008c, Atiyeh et al., 2009, WHO, 2008a). Web-based interventions have recently become popular owing to the exponential growth of the internet (Webb et al., 2010, Van Beelen et al., 2014, Lehna et al., 2011, Nieuwboer et al., 2013). Supplementary delivery modes such as SMS messaging, email, telephone, and videoconferencing have also become popular and are used for influencing the effectiveness of educational interventions (Webb et al., 2010). Health educational interventions can either be delivered on an individual, group or community level.

Print materials such as leaflets and brochures have traditionally been used for health education for many years. These materials often have the advantage of being easy to distribute and can be utilised without additional equipment (Meade et al., 1994). Additionally, they allow individuals to control their own rate of learning and the sequence in which they choose to pay attention to information (Wilson et al., 2012). However, print materials are heavily reliant on the active participation of the individual and their reading skills, with some materials produced at reading levels above that of the intended reader (Meade et al., 1994). They also cannot depict certain types of information such as motion or procedures involving complex interactions (Wilson et al., 2012). Multimedia and audio-visual tools on the other hand, have been able to counter these disadvantages of print materials and have been shown to be very effective in the dissemination of health information. The use of multi-media based approaches has yielded positive

results when used in smoking cessation programmes (Brendryen and Kraft, 2008), breast cancer and abusive head trauma prevention (Bouton et al., 2012, Altman et al., 2011), and also when utilised as decision-aids for surgery (Arterburn et al., 2011).

#### **1.14.5 Multimedia-based education**

A number of studies have reported on evidence in support of multimedia-based education. Studies by Mayer have shown that individuals tend to grasp information more deeply when visual and auditory materials are presented simultaneously (Mayer, 2002, Mayer, 2008, Mayer, 2011, Mayer et al., 2001). This finding forms the basis of the cognitive theory of multimedia learning popularized by Mayer and other cognitive science researchers. The Cognitive Theory of Multimedia Learning has its roots in the Social Learning and Social Cognitive Theories originated by Bandura (Bandura, 1988, Bandura and Walters, 1977). According to Mayer, multimedia learning occurs when an individual builds a mental representation from a combination of words and pictures such as when watching and listening to a narrated animation or playing an educational video game (Mayer, 2002, Mayer, 2008). Multimedia and video tools not only enhance the uptake of information, but also promote positive health behaviour change in targeted populations (Aronson et al., 2012). With regards to child injury prevention, video-based interventions have been shown to enhance parental knowledge retention and attitudes, which in turn translates to greater uptake of recommended injury prevention techniques (Swartz et al., 2013).

A recent review of the literature (Wilson et al., 2012) comparing the effectiveness of print and multimedia health materials, showed that multimedia was advantageous at promoting better health outcomes including preference, comprehension, and behaviour. Of the 30 studies comparing multimedia and print materials, multimedia led to better outcomes in 21 comparisons compared to five instances for print. Twenty four studies had knowledge as an outcome variable, the evidence in 12

studies favoured the use of multimedia materials while one study favoured print materials. A systematic review (Hieftje et al., 2013) evaluated the effects of electronic media-based interventions on health and safety behaviour change. Seventeen of the nineteen included studies reported at least one statistically significant effect on behaviour change outcomes, including acquisition of fire safety skills, increase in physical activity, and improved asthma management.

Other relevant studies demonstrating evidence in favour of multimedia-based education include: a randomised controlled trial (RCT) by Meade et al. (1994) evaluating the effectiveness of printed and videotaped information on cancer knowledge recall; an RCT (Snyder-Ramos et al., 2005) investigating patient satisfaction and information gain after pre-anaesthetic visit; an RCT (O'Donnell et al., 1998) evaluating the effectiveness of a video-based intervention in reducing sexually transmitted diseases (STD) in African-American and Hispanic men attending an STD clinic; and an RCT (Brendryen and Kraft, 2008) assessing the effectiveness of a digital multimedia smoking cessation intervention.

There is also evidence to suggest that parents of young children favour multimedia-based presentation of information over other forms of presentation (Morrongiello et al., 2009, Armstrong et al., 2011, Dunn et al., 1998). Videos have been shown to increase and facilitate parental knowledge about complex paediatric health problems (Dunn et al., 1998, Turcotte et al., 2011). A recent study (Snowdon et al., 2008) demonstrated the effectiveness of a multimedia-based intervention at significantly increasing parental knowledge and usage of vehicle safety systems for children. A study, (Turcotte et al., 2011) demonstrated the effectiveness of a multimedia educational resource in improving parental injury prevention practices with regards to infants, toddlers and pre-schoolers.

Given the morbidity and mortality associated with burn injuries and the number of young children that fall victim, there is a clear need for a targeted preventative intervention aimed at reducing the risk of burns in

young children and improving the first aid knowledge of their parents. The evidence favouring multimedia-based communications over other intervention formats is strong, including parental preference for multimedia-based communications. Utilising this medium in a prevention programme can potentially improve parental knowledge and child safety outcomes and reduce the likelihood of burn injuries in young children.

### **1.15 RATIONALE FOR RESEARCH**

The *Toddler-Safe* study is an intervention study aimed at improving parental burns prevention and first aid knowledge, attitudes, and practices, and reducing the risk of future burns in pre-school children. The overall aim of this study is to reduce child morbidity and mortality from burns. The *Toddler-Safe* study aims to achieve this by engaging parents and carers of pre-school children in a parenting intervention which would improve their knowledge and attitudes towards burns prevention and first aid, and then consequently improve their burns safety behaviours, and finally lead to a reduction in child burn injury incidence (see Logic model Figure 1.8). Modifying parental behaviour is central to achieving the overall aim of this study, therefore the author of this PhD thesis will be drawing from specific theories and models of behaviour change relevant to knowledge acquisition and injury prevention in the design and development of the *Toddler-Safe* intervention.

As highlighted earlier in the chapter, for any change in behaviour to occur, an individual would need to be capable (C), have the right opportunity (O), and must be motivated (M) to perform the desired behaviour (Michie et al., 2011). The *Toddler-Safe* intervention will be based on this COM-B model of behaviour popularised by Michie et al (2011). This model is robust and has already been applied successfully in several clinical contexts requiring behavioural modification (Barker et al., 2016, Alexander et al., 2014, Jackson et al., 2014). It is therefore justifiable to apply this model to a study aimed at modifying parental burns safety behaviour by improving their burns prevention and first aid knowledge and

attitudes. In the *Toddler-Safe* study, priority will be given to all three components of the COM-B model. Capability will be fulfilled by parental burns safety knowledge acquisition. The *Toddler-Safe* intervention will contain current and relevant information on child burns prevention and first aid, and will be delivered using methods known to be effective for optimal information processing. Due to the nature and context of the *Toddler-Safe* study, there will be ample Opportunities to perform burns safety behaviours. The study focuses on burns likely to occur in the home and participants, having received the intervention at recruitment, will have plenty of opportunities to perform the desired safety behaviours during the study follow-up period. With regards to Motivation, the *Toddler-Safe* intervention will contain information on the severity of burns and the vulnerability of young children to burns. It is hoped that this information will be able to motivate parents in the study to modify their health-related behaviours, especially as it would relate to their own young children. This point ties in with the Health Belief Model (see below).

The elements required for the theoretical framework of the *Toddler-Safe* intervention would be those which emphasise on burn severity, vulnerability of young children to burns, benefits and barriers to adoption of burn safety behaviours, human learning, and information processing.

- The Health Belief Model, most suited for predicting behavioural patterns, has four key constructs – perceived severity, perceived susceptibility, perceived benefits, and perceived barriers (Janz and Becker, 1984). These constructs will be embedded in the *Toddler-Safe* intervention and therefore enable behaviour change in study participants. A trigger or cue is normally required to set into motion the desired health behaviour. In the *Toddler-Safe* study, this cue would be the exposure of the participant to the intervention at recruitment. It is therefore an ideal theory to guide the development of the *Toddler-Safe* intervention.

- In order to improve parental burns safety knowledge acquisition, a method of information dissemination shown to be effective at enhancing learning must be selected. The Cognitive Theory of Multimedia Learning (which has its origins in Social Learning/Social Cognitive Theory) posits that optimal learning occurs when visual and auditory materials are presented simultaneously (Mayer, 2002). It is therefore an ideal theory to incorporate into the design and development of the *Toddler-Safe* intervention.
- To aid in the assimilation of the burns safety messages presented in the study, these messages have to be ‘tailored’ to the needs and interests of the intended recipients. Message tailoring is based on the Elaboration Likelihood Model which posits that more personally relevant messages are more likely to be processed, remembered, and used (Cacioppo and Petty, 1984). In addition, the HBM - due to its focus on individualised recognition of susceptibility and seriousness of a disease or outcome, has been used as a basis for tailoring health behaviour change messages (Noar et al., 2007). The *Toddler-Safe* study will therefore draw from these theories, which will be used to guide the development of the *Toddler-Safe* intervention.

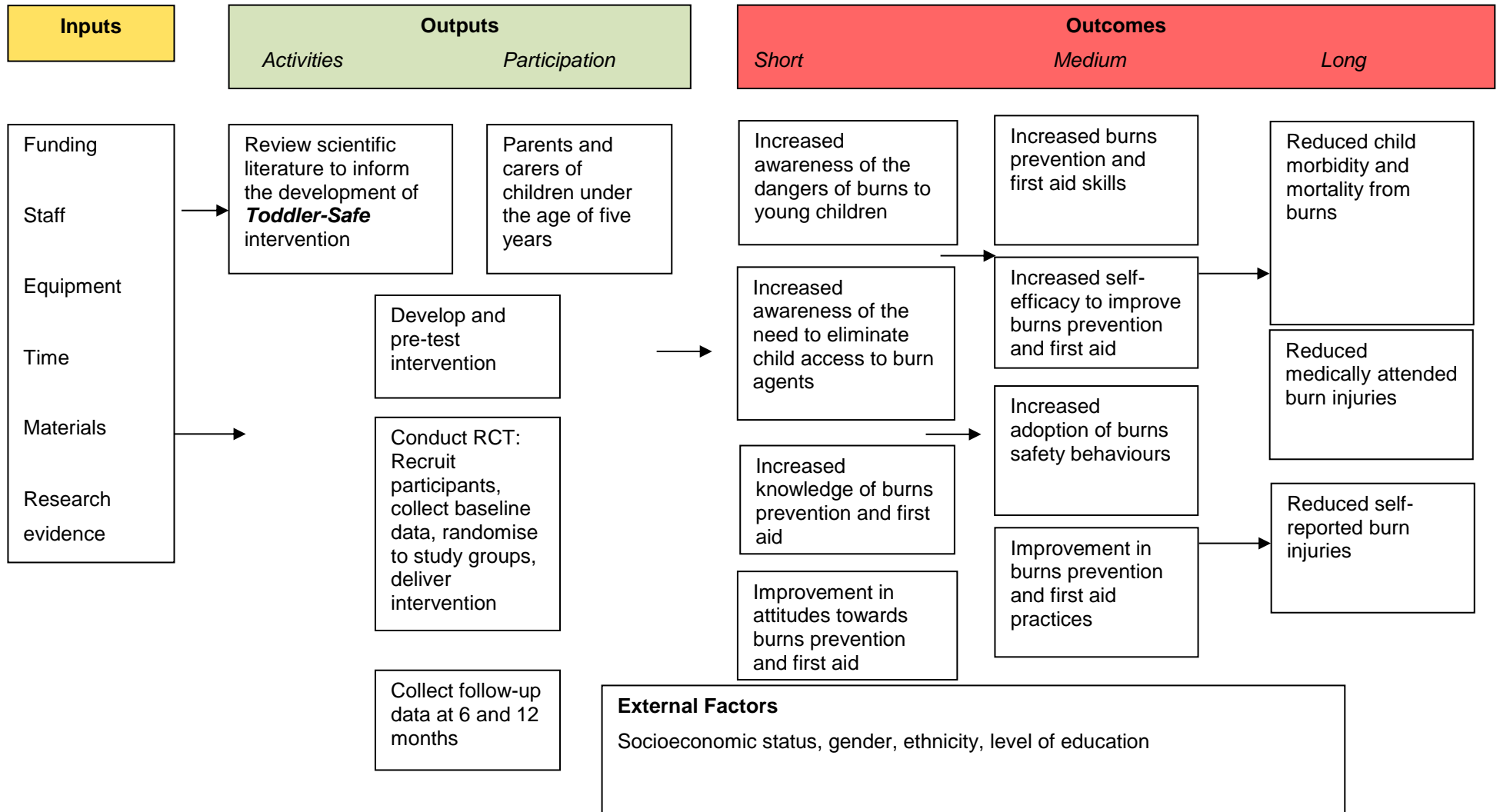
Having described the theoretical underpinnings for the proposed *Toddler-Safe* study, the reasons why it is important and justified to develop and undertake this study are highlighted below.

- Burns to young children are a significant public health problem globally, and therefore requires urgent attention
- Passive prevention measures are not always available for every type of childhood burn. Therefore active prevention

measures – conveyed through health education, are needed to address this research gap.

- Poor burn hazard perception and knowledge of burns first aid and burns prevention have been reported in parents and carers of young children
- There is good research evidence suggesting that parenting interventions are effective at improving child outcomes - including unintentional injury prevention. However, there is currently a lack of research demonstrating this effectiveness specifically for burn injuries in children under the age of five, particularly in the UK.
- The few research studies that address childhood burns prevention either do so as part of a generic intervention addressing other types of injuries, or focus on particular types of burns (the most common being scalds)
- A recent systematic review on prevention of childhood scalds within the home (Zou et al., 2015), did not find much evidence with which to draw conclusions from. The authors of this review recommended for further research to be conducted in this area.
- Effective health educational interventions have been demonstrated to improve parental burns safety behaviour and reduce the incidence of childhood burns.

Figure 1.8: Toddler-Safe Logic Model





## 1.16 RESEARCH AIMS AND OBJECTIVES

### 1.16.1 Research aims

The aims of this programme of research are:

- To review the scientific literature to inform the process of developing a parental intervention aimed at preventing unintentional injury of pre-school children in the home
- To determine whether a targeted preventative intervention improves parent/carer burns safety knowledge and behaviour in the home and reduces the risk of future burns
- To determine whether a targeted preventative intervention improves parental burns first aid knowledge and behaviour.

### 1.16.2 Research objectives

1. To conduct a systematic review to address the question - Are targeted parenting interventions effective at preventing childhood unintentional injuries or improving parent/carer child safety knowledge and behaviour?
2. To design a parenting intervention '*Toddler-Safe*' aimed at improving parent/carer childhood burns safety and first aid knowledge and behaviour
3. To conduct a randomised controlled trial:
  - a. To determine if the *Toddler-Safe* intervention is effective at promoting change in parental/carer knowledge, attitudes and practices regarding burns prevention and first aid

- b. To assess the efficacy of *Toddler-Safe* in reducing the incidence of childhood burns and improving first aid administered to children and family members should they sustain a burn

### **1.17 HYPOTHESIS**

This study will test the hypothesis that parents exposed to a targeted parenting intervention (*Toddler-Safe*) will demonstrate better knowledge and improved child safety behaviours regarding burns prevention and appropriate first aid, when compared to parents who were not exposed to the intervention.

### **1.18 SUMMARY OF CHAPTER ONE**

- Burn injuries are a serious public health problem responsible for significant morbidity and mortality worldwide. Burns are the third most frequent cause of childhood injury resulting in death following motor vehicle accidents and drowning. Children younger than five years of age are more at risk of suffering burns. Most childhood burn incidents are accidental and occur in the home environment. Approximately 60% of all childhood burns requiring hospital admission are caused by scalds, with hot beverages being the most frequent agent.
- Non-fatal burns are a leading cause of morbidity, with long-term physical, psychological and economic consequences. Burn survivors are often faced with lifelong challenges including stigmatisation, social segregation, unemployment and abandonment by family and friends.

- Risk factors for childhood burns include: male gender; low socio-economic status; underlying medical conditions such as ADHD and epilepsy; overcrowding; lack of access to water supply; alcohol abuse and smoking; and poor parental supervision.
- A thorough understanding of the epidemiology, risk factors, and mechanisms of childhood burn injury are fundamental in aiding preventive efforts.
- Initial first aid plays an important role in burn outcome. Current recommendations involve application of cool running water at a temperature of between 5 and 25 degrees Celsius for 10 to 30 minutes within the first three hours, covering with polyvinyl chloride film (cling film), and providing analgesia. Parental knowledge of burns first aid is poor.
- Most childhood burns are preventable. Active and passive measures have been used to prevent unintentional injuries in children. Prevention strategies should: be based on sound epidemiological evidence; address the hazards for specific burn injuries; and provide education for vulnerable populations. Multi-faceted approaches incorporating active and passive elements have been shown to be effective at reducing the incidence of childhood burns.
- Behaviour change interventions have been shown to be effective at modifying human behaviour. These interventions need to be based on appropriate behaviour change theories and models to be effective. The *Toddler-Safe* study will apply the COM-B model of behaviour. The study's intervention will be based on the Health Belief Model,

Cognitive Theory of Multimedia Learning, and The Elaboration Likelihood Model.

- Parenting programmes and interventions have the potential to improve the health and well-being of both parents and children. They have been demonstrated to be effective at improving a range of psychosocial and developmental outcomes in mothers and their children, improving parenting in families at risk of abuse and neglect, and preventing unintentional injury in children.
- Health education messages need to be tailored and targeted to the specific needs and interests of their intended audience. Parental educational programmes must be cost effective and address issues of literacy in order to be effective at changing behaviour. Multimedia and audio-visual tools have been shown to be effective at improving and facilitating parental knowledge of complex paediatric health problems.

## CHAPTER TWO

## **CHAPTER TWO: A SYSTEMATIC REVIEW OF PARENTING INTERVENTIONS FOR THE PREVENTION OF UNINTENTIONAL INJURIES IN PRE-SCHOOL CHILDREN**

### **2.1 INTRODUCTION**

This chapter presents a systematic review of the international scientific literature to establish whether interventions aimed specifically at parents of pre-school children are effective at preventing childhood unintentional injuries and improving parent/carer child safety knowledge and behaviour. A systematic review (Kendrick et al., 2007) published on this theme in 2007 was aimed primarily at home safety education with or without the provision of safety equipment for children aged 18 years and younger. This review on the other hand, serves to inform the prevention of burns to pre-school children, who represent the largest proportion of childhood burns. The results will inform the *Toddler-Safe* design and evaluation methodology. The intention of this review was to focus on studies explicitly addressing burns prevention in pre-school children, but a ‘scoping search’ indicated that there were very few explicitly targeting burns. Most of the studies that addressed burn injuries did so as part of a generic intervention addressing other types of childhood injuries. The scope was therefore widened to include all unintentional injury prevention aimed at the pre-school age group. This chapter addresses the first objective of the PhD project (see section 1.16.2).

### **2.2 CHAPTER OVERVIEW**

This chapter begins with a brief background of childhood unintentional injuries (section 2.3) highlighting important epidemiological and sociodemographic factors. After a brief outline of the review objectives (section 2.4), and research questions (section 2.5), the methodology of the systematic review is presented in detail (section 2.6). This section outlines the eligibility criteria for study selection; search methods for identification of studies; quality assessment, as well as data extraction and management of

included studies. Section 2.7 describes how the data collected in the course of the systematic review is analysed. Section 2.8 outlines a detailed presentation of the systematic review findings. This is followed by a brief discussion and conclusion (section 2.9), including a summary of the review's findings; comparisons with recent literature; an outline of the review's strengths and limitations; implications for policy, practice, and research; and a discussion on how the systematic review has helped inform the methodology and design of the *Toddler-Safe* study. Chapter two concludes with a brief summary of all key points (section 2.10).

### **2.3 BACKGROUND**

Injuries are a major public health concern and a leading cause of morbidity and mortality throughout childhood. Every year, an estimated 950,000 children die globally as a result of injury (WHO, 2008c) – 96,000 of whom are due to burn injuries (WHO, 2008b). Millions more are treated in EDs and hospitals for non-fatal injuries (WHO, 2008b, Rivara, 1995). Survivors may undergo intensive medical treatment and prolonged rehabilitation, creating a continuum of physical, economical and psychological challenges (Cox et al., 2009, Joseph et al., 2002, Morrongiello and Schwebel, 2008). Children less than five years old are more vulnerable to injury (Mytton et al., 2009, Nansel et al., 2008). However, the type of injury varies with the developmental stage of the child (Osifo et al., 2012).

Ninety percent of childhood injuries are unintentional, occur in the home environment, and are largely preventable (Rivara, 1995, Morrongiello et al., 2008, WHO, 2008c). According to WHO reports, more than 2,000 children die daily from unintentional injuries (WHO, 2008c). Most deaths are caused by falls from heights, burns and scalds, and poisonings (Mytton et al., 2009, WHO, 2008c). In England and Wales, an estimated 134,000 children are admitted to hospitals every year for treatment of unintentional injuries (South West Public Health Observatory, 2013). One hundred and

forty three children died from preventable accidents in 2011 – 68 of whom were younger than five years of age (Making The Link, 2013).

Numerous risk factors that influence child injury rates have been identified and relate to factors within the child, the family, and the social and physical environment. These include: child's age, gender and birth order, family's socio-economic status, maternal age, and level of supervision (Ribas et al., 2006, Mayer, 2011, Kendrick et al., 2012, Morrongiello and Schwebel, 2008, Nilsen, 2006). Psychiatric disorders of mothers of infants and toddlers, as well as adverse neonatal conditions in-utero, have been linked with increased risk of hospitalization for unintentional injuries in childhood (Miller et al., 2000, Schwebel and Brezausek, 2008).

Significant associations have been demonstrated in the scientific literature between parental factors and unintentional injuries in childhood (Mercier and Blond, 1999, Morrongiello and Corbett, 2006, Joseph et al., 2002). There is evidence to suggest that educational interventions specifically targeting parents of young children not only improve parental knowledge and supervision skills, but also have a positive effect on maternal psychosocial health and self-esteem (Barlow and Parsons, 2003, Kendrick et al., 2007). Findings from a number of systematic reviews have demonstrated the effectiveness of parenting interventions in improving a range of outcomes for both parents and their children (Coren et al., 2003, Bass et al., 1993, Bablouzian et al., 1997, Kendrick et al., 2007). It can therefore be hypothesised that targeting prevention efforts at parents of young children can improve parental child safety knowledge and behaviour as well as reduce the incidence of childhood unintentional injuries. This systematic review of the international scientific literature seeks to test this hypothesis as well as inform the *Toddler-Safe* methodology.



## **2.4 REVIEW OBJECTIVES**

This systematic review of the international scientific literature was undertaken in order to assess the research evidence for the effectiveness of parenting interventions in preventing unintentional injuries in children younger than five years of age .

The objectives of this review are to establish whether parenting interventions are:

- a. Effective at preventing unintentional injury in pre-school children
- b. Effective at improving parental child safety knowledge
- c. Effective at improving parental child safety practices
- d. To determine what form of intervention is the most effective at achieving better parental child safety knowledge and practices
- e. To explore what methods and forms of programme evaluation are effective

## **2.5 RESEARCH QUESTIONS**

In order to inform the methodology of the *Toddler-Safe* study, this systematic review aimed to answer the following research questions:

1. What is the evidence relating to the impact of parenting interventions on childhood unintentional injury?
2. Are parenting interventions capable of improving parental injury prevention knowledge and behaviour?

## **2.6 METHODOLOGY OF THE SYSTEMATIC REVIEW**

This systematic review was conducted and reported in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Figure 2.1) (Moher et al., 2010), and adhered to key stages of a systematic review recommended in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins Julian and Green, 2011).

### **2.6.1 Eligibility criteria**

The eligibility criteria for inclusion and exclusion of studies into this review were defined using the PICOS process (see Table 2.1). The PICOS acronym stands for; **P**opulation, **I**ntervention, **C**omparator, **O**utcomes, and **S**tudy design.

#### **2.6.1.1 Inclusion criteria: Population**

To be eligible for inclusion into this review, studies had to involve parents or carers of children aged 0 to 5 completed years. The parent or carer had to be the primary caregiver of the child. A primary caregiver refers to a person who has the greatest responsibility for the daily care and rearing of the child (Theilheimer, 2006).

#### **2.6.1.2 Inclusion criteria: Intervention**

Studies were eligible for inclusion if they evaluated the effectiveness of individual or group/community-based parenting programmes/interventions that specifically targeted parents of children five completed years of age or younger. For the purpose of this review, ‘parenting interventions’ were defined as any interventions involving parents of young children and designed specifically to reduce unintentional injuries, and/or change knowledge, attitudes or behaviours regarding child safety.

### **2.6.1.3 Inclusion criteria: Comparator**

Studies were eligible for inclusion into this review if they included a comparator or control group which did not receive a parenting intervention. The comparisons of interest were: parenting intervention versus no intervention, or parenting intervention versus any other type of intervention.

### **2.6.1.4 Inclusion criteria: Outcome measures**

To be eligible for inclusion in the review, studies had to report:

- Self-reported or medically attended unintentional injury in a child aged five completed years or younger. Self-reported unintentional injuries are those injuries that were reported by the child's parent as having occurred. Medically attended unintentional injuries are those injuries that necessitated medical care and were reported in the child's hospital or primary care records
- Parental child injury safety practices (including quality of the home environment)
- Parental safety knowledge

### **2.6.1.5 Inclusion criteria: Study design**

Primary research papers reporting any of the following study designs that incorporated a comparative element were considered eligible for inclusion into the systematic review:

- Randomised controlled trials (individual and cluster)
- Non-randomised controlled trials (trials using a quasi-random method of allocation)
- Controlled before and after studies
- Case-control studies

- Longitudinal studies (prospective and retrospective cohort)

#### **2.6.1.6 Exclusion criteria**

Studies were excluded from the review if they involved the following:

- Parents of children older than five years of age
- Parents or carers were secondary caregivers (spend the least amount of time with the children)
- Not aimed directly at parents/carers of children 0 to 5 completed years of age
- Studies addressing intentional or inflicted injuries (however, studies with injury outcomes as a consequence of child neglect were included)
- Studies addressing the management of injuries
- No comparator/control group
- Non English language paper
- Studies addressing the use of Ipecac syrup were excluded from this review. This is because Ipecac syrup is no longer recommended for management of poisonings. However, studies with generic interventions incorporating the use of Ipecac syrup in combination with other preventative measures, were included. All data pertaining to Ipecac syrup were discarded

**Table 2.1: Inclusion and exclusion criteria**

	<b>Inclusion</b>	<b>Exclusion</b>
<b>Population</b>	Parents/carers of children aged five completed years of age or younger Primary caregiver	Adults who are not parents/carers of children aged five completed years of age or younger Parents/carers of children older than five completed years of age Secondary caregiver
<b>Intervention</b>	Individual or group-based parenting programme or intervention aimed specifically at parents/carers of children aged five years or younger	Non-parenting intervention Intervention aimed at children
<b>Comparator</b>	Comparator/control group not receiving a parenting intervention	No comparator group
<b>Outcomes</b>	Self-reported or medically attended unintentional injuries in a child aged five years or younger Child injury safety practices Parental child safety knowledge	Intentional or inflicted injuries Management of injuries
<b>Study design</b>	Study designs with a comparative element Primary research studies	Study designs with no comparative element Review articles, secondary or tertiary research studies
<b>Study limits</b>	<ul style="list-style-type: none"> <li>• Published between inception of database and July 2016</li> <li>• English language</li> </ul>	

### **2.6.2 Search methods for identification of studies**

The search for relevant studies was undertaken in three stages;

1. Electronic searches of bibliographic databases (section 2.6.2.1)
2. Searching other resources (section 2.6.2.2)

### 3. Key author consultation

#### 2.6.2.1 Electronic database searches

An initial ‘scoping search’ was conducted by the author of this PhD thesis, using key words in the electronic databases; Web of Science and Google Scholar, in order to establish the size of the relevant literature and refine the review objectives, study inclusion and exclusion criteria. This search was further refined by the author and his two supervisors, after which a final search was conducted.

A search strategy, designed to take into account the review’s PICOS process, was designed following the advice of an experienced systematic reviewer at the Specialist Unit for Review Evidence, Cardiff University. The search strategy was developed in the database ‘Ovid MEDLINE’ and adapted for other electronic databases (see Appendix 1). Subject and key word searches were conducted on 12 electronic databases (see Table 2.2 below) using a range of terms representing ‘child’, ‘parent’, ‘injury’, ‘injury prevention’, and ‘parenting programme’. In order to access the maximum amount of literature around childhood unintentional injury prevention, these databases were searched from their date of inception until July 2016 . Searches were limited to English language and human.

**Table 2.2: Electronic databases searched**

MEDLINE	1946 - 2016
MEDLINE in-process	1960 - 2016
SCOPUS	1960 - 2016
ASSIA (Applied Social Sciences Index and Abstracts)	1987 - 2016
Cochrane Database of Systematic Reviews (CDSR)	1970 - 2016
Cochrane Central Register of Controlled Trials (CENTRAL)	1970 - 2016
CINAHL (Cumulative Index to Nursing & Applied Health Literature)	1950 - 2016

Database of Abstracts of Reviews of Effects (DARE)	1960 - 2016
Web of Science – ISI Citation Index	1950 - 2016
EMBASE	1947 - 2016
PsycINFO	1806 - 2016
Health Management Information Consortium (HMIC)	1960 - 2016

### 2.6.2.2 Searching other resources

Other sources of information were searched for relevant studies.

These included the following:

- Reference lists of all included studies as well as previously published systematic and non-systematic review articles
- Abstracts from the World Conferences on Injury Prevention and Control
- Table of contents of relevant journals
- Internet search for grey literature using Google and Google Scholar
- Web pages of relevant child injury prevention organisations such as:
  - ❖ Children in Wales  
(<http://www.childreninwales.org.uk/index.html>) - accessed 1 May 2013
  - ❖ Child Accident Prevention Trust (CAPT)  
(<http://capt.org.uk/>) – accessed 1 May 2013

- ❖ The Royal Society for the Prevention of Accidents (ROSPA) (<http://www.rospa.com/>) – accessed 1 May 2013
  - ❖ Injury Observatory for Britain and Ireland (IOBI) (<http://www.injuryobservatory.net/>) – accessed 1 May 2013
  - ❖ Collaboration for Accident Prevention and Injury Control (CAPIC) (<http://www.capic.org.uk/>) – accessed 1 May 2013
  - ❖ Sure Start (<https://www.gov.uk/find-sure-start-childrens-centre>) – accessed 1 May 2013
  - ❖ Flying Start (<http://wales.gov.uk/topics/childrenyoungpeople/parenting-support-guidance/help/flyingstart/?lang=en>) – accessed 1 May 2013
- The main authors of studies and experts in injury prevention research were contacted to determine if they were involved in any unreported or on-going trials.

The primary search of electronic databases and all other sources of information were initially carried out between 17 April 2013 and 7 May 2013. An updated search was carried out on 10 July 2016. A search log was maintained detailing the names of the databases searched, the database coverage, date of search, search terms used and the search results. Titles and abstracts of studies to be considered for retrieval were stored on an electronic reference management software (EndNote X7; Thomson Reuters, Philadelphia, Pennsylvania).



### **2.6.2.3 De-duplication of references**

One of the major problems arising from searching electronic databases is the retrieval of duplicate records. Estimates of the prevalence of duplicate publication, range from 1.4% to 28% (Centre for Reviews and Dissemination, 2008). Removal of duplicates (de-duplication) is therefore essential to ensure systematic reviewers do not waste time and effort screening the same records multiple times (Rathbone et al., 2015). De-duplication of records can be carried out electronically using reference management software such as EndNote®, ProCite®, and Reference Manager®. However, inconsistencies in the way citations are presented, missing information or errors in the records, can lead to duplicates bypassing electronic management software (Rathbone et al., 2015). In order to prevent this, the author of this PhD thesis carried out the de-duplication process in two stages. The first stage was by auto-deduplication using the electronic reference management software, EndNote (version X7). The second stage was performed by the author manually assessing the titles of each individual record. All duplicate references were identified and discarded. In situations where two or more articles contained duplicate or partly duplicate samples, for instance articles from different authors reporting on the same study, the article that contained results most relevant to this systematic review was selected and the others discarded.

### **2.6.3 Data collection**

#### **2.6.3.1 Selection of studies**

A two-stage screening process for selection of studies was undertaken by the author of this PhD thesis. The first stage involved an initial screening of titles and abstracts against the systematic review's inclusion and exclusion criteria (see Table 2.1) to identify potentially relevant papers. All references from electronic searches, hand searched journals, and other resources were screened for eligibility. Titles and abstracts that did not meet the review's inclusion criteria were rejected. The second stage of screening was carried out by closely reading and assessing

the full text copies of papers from the initial screening that appeared to meet the review's inclusion criteria. One in five decisions was independently checked by two experienced researchers (the author's supervisors) including articles where the author was uncertain about the final decision. Any disagreements were discussed and resolved by consensus. Studies that did not meet the review's inclusion criteria were rejected with reason (see Figure 2.1). All references were recorded in the electronic reference management software, EndNote (version X7).

### **2.6.3.2 Assessment of quality and risk of bias in included studies**

Critical appraisal of the included studies was conducted using a standard critical appraisal form (See Appendix 2). The Cochrane Collaboration's tool for assessing risk of bias (Higgins Julian and Green, 2011) was used to assess the quality of included studies. This tool assesses seven specific domains:

1. Sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment
5. Incomplete outcome data
6. Selective outcome reporting
7. Other sources of bias.

All included studies were first assessed by the author of this PhD thesis. In order to enhance the validity of the critical appraisal process, 20% of the included studies were selected at random and a second review was undertaken by four independent reviewers with expertise in critical appraisal methodology. All reviewers assessed the degree to which the risk of bias parameters detailed above had been adequately addressed by the authors of the individual studies. The reviewers assigned a judgement of 'Low risk' of

bias, ‘High risk’ of bias, or ‘Unclear risk’ of bias, relating to the risk of bias within each entry. In assessing the overall risk of bias, three ‘key domains’ were judged as being the most important domains for this review: random sequence generation; allocation concealment; and incomplete outcome data. Any disagreement between reviewers was resolved by arbitration or by consensus.

### **2.6.3.3 Data extraction and management**

Data from studies meeting the inclusion criteria were extracted using a pre-defined electronic data extraction form, developed in line with the Centre for Reviews and Dissemination’s (CRD) guidance for undertaking reviews in health care (Centre for Reviews and Dissemination, 2008) (see Appendix 2). This form was piloted on a small selection of studies, and amendments made where necessary. Final data extraction was carried out by the author of this PhD thesis. A random sample of 20% of included studies was independently checked for accuracy and completeness by two independent reviewers (the author’s supervisors). All reviewers compared collected data and resolved disagreements by consensus.

For each study, the following data were extracted:

- Basic study information - authors, study title, year of publication, and country in which the study was conducted
- Population description - number of children/parents, age of children, and ethnicity
- Methods - study design, aim of study, outcome measures, inclusion and exclusion criteria, duration of study, methods of recruiting participants, and sources of bias
- Nature of injury being prevented
- Study outcome and results

- General comments

Socio-demographic data on the study population were also extracted together with data on the type of intervention (educational, home-visiting, individual or group-based), and type of environment where the intervention was carried out. Clarification or missing information was sought by contacting the authors of the individual studies.

## **2.7 DATA ANALYSIS AND SYNTHESIS**

A meta-analysis was undertaken for subsets of data that were identified as being sufficiently homogenous. Random effects models were used to allow for statistical heterogeneity between individual studies. Heterogeneity was explored by chi-square tests, with significance level set at p-value 0.1, and the I-squared statistic. The I-squared statistic describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (Higgins Julian and Green, 2011). An I-squared statistic of more than 50% is generally considered to be high, and therefore represents substantial heterogeneity (Higgins Julian and Green, 2011).

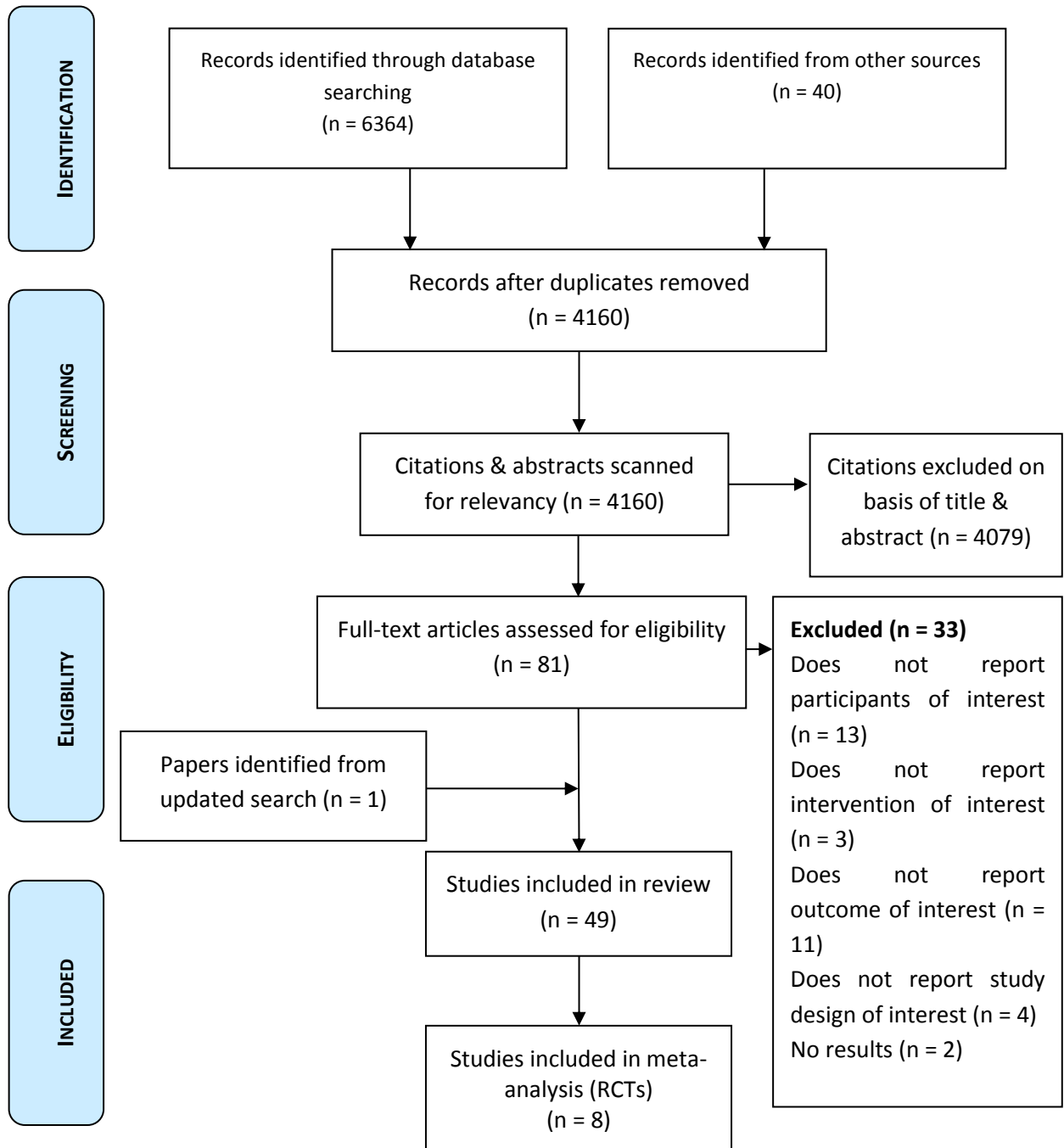
Meta-analysis was performed according to Cochrane Collaboration's guidelines (Higgins Julian and Green, 2011) using the software package - Review Manager (version 5.3 for Windows) (Review Manager, 2014). Where there was sufficient clinical or statistical heterogeneity to prevent a valid numerical synthesis, a narrative synthesis approach (Popay et al., 2006), was used to describe parenting programmes, their mode of delivery, and how effectively they prevented childhood unintentional injury or improved parental child safety knowledge and behaviour. For dichotomous outcomes, risk ratios (RR) with 95% confidence interval (CI) were calculated if there were three or more trials for an outcome. For continuous outcomes, mean scores with 95% CI were calculated. For both dichotomous and continuous outcomes a p-value of  $< 0.05$  was deemed statistically significant.

## **2.8 RESULTS**

### **2.8.1 Search results**

In the initial review, electronic database searches yielded 6324 studies while searches from other sources yielded an additional 40 studies. A combined total of 4160 studies were identified after removal of duplicates. Of the 4160 studies identified, 4079 were not relevant to the review (based on title and abstract) and were therefore discarded. Full text copies of the remaining 81 studies were retrieved and screened against the review's inclusion and exclusion criteria. Of the 81 studies screened, 48 were relevant and included in the review. An updated search conducted on 10 July 2016 yielded an additional potential 10 studies, only one of which was relevant to the review. The total number of included studies was therefore 49. The PRISMA flowchart detailing the process of study selection for all included studies can be seen in Figure 2.1.

**Figure 2.1: PRISMA flow chart detailing the process of study selection for all studies included in the review**

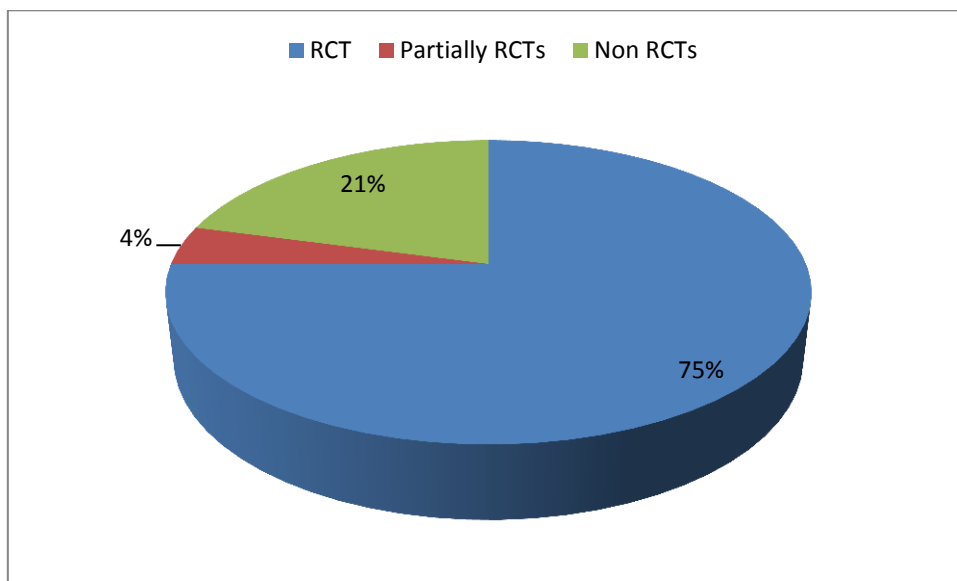


## 2.8.2 Study characteristics

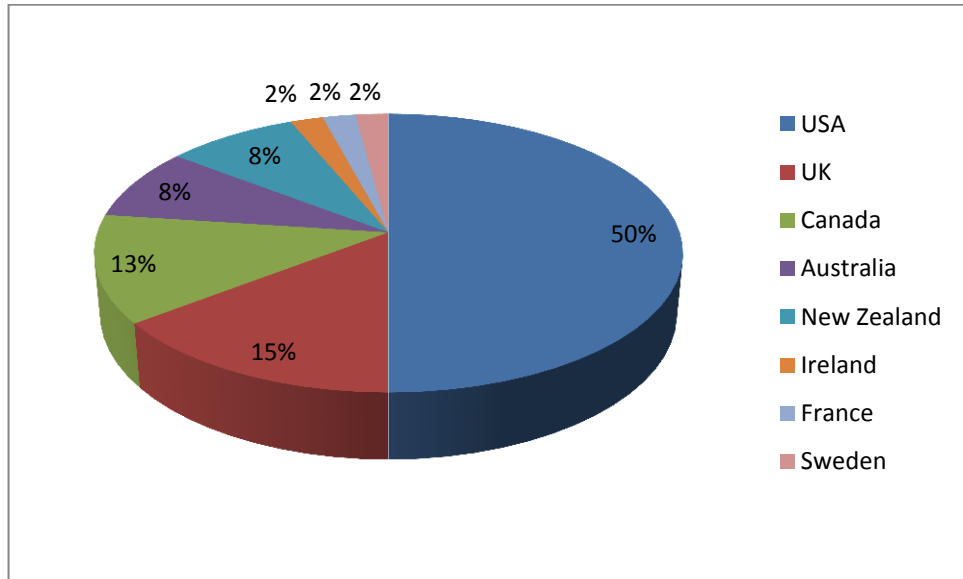
### 2.8.2.1 Type of studies

Forty nine studies from 48 articles were included in this systematic review. Table 2.3 shows the characteristics of all included studies – studies showing significant effect are colour coded in green while those showing insignificant effect are colour coded in red. Thirty seven studies were RCTs, two studies were partially randomised controlled trials, and ten studies were non-RCTs (see Figure 2.2). One paper, (Minkovitz et al., 2003), presented results for both an RCT and a non-RCT. Fifty percent of the included studies were conducted in the USA, with the remainder as shown in Figure 2.3 below.

**Figure 2.2: Pie chart showing study design of included studies**



**Figure 2.3: Pie chart showing sources of included studies**



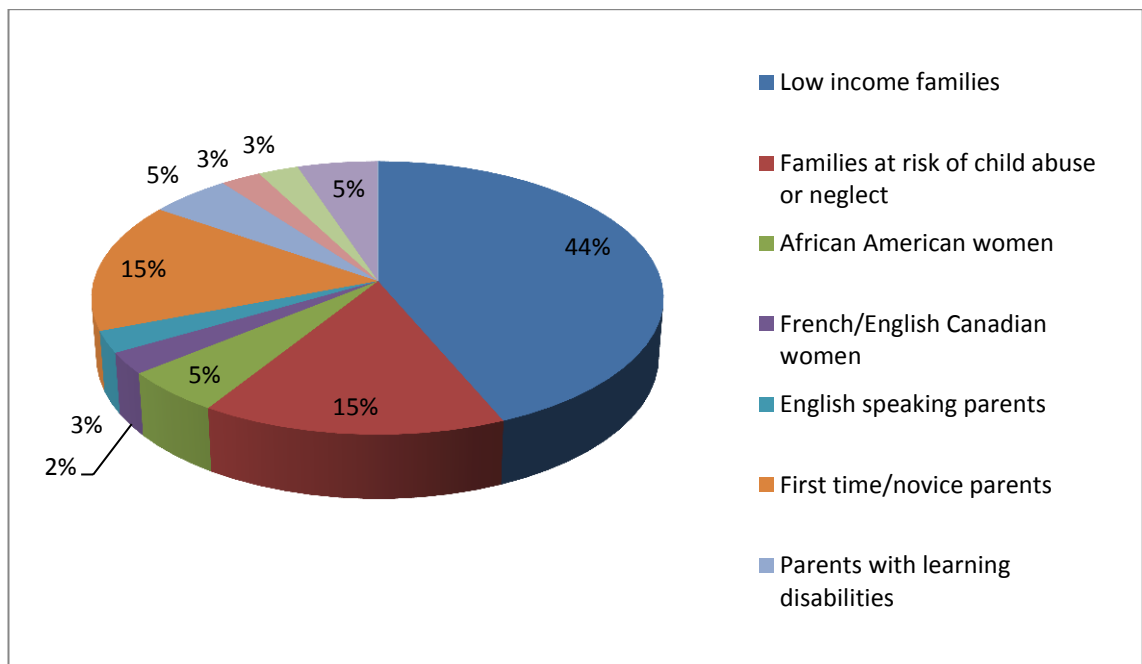
### **2.8.2.2 Types of participants**

The majority of included studies focused on high risk/vulnerable families (see figure 2.4). Sixteen of the forty nine included studies recruited participants from low income families (Alvarez and Jason, 1993, Campbell et al., 2011b, Clamp and Kendrick, 1998, Caldera et al., 2007, Gielen et al., 2002, Gielen et al., 2007, Hendrickson, 2005, Johnson et al., 1993, Kemp et al., 2011, Kitzman et al., 1997, Posner et al., 2004, Reich et al., 2011, Watson et al., 2005, Emond et al., 2002, Johnston et al., 2000, Keay et al., 2012). Six studies recruited participants from vulnerable families or those considered to be at risk of child abuse or neglect (Armstrong et al., 2000, Barlow et al., 2007, Caldera et al., 2007, Feldman et al., 1992, Hardy and Streett, 1989, Fergusson et al., 2005). Three studies recruited participants from specific ethnic groups: Black/African American women (Hardy and Streett, 1989, Kitzman et al., 1997); French Canadian or English Canadian women (Larson, 1980). One Canadian study recruited only English speaking parents (Babul et al., 2007). Five studies recruited first time parents (Culp et al., 2007, Emond et al., 2002, Johnson et al., 1993, Kitzman et al., 1997,



Reich et al., 2011), while one study recruited “novice parents” i.e. parents whose eldest child was less than 24 months of age (Swartz et al., 2013). Two studies recruited participants with learning disabilities (Feldman et al., 1992, Llewellyn et al., 2003), one study recruited participants from low educational backgrounds (Carlsson et al., 2011), and one study recruited participants from middle to upper-middle class socioeconomic backgrounds (Christophersen et al., 1985). Two studies recruited pregnant women - one recruited pregnant women of at least 28 weeks gestation (Kendrick et al., 2005), while the other recruited pregnant women of at least seven months gestation (Tessier, 2010).

**Figure 2.4: Pie chart showing types of participants in included studies**

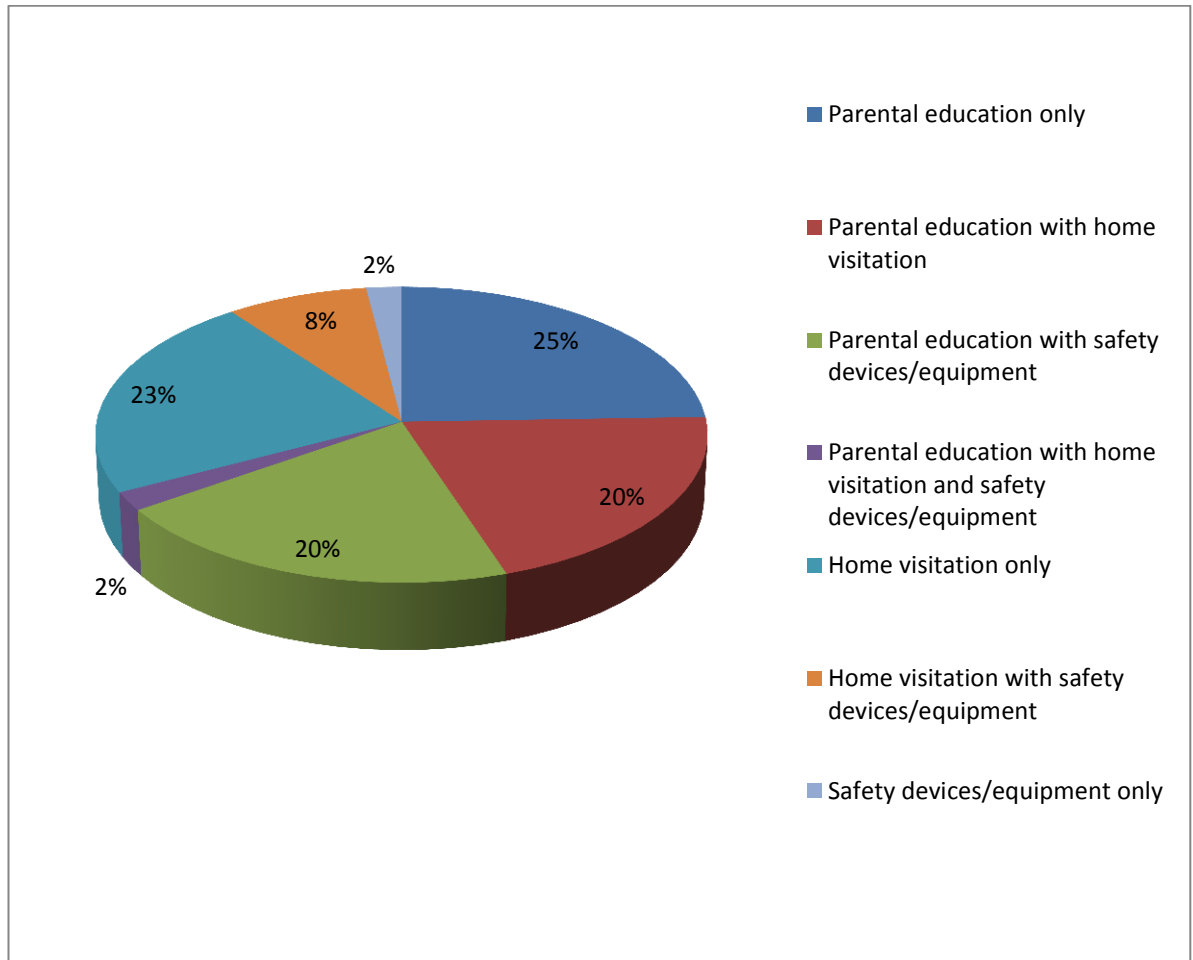


### 2.8.2.3 Types of interventions

The majority of interventions delivered to study participants had an educational component (see figure 2.5). Thirty three of the forty nine included studies provided parental educational interventions (Llewellyn et al., 2003, Gielen et al., 2002, Carlsson et al., 2011, Minkovitz et al., 2003,

Campbell et al., 2011b, Feldman et al., 1992, Gielen et al., 2007, Kendrick et al., 2005, Morrongiello et al., 2013, Reich et al., 2011, Shields et al., 2013, Thomas et al., 1984, Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, McDonald et al., 2005, Kelly et al., 1987, Geddis and Pettengell, 1982, Guyer et al., 1989, Nansel et al., 2008, Alvarez and Jason, 1993, Christophersen et al., 1985, Clamp and Kendrick, 1998, Dershewitz and Williamson, 1977, Keay et al., 2012, Kendrick, 1999, Kendrick et al., 2011, Posner et al., 2004, Sangvai et al., 2007, Tessier, 2010, Watson et al., 2005, Swartz et al., 2013, Waller et al., 1993). Twelve of these studies provided solely parental education (by healthcare workers) in the home (Campbell et al., 2011a, Llewellyn et al., 2003, Feldman et al., 1992, Swartz et al., 2013, Guyer et al., 1989) or ED/practice (Gielen et al., 2007, Kendrick et al., 2005, Morrongiello et al., 2013, Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, McDonald et al., 2005, Nansel et al., 2008). Ten studies provided parental education with some home visiting (Gielen et al., 2002, Carlsson et al., 2011, Minkovitz et al., 2003, Reich et al., 2011, Shields et al., 2013, Thomas et al., 1984, Kelly et al., 1987, Geddis and Pettengell, 1982, Waller et al., 1993). Ten studies provided parental education in combination with provision of free or discounted safety devices/equipment (Alvarez and Jason, 1993, Christophersen et al., 1985, Clamp and Kendrick, 1998, Keay et al., 2012, Kendrick, 1999, Kendrick et al., 2011, Posner et al., 2004, Sangvai et al., 2007, Tessier, 2010, Watson et al., 2005), and one study provided a combination of parental education, home visiting, and provision of safety devices (Dershewitz and Williamson, 1977).

**Figure 2.5: Pie chart showing types of interventions delivered to participants**



Parental education was provided mainly by verbal instruction or distribution of educational brochures/leaflets. Seven studies provided parental education by way of educational videos (Tessier, 2010, Geddis and Pettengell, 1982, Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, Keay et al., 2012, Morrongiello et al., 2013, Swartz et al., 2013). Tailored computer-based kiosk interventions were used in five studies (Shields et al., 2013, McDonald et al., 2005, Gielen et al., 2007, Sangvai et al., 2007, Nansel et al., 2008).

Eleven studies provided solely home visiting programmes delivered by trained health visitors or community health nurses (Armstrong et al., 2000, Barlow et al., 2007, Caldera et al., 2007, Fergusson et al., 2005, Johnson et al., 1993, Kemp et al., 2011, Kitzman et al., 1997, Larson, 1980,

Culp et al., 2007, Hardy and Streett, 1989, Emond et al., 2002). Four studies provided a combination of home visitation and provision of safety devices (Babul et al., 2007, Johnston et al., 2000, Hendrickson, 2005, Sznajder et al., 2003). Only one study provided solely safety devices to participating parents (Fergusson et al., 1982).

Thirty nine of the included studies reported interventions delivered to parents on a one-to-one basis (Alvarez and Jason, 1993, Armstrong et al., 2000, Babul et al., 2007, Barlow et al., 2007, Caldera et al., 2007, Campbell et al., 2011b, Christophersen et al., 1985, Clamp and Kendrick, 1998, Dershewitz and Williamson, 1977, Feldman et al., 1992, Fergusson et al., 2005, Gielen et al., 2007, Hendrickson, 2005, Johnson et al., 1993, Kemp et al., 2011, Kitzman et al., 1997, Larson, 1980, Llewellyn et al., 2003, Morrongiello et al., 2013, Posner et al., 2004, Reich et al., 2011, Sangvai et al., 2007, Shields et al., 2013, Sznajder et al., 2003, Watson et al., 2005, Gielen et al., 2002, McDonald et al., 2005, Kelly et al., 1987, Culp et al., 2007, Fergusson et al., 1982, Hardy and Streett, 1989, Emond et al., 2002, Waller et al., 1993, Nansel et al., 2008, Johnston et al., 2000, Swartz et al., 2013). Five studies reported group or community based interventions (Keay et al., 2012, Thomas et al., 1984, Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, Guyer et al., 1989), while three studies reported a combination of both one-to-one and group/community based interventions (Minkovitz et al., 2003, Carlsson et al., 2011). In the remaining two studies it was not clear if the interventions were provided to parents on a one-to-one basis or in groups (Tessier, 2010, Geddis and Pettengell, 1982).

The majority of included studies were evaluated using pre- and post-test interviewing methods. Twenty three studies were evaluated using pre- and post-test questionnaires (Babul et al., 2007, Campbell et al., 2011b, Carlsson et al., 2011, Clamp and Kendrick, 1998, Culp et al., 2007, Dershewitz and Williamson, 1977, Hendrickson, 2005, Johnson et al., 1993, Kendrick et al., 1999, Kendrick et al., 2005, Kendrick et al., 2011, McDonald et al., 2005, Nansel et al., 2008, Posner et al., 2004, Sangvai et al., 2007, Shields et al., 2013, Sznajder et al., 2003, Tessier, 2010, Turcotte

and Babul-Wellar, 2011, Turcotte et al., 2011, Watson et al., 2005, Barlow et al., 2007, Swartz et al., 2013). Thirteen studies were evaluated using pre-and/or post-test telephone interviews (Alvarez and Jason, 1993, Clamp and Kendrick, 1998, Gielen et al., 2007, Guyer et al., 1989, Hardy and Streett, 1989, Kendrick et al., 2011, Kitzman et al., 1997, McDonald et al., 2005, Minkovitz et al., 2003, Nansel et al., 2008, Posner et al., 2004, Sangvai et al., 2007, Shields et al., 2013), while sixteen studies used face-to-face verbal interviews (Caldera et al., 2007, Culp et al., 2007, Feldman et al., 1992, Fergusson et al., 1982, Fergusson et al., 2005, Gielen et al., 2002, Johnston et al., 2000, Keay et al., 2012, Kelly et al., 1987, Kemp et al., 2011, Llewellyn et al., 2003, Reich et al., 2011, Sznajder et al., 2003, Thomas et al., 1984, Waller et al., 1993, Armstrong et al., 2000).

Eleven studies assessed children's medical records for injuries (Caldera et al., 2007, Emond et al., 2002, Fergusson et al., 1982, Fergusson et al., 2005, Guyer et al., 1989, Hardy and Streett, 1989, Kemp et al., 2011, Kendrick et al., 1999, Minkovitz et al., 2003, Sangvai et al., 2007, Watson et al., 2005). Eight studies relied on parental reports of injuries or safety practices (Fergusson et al., 1982, Guyer et al., 1989, Kelly et al., 1987, Kemp et al., 2011, Kendrick et al., 1999, Kitzman et al., 1997, McDonald et al., 2005, Sangvai et al., 2007).

**Table 2.3: Characteristics of included studies**

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
Alvarez 1993 USA RCT	To examine the effectiveness of education and modelling on infant automobile restraint use	Low-income Hispanic mothers attending a prenatal clinic affiliated with a Chicago hospital and scheduled to deliver in August 1984  N = 14	<p><b>Intervention group</b> (n = 7) Received 1. A discussion of the Illinois child passenger legislation 2. An explanation of the benefits of automobile restraint devices, along with behavioural modification strategies for use in the automobile 3. A list of available infant and toddler restraint devices 4. A demonstration of the proper use of one type of infant automobile restraint device (Century 100) 5. An infant automobile restraint device on loan for five months for a \$10 deposit.</p> <p><b>Control group</b> (n = 7) Received: 1. a discussion of the Illinois child passenger legislation 2. An explanation of the benefits of automobile restraint devices, along with behavioural modification strategies for use in the automobile 3. A list of available infant and toddler restraint devices 4. A demonstration of the proper use of one type of infant automobile restraint device (Century 100).</p>	Observed use of infant automobile restraint device	Three months	<p>At time of discharge from hospital, 6 of the 7 infants whose mothers participated in the education-loaner programme were restrained on the first ride home. In education only group, only 1 of 7 infants was properly restrained (<math>p &lt; 0.01</math>).</p> <p>At 6 weeks; 4 of 7 in EL group, 1 of 7 in E group (<math>p &gt; 0.05</math>).</p> <p>At 3 months: safety practices averaged 74% in EL group and 71% in E group</p>
Armstrong 2000	To evaluate the efficacy of an early home-based intervention on the	Families of new-borns attending an inner city obstetric hospital. At risk of child abuse or	<b>Intervention arm (n = 90):</b> Child health nurse visits weekly for the first six weeks, fortnightly until three months, then monthly until six months	Home Observation for Measurement of the Environment (HOME) scores, parental reports	Four months	The intervention group self-reported significantly fewer injuries and bruises. All aspects of the home

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
Australia  RCT	quality of maternal–infant attachment, maternal mood and child health parameters in a cohort of vulnerable families.	neglect (vulnerable families). English literary skills sufficient to complete questionnaire with minimal assistance  N = 181	postpartum.  <b>Control arm (n = 91):</b> Existing community child health services	of injury		environment were significantly enhanced. A statistically significant difference was shown between groups on all subscales, as well as the total HOME score ( $p < 0.05$ ).
Babul 2007 Canada  RCT	To test a developmentally targeted intervention aimed at addressing the risk of injury in infants 2 – 12 months of age.	English-speaking parents of infants born at Chilliwack General Hospital and residing in the District of Chilliwack, British Columbia  N = 600	<b>Two intervention groups:</b> Group one (n = 202) received a home visit by a community health nurse. Group two (n = 206) received a home safety kit.  <b>Control group</b> (n = 192) received the standard services provided by the community health unit for families with newborn infants.	Primary outcome: parent-reported use of preventive safety measures and removal of potential hazards in the home. Secondary outcome: parent-reported medically attended injuries	12 months	At 12 months, 69.3% (n = 113) of parents in the safety kit group reported adjusting their hot water to a safe temperature, compared to 53.7% (n = 80) of those in control group (OR 2.21, 95% CI 1.32 to 3.69). At 6 months, the odds of having the hot water temperature adjusted safely was significantly higher for the safety kit plus home visit group compared to the control group (OR 2.25, 95% CI 1.37 to 3.71). At 12 months, a higher proportion of parents in the safety kit plus home visit group (69.9%, n=121), compared to the control group (53.7%, n=80), also reported safe adjustment of their home hot

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
						<p>water temperature (OR 2.6, 95% CI 1.57 to 4.46)            At 12 months, 79% of parents (n=136) in the kit plus home visit group reported that they kept plants out of reach compared to 76.3% (n=112) in the control group (OR 1.90, 95% CI 1.03 to 3.52)            Use of the hot water temperature cards was significantly higher in the kit plus home visit group as compared with the kit only group (OR 2.38, CI 1.42 – 3.97).</p> <p>Neither of the interventions was associated with a reduction in parent-reported injuries among children</p>
Barlow 2007 UK RCT	To evaluate the effectiveness and cost effectiveness of an intensive home visiting programme in improving outcomes for vulnerable families.	Vulnerable pregnant women at risk of child abuse or neglect, identified by community midwives from 40 General Practitioner (GP) practices across two UK counties	<p><b>Intervention group (n = 67):</b> 18 months of weekly visits from a health visitor trained in understanding the processes of helping, skills of relating to parents effectively and methods of promoting parent–infant interaction using the Family Partnership Model.</p> <p><b>Control group (n = 64):</b> standard help</p>	HOME scores at 12 months postnatal	12 months	No significant differences were found between the two arms on the HOME inventory



Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
		N = 131	currently available to such families.			
Caldera 2007 USA RCT	To assess the impact of a voluntary, paraprofessional home visiting program on promoting child health and development and maternal parenting knowledge, attitudes, and behaviours.	“At-risk” families: risks included maternal mental health, maternal substance abuse, partner violence  N = 325	<b>Intervention group (n = 162):</b> Families receiving the intervention were given home visits weekly for the first six to nine months. Home visitors provided the participants with information on positive child health and welfare.  <b>Control group (n = 163):</b> The paper did not specify what intervention the control group received	HOME scores. Injuries requiring medical care	24 months	Group scores did not differ significantly on Total HOME score or any HOME subscale. No significant differences in number of injuries requiring medical care (p = 0.83)
Campbell 2011 USA RCT	To test whether primary prevention interventions in the newborn period prevent elevated blood lead levels	Families of newborn children from urban outpatient practices located in low-income neighbourhoods of Philadelphia, where the prevalence of children with elevated Blood lead levels (BLLs) is higher than average  N = 314	<b>Intervention group (n = 154):</b> standard lead-poisoning prevention education with additional extensive education regarding essential maintenance practices for keeping a home in lead safe condition.  <b>Control group (n = 160):</b> standard lead education	Parental lead knowledge	12 months	Both groups showed a significant increase in parental scores on a lead education test. Median scores were not significantly different between arms

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
Carlsson 2011 Sweden Non-RCT	To investigate the effectiveness of individual-based information given to mothers with low education, on precautions taken against child injuries in the home	Families of low educational level attending child health care centres in two separate areas of a city in southern Sweden  N = 99	<b>Both groups</b> (intervention n = 50, control n = 49) attended a workshop on prevention of scalds and burns at home. <b>Intervention group</b> mothers in addition, received a home visit where individual-based information regarding child injury prevention in the home was offered	Self-reported precautions against child injuries in the home	Seven months	In 4 out of 5 precautions against child injuries in the home assessed before and after individual-based information, the mothers in the intervention group had significantly improved their preventative activity.  Mothers in the intervention group had significantly improved their preventative activity including: used a cooker with child protection fitted (p < 0.001), taken action to properly anchor cooker (p < 0.02), removed possibilities for a child to climb into sink or cooker (p < 0.001), and secured electric cords to iron and water heating appliances (p < 0.001).
Christopherson 1985 USA RCT	To compare two comprehensive programmes for encouraging new parents to use child restraints	Mothers of newborns delivered at medical centre serving the south-western suburban Kansas city area. Mothers were of middle or upper-middle	<b>Intervention group:</b> received regular hospital program plus a mock-up demonstration of the correct method of fastening a baby into a car seat, written handouts on how to use a car seat, physicians order for the mock-up demonstration, and a physician's order to	Correct use of infant car seat	12 months	The comprehensive child passenger safety programme was effective from hospital discharge to 12-month follow-up, however there was not a significant difference between groups.

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
		socioeconomic status  N = 129	be discharged in a car seat.  <b>Control group:</b> received regular hospital program which included discharging mothers in the usual manner and offering them the opportunity to rent a car seat			
Clamp 1998 UK RCT	To assess effectiveness of general practitioner advice about child safety, and provision of low cost safety equipment to low income families, on use of safety equipment and safe practices at home.	Low income families with children aged less than five years that registered with a single handed general practice in an urban area of Nottingham  N = 165	<b>Intervention group (n = 83):</b> GP safety advice plus, for families receiving means tested state benefits, access to safety equipment at low cost.  <b>Control group (n = 82):</b> control families received usual care	Possession and use of safety equipment and safe practices at home	Six weeks	After intervention, significantly more families in intervention group used fireguards (relative risk 1.89, 95% confidence interval 1.18 to 2.94), smoke alarms (1.14, 1.04 to 1.25), socket covers (1.27, 1.10 to 1.48), locks on cupboards for storing cleaning materials (1.38, 1.02 to 1.88), and door slam devices (3.60, 2.17 to 5.97). Also, significantly more families in intervention group showed very safe practice in storage of sharp objects (1.98, 1.38 to 2.83), storage of medicines (1.15, 1.03 to 1.28), window safety (1.30, 1.06 to 1.58), fireplace safety (1.84, 1.34 to 2.54), socket safety (1.77, 1.37 to 2.28), smoke alarm safety (1.11, 1.01 to 1.22), and door slam safety (7.00, 3.15

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
						to 15.6).
Culp 2007 USA Non-RCT	To evaluate a health education program which used child development specialists as home visitors and served a population of first time mothers living in rural communities	First time mothers living in a rural community recruited prior to 28th week of pregnancy  N = 263	<b>Intervention group (n = 156):</b> Intervention participants received home visits weekly during the first month after enrolment, biweekly for the remainder of their pregnancy, weekly for the first three postpartum months and biweekly from 3 to 12 postpartum months.  <b>Control group (n = 107):</b> Control participants received standard health department services that did not include home visitation	Household safety  Number of hospital and emergency department visits	12 months	At 12 months, the intervention group had significantly safer homes (M = 38.1, SD = 2.4) than did the control group (M = 36.9, SD = 2.6) based on the Massachusetts Home Safety Questionnaire, $t(261) = 3.9$ , $P = 0.0001$ .  There were no significant differences between the intervention and control groups on number of hospital and emergency room visits at either 6 or 12 months
Dershewitz 1977 USA RCT	To evaluate the implementation of a health education program intended to reduce the risk of childhood household injuries.	The study population were members of the prepaid Columbia Medical Plan (CMP) in the new planned city of Columbia, Maryland. Ninety percent of the household heads attended college, 81 per cent of the household heads were white, and the median	<b>Intervention group (n = 101):</b> participated in a personalised health education program to effect reduction of household hazards.  <b>Control group (n = 104):</b> received no intervention. One month after completion of the health education program, both experimental and control groups received an unannounced household hazard assessment and survey questionnaire by a	Household hazard scale, knowledge of house accidents	Two months	There was no significant difference in total household hazard scores for the two groups (Intervention 53.20 v control 52.99; $p > 0.05$ )  No difference in accident-related preventive behaviour and knowledge of household accidents

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
		household annual income was \$19,000  N = 308	home visitor who was unaware of whether the mother belonged to the experimental or control group.			
Emond 2002 UK Non-RCT	To assess outcomes in families who received the First Parent Health Visitor Scheme (FPHVS), in comparison with families who received conventional (“generic”) health visiting.	First time parents in three areas of socioeconomic deprivation (two inner city areas and one suburban estate) in Bristol  N = 459	<b>Intervention group (n = 205):</b> were visited at home antenatally (in the third trimester), at the statutory primary birth visit, at three weeks postnatally, and then every five weeks until the infant is eight months old.  <b>Control group (n = 259):</b> normal home visiting	Use of electric socket covers and safety gates, number of accidents in the last 12 months	Two years	Receipt of the FPHVS was associated with increased use of electric socket covers (OR = 1.92; 95% CI 1.07-3.44; p = 0.019), and lower accident rates in the second year of life (OR = 1.92; 95% CI 0.31-0.93; p = 0.022).
Feldman 1992 Canada RCT	To evaluate a home-based parent training intervention consisting of instructions, picture books, modelling, feedback, and tangible reinforcement to teach crucial child-care skills to low IQ mothers considered at-risk for child	Low IQ mothers considered at risk of child neglect, with children aged 1-23 months of age. Welfare recipients with family income less than C\$15,000  N = 22	<b>Intervention group (n = 11)</b> received: Parent training consisting of: (a) verbal instructions, (b) specially designed picture books depicting each step of the task analysis (the books were available for diapering, bathing, crib and sleep safety, formula preparation, and treating diaper rash), (c) modelling of each step by the trainer, and (d) feedback on the mother's actual performance during and following the training session. In addition, mothers received coupons contingent on scoring 80% correct on the trained skills.	Demonstrated kitchen safety (including scald prevention), crib and sleep safety tasks	14 weeks	Parent training improved the child-care skills of low IQ mothers considered at risk for child neglect. The training group scored significantly higher than the control group on the post-test. The mean pre/post scores of the training group were 62.5% and 88.1%; the mean pre/post scores of the control group were 65.2% and 60.6% (all ps < 0.001)

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	neglect		<b>Control group (n = 11)</b> received no parent training			
Fergusson 1982 New Zealand Non-RCT	To determine the effectiveness of a poisoning prevention aid for children aged 2 to 3 years	Families participating in the Christchurch child development study (92% of a birth cohort of infants born in Christchurch, New Zealand between April 15 and August 5, 1977)  N = 1156	<b>Intervention group (n = 599):</b> Each mother in the experimental group was supplied with: (1) an introductory leaflet outlining the Mr Yuk program and describing the way she should introduce Mr Yuk to her child (2) a list indicating the household products to which Mr Yuk should be attached (3) three sheets each containing 12 Mr Yuk stickers of assorted sizes.  <b>Control group (n = 557):</b> Mothers in the control series did not receive these instructions or materials.	Rates of poisoning incidents, childhood poisoning incidents	12 months	No evidence to suggest that the supply of Mr Yuk stickers had any detectable effect on rates of poisoning or poison hazards in the home. No statistical difference in the rates of poisoning for the experimental and control groups (10.81 v 11.05; $p > 0.05$ )  Mean number of poisons within child's reach: Intervention 14.70 v control 14.80; $p > 0.05$ .
Fergusson 2005 New Zealand RCT	To evaluate the extent to which a program of home visitation (Early Start), targeted	Participants were those screened by Plunket community nurses as having two or more risk factors identified from a screening	<b>Intervention group (n = 220):</b> The intervention arm received the Early Start programme which was a home visiting programme.  <b>Control arm (n = 223):</b> received no	Rates of hospital attendance for accidents/injuries and accidental poisoning in 36 months	36 months	Children in the Early Start series had fewer hospital attendances for accidents/injuries and accidental poisoning (17.5 v 26.3; 0.59 95% CI 0.36-

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	at families who are facing stress and difficulty, had beneficial consequences for child health, preschool education, service utilization, parenting, child abuse and neglect, and behavioural adjustment	measure covering a series of areas of parent and family functioning including; parental age, planning of pregnancy, parental substance use, financial situation and family violence  N = 443	intervention			0.98; p < 0.05)
Geddis 1982 New Zealand  Non-RCT	To evaluate the effectiveness of health education material on how parents transported their children in cars	All women who had babies in the Queen Mary maternity hospital in Dunedin in May, June and July 1980  N = 380	Group one ( n = 117) served as <b>control</b> (no intervention).  Groups two (n = 137) and three (n = 126) ( <b>intervention groups</b> ): group two received pamphlets on child car safety. Group three received the pamphlets and viewed a film on car safety restraint systems	Observed method of transport of infant from clinic	Six months	At 6 month follow-up no significant statistical difference was noted in the way the 3 groups transported their infants
Gielen 2002 USA RCT	To evaluate the effectiveness of an intervention aimed at enhancing parents' home safety practices through paediatric safety counselling, home visits, and an	Low income parents of infants no older than six months attending a paediatric resident continuity clinic in a large urban teaching hospital	Parents in the <b>standard intervention group</b> (n = 93) received safety counselling and referral to the children's safety centre.  Parents in the <b>enhanced intervention group</b> (n = 94) received the standard services plus a home safety visit by a community health worker	Number of visits to the children's safety centre, self-reported and observed safety practices: reduction of hot water temperature, poison storage, presence of smoke alarms, safety gates	18 months	No significant differences in safety practices were found between study groups. However, families who visited the children's safety centre compared with those who did not had a significantly greater number of safety practices (34% v

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	on-site children's safety centre	N = 187				17%; p = 0.01)
Gielen 2007 USA RCT	To evaluate a theory based, computer-tailored intervention, which was designed to promote parents' car seat, smoke alarm, and poison storage safety knowledge and behaviours.	Low income urban families attending the emergency department of a level one paediatric trauma centre  N = 901	<b>Intervention group</b> (n = 448) received a personalized report containing tailored, stage-based safety messages based on the precaution adoption process model.  <b>The control group</b> (n = 453) received a report on other child health topics	Child safety knowledge and behaviours	Two – four weeks	The intervention group had significantly higher smoke alarm, poison storage, and total safety knowledge scores (intervention 72.6 +/- 13.9 v control 66.4 +/- 14.8; t = 5.87; p < 0.001). The intervention group was more likely to report correct child safety seat use.
Guyer 1989 USA Non-RCT	To evaluate the effectiveness of a community-based injury prevention program designed to reduce the incidence of burns, falls in the home, motor vehicle occupant injuries, and poisonings and suffocations among children ages 0-5 years	Families with children 0-5 years of age in selected Massachusetts cities  N = 1200	<b>Intervention communities</b> (n = 230) received: Injury counselling for the parents, School and community burn prevention education, household injury hazard identification and control, community-wide promotion of the Massachusetts poison control system's telephone information service and public education about poison prevention, and promotion of child automobile restraint use  <b>Control communities</b> (n = 256) did not receive any intervention	Changes in safety knowledge and practices, changes in injury incidence	22 months	There was a reduction in motor vehicle occupant injuries among children 0-5 years in the intervention compared with control communities (21.54 v 60.77; OR = 2.78, 95% CI 1.66-4.66). Households that reported participatory exposure to the interventions had higher safety knowledge and behaviour scores than those that received other community exposure or no exposure to intervention activities



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Hardy 1989 USA Non-RCT	To assess the effect and cost of providing parenting and child care education in the home to inner-city mothers of poor infants receiving comprehensive health care in a large federal children and youth programme	Vulnerable black women aged 18 years or older with babies weighing more than 2000g born, between August 1983 and April 1985  N = 290	<b>Intervention group (n = 143):</b> Home visits by community woman. Curriculum addressed topics appropriate for the age of the infants visited and included child safety, feeding, clothing, and sick care.  <b>Control group (n = 147):</b> conventional medical, developmental and social assessments	Emergency department visits for sustained closed head trauma	Two years	Study children made slightly fewer C&Y clinic visits than control subjects (15.5 v 16.6)  Study children had fewer ED visits for sustained closed head trauma than controls (8 v 15; p > 0.05)
Hendrickson 2005 USA RCT	To access an underserved, mobile segment of a monolingual Spanish speaking population and to improve maternal self-efficacy for home safety behaviours using a culturally appropriate intervention.	Low income Hispanic mothers of children one - four years of age resident in a non-urban area of Texas  N = 82	<b>Intervention group</b> mothers (n = 41) received three home visits where they received counselling regarding hazards in the home, assessment of maternal safety practices, and provision of safety items.  <b>Control group</b> mothers (n = 41) received two home visits	Maternal childhood injury health beliefs (MCIHB) and observed controllable safety hazards (CSH) scores	18 months	The intervention group indicated improved self-efficacy for home safety behaviours The intervention group demonstrated improved self efficacy for home safety behaviours (F (2, 77) = 7.50, p = 0.01), not only by scoring higher on that subscale, but also by having fewer observed hazards
Johnson 1993 Ireland RCT	To evaluate a community mothers' programme to see if non-professionals	First time mothers who delivered babies over six months in 1989 and lived in a defined deprived area of Dublin	<b>Intervention group</b> mothers (n = 141) received the services of a community mother, who was scheduled to visit monthly during the first year of the child's life.	Hospital admissions for injury	12 months	The community mothers' programme failed to show a benefit with respect to hospitalisation. The child development programme

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	could deliver the child development programme effectively.	N = 262	<b>Control group</b> mothers (n = 121) received standard support from public health nurse, consisting of home visits at birth and six weeks			was associated with a sharp drop in admissions and accidents in the intervention group. Hospital admissions for injury: intervention group 0 v control group 2. Eleven children suffered an accident during the period, three in the intervention group and eight controls (NS). The relative risk of having an accident was 0.3 in the intervention group compared with controls (95% CI 0.08 to 1.14).
Johnston 2000 USA Non-RCT	To evaluate the feasibility, acceptability, and effectiveness of an injury prevention program delivered by school based home visitors to the families of low income children attending preschool enrichment programs in Washington State	Low-income families of children in a defined geographic area who were four or five years old and enrolled in Head Start or Early Childhood Education and Assistance Program (ECEAP) between January and June 1998  N = 481	<b>Intervention group (n = 274):</b> Families in the intervention group were given safety related information and supplies which included new smoke detector or smoke detector batteries, syrup of ipecac and written material regarding its appropriate use, or a free booster seat if the family vehicle was equipped with rear seat lap-shoulder restraints.  <b>Control group (n = 207):</b> Families in the control group only received written information encouraging them to install smoke detectors or to replace batteries if needed, to obtain ipecac, and to obtain	Presence of working smoke detector, presence of poisons and unused medication in the home, poisoning prevention knowledge and knowledge of poison control line, presence and use of age appropriate child safety restraints	Three months	Among families without a working smoke detector at baseline, the intervention was associated with an increased probability of having a working detector at follow up (RR 3.3, 95% CI 1.3 to 8.6). Intervention families with at least one working smoke detector at baseline were twice as likely to have increased the number of working smoke detectors at follow up than were families in the comparison group (RR =

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			and properly use a booster seat.			<p>2.0, 95% CI = 1.2 to 3.1).</p> <p>Intervention families were more likely to have obtained an age appropriate booster seat (RR 4.1, 95% CI 1.9 to 8.8) at follow up.</p> <p>Among those families who reported poisonous substances in their home at the baseline, those in the intervention group were twice as likely to have removed these substances at follow up than were families in the comparison group (RR = 2.1, 95% CI = 1.3 to 3.2).</p>
<p>Keay 2012 Australia RCT (cluster)</p>	<p>To evaluate an education, distribution, and fitting program for increasing age-appropriate and correct child restraint use</p>	<p>Families with children aged three – five years resident in a diverse low socioeconomic area of Sydney</p> <p>N = 689</p>	<p><b>Intervention families</b> (n = 328) received an information pack containing an educational DVD, printed educational material, and a voucher for a free fitting check at a local authorised child restraint fitter. A limited number of child restraints were also offered at a subsidized cost of A\$50, approximately 25% of the recommended retail price.</p> <p><b>Control families</b> (n = 361) received their</p>	<p>Correct use of appropriate child-restraint systems</p>	<p>10 months</p>	<p>More children attending intervention centres were optimally restrained (43% v 31%, p = 0.01). Among non-English-speaking families, more children attending intervention centres were optimally restrained (43% v 17%; P = 0.002)</p>

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
			usual educational programming and were offered the Buckle-Up Safely program on study completion.			
Kelly 1987 USA RCT	To assess the effectiveness of age-appropriate safety education on parental knowledge and safety practices	Parents of six month old children who were followed at the Yale-New Haven hospital primary care centre  N = 171	<p><b>Intervention group (n=85):</b> Parents in the intervention group received a three-part individualized course in child safety that required active parental participation. Parts one, two, and three were given at the six-month, nine-month, and 12-month well-child visits, respectively.</p> <p><b>Control group (n = 86):</b> Parents in the control group received routine safety education as provided at well-child visits.</p>	Parental knowledge of household hazards, hazards in the home, reported automobile practices, reported accidents	12 months	<p>Parental knowledge of hazards was higher in the intervention group than the control. Of 13 possible hazards, the mean number of hazards recognised by the intervention group parents was 9.4 v 8.4 by the control parents (t = 2.1, p &lt; 0.05). The mean hazard score for the intervention group was 2.4 v 3.0 for the control group (t = 2.4, p &lt; 0.02).</p> <p>Automobile practices between the two groups revealed that 33% of the children in the intervention group usually sat in the front seat versus 53% in the control group (p &lt; 0.05)</p> <p>Parentally reported accidents and accidents reported in hospital records were similar for both groups.</p>

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
Kemp 2011 Australia RCT	To investigate the impact of a long-term nurse home visiting programme, embedded within a universal child health system, on the health, development and well-being of the child, mother and family.	At-risk mothers living in a socioeconomically disadvantaged area in Sydney, booking into the local public hospital for confinement. Mothers were eligible to participate if they did not require the use of an interpreter, and reported one or more of the following risk factors for poor maternal or child outcomes: maternal age under 19 years; current probable distress (assessed as an Edinburgh Depression Scale (EDS) 17 score of 10 or more); lack of emotional and practical support; late antenatal care (after 20 weeks gestation); major stressors in the past 12 months; current substance misuse;	<p><b>Intervention group (n = 111):</b> Women in the intervention group received an average of 16.3 (range 0–52) visits, each of 60–90 min duration, by a child health nurse commencing at on average 26 weeks gestation (range 12–40), and continuing to their child’s second birthday. They also received usual antenatal midwifery, obstetric and birthing services</p> <p><b>Control group</b> women (n = 97) were expected to receive a home visit by a child health nurse within two weeks of giving birth, in accordance with standard practice in New South Wales. They also received usual antenatal midwifery, obstetric and birthing services</p>	HOME scores at 12 and 24 months (subscales - organisation of environment and provision of appropriate play materials)	24 months	No statistically significant difference between groups in the home environment subscale of the HOME inventory. No significant main intervention effects for other components of the quality of the home environment

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
		<p>current or history of mental health problem or disorder; history of abuse in mother's own childhood; and history of domestic violence</p> <p>N = 208</p>				
<p>Kendrick 1999 UK RCT (cluster)</p>	<p>To assess the effectiveness of safety advice at child health surveillance consultations, provision of low cost safety equipment to families receiving means tested state benefits, home safety checks, and first aid training on frequency and severity of unintentional injuries in children at home</p>	<p>All children aged 3 – 12 months registered with the participating practices in Nottingham on 30 June 1995</p> <p>N = 2152</p>	<p><b>Intervention group</b> (n = 1124) received; a package of safety advice at child health surveillance consultations at 6 - 9, 12 - 15, and 18 - 24 months; provision of low cost safety equipment to families on means tested state benefits; and home safety checks and first aid training by health visitors.</p> <p><b>Control group</b> (n = 1028) received usual care</p>	<p>Primary outcome measures: frequency and severity of medically attended injuries. Secondary outcomes: self-reported safety practices, possession and use of safety equipment</p>	<p>24 months</p>	<p>The intervention group was more confident in dealing with choking incidents than the control group (15.1% (55/364) not very confident versus 24.7% (91/368) respectively, <math>X^2 = 10.86</math>, 2 df, <math>P = 0.004</math>) and was more likely to know the correct action for bleach ingestion (59.3% (216/364) versus 48.9% (180/368), <math>X^2 = 7.75</math>, 1 df, <math>P = 0.005</math>), but no difference was found for the other injury scenarios.</p> <p>No significant difference was found in frequency of at least one medically attended injury (OR 0.97, 95% CI 0.72 to 1.30), at least one attendance at an accident</p>

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						<p>and emergency department for injury (1.02, 0.76 to 1.37), at least one primary care attendance for injury (0.75, 0.48 to 1.17), or at least one hospital admission for injury (0.69, 0.42 to 1.12).</p> <p>There was no difference in the number of unsafe practices between groups (U = 42 060, Z = - 1.12, P = 0.26).</p> <p>There were no differences between the two groups in scores for perceptions of risk of injury or risk of hazards (U = 55 340, Z = - 0.24, P = 0.81 and U= 52 911, Z= - 1.15, P = 0.25 respectively).</p>
Kendrick 2005 UK RCT (cluster)	To evaluate the effectiveness of an educational package provided by midwives and health visitors to reduce baby walker possession and use.	Pregnant women of at least 28 weeks gestation registered in one of seventy-one practices in four Nottingham Primary care trusts (PCTs) and 15 in Newark and Sherwood PCT	<p><b>Intervention group</b> (n = 539) received an educational package aimed at discouraging mothers-to-be from obtaining and using a walker.</p> <p><b>Control group</b> (n = 635) received usual care</p>	Primary outcome measures were the possession and use of a walker. Secondary outcome measures included the frequency and duration of walker use, knowledge and attitudes towards	Nine months	Intervention arm participants were significantly less likely to own (OR = 0.63, 95% CI = 0.43 to 0.93) or to use a walker (OR = 0.26, 95% CI = 0.08 to 0.84). They were significantly less likely to plan to use a walker with their next child (OR = 0.52,

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		N = 1174		walkers, plans to use a walker with future children, recommending a walker to a friend, and use of stair gates and fire guards		95% CI = 0.31 to 0.86) or to agree that walkers keep children safe (OR = 0.35, 95% CI = 0.16 to 0.78). There was some evidence that they were less likely to recommend a walker to a friend (OR = 0.51, 95% CI = 0.28 to 0.91) or to agree that they help children to walk more quickly (OR = 0.53, 95% CI = 0.29 to 0.95). Intervention arm participants had at least one knowledge question correct 42.7% v 32.7%, OR=1.47 (1.12-1.93) p = 0.006, (unadjusted). OR=1.37 (0.97-1.94) p=0.07 (adjusted)
Kendrick 2011 UK RCT	To assess the effectiveness of thermostatic mixing valves (TMVs) in reducing bath hot tap water temperature, assess acceptability of TMVs to families and impact on bath time safety practices.	Families with at least one child under the age of five years living in Glasgow Housing association housing  N = 124	<b>Intervention group</b> (n = 62) received: an educational leaflet providing information on how bath water scalds happen, the time taken for scalds to occur at different temperatures, usual bathing temperatures, what a thermostatic mixing valve (TMV) is and a true story of a two-year-old child scalded from hot bath water, a TMV set at a maximum temperature of 45°C fitted by a qualified plumber.	Bath hot tap water temperature at 3 and 12 months	12 months	Intervention arm families had a significantly lower bath hot water temperature at 3-month and 12-month follow-up than families in the control arm (3 months: intervention arm median 45.0°C, control arm median 56.0°C, difference between medians, -11.0, 95% CI -14.3 to -7.7); 12 months: intervention arm median



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			<b>Control group (n = 62)</b> were offered the intervention after collection of follow-up data			46.0°C, control arm median 55.0°C, difference between medians -9.0, 95% CI -11.8 to -6.2)
Kitzman 1997 USA RCT	To test the effect of prenatal and infancy home visits by nurses on various maternal and child outcomes including childhood injuries	African-American women of less than 29 weeks gestation, with no previous live births, and with at least two sociodemographic risk characteristics: unmarried, less than 12 years of education, unemployed  N = 1139	<b>Intervention group 1 (n = 166):</b> Free transportation for scheduled prenatal care appointments <b>Intervention group 2 (n = 515):</b> Free transportation for scheduled prenatal care plus developmental screening and referral services for the child at 6, 12, and 24 months of age. <b>Intervention group 3 (n = 230):</b> Free transportation and screening services plus intensive nurse home-visitation services during pregnancy, one postpartum visit in the hospital before discharge, and one postpartum visit in the home. <b>Intervention group 4 (n = 228):</b> All the services provided to group 3, plus continued visitation by nurses through the child's second birthday.	Childhood injuries and ingestions, HOME scales	24 months	During the first 2 years of their lives, nurse-visited children had fewer healthcare encounters in which injuries and ingestions were detected than did children in the comparison group (0.43 v 0.55; p = 0.05). Nurse-visited children were hospitalised for fewer days with injuries and/or ingestions than were children in the comparison group (0.03 v 0.16; p < 0.001). The homes of nurse-visited women were rated as more conducive to children's development by means of the HOME scale (p = 0.003)
Larson 1980 Canada  Partially RCT	To evaluate the efficacy of home visits designed to promote better child health and development for	French-Canadian or English-Canadian pregnant women aged 18 to 35 years attending the private offices of obstetricians	Group A received home visits starting prenatally. Group B received visits from six weeks post-partum Group C received no visits	HOME scores, cumulative emergency department visits and accident rates	18 months	The cumulative accident rate per child was significantly lower in group A than in groups B and C [0.86 (27) v 1.26 (41) v 1.55 (63); p < 0.01].

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	infants of working class families	who deliver at the maternity pavilion of the Royal Victoria Hospital Montreal  N = 115				The cumulative emergency room visit rate per child was lower in group A than groups B and C, however this difference was not statistically significant [0.95 (29) v 1.14 (38) v 1.05 (44); p > 0.05)  Significant differences in HOME scores favouring group A over groups B and C were seen at each assessment period: 6 weeks 29.3 v 25.8 v 26.7; p < 0.001. 6 months 35.2 v 33.7 v 33.2; p < 0.055. 12 months 40.1 v 37.8 v 37.8; p < 0.17. 18 months 41.2 v 38.6 v 39.0; p < 0.041. At 18 months, the means for each section of the HOME scale were higher in group A
Llewellyn 2003 Australia  RCT	To evaluate the efficacy of a home-based intervention targeted to parents with intellectual disability to promote child health and home safety in the	Parents with intellectual disability whose first language was English, and who were the primary carers of children under five years	Group 1 (n = 20): Home learning program Group 2 (n = 11): Home visits only Group 3 (n = 10): Current services only Group 4 (n = 4): Current services only	Dangers identified in the home, precautions identified for the dangers, precautions taken by parent to deal with home dangers	Three months	The intervention improved parents' ability to recognize home dangers, to identify precautions to deal with these dangers and resulted in a significant increase in the number of safety precautions parents implemented in their homes with all gains being

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	preschool years.	N = 45				<p>maintained at 3 months post-intervention.</p> <p>(1) A significantly greater number of home dangers identified by parents in home illustrations compared with Visits Only and Current Services Only (F = 37:27, p &lt; 0.001) and Lesson Booklets Only (F = 17:92, p &lt; 0.001).</p> <p>(2) A significant increase in the number of precautions identified by parents to deal with the dangers depicted in the home illustrations compared with Visits Only and Current Services Only (F = 41:29, p &lt; 0.001) and Lesson Booklets Only (F = 23:95, p &lt; 0.001).</p> <p>(3) A significantly greater number of home precautions implemented by parents compared with Lesson Booklets Only (F = 27:09, p &lt; 0.001).</p>
McDonald 2005 USA	To: (1) describe the development and feasibility of	Parents of children between the ages of six weeks and 24 months who were under the	<b>Intervention group</b> parents (n = 70) completed a 50-item assessment of knowledge, beliefs and behaviours related to four injury topics—smoke	Parental safety knowledge, self-reported safety behaviours, prevention	Four weeks	Compared to control group parents, intervention group parents were more knowledgeable about the

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RCT	implementing a computer tailored injury prevention intervention in a busy urban primary care practice, and (2) report the results of the program's impact on parents' home and child passenger safety knowledge, beliefs, and behaviours.	care of one of the participating physicians in an urban hospital-based academic primary care practice  N = 144	alarms, child passenger safety, poisons, and falls. At the end of the assessment, intervention parents were asked to select two of the injury topics that they would "like to learn more about". Parents then received the Parent Feedback Report that included tailored information about the two selected injury topics, as well as a shopping list of all safety products needed to address any of the four injury topics which, based on the parents' responses, were necessary.  <b>Control group</b> parents (n = 74) answered approximately 10 questions about contact and demographic information	beliefs		inappropriateness of young children riding in the front seat of a car (16% versus 5%, $p < 0.05$ ), and less likely to believe that teaching a child to mind you is the best way to prevent injuries (64% versus 86%, $p < 0.05$ ),
Minkovitz 2003a USA RCT	To determine the impact of the Healthy Steps for Young Children Programme on quality of early childhood health care and parenting practices	Families with newborns up to four weeks of age attending one of the study paediatric practices  N = 2235	<b>Intervention families</b> (n = 1133) received standard paediatric care plus the Healthy Steps program - enhanced well-child care, six home visits in the first three years, Healthy Steps Specialist-staffed child development telephone line to address parents' developmental concerns, developmental assessments, written materials emphasizing prevention and health promotion, parent group offering support and learning opportunities, and linkages to community resources through targeted referrals.  <b>Control families</b> (n = 1102) received	Safety practices, maternal reports of emergency department visits for injuries	33 months	Families receiving parental education and home visitation, were more likely to use electric socket covers 33 months post intervention compared to control group families (intervention group 92% versus control group 89%; $p = 0.04$ ).  No significant differences in other safety practices between intervention and control families.

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
			standard paediatric care			The intervention did not influence hospitalizations or overall ED use
Minkovitz 2003b USA Non-RCT	To determine the impact of the Healthy Steps for Young Children Programme on quality of early childhood health care and parenting practices	Families with newborns up to four weeks of age attending one of the study paediatric practices  N = 3330	<b>Intervention families</b> (n = 1830) received standard paediatric care plus the Healthy Steps program - enhanced well-child care, six home visits in the first three years, Healthy Steps Specialist-staffed child development telephone line to address parents' developmental concerns, developmental assessments, written materials emphasizing prevention and health promotion, parent group offering support and learning opportunities, and linkages to community resources through targeted referrals.  <b>Control families</b> (n = 1500) received standard paediatric care	Safety practices, maternal reports of emergency department visits for injuries	33 months	No significant differences in safety practices between intervention and control families. The intervention did not influence hospitalizations or overall ED use
Morrongiello 2013a Canada RCT	To evaluate the impact of the Supervising for Home Safety program on parent supervision practices in the home and when unobtrusively observed in a naturalistic	Parents in the community with children aged 2 to 5 years  N = 228	<b>Intervention group</b> (n = 116) watched the 20 minute Watchful parents, Safe Children video.  <b>Control group</b> (n = 112) watched the Healthy Lifestyles, Healthy Children video which focused on child nutrition and active lifestyles.	Length of time children were unsupervised, in-view supervision, level of supervision when children were out of view	Three months	The intervention group showed a significant decrease in time that children were unsupervised $F(1,83) = 4.81, p < 0.05$ , an increase in in-view supervision $F(1, 181) = 4.44, p < 0.05$ , and an increase in level of supervision when children were out of view $t(166) = 2.99, p < 0.01$ .

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	laboratory setting.					
Nansel 2008 USA Partially RCT	To determine the efficacy of providing (i) tailored injury prevention information (T-IPI) to parents and (ii) concurrent T-IPI to parents and providers to promote parent adoption of safety practices.	Low-income parents of children aged four and younger attending a well-child visit at one of three Midwestern paediatric clinics  N = 594	Group one (n = 188) received generic injury prevention information (G-IPI). Group two (n = 192) received tailored injury prevention information (T-IPI). Group three (n = 221) received T-IPI plus supplementary tailored provider information (T-IPI + P)	Self-reported adoption of new injury prevention behaviour	One month	Parents receiving T-IPI alone or with supplementary provider information were more likely to report adopting a new injury prevention behaviour than those receiving generic information (49 and 45%, respectively, compared with 32%; odds ratio = 2.0 and 1.9, respectively)
Posner 2004 USA RCT	To assess the effectiveness of an emergency department-based home safety intervention on caregivers' behaviours and practices related to home safety.	Low-income caregivers of children younger than five years presenting to an urban paediatric emergency department for treatment of acute, unintentional injuries sustained in the home  N = 136	All participants received the usual verbal emergency department discharge instructions related to the type of injury sustained by the child plus a brochure entitled "Home Safety Tips: How to Make Your Home Safer for You and Your Child."  <b>Intervention group</b> participants (n = 67) were provided with comprehensive home safety counselling via a scripted, verbal review of the entire handout as well as the distribution and explanation of the contents of a home safety kit provided free of charge.	The degree of improvement in safety practices as assessed by improvement in safety scores.	Six – eight weeks	The intervention group demonstrated a significantly higher average overall safety score at follow-up than the control group (73.3% +/- 8.4% v 66.8% +/- 11.1) and significant improvements in poison, cut/piercing, and burns category scores. Caregivers in the intervention group also demonstrated greater improvement in reported use of the distributed safety devices.

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
			<p><b>Control group</b> participants (n = 69) received the handout with verbal counselling limited to prevention of the type of injury sustained by the child.</p>			
Reich 2011 USA RCT	To determine whether educational baby books are an effective method for increasing low-income, first-time mothers' safety practices during their child's first 18 months.	Low-income first time mothers in their third trimester of pregnancy attending obstetric resident continuity clinics in an urban area  N = 167	<p><b>Group one</b> (n = 53) received an educational intervention book during the third trimester of pregnancy and additional books when their babies were two, four, six, nine, and 12 months old.</p> <p><b>Group two</b> (n = 56) was given books with the same illustrations, but different non-educational text on the same schedule.</p> <p><b>Group three</b> (n = 58) was not given any books</p>	Observed home safety practices, hazards in the home	18 months	Women in the educational book group had fewer risks in their homes and exercised more safety practices than the no-book group (- 20% risk reduction; effect size = - 0.30, p < 0.01). When the safety practices involved little time or expense (e.g., putting away sharp objects), the educational book group was significantly more likely to engage in these behaviours than the no-book group (40% higher practices; effect size = 0.19) or non-educational book group (27% higher practices; effect size = 0.13).
Sangvai 2007 USA RCT	To determine feasibility and effectiveness of a chronic care model approach to injury prevention	Parents of children aged zero to five years attending a paediatric clinic for a health maintenance visit	<b>Intervention group</b> ( n = 160) received: (1) focused counselling from their physician based on the summarized individual EnterVue responses, (2) brief safety counselling from a research health assistant, (3) free safety equipment,	(1) The number of household safety practices observed at the time of a home visit, (2) proper automobile restraint	Six months	Smoke detectors were present and functional in 16 of 17 intervention households compared with 5 of 10 control households (P = 0.015). Hazardous

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	compared with standard anticipatory guidance	N = 319	including smoke detectors, gun locks, cabinet locks, and water temperature cards, (4) an appointment for a car seat evaluation with a local organization, and (5) a brief educational handout for parents.  <b>The control group</b> (n = 159) received standard counselling from their physician during their visit	practices (observed by the home visitor), (3) Caregiver self-report of injuries that occurred in the past six months, and (4) unintentional injuries documented by medical chart review.		substances were not found in the low cabinets of 13 of 16 (information not recorded for hazardous substances in one intervention household) intervention households compared to 3 of 10 control households (P = 0.015).  No other differences were noted between groups. A chart review showed no significant difference in number of medically attended injuries between control and intervention groups (19 of 160 children in the intervention group compared with 22 of 159 children in the control group; P = 0.6).
Shields 2013 USA RCT	To evaluate the impact of a computer kiosk intervention on parents' self-reported safety knowledge as well as observed child safety seat, smoke alarm use, and safe poison storage and	Parents of young children (four months to five years) in a paediatric emergency department of a level one paediatric trauma centre  N = 901	<b>Intervention group (n = 448):</b> completed a 10 – 12 minute Precaution Adoption Process Model (PAPM) stage-based assessment of the three safety behaviours of interest – child safety seats, smoke alarms, and poison storage. The computer programme then printed a personalised PAPM stage tailored, 4 – page safety report based on the participants' responses.	Safety knowledge, self-reported and observed safety behaviours	Six months	The intervention group had significantly higher smoke alarm (82% v 78%) and poison storage (83% v 78%) knowledge scores. The intervention group was more likely to report correct child safety seat use (OR, 1.36; 95% CI, 1.05-1.77; P = 0.02). Observed safety behaviours



Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	to compare self-reported versus observed behaviours		<b>Control group</b> (n = 453) received participants completed an assessment based on sociodemographic characteristics and questions about development, sleep, neighbourhood safety, and dog bites. Control group then received a 4 – page report containing generic information.			were lower than self-reported use for both groups.
Swartz 2013 USA RCT	To evaluate Keeping Baby Safe In and Around the Car, a multimedia DVD designed to improve knowledge about car seat installation among parents of infants and toddlers.	Parents of children aged 0 – 24 months resident in four Oregon communities  N = 195	<b>Intervention group</b> participants (n = 101) viewed the Keeping Baby Safe In and Around the Car DVD, a 2-part DVD series designed to improve child safety seat installation and use among parents of infants and toddlers.  <b>Control group</b> (n = 94) participants viewed a portion of the Keeping Baby Safe In and Around the Home DVD, which provided comparable exposure to home safety-relevant content but no information about car safety.	Knowledge about child safety seats Correct child safety seat installation	Immediately post-intervention	Post-test scores on both knowledge (7.48 v 4.81; p < 0.001) and car seat simulation measures [(0-12 months - 6.11 v 3.26; p < 0.001) (13-24 months - 4.64 v 2.99; p < 0.001)] for the intervention condition were significantly higher than the control condition after adjusting for any baseline differences. No interaction effects were statistically significant in the models
Sznajder 2003 France RCT	To test the effectiveness of free preventive devices and counselling for low socioeconomic status families	Families with children six – nine months of age resident in four selected towns in the Paris suburbs  N = 100	Group one (n = 50) received counselling and a kit including preventive devices and pamphlets about indoor injuries and ways to avoid them.  Group two (n = 50) received counselling but not the kit	Safety behaviour and use of safety devices	Six – eight weeks	Between the first and the second visits, safety improvement was significantly higher in the group with the kit. This was mainly related to the risk of fall (p<0.02), fire and burns (p<0.001), poisoning

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
						(p<0.01), and suffocation (p<0.001). For improvement related to devices provided in the kit, the difference between the groups was significant: 64.4% improvement in group 1 versus 41.2% in group 2 (p<0.01). The relative risk (RR) of safety improvement between groups was 1.56 (95% CI 1.35 to 1.80). Even for improvements not related to the kit the difference remained significant: 31.2% in group 1 versus 20.2% in group 2 (p<0.05); RR = 1.54 (95% CI 1.22 to 1.93).
Tessier 2010 USA RCT	To evaluate whether a hands-on educational intervention makes a significant difference in the proper use of a child passenger restraint by a parent	All expectant parents of at least seven months gestation who lived on Oahu, had some connection with the medical centre used for the study, and who planned to transport their infants in passenger motor vehicles  N = 124	<b>The intervention group</b> (n = 64) received a free car seat and a standardized education session on the safety and use of child passenger restraints plus an additional component consisting of a hands-on demonstration and return demonstration of correct installation and use in their own vehicle.  <b>Control group participants</b> (n = 60) received a free car seat and a standardized education session on the safety and use of child passenger	Correct use of child passenger restraint	Two months	A total of 24 (22%) parents correctly used the car seat; of these, 18 (32%) were in the intervention group and 6 (11%) were in the control group. The intervention group was four times more likely to have correct use than the control group (odds ratio 4.3, p-value = 0.0074).

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
			restraints.			
Thomas 1984 USA RCT	To assess the effectiveness of a group well-child class on parental compliance with several home safety recommendations	Parents enrolled to attend well-baby classes within a Health Maintenance Organization  N = 55	<b>Intervention group</b> received the same information as the control group plus a special educational protocol covering a range of safety topics N = 29  <b>Control group</b> received standard information and literature on a number of health related topics. N = 26	Safety knowledge, proper usage of smoke detectors, hot water temperature	Six weeks	The intervention group was significantly more compliant with the recommendations on hot water temperature settings made during the well-child classes than the control subjects (76% compliance v 23 % compliance). 66% of the intervention group subjects reported changing their hot water temperature settings after the class whereas none of the control subjects reported such a change (p = 0.01). Subjects in the intervention group had significantly higher scores on the Fire safety Knowledge test. Mean intervention group score was 20.28 +/- 0.75 (SD) and mean control group score was 18.58 +/- 1.70 (SD) (t test = -4.6984; df = 33.6; p = 0.0001). A significantly higher number of the subjects in the intervention group reported

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
						that they had purchased and installed smoke alarms after the class (p = 0.03)
Turcotte 2011a Canada RCT	To evaluate <i>Too Hot for Tots!</i> in its ability to change knowledge, attitudes and practices (KAP) around the perception of burn risk, and to highlight burn prevention efforts that can be taken by parents and caregivers of children less than 5 years of age.	Parents and/or caregivers of children less than five years of age who visit a 'Mom and Baby' drop-in centre at a sample of health units located throughout the Vancouver Coastal Health Authority  N = 268	<b>The video group</b> (n = 133) completed a pre-intervention Knowledge, Attitudes, and Practices (KAP) questionnaire, had a viewing of the video followed by group discussion, and then received a brochure package.  Subjects in the <b>brochure group</b> (n = 135) received the take-home brochure package only.	Change in knowledge, attitudes and practices	Four months	The video group was seen to improve on all three KAP scores from pre-session to post-session, while also demonstrating higher KAP scores for each of the three categories when comparing the post-session scores with the brochure group. Knowledge (79.3% v 64.0%; p < 0.001); Attitudes (93.1% v 87.1%; p < 0.001); Practices (76.8% v 69.8%; p < 0.001)
Turcotte 2011b Canada RCT	To evaluate the effectiveness of the <i>Give Your Child a Safe Start</i> video in promoting a change in parental knowledge, attitudes and practices regarding injury prevention for children 0 to 5	Parents and/or caregivers of children less than five years of age who visit a 'Mom and Baby' drop-in centre at a sample of health units located within the Fraser Health Authority  N = 116	<b>Intervention groups</b> (n = 60) were shown the Give Your Child a Safe Start video addressing falls, burns, car safety, poisoning, choking, product safety, water safety, and safe sleeping; with subsequent discussion.  <b>The control groups</b> (n = 56) discussed a non-injury related topic with the Public Health Nurse, such as dental care, immunization, etc.	Change in knowledge, attitudes and practices	Four months	Paired t-tests found statistically significant differences in participants' knowledge and practices between the pre- and post-test scores for the intervention group; while the comparison group demonstrated significant differences for knowledge, attitudes and injury prevention practices. The

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
	years of age.					linear mixed effects modelling demonstrated a significant difference between the intervention and comparison groups for practices – the change in practice scores was significantly higher in the intervention group as compared to the comparison group. The intervention group demonstrated a statistically significant improvement over the comparison group in terms of improved injury prevention practices four months after receiving the intervention.
Waller 1993 New Zealand Non-RCT	To evaluate a programme designed to lower the temperature of home tap water in Dunedin, New Zealand	Households with children less than three years of age in Dunedin  N = 144	<b>The intervention group</b> (n = 54) received a half-hour home visit by a nurse during which the dangers of hot water in the home and other general safety measures were discussed.  <b>The control group</b> (n = 56) did not receive any home visits	Home hot water temperature, knowledge about hot water	Four months	There were significant decreases in tap water temperature across all groups but the majority of households still had temperatures above 55 degrees C at the end of the study
Watson 2005 UK	To assess the effectiveness of safety advice and safety equipment in	Low-income families, with one or more children younger than five years from the	<b>Intervention group</b> (n = 1711) received a standardised safety consultation and provision of free and fitted stair gates, fire guards, smoke alarms,	Medically attended injury, rates of attendance in primary and secondary care,	24 months	At one year, families in the intervention arm were significantly more likely to be safe in terms of stairs

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow-up	Results
RCT	reducing unintentional injuries for families with children aged less than 5 years and living in deprived areas.	caseloads of participating health visitors, resident in deprived areas  N = 3995	cupboard locks, and window locks.  <b>Control group</b> (n = 1717) received usual care	and hospital admission, possession of safety equipment and safety practices		<p>(P = 0.0004), smoke alarms (P = 0.0002), windows (P = 0.03), and storage of cleaning products (P = 0.006) and sharp objects (P = 0.005) in the kitchen than families in the control arm.</p> <p>At two years, families in the intervention arm were significantly more likely to be safe in terms of smoke alarms (P = 0.002), storage of medicines (P = 0.05), and cleaning products (P = 0.008) in the kitchen than families in the control arm</p> <p>No significant difference was found in the proportion of families in which a child had a medically attended injury (OR 1.14, 95% CI 0.98 to 1.50) or in the rates of attendance in secondary care (incidence rate ratio 1.02, 0.90 to 1.13) or admission to hospital (1.02, 0.70 to 1.48). However, children in the intervention arm had a significantly higher attendance rate for</p>

Study Details (First author, year, country, study design)	Aims/objectives	Study population and total number of participants	Intervention and comparison groups	Outcome measures	Length of follow- up	Results
						injuries in primary care (1.37, 1.11 to 1.70, P = 0.003).

	Studies showing significant effect
	Studies showing insignificant effect

#### **2.8.2.4 Types of outcome measures**

With regards to outcome measures, 18 of the 49 included studies reported self-reported or medically-attended unintentional injury (see section 2.8.3). Several studies reported a range of child injury safety measures. These included: lowering hot tap water temperature (Thomas et al., 1984, Babul et al., 2007, Kendrick et al., 2011, Waller et al., 1993, Minkovitz et al., 2003, Sangvai et al., 2007, Gielen et al., 2002, Kelly et al., 1987); presence of functional smoke detectors (Thomas et al., 1984, Clamp and Kendrick, 1998, Shields et al., 2013, McDonald et al., 2005, Sangvai et al., 2007, Watson et al., 2005, Gielen et al., 2002, Johnston et al., 2000); use of and correct installation of appropriate child safety seats (Alvarez and Jason, 1993, Christophersen et al., 1985, Keay et al., 2012, Tessier, 2010, McDonald et al., 2005, Johnston et al., 2000, Geddis and Pettengell, 1982, Swartz et al., 2013); use of electric socket covers (Emond et al., 2002, Clamp and Kendrick, 1998, Minkovitz et al., 2003); safe storage or removal of poisonous substances (Johnston et al., 2000, Shields et al., 2013, McDonald et al., 2005, Watson et al., 2005, Gielen et al., 2002); use of stair gates (McDonald et al., 2005, Watson et al., 2005, Gielen et al., 2002, Clamp and Kendrick, 1998); use of baby walkers (Kendrick et al., 2005); presence of fire guards (Watson et al., 2005, Clamp and Kendrick, 1998) and window locks (Watson et al., 2005); and safe storage of guns (Sangvai et al., 2007).

The quality of the child's home environment was assessed using a range of home safety scoring tools. Six studies – five RCTs and one partially randomised trial (Armstrong et al., 2000, Barlow et al., 2007, Caldera et al., 2007, Kemp et al., 2011, Kitzman et al., 1997, Larson, 1980) assessed home safety using the HOME (Home Observation for Measurement of the Environment) inventory. One RCT (Hendrickson, 2005) used a home hazards list to derive Controllable Safety Hazards (CSH) scores. The study by (Culp et al., 2007) used the Massachusetts Home Safety Questionnaire, while (Dershewitz and Williamson, 1977) used the Household Hazard Scale.

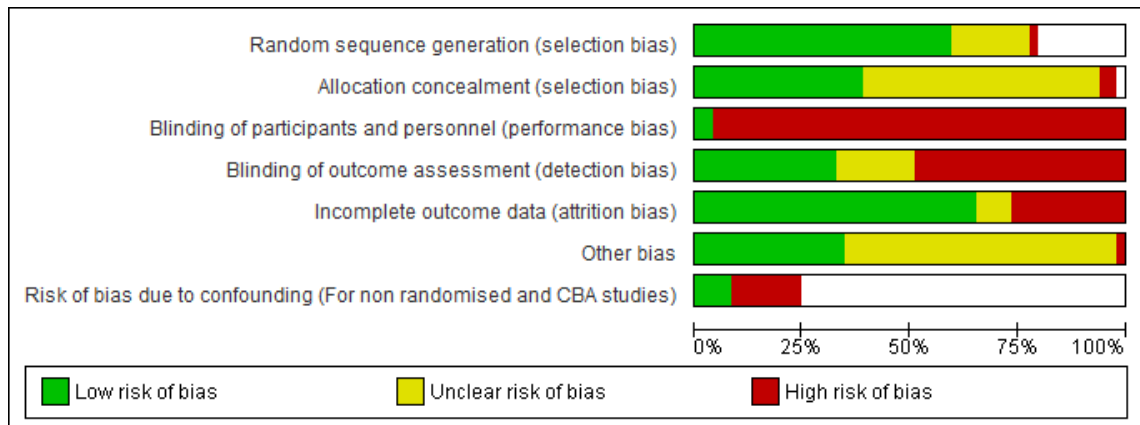


Thirteen studies – 12 RCTs and one non-RCT (Campbell et al., 2011b, Gielen et al., 2007, Shields et al., 2013, Thomas et al., 1984, Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, McDonald et al., 2005, Kelly et al., 1987, Swartz et al., 2013, Guyer et al., 1989, Dershewitz and Williamson, 1977, Kendrick et al., 2005, Feldman et al., 1992) reported levels of parental knowledge on a range of safety topics. These included: lead exposure prevention (Campbell et al., 2011b), fire safety and smoke detectors (Gielen et al., 2007, Shields et al., 2013, Thomas et al., 1984, McDonald et al., 2005), child safety seats (Gielen et al., 2007, Shields et al., 2013, Turcotte et al., 2011, McDonald et al., 2005, Kelly et al., 1987, Swartz et al., 2013), poisoning (Turcotte et al., 2011, Gielen et al., 2007, Shields et al., 2013, McDonald et al., 2005), burns and scalds prevention (Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011, Kelly et al., 1987, Guyer et al., 1989), falls prevention (Turcotte et al., 2011, McDonald et al., 2005, Kelly et al., 1987), baby walkers (Kendrick et al., 2005), household safety and accidents (Guyer et al., 1989, Dershewitz and Williamson, 1977), and water safety (Turcotte et al., 2011, Kelly et al., 1987).

#### **2.8.2.5 Quality assessment of included studies**

The quality of included studies was assessed using the Cochrane Collaboration's 'Risk of bias' tool described in section 2.6.3.2. In assessing the overall risk of bias, three 'key domains' were judged as being the most important domains for this review: random sequence generation; allocation concealment; and incomplete outcome data. These key domains were chosen because in intervention studies comparing more than one group, it is important to prevent systematic differences between these groups. This is achieved by minimising selection bias as well as attrition bias. When considering the hierarchy of evidence, RCTs were graded higher than observational studies. A full summary of the quality assessment process can be seen in Figure 2.4 and Table 2.4. Both diagrammatic representations are colour coded to better emphasise the risk of bias categorisation.

**Figure 2.6: Graph showing judgements on risk of bias of included studies**



Random sequence generation was judged to be adequate in 29 (78%) of the 37 included RCTs. Allocation concealment was adequate in 20 (54%) of the 37 included RCTs. Twenty nine (59%), of the 49 included studies reported loss to follow-up or survey non-response rates of less than 20%. In trials of parenting programmes, it is not normally possible to blind either study personnel or parents to the type of treatment being implemented or received (Barlow and Parsons, 2003). Parents were blinded to the treatment received in only two (4%) of the 49 included studies. In 17 studies (35%), outcome assessors were blinded to treatment allocation. Based on an assessment of the overall risk of bias, 25 (68%) of the 37 included RCTs were judged as being of low risk of bias.

**Table 2.4: Risk of bias table of included studies**

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
Alvarez 1993 (study 2)	Not reported (unclear risk)	Not reported (unclear risk)	Not blinded (High risk)	Observations were done by rater blinded to intervention (Low risk)	Not reported (unclear risk)	Not reported (unclear risk)	N/A
Armstrong 2000	Random number table (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Outcome assessors were blinded to treatment arm allocation (Low risk)	Low attrition rate 12% (Low risk)	Not reported (unclear risk)	N/A
Babul 2007	Random numbers generator (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 17% (Low risk)	Not reported (unclear risk)	N/A
Barlow 2007	Not reported (unclear risk)	Adequate (Low risk)	Not blinded (High risk)	Researchers involved in data collection, coding and analysis were blinded to the intervention (Low risk)	Low attrition rate < 10% (Low risk)	ITT undertaken (low risk)	N/A
Caldera 2007	Random number table (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Baseline and follow-up data were collected by research staff blinded to family group assignment (Low risk)	Low attrition rate < 20% (Low risk)	ITT undertaken (low risk)	N/A

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
Campbell 2011	Computer-generated random numbers (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	High attrition rate > 50% (High risk)	Not reported (unclear risk)	N/A
Carlsson 2011	N/A	Control site selected from city area with similar demographic characteristics (unclear risk)	Not blinded (High risk)	Not clear (unclear risk)	Attrition rate 20% (Low risk)	Not reported (unclear risk)	There was an assessment of distribution of confounders between arms and some differences existed between arms (High risk)
Christopherson 1985	Coin toss (Low risk)	Not reported (unclear risk)	Participants were blinded to study (Low risk)	Not blinded (High risk)	High attrition rate 41% (High risk)	Not reported (unclear risk)	N/A
Clamp 1998	Random number table (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 0% (Low risk)	ITT undertaken (low risk)	N/A
Culp 2007	N/A	Control sites selected from counties with similar risk and demographic characteristics (unclear risk)	Not blinded (High risk)	Not reported (unclear risk)	High attrition 26% however unlikely to affect results as ITT analysis was undertaken (low risk)	ITT undertaken (low risk)	There was an assessment of maternal characteristics at recruitment and the treatment arms appear similar (Low risk)
Dershewitz 1977	Random number table (Low risk)	Inadequate (High risk)	Not blinded (High risk)	home visitor was blinded to treatment allocation (Low risk)	High attrition rate 34% (High risk)	Not reported (unclear risk)	N/A

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
Emond 2002	N/A	Control sites chosen from areas with closely matched socio-demographic characteristics (unclear-risk)	Not blinded (High risk)	Not blinded (High risk)	Attrition rate 24% (High risk)	Not reported (unclear risk)	There was an assessment of distribution of confounders between arms and some differences existed between arms (High risk)
Feldman 1992	Not reported (unclear risk)	Not reported (unclear risk)	Not blinded (High risk)	Both the primary observers and reliability checkers were Not told of the group assignment (Low risk)	Low attrition rate 14% (Low risk)	Not reported (unclear risk)	N/A
Fergusson 1982	N/A	Allocated according to child's birth date (unclear risk)	Not blinded (High risk)	Not reported (unclear risk)	Low attrition rate 2.6% (Low risk)	Not reported (unclear risk)	There was an assessment of eight social and demographic variables between treatment arms and the arms appear similar (Low risk)
Fergusson 2005	Computer-generated random numbers (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate <20% (Low risk)	ITT undertaken (low risk)	N/A
Geddis 1982	N/A	Allocated according to month of delivery (unclear risk)	Not blinded (High risk)	Not reported (unclear risk)	High attrition 24% (High risk)	Not reported (unclear risk)	No assessment was carried out on the distribution of confounders between treatment arms (High risk)

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
Gielen 2002	Random numbers table (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not reported (unclear risk)	High attrition 35% (High risk)	Not reported (unclear risk)	N/A
Gielen 2007	Computer-generated random numbers (Low risk)	Adequate (Low risk)	Not blinded (High risk)	blinded (Low risk)	Low attrition rate <20% (Low risk)	ITT undertaken (Low risk)	N/A
Guyer 1989	N/A	Control sites chosen from areas with closely matched demographic characteristics (unclear-risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 13% (Low risk)	Not reported (unclear risk)	N/A
Hardy 1989	N/A	allocated based on odd/even medical record numbers (Low risk)	Not blinded (High risk)	Not reported (unclear risk)	Low attrition rate 9.3% (Low risk)	Not reported (unclear risk)	There was an assessment of the distribution of confounders between arms. Arms appear similar (Low risk)
Hendrickson 2005	Coin toss by mother (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate < 5% (Low risk)	Not reported (unclear risk)	N/A
Johnson 1993	Random number table (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 11% (Low risk)	Not reported (unclear risk)	N/A
Johnston 2000	N/A	Groups were chosen based on size, geographic proximity, and independence of programme staff. Coin toss to	Not blinded (High risk)	Not reported (unclear risk)	High attrition rate 29%, however unlikely to affect results as ITT analysis undertaken (Low risk)	ITT undertaken (Low risk)	No assessment was carried out on the distribution of confounders between treatment arms (High risk)

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
		determine which group would receive intervention (unclear risk)					
Keay 2012	Not reported (unclear risk)	Adequate (Low risk)	Not blinded (High risk)	Observers were blinded to centre allocation (Low risk)	Low attrition < 10% (Low risk)	ITT undertaken (low risk)	N/A
Kelly 1987	Not reported (unclear risk)	Not reported (unclear risk)	Not blinded (High risk)	Observations were carried out by a community health worker unaware of the randomisation status of the family (Low risk)	Low attrition rate 15.5% (Low risk)	Not reported (unclear risk)	N/A
Kemp 2011	permuted block design (low risk)	Adequate (Low risk)	Not blinded (High risk)	RA collecting outcome data was initially blinded to group allocation however, some participants revealed their group allocation during the process of data collection (High risk)	Attrition rate 26%, however an ITT analysis was undertaken so attrition would not affect outcome (Low risk)	ITT undertaken (low risk)	N/A
Kendrick 1999	Random number table (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 8% (Low risk)	ITT undertaken (low risk)	N/A
Kendrick 2005	computer generated allocation schedule	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 14% (Low risk)	Not reported (unclear risk)	N/A

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
	(Low risk)						
Kendrick 2011	randomisation using Stata (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	High attrition rate > 25%, however an ITT analysis was undertaken so unlikely to affect results (low risk)	ITT undertaken (low risk)	N/A
Kitzman 1997	use of a computer programme (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Interviews were carried out by staff members who were unaware of the women's treatment assignment (Low RISK)	Low attrition rate 6% (Low risk)	ITT undertaken (low risk)	N/A
Larson 1980	Not reported (unclear risk)	Not reported (unclear risk)	Not blinded (High risk)	observers were blinded to group assignment (Low risk)	attrition rate 22% (High risk)	Not reported (unclear risk)	There was an assessment of the distribution of confounders between treatment arms and the arms appear similar (low risk)
Llewellyn 2003	Random number table (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Trained parent assessors were blinded to parent's groups (Low risk)	Attrition rate 29% (High risk)	Not reported (unclear risk)	N/A
McDonald 2005	Computerised automatic randomization	Adequate (Low risk)	Not blinded (High risk)	Not reported (unclear risk)	Low attrition 16% (Low risk)	Not reported (unclear risk)	N/A



First author and year	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete Outcome data (attrition bias)	ITT analysis (other bias)	Risk of bias due to confounding (Non-RCTs, CBAs)
	program (Low risk)						
Minkovitz 2003a	Computer generated assignment (Low risk)	Concealed in sealed envelopes (Low risk)	Not blinded (High risk)	Not blinded (High risk)	High attrition rate 29%, however ITT analysis was undertaken so unlikely to affect results (Low risk)	ITT undertaken (Low risk)	N/A
Minkovitz 2003b	N/A	Does Not describe how sites were chosen (unclear risk)	Not blinded (High risk)	Not reported (unclear risk)	High attrition rate 64%, however ITT analysis undertaken so unlikely to affect results (Low risk)	ITT undertaken (Low risk)	There was an assessment of the distribution of confounders between arms and some differences existed (High risk)
Morrongiello 2013a	Random number table (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 18% (Low risk)	Not reported (unclear risk)	N/A
Nansel 2008	First two groups randomly assigned by computer until 2/3 of the planned number of participants were recruited while all subsequent participants were assigned to the 3rd group (High risk)	Does not describe how sites were chosen (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 13.4% (Low risk)	Not undertaken (High risk)	No assessment was carried out on the distribution of confounders between treatment arms (High risk)
Posner 2004	Computer generated allocation schedule	Adequate (Low risk)	Not blinded (High risk)	Trained study personnel were	High attrition rate 29%, however ITT	ITT undertaken (Low risk)	N/A

<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
	(Low risk)			unaware of group status (Low risk)	analysis undertaken so unlikely to affect results (Low risk)		
Reich 2011	Not reported (unclear risk)	Not reported (unclear risk)	participants were blinded to study (Low risk )	trained researcher blinded to experimental assignment carried out post assessment (Low risk)	Low attrition rate 13% (Low risk)	Not reported (unclear risk)	N/A
Sangvai 2007	Generated by research coordinator in blocks of 4 (Low risk)	Adequate (Low risk)	Not blinded (High risk)	RA blinded to group assignment carried out observations (Low risk)	High attrition rate 92% (High risk)	Not reported (unclear risk)	N/A
Shields 2013	Random number generator program (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	attrition rate 20% (Low risk)	Not reported (unclear risk)	N/A
Swartz 2013	Computer-generated allocation sequence randomisation (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Not blinded (High risk)	Attrition rate 0% (low risk)	ITT analysis undertaken (low risk)	N/A
Sznajder 2003	Not reported (unclear risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 1% (Low risk)	Not reported (unclear risk)	N/A
Tessier 2010	Random numbers (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Low attrition rate 10% (Low risk)	ITT undertaken (low risk)	N/A
Thomas 1984	Coin toss (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Does not report any dropouts (Low risk)	Not reported (unclear risk)	N/A

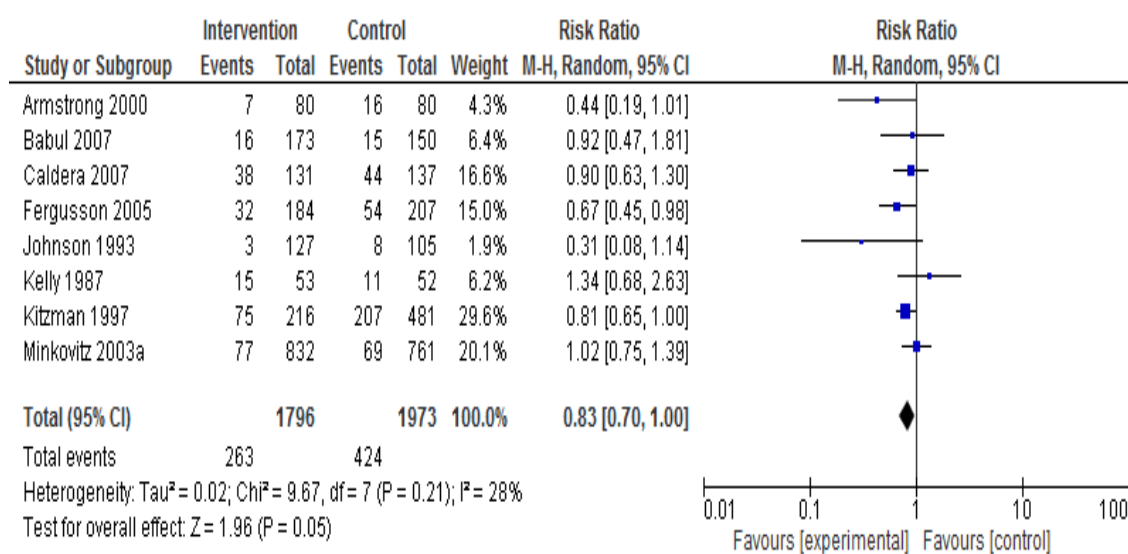
<b>First author and year</b>	<b>Random sequence generation (selection bias)</b>	<b>Allocation concealment (selection bias)</b>	<b>Blinding of participants and personnel (performance bias)</b>	<b>Blinding of outcome assessment (detection bias)</b>	<b>Incomplete Outcome data (attrition bias)</b>	<b>ITT analysis (other bias)</b>	<b>Risk of bias due to confounding (Non-RCTs, CBAs)</b>
Turcotte 2011a	Coin toss (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	High attrition rate 28% (High risk)	Not reported (unclear risk)	N/A
Turcotte 2011b	Coin toss (Low risk)	Not reported (unclear risk)	Not blinded (High risk)	Not blinded (High risk)	Attrition rate 22% (High risk)	Not reported (unclear risk)	N/A
Waller 1993	N/A	Control groups were selected by presence or Not of a 'wetback system' (unclear risk)	Not blinded (High risk)	Researcher carrying out telephone interviews blinded to treatment group allocation (Low risk)	High attrition rate 49% (High risk)	Not reported (unclear risk)	No assessment was carried out on the distribution of confounders between treatment arms (High risk)
Watson 2005	Computer generated allocation schedule (Low risk)	Adequate (Low risk)	Not blinded (High risk)	Outcome assessors were blinded to treatment arm allocation (Low risk)	Low attrition rate 12.6% (Low risk)	ITT undertaken (low risk)	N/A

	Low risk of bias
	Unclear risk of bias
	High risk of bias

### 2.8.3 Self-reported or medically attended injury

Eighteen studies reported self-reported or medically attended injuries - eleven RCTs and seven non-RCTs. Nine studies showed positive benefits of the intervention on participating families – four RCTs (Armstrong et al., 2000, Fergusson et al., 2005, Minkovitz et al., 2003, Kitzman et al., 1997) and five non-RCTs (Larson, 1980, Hardy and Streett, 1989, Emond et al., 2002, Minkovitz et al., 2003, Guyer et al., 1989). Data from eight of the RCTs judged to be of low risk of bias, were suitable for a meta-analysis (Table 2.5). The results showed that families in the intervention group had a statistically significant lower risk of injury when compared to families in the control group (RR 0.83, 95% CI 0.70 to 1.00;  $\text{Chi}^2 = 9.67$ ,  $\text{df} = 7$ ,  $P = 0.21$ ;  $I^2 = 28\%$ ;  $Z = 1.96$ ,  $p = 0.05$ ). There was no evidence of statistical heterogeneity in the analysis as evidenced by  $I^2$  of less than 50%. The three RCTs not eligible for inclusion in the meta-analysis (Kendrick, 1999, Sangvai et al., 2007, Watson et al., 2005) did not provide data in an appropriate format for running a meta-analysis.

**Table 2.5: Meta-analysis of the risk ratio of injury between intervention and control families (RCTs only)**



All eight RCTs included in the meta-analysis evaluated home-visitation programmes – five as a standalone programme (Kitzman et al., 1997,

Armstrong et al., 2000, Caldera et al., 2007, Fergusson et al., 2005, Johnson et al., 1993), and three in combination with either parental education or provision of safety equipment (Babul et al., 2007, Kelly et al., 1987, Minkovitz et al., 2003). Seven of the eight studies eligible for inclusion in the meta-analysis were evaluated using pre- and post-intervention interviewing methods - two studies used questionnaires (Babul et al., 2007, Johnson et al., 1993), three studies used face-to-face verbal interviews (Caldera et al., 2007, Fergusson et al., 2005, Kelly et al., 1987), and two studies were evaluated using telephone interviews (Minkovitz et al., 2003, Kitzman et al., 1997). Three studies assessed children's medical records for injuries (Caldera et al., 2007, Fergusson et al., 2005, Minkovitz et al., 2003).

Seven of the eight studies included in the meta-analysis reported interventions delivered to parents on a one-to-one basis (Armstrong et al., 2000, Babul et al., 2007, Caldera et al., 2007, Fergusson et al., 2005, Johnson et al., 1993, Kelly et al., 1987, Kitzman et al., 1997). The remaining study (Minkovitz et al., 2003) reported a combination of both one-to-one and group-based interventions.

Six of the eight studies included in the meta-analysis evaluated interventions delivered during the early perinatal or postnatal periods – three of which reported findings in favour of the intervention group. Armstrong et al. (2000) found that vulnerable women visited by child health nurses in the immediate postnatal period, were significantly more likely to report fewer childhood injuries (1.3% versus 7.9%,  $p = 0.05$ ) and bruises ( 8.8% versus 20.3%,  $p < 0.05$ ) than women in the control group. The study by Fergusson et al. (2005) also evaluated an early home visitation programme and reported fewer hospital attendances for injuries and poisonings in intervention group families compared to controls (17.5 versus 26.3;  $p < 0.05$ ). Likewise, Kitzman et al. (1997) evaluated the effectiveness of a prenatal and infancy home-visitation intervention on African-American women at less than 29 weeks' gestation, and found that intervention group women had fewer health encounters for children in which injuries or ingestions were detected (0.43 versus 0.55;  $p = 0.05$ ). Johnson et al. (1993)

evaluated the effectiveness of an early home-visitation intervention for first time mothers and found no significant differences in child accidents between study groups. Similar non-significant findings were reported by Babul et al. (2007) for an assessment of an infant home safety programme. Likewise, Minkovitz et al. (2003) evaluated the effectiveness of an early intervention incorporating parental education and health visitation, and found no significant differences between study groups in the percentage of children visiting the ED for injury-related reasons.

Three of the RCTs that reported significant findings in favour of intervention group families (Armstrong et al., 2000, Fergusson et al., 2005, Kitzman et al., 1997), evaluated home-visitation programmes, and were delivered on a one-to-one basis during the perinatal or early postnatal periods. Minkovitz et al. (2003) evaluated an intervention incorporating parental education with home visiting, and was delivered both on a one-to-one and group basis. All four studies were evaluated using interviewing methods – Fergusson et al. (2005) used face-to-face verbal interviews as well as assessment of the children’s medical records for injury. Minkovitz et al. (2003) used telephone interviews. Armstrong et al. (2000) used face-to-face verbal interviews and direct observations during home visits, while Kitzman et al. (1997) was evaluated using face-to-face verbal and telephone interviews, as well as parental reports of injury.

Of the seven non-RCTs reporting self-reported or medically attended injuries, five evaluated home-visitation programmes – three as standalone programmes (Emond et al., 2002, Culp et al., 2007, Larson, 1980), and two in combination with parental education (Hardy and Streett, 1989, Minkovitz et al., 2003). Fergusson et al. (1982) evaluated a parenting intervention incorporating parental education with provision of safety stickers, while Guyer et al (1989) evaluated a community-based parental educational programme. Five showed significant effects in favour of intervention group families (Larson, 1980, Hardy and Streett, 1989, Emond et al., 2002, Minkovitz et al., 2003, Guyer et al., 1989). Larson (1980) evaluated the effectiveness of a prenatal and early perinatal intervention, and found that

children from intervention families had significantly reduced accident rates compared to children from control families (Group A 27% versus Group B 41% versus Group C 63%;  $p < 0.01$ ). Emond et al. (2002) found that first time mothers who took part in a health visitor scheme that included antenatal and early safety education reported significantly fewer childhood accidents in the following 12 months after adjusting for confounders and clustering (OR 0.54, 95% CI 0.33 to 0.88,  $p = 0.022$ ). Guyer et al. (1989) evaluated the effectiveness of a community-based injury prevention programme and found a reduction in motor vehicle occupant injuries among children aged 0-5 years in the intervention compared with control communities (21.54 versus 60.77; OR = 2.78, 95% CI 1.66-4.66). The non-RCT component of Minkovitz et al. (2003) evaluated the effectiveness of an early intervention incorporating parental education and health visitation and found statistically significant differences in the percentage of children using the ED for injury-related reasons at 33 months post intervention (8.8% versus 11.7%,  $p = 0.02$ ). Similarly, Hardy and Streett (1989) evaluating a family support and parenting education intervention, found that intervention group children sustained fewer injuries necessitating ED visits compared to control group children ( $n = 8$  (6.1%) versus  $n = 15$  (11.4%); no  $p$ -values or CIs reported).

In contrast, Culp et al. (2007), evaluating the effectiveness of a home visitation programme for first time mothers recruited prior to the 28<sup>th</sup> week of pregnancy, did not report a significant difference between the intervention and control groups on number of emergency room visits in the succeeding six and 12 months. The study authors stated that this non significance could be as a result of mothers in both study groups using the emergency room as a physician's office for all illnesses. Likewise Fergusson et al. (1982) evaluating a poisoning prevention aid for children, did not find any difference in the rates of poisoning between study groups.

Five of the seven non-RCTs were delivered on a one-to-one basis. The remaining studies, Minkovitz et al. (2003) and Guyer et al. (1989) reported a combination of one-to-one and group-based delivery, and group-based

delivery respectively. A range of methods were used for evaluating the studies. Minkovitz et al. (2003) and Hardy and Streett (1989) were evaluated by telephone interviews and assessing medical records, while Fergusson et al. (1982) was evaluated by verbal interviews and assessing medical records. Larson (1980) was evaluated by direct home observations, while Emond et al. (2002) relied on medical records. Culp et al. (2007) was evaluated using a combination of questionnaires, surveys, and verbal interviews. Guyer et al. (1989) was evaluated using pre- and post-telephone interviews.

#### **2.8.4 Child safety practices**

Twenty nine studies (22 RCTS and 7 non-RCTs) reported on child injury safety practices. Nine of these studies addressed safe hot water temperatures; eleven addressed the presence or use of functional smoke detectors; ten addressed correct child safety seat use; four reported on the use of electric socket covers; seven addressed storage of medicines and other poisons; four reported on the use of stair gates; two reported on the use of fireguards and window locks; while one study reported on baby walkers.

Twenty five of the 29 studies showed positive effects of the interventions. Due to substantial statistical heterogeneity ( $I^2 > 50\%$ ) in the results of the studies reporting child safety practices, it was not possible to conduct a valid meta-analysis. The studies were therefore grouped into the individual child safety practices, and presented using a narrative synthesis approach as can be seen in the sub-sections below.

##### **2.8.4.1 Safe hot water temperature**

Nine studies addressed safe hot water temperatures in the home – seven RCTs and two non-RCTs. Three studies found statistically significant differences between study groups. All three were RCTs. Thomas et al. (1984) evaluated the effectiveness of an intervention incorporating group-based education and home visiting on parental compliance with several



home safety recommendations. The results showed that families receiving the intervention were significantly more likely to have 'safe' hot tap water temperatures (safe water temperature was defined by the study authors as any water temperature  $\leq 54.4^{\circ}\text{C}$ ) when compared to families that did not receive the intervention (76% versus 23%;  $p = 0.0001$ ; no confidence intervals reported). In Babul et al. (2007), parents in both intervention groups (safety kit alone and safety kit plus home visit), were more likely to report safe adjustment of their hot tap water temperature at 12 months post-intervention compared to controls [(safety kit alone: 69.3% versus 53.7%; OR 2.21, 95% CI 1.32 to 3.69) (safety kit plus home visit: 69.9% versus 53.7%; OR 2.6, 95% CI 1.57 to 4.46)]. Kendrick et al. (2011) evaluated the effectiveness of TMVs in reducing bath hot tap water temperatures, and reported significantly lower hot water temperatures in intervention families at both three-month (intervention arm median  $45.0^{\circ}\text{C}$ , control arm median  $56.0^{\circ}\text{C}$ ; difference between medians,  $-11.0$ , 95% CI  $-14.3$  to  $-7.7$ ) and 12-month follow up (intervention arm median  $46.0^{\circ}\text{C}$ , control arm median  $55.0^{\circ}\text{C}$ ; difference between medians,  $-9.0$ , 95% CI  $-11.8$  to  $-6$ ).

Six studies found no statistically significant difference between intervention and control group families. Minkovitz et al. (2003) sought to determine the impact of a universal paediatric practice-based educational and home-visiting intervention on a range of child health outcomes. Results from the both the study's RCT (Minkovitz 2003a) and non-RCT (Minkovitz 2003b) components, found no significant differences in the number of families in either treatment group with safe hot water temperatures post intervention: (intervention group  $n = 519$  (64%) versus control group  $n = 441$  (60%);  $p = 0.11$ ) and (intervention group  $n = 645$  (57%) versus control group  $n = 516$  (56%);  $p = 0.82$ ) respectively. Similarly, Gielen et al. (2002) evaluated the effectiveness of a hospital-based intervention incorporating paediatric safety counselling and home visitation, and found no significant differences in the number of participants with safe hot water temperatures (standard intervention group  $n = 27$  (47%) versus enhanced intervention group  $n = 27$  (47%); no p-value reported). Waller et al. (1993) evaluated the effectiveness of an educational intervention on tap water temperatures in

households with young children but found no significant difference between intervention and comparison households (no statistical analysis reported). Likewise, Sangvai et al. (2007) and Kelly et al. (1987) found no significant differences in the number of households with safe hot water temperatures post intervention.

The effective interventions appeared to be ones incorporating parental education and home visitation with provision of free or discounted safety devices. Thomas et al. (1984) evaluated a practice-based programme incorporating parental education (by way of lectures, pamphlets, and hand-outs), and home-visitation. Babul et al. (2007) evaluated a home visitation programme incorporating provision of safety devices. Parental education was delivered via verbal instruction during home visits. Kendrick et al. (2011) evaluated a home-based programme incorporating parental education (using leaflets) with provision of safety devices. The three studies reporting significant effects in favour of intervention group families, were evaluated using interviewing techniques. Thomas et al. (1984) used face-to-face verbal interviews as well as direct home observations. Babul et al. (2007) was evaluated using questionnaires, while Kendrick et al. (2011) was evaluated using both questionnaires (postal or telephone) and home observations.

#### **2.8.4.2 Use of functional smoke detectors**

Eleven studies (nine RCTs and two non-RCTs) addressed the presence of or use of functional smoke detectors in the home, with four studies (three RCTs and one non-RCT) showing significant positive effects in favour of intervention group families. Watson et al. (2005) evaluated the effectiveness of a GP practice-based intervention incorporating the use of both safety consultation and provision of free safety equipment. The findings from this study showed that at both 12 and 24 months post intervention, families in the intervention group were significantly more likely to own and use functional smoke detectors compared to families in the control group [(12 months: 90.6% versus 84.0%; OR 1.83, 95% CI 1.33-2.52;  $p=0.0002$ ), (24 months: 91.5% versus 86.5%; OR 1.67, 95% CI 1.21-2.32;  $p = 0.0002$ )]. Sangvai et al. (2007), evaluating the effectiveness of an

intervention incorporating safety counselling, free safety equipment (including smoke detectors), and educational hand-outs, found that intervention families were more likely to have a functional smoke detector six months after the intervention compared to control families (94% versus 50%;  $p = 0.015$ ; no confidence intervals reported). Likewise, Clamp and Kendrick (1998) found that families receiving an intervention incorporating GP safety advice and provision of safety equipment, were significantly more likely to use functional smoke detectors, compared to families that did not receive the intervention (99% versus 87%; RR 1.14, 95% CI 1.04 to 1.25). Johnston et al. (2000) was the only non-RCT reporting significant findings. This study found that families receiving home-visitation, educational material and safety equipment, were three times more likely to have a functional smoke detector installed in their homes at three months post intervention, when compared to control families who did not receive any intervention (100% versus 30%; RR 3.3, 95% CI 1.3 to 8.6).

Seven studies found no statistically significant difference between study groups. Thomas et al. (1984) reported no significant difference between study groups on observed smoke detector installation and use six weeks post intervention ( $p < 0.12$ ; no other data reported), however, a significantly higher number of participants in the intervention group reported purchase and installation of smoke detectors following completion of the intervention. Similarly, Shields et al. (2013) did not show any significant difference in smoke detector use between groups (OR 1.17, 95% CI 0.76 to 1.79). Gielen et al. (2002) presented results for an intervention incorporating both paediatric safety counselling and home visitation but found no significant differences between study groups on a number of safety practices including presence of functional smoke detectors (intervention 81% versus control 84%; no statistical analysis reported). Similar results were reported by Kelly et al. (1987), in which intervention and control groups did not differ significantly with regards to the presence of functional smoke detectors (15% vs. 11%; no statistical analysis reported). Likewise, no significant differences in smoke detector use was reported by either

McDonald et al. (2005) or both RCT and non-RCT components of Minkovitz et al. (2003).

The studies demonstrating positive effects were those in which intervention families were provided with free or discounted smoke detectors alongside either safety education or home visitation. The non-effective interventions were either solely educational or in combination with home visitation. The studies by Watson et al. (2005), Sangvai et al. (2007) and Clamp and Kendrick (1998), evaluated practice-based programmes incorporating parental education with provision of smoke detectors. Education was delivered via verbal instruction, educational hand-outs, and leaflets. Johnston et al. (2000) evaluated a home-based parenting programme incorporating parental education, home visiting, and provision of smoke detectors. Parental education was delivered by way of hand-outs. All four effective interventions were delivered on a one-to-one basis and were evaluated using pre- and post-test interview techniques. The studies by Clamp and Kendrick (1998) and Sangvai et al. (2007) utilised pre-test questionnaires at baseline and telephone interviews at follow-up. Watson et al. (2005) was evaluated using postal questionnaires, as well as direct home observations. Johnston et al. (2000) was evaluated using pre- and post-test questionnaires.

#### **2.8.4.3 Use of appropriate car safety seats**

Ten studies addressed the use of appropriate car safety seats, with six (five RCTs and one non-RCT) reporting significant differences in favour of intervention group families. Tessier (2010) evaluated the effectiveness of an educational intervention on parental child safety car use, and found that intervention group parents were four times more likely to demonstrate correct usage of safety seats than control group parents (intervention  $n = 18$  (32%) versus control  $n = 6$  (11%); odds ratio 4.3;  $p = 0.0074$ ). Keay et al. (2012) reported on the impact of an education, distribution, and fitting programme for increasing parental car safety seat use and found that age-appropriate car seats were more commonly observed in children from intervention centres compared to children from control centres (82% versus

73%;  $p = 0.02$ ;  $ICC = 0.034$ ). Swartz et al. (2013) evaluated a multimedia DVD intervention and found significantly higher post-test scores on car seat simulation measures in intervention group parents compared to controls [(0-12 months - 6.11 v 3.26;  $p < 0.001$ ) (13-24 months - 4.64 v 2.99;  $p < 0.001$ )]. Shields et al. (2013) evaluated the impact of a computer kiosk intervention on observed parental child safety practices, and found that at six months post intervention, parents in the intervention group were significantly more likely to report correct child car safety seat use compared to parents in the control group (OR 1.36, 95% CI 1.05 to 1.77;  $p = 0.02$ ). The study by Alvarez and Jason (1993) found that infants of mothers who had participated in an education-loaner programme were more likely to be restrained on the first ride home from clinic compared to infants of mothers who received only the educational intervention (6/7 versus 1/7;  $p < 0.01$ ). However, this effect was not sustained up until the infants' six week follow-up visit. Similarly, Johnston et al. (2000) reported that families taking part in a preschool safety and injury prevention programme were more likely to report usage of age appropriate car safety seats three months after taking part in the programme, compared to control families (22% versus 5%; RR 4.1, 95% CI 1.9 to 8.8). A practice-based study by Kelly et al. (1987) presented no results for car safety seat use but reported that families receiving a safety education intervention were more likely to report not having their children sitting in the front seat while being transported, compared to control group families (67% versus 47%;  $p < 0.05$ ).

Four studies found no statistically significant difference between study groups. McDonald et al. (2005) evaluating the effectiveness of a kiosk-based intervention did not find any statistically significant differences between study arms on car safety seat use (95% versus 98%; no statistical analysis reported). Geddis and Pettengell (1982) reported on the effectiveness of an educational intervention but found no significant difference in the way families in the study groups transported their infants at follow-up. Likewise, the studies by Christopherson et al. (1985) and Sangvai et al. (2007) did not find any significant differences between study groups on the use of appropriate car seats.

The effective interventions appear to be the ones in which intervention group families were provided with free or discounted car safety seats, alongside either parental education or home visitation. Tessier (2010) and Keay et al. (2012) evaluated practice-based programmes incorporating parental education and provision of car safety seats. Parental education was delivered using videos and printed educational material. Alvarez and Jason (1993) evaluated a practice-based programme incorporating parental education (verbal instruction) and provision of car safety seats. All six effective interventions were evaluated using pre- and post-test interview methods. Keay et al. (2012), Kelly et al. (1987), and Johnston et al. (2000), were assessed using face-to-face verbal interviews. Tessier (2010) and Swartz et al. (2013) used pre- and post-test questionnaires, while Shields et al. (2013) was evaluated using a computer questionnaire at baseline and telephone interview at follow up. The study by Alvarez and Jason (1993) was evaluated using both direct observation and telephone interviews.

#### **2.8.4.4 Safe storage of medicines and poisons**

Seven studies addressed the safe storage of medicines and poisons, with four (three RCTs and one non-RCT) showing positive effects in favour of intervention group families. Watson et al. (2005) reported that intervention group families were significantly more likely to be safe in terms of storage of cleaning products 12 months ( $p = 0.006$ ) and 24 months ( $p = 0.008$ ) after receiving an intervention incorporating safety advice and provision of safety equipment. Clamp and Kendrick (1998) reported on a similar intervention, and found that significantly more families in the intervention group used locks on cupboards for storing cleaning materials (RR = 1.38, 95% CI 1.02 to 1.88) and medicines (RR = 1.15, 95% CI 1.03 to 1.28). Sangvai et al. (2007) evaluated an intervention incorporating focused counselling, educational handouts, and access to free safety devices, and found that hazardous substances were not found in the low cabinets of 13 of 16 intervention households compared to 3 of 10 control households ( $p = 0.015$ ). Johnston et al. (2000) evaluated the effectiveness of an injury prevention programme on low income families and found that intervention

families were more likely to report safe storage of poisonous substances (30% vs. 15%; RR 2.1, 95% CI 1.3 to 3.2) compared to control families. Shields et al. (2013) presenting results for both self-reported and observed safety behaviours, found no differences between intervention or control groups on self-reported poison storage (OR 1.12; 95% CI 0.80 to 1.57). No differences were reported on observed poison storage (intervention group 16% versus control group 14%;  $p = 1.0$ ). Similarly, McDonald et al. (2005) and Gielen et al. (2002) found no effect of their interventions on the extent to which parents stored medicines and poisonous substances (intervention group 10% versus control group 7%; no statistical analysis reported) and (intervention arm 10% versus control arm 12%; no statistical analysis reported) respectively.

The effective interventions were delivered on a one-to-one basis and involved provision of safety devices alongside parental education. All the effective interventions were evaluated using pre- and post-test questionnaires.

#### **2.8.4.5 Other child safety practices**

Four studies (all RCTs) reported on the use of stair gates – two showing significant effects in favour of intervention group families. Clamp and Kendrick (1998) assessed the effectiveness of an intervention incorporating GP safety advice and provision of low cost safety equipment to low income families, and found that intervention group families were significantly more likely to use stair gates than control group families six weeks post intervention (62% versus 51%; RR 1.26, 95% CI 0.95 to 1.67). Similar results were reported by Watson et al. (2005) for an intervention incorporating safety consultation and provision of free safety equipment. Families in the intervention group were significantly more likely to have fitted and used stair gates at 12 months follow up compared to controls (intervention  $n = 408$  (55%) versus control  $n = 328$  (45.7%) OR 1.46, 95% CI (1.19 to 1.80); ( $p = 0.0004$ ). Both of these effective interventions were delivered on a one-to-one basis; incorporated parental education with

provision of free or discounted stair gates; and where evaluated using questionnaires.

Four studies (two RCTs and two non-RCTs) reported on the use of electric socket covers. Both of the RCTs (Clamp and Kendrick 1998 and the RCT component of Minkovitz et al. 2003) and one non-RCT (Emond et al. 2002), showed significant effects favouring intervention group families. The non-RCT component of Minkovitz et al. (2003) showed no statistically significant difference between study groups. Clamp and Kendrick (1998) found that low income families receiving GP safety advice and low cost safety equipment, were significantly more likely to use electric socket covers six weeks post intervention (intervention group 92% versus control group 72%; RR 1.27, 95% CI 1.10 to 1.48). The RCT component of Minkovitz et al. (2003) reported that families receiving parental education and home visitation, were more likely to use electric socket covers 33 months post intervention compared to control group families (intervention group 92% versus control group 89%;  $p = 0.04$ ). Similarly, Emond et al. (2002) found that first time mothers who took part in a health visitor scheme were more likely to use electric socket covers 24 months after the intervention was delivered (OR 1.92, 95% CI 1.16 to 3.17;  $p = 0.019$ ). No significant differences in electric socket cover use was reported in the non-RCT component of Minkovitz et al. (2003) - (intervention group 91% versus control group 90%;  $p = 0.46$ ). The effective interventions were delivered to participants on a one-to-one basis (Minkovitz et al. 2003 used a combination of one-to-one and group based methods); and were evaluated using questionnaires (Clamp and Kendrick 1998), telephone interviews (Minkovitz et al. 2003), and verbal interviews (Emond et al. 2002).

Two studies reported on the use of fire guards and window locks. Both studies were RCTs and reported interventions incorporating parental safety education and provision of free or discounted safety equipment. Clamp and Kendrick (1998) found that intervention group families were significantly more likely to use fire guards (55.4% versus 32%; RR 1.89, 95% CI 1.18 to 2.94) and window locks (96.4% versus 87.8%; RR 1.10



(1.00 to 1.20) six weeks post intervention. Similar results were reported by Watson et al. (2005) after 12 months: fireguard (54.3% versus 50.9%; OR 1.14, 95% CI 0.93 to 1.40; no p-value stated); window locks (71.7% versus 66.5%; OR 1.28, 95% CI 1.02 to 1.59;  $p = 0.03$ ). Both interventions were delivered to parents on a one-to-one basis and were evaluated using questionnaires.

One study reported on the use of baby walkers. Kendrick et al. (2005) undertook a cluster RCT evaluating the effectiveness of an educational intervention aimed at reducing baby walker possession and use. The findings from this study showed that intervention group participants were significantly less likely to own (OR 0.63, 95% CI 0.43 to 0.93) or to use a baby walker (OR 0.26, 95% CI 0.08 to 0.84). Participants that received the intervention were also significantly less likely to plan to use a walker with their next child (OR 0.52, 95% CI 0.31 to 0.86) or to agree that walkers keep children safe (OR 0.35, 95% CI 0.16 to 0.78). The intervention was delivered to participants on a one-to-one basis during the prenatal period (participants were mothers-to-be of at least 28 weeks gestation), and was evaluated using self-completion questionnaires.

Carlsson et al (2011) conducted a quasi-experimental intervention study to investigate the effect of individual-based education on mothers' burn and scald prevention practices. The findings from the study showed that mothers in the intervention group had significantly improved their preventative activity including: used a cooker with child protection fitted ( $p < 0.001$ ), taken action to properly anchor cooker ( $p < 0.02$ ), removed possibilities for a child to climb into sink or cooker ( $p < 0.001$ ), and secured electric cords to iron and water heating appliances ( $p < 0.001$ ). The intervention incorporated parental education with home visiting, was delivered on a one-to-one basis, and evaluated using pre- and post-test questionnaires.

Morrongiello et al. (2013) evaluated the impact of a home safety programme on parent supervision and found that intervention group parents

showed a significant decrease in time that children were unsupervised  $F(1,83) = 4.81, p < 0.05$ , an increase in in-view supervision  $F(1, 181) = 4.44, p < 0.05$ , and an increase in level of supervision when children were out of view  $t(166) = 2.99, p < 0.01$ . The intervention was solely educational, was delivered to parents on a one-to-one basis, and was evaluated using pre- and post-intervention video recordings.

Llewellyn et al (2003) evaluated a home-based intervention targeted at parents with intellectual disability. The intervention improved parents' ability to recognize home dangers, to identify precautions to deal with these dangers and resulted in a significant increase in the number of safety precautions parents implemented in their homes with all gains being maintained at three months post-intervention. These improvements included: (1) A significantly greater number of home dangers identified by parents in home illustrations compared with Visits Only and Current Services Only ( $F = 37:27, p < 0.001$ ) and Lesson Booklets Only ( $F = 17:92, p < 0.001$ ). (2) A significant increase in the number of precautions identified by parents to deal with the dangers depicted in the home illustrations compared with Visits Only and Current Services Only ( $F = 41:29, p < 0.001$ ) and Lesson Booklets Only ( $F = 23:95, p < 0.001$ ). (3) A significantly greater number of home precautions implemented by parents compared with Lesson Booklets Only ( $F = 27:09, p < 0.001$ ). The intervention consisted of solely parental education, was delivered on a one-to-one basis, and was evaluated using face-to-face verbal interviews.

Nansel et al. (2008) evaluated the efficacy of tailored information on adoption of safety practices. Parents receiving the intervention were more likely to report adopting a new injury prevention behaviour than those receiving generic information (49 and 45%, respectively, compared with 32%; odds ratio = 2.0 and 1.9, respectively). This educational intervention was delivered on a one-to-one basis, and was evaluated using pre- and post-test questionnaires.

Posner et al. (2004) assessed the effectiveness of an ED-based home safety intervention on caregivers' behaviours and practices. Findings from this study showed that the intervention group demonstrated a significantly higher average overall safety score at follow-up than the control group (73.3% +/- 8.4% versus 66.8% +/- 11.1) and significant improvements in poison, cut/piercing, and burns category scores. Caregivers in the intervention group also demonstrated greater improvement in reported use of the distributed safety devices. The intervention consisted of parental education and provision of safety devices, was delivered on a one-to-one basis, and was evaluated using questionnaires.

Reich et al. (2011) assessed the effectiveness of educational baby books on mothers' safety practices. The results showed that mothers in the educational book group had fewer risks in their homes and exercised more safety practices than the no-book group (- 20% risk reduction; effect size = - 0.30,  $p < 0.01$ ). The intervention consisted of parental education with some home visitation, was delivered on a one-to-one basis, and evaluated using face-to-face verbal interviews.

Sznajder et al (2003) conducted an RCT to assess if home delivery of counselling and provision of safety devices to prevent child injuries could help parents adopt safe behaviours. The intervention was delivered to parents on a one-to-one basis and was evaluated using pre- and post-test questionnaires. The results showed that safety improvement was significantly higher in the intervention group: risk of fall ( $p < 0.02$ ), fire and burns ( $p < 0.001$ ), poisoning ( $p < 0.01$ ), and suffocation ( $p < 0.001$ ). The relative risk of safety improvement between groups was 1.56 (95% CI 1.35 to 1.80).

### **2.8.5 Quality of the home environment**

The quality of the child's home environment was assessed using a number of home safety scoring instruments. Six studies assessed home safety using the HOME (Home Observation for Measurement of the Environment) inventory; one study used a home hazards list to derive

Controllable Safety Hazards (CHS) scores; one study used the Massachusetts Home Safety Questionnaire; and one study used a Household Hazard Scale.

### **2.8.5.1 HOME inventory**

The HOME inventory is designed to be a measure of the quality and quantity of stimulation and support available to a child in the home environment (Caldwell and Bradley, 1984). The infant/toddler HOME inventory is composed of 45 items contained in six subscales, one of which measures the organisation of the child's environment. Higher total HOME scores indicate a more enriched home environment. No cut-off points are specified in the manual but scores falling in the lowest fourth of the score range indicate a home environment that may pose a risk to the child's development (Totsika and Sylva, 2004).

Of the six studies reporting HOME scores, five were RCTs and the remaining study (Larson 1980) was a partially RCT. Three studies found statistically significant differences between study groups. Armstrong et al. (2000) found that at four months, intervention group mothers had better scores on all subscales of the HOME inventory as well as total HOME scores. This study also reported positive results for the organisation of the environment subscale [intervention 5.70 (SD 0.77) vs. control 5.11 (SD 1.16);  $p < 0.05$ ]. Kitzman et al. (1997) found that at two years postpartum, the homes of nurse-visited women were rated as more conducive to children's development by means of the HOME scale (intervention group 32.3 vs. control group 30.9; mean difference -1.3, 95% CI -2.2 to -0.4,  $p = 0.003$ ). Larson (1980) evaluated the efficacy of home visits on the health and development of infants of working class families, and reported statistically significant total HOME scores favouring the intervention group (A) at different time points: six weeks (Group A 29.3, Group B 25.8, Group C 26.7;  $p < 0.001$ ); 12 months (Group A 40.1, Group B 37.8, Group C 37.8;  $p < 0.017$ ); 18 months (Group A 41.2, Group B 38.6, Group C 39.0;  $p < 0.041$ ). All three effective studies evaluated home-visitation interventions and were delivered on a one-to-one basis to study participants.

It was not possible to undertake a meta-analysis of total HOME scores or any of the subscales due to differences in statistical parameters presented.

#### **2.8.5.2 Controllable Safety Hazards score**

One RCT - Hendrickson (2005), assessed the quality of the child's environment by measuring observed in-home hazards using CHS scores. Intervention group mothers received counselling, assessment of maternal safety practices, and provision of safety items. The CHS tool was piloted and validated prior to its implementation in the study (Cronbach's alpha > 0.70). A statistically significant difference was found in CHS between study groups: ( $F(1, 77) = 99.6, p < 0.001$ ). Intervention group mothers were also found to demonstrate improved self-efficacy for home safety behaviours, and had significantly fewer observed hazards when compared to controls ( $F(2, 77) = 7.50, p = 0.01$ ). The intervention was delivered on a one-to-one basis to study participants.

#### **2.8.5.3 Massachusetts Home Safety Questionnaire**

One non-RCT - Culp et al. (2007), measured home safety using the Massachusetts Home Safety Questionnaire and found that participants taking part in a home-visitation programme had significantly 'safer homes' – (intervention group  $M = 38.1, SD = 2.4$ ; control group  $M = 26.9, SD = 2.6$ ;  $p$  value = 0.0001) at 12 months, when compared to controls. The intervention was delivered on a one-to-one basis to first-time mothers prior to the 28<sup>th</sup> week of pregnancy.

#### **2.8.5.4 Household Hazard Scale**

One RCT - Dershewitz and Williamson (1977), assessed observed home hazards using the Household Hazard Scale. This instrument measures the degree of exposure to a specified hazard, and the degree of potential injury severity. The study found no statistically significant difference in total hazard scores between study groups (intervention group 53.20 vs. control group 52.99; no  $p$ -value reported).

### 2.8.6 Safety knowledge

Fourteen studies reported parental child safety knowledge outcomes, with ten studies (all RCTs) showing effects favouring intervention group families. Gielen et al. (2007) evaluated the effectiveness of an ED-based computer kiosk intervention on parental child safety seat, smoke detector, and poison storage knowledge. The results showed that at follow-up, parents receiving the intervention had significantly higher smoke detector (82.5 +/- 23.6 vs. 77.6 +/- 23.9;  $p = 0.005$ ), poison storage (81.2 +/- 21.6 vs. 70.7 +/- 23.4;  $p = 0.001$ ), and total safety knowledge scores (72.6 +/- 13.9 vs. 66.4 +/- 14.8;  $p = 0.001$ ) than parents who did not receive the intervention. Similarly, Shields et al. (2013) evaluating the impact of a computer kiosk intervention, reported statistically significant differences between study groups on smoke alarm (intervention 82.0%, SD 22.5 vs. control 77.8%, SD 22.6;  $p = 0.01$ ), poison storage (intervention 82.6%, SD 22.4 vs. control 77.96%, SD 21.9;  $p = 0.001$ ), as well as total knowledge scores (intervention 73.08%, SD 13.6 vs. control 69.41%, SD 14.08;  $p = 0.001$ ). Another kiosk-based intervention by McDonald et al. (2005) found that intervention group parents were more knowledgeable on child car seat safety than control group parents (95% vs. 84%;  $p = 0.05$ ). These findings seem to suggest that practice-based tailored interventions delivered by way of computer kiosks can be effective at improving parental knowledge of various child safety outcomes. All three computer kiosk interventions were also associated with improved child safety practices. Thomas et al. (1984) found that families receiving an educational burns prevention intervention had significantly higher fire safety knowledge scores than control families (mean intervention group score 20.28 +/- 0.75 versus mean control group score 18.58 +/- 1.70;  $p = 0.0001$ ). Intervention group families were significantly more compliant with recommendations made during the intervention and reported safer tap hot water temperatures than control group families. Turcotte and Babul-Wellar (2011) evaluated the effectiveness of an educational video on parental knowledge of burns prevention in the home. The results showed that parents in the intervention group had significantly higher knowledge scores (79.3% versus 64.0%;  $p <$

0.001) than parents in the control group. Likewise, Swartz et al. (2013) found that families receiving a multimedia DVD intervention had significantly higher post-test child safety seat knowledge scores (7.48 versus 4.81;  $F = 103.71$ ;  $p < 0.001$ ) than control group families. Intervention families also scored higher on child safety seat simulation recognition [(0-12 month old child: 6.11 versus 3.26;  $F = 112.90$ ;  $p < 0.001$ ); (13-24 month old child: 4.64 versus 2.99;  $F = 25.65$ ;  $p < 0.001$ )]. Kelly et al. (1987) showed that parents enrolled on a developmentally oriented course in child safety (intervention) were more knowledgeable about household hazards than parents who were not enrolled on the course (controls) [mean score: 9.4 vs. 8.4;  $p < 0.05$ ]. Families receiving the intervention were also reported as having significantly less observable hazards at a subsequent home visit ( $p < 0.02$ ). These results seem to suggest that improving parental child safety knowledge could lead to behaviour change and improvements in child safety practices. Feldman et al (1992) reported that low IQ parents receiving a home-based parent training programme scored significantly higher than the control group at post-test on a number of child-care skills. The mean pre/post scores of the training group were 62.5% and 88.1%; the mean pre/post scores of the control group were 65.2% and 60.6% (all  $ps < 0.001$ ). Kendrick et al. (1999) found that families receiving a package of safety advice, home safety checks, and low cost safety equipment, were more confident in dealing with choking incidents than the control group (15.1% (55/364) not very confident versus 24.7% (91/368) respectively,  $X^2 = 10.86$ , 2 df,  $P = 0.004$ ) and were more likely to know the correct action for bleach ingestion (59.3% (216/364) versus 48.9% (180/368),  $X^2 = 7.75$ , 1 df,  $P = 0.005$ ). Similarly, Kendrick et al. (2005) found that families receiving an educational package aimed at discouraging parents from using baby walkers, were more likely to answer at least one knowledge question correctly when compared to controls (42.7% versus 32.7%; OR 1.47 (1.12-1.93);  $p = 0.006$ ).

Of the ten studies reporting effective interventions, eight were delivered on a one-to-one basis to study participants (Feldman et al., 1992, Gielen et al., 2007, Shields et al., 2013, McDonald et al., 2005, Kendrick,

1999, Kendrick et al., 2005, Swartz et al., 2013, Kelly et al., 1987). The remaining two studies were delivered on a group basis (Thomas et al., 1984, Turcotte and Babul-Wellar, 2011). All ten effective studies evaluated educational interventions – six solely (Feldman et al., 1992, Turcotte and Babul-Wellar, 2011, Gielen et al., 2007, Kendrick et al., 2005, Swartz et al., 2013, McDonald et al., 2005); three in combination with home visitation (Shields et al., 2013, Thomas et al., 1984, Kelly et al., 1987); and one in combination with free or discounted safety equipment and home safety checks (Kendrick, 1999). Seven of the ten effective studies were conducted in a clinical setting (paediatric practice, GP practice, ED) (Gielen et al., 2007, Shields et al., 2013, Thomas et al., 1984, McDonald et al., 2005, Kelly et al., 1987, Kendrick, 1999, Kendrick et al., 2005); two in community centres (Turcotte and Babul-Wellar, 2011, Swartz et al., 2013); and one at home (Feldman et al., 1992). All ten effective studies were evaluated using pre- and post-test interviewing methods: four studies used pre- and post-test questionnaires (Turcotte and Babul-Wellar, 2011, Kendrick, 1999, Kendrick et al., 2005, Swartz et al., 2013); three studies used pre-test questionnaires and follow-up telephone interviews (Shields et al., 2013, Gielen et al., 2007, McDonald et al., 2005); two studies used face-to-face verbal interviews (Thomas et al., 1984, Kelly et al., 1987), and one study was evaluated by direct observation (Feldman et al., 1992).

## **2.9 DISCUSSION AND CONCLUSION**

This systematic review sought to test the hypothesis that targeting preventative efforts at parents of pre-school children can prevent unintentional injuries or improve child safety knowledge and safety practices. The results of this review suggests that parenting interventions are effective at reducing the likelihood of unintentional injury in pre-school children, promoting the adoption of child safety behaviours in the home, and improving parental knowledge of various household hazards and child safety measures. Thirty seven of the 49 included studies showed positive benefit of parenting interventions on participating families (see Table 2.3).



This review also demonstrates the importance of an intervention's design, mode of delivery, and method of evaluation.

### **2.9.1 Summary of findings**

This systematic review concluded from the eight high quality RCTs included in the meta-analysis, that there was a positive impact of parenting interventions on overall self-reported or medically attended injuries in children younger than five years of age. This finding was robust in the sense that all of the RCTs included in the meta-analysis were judged as having an overall low risk of bias. Home visitation interventions delivered on a one-to-one basis, were generally effective at reducing the likelihood of self-reported or medically attended injury in children younger than five years of age. Thirteen of the 18 studies reporting injury outcomes had home visiting as a component of their interventions. Of this number, six showed positive benefits of the intervention on participating families. Seventeen studies were delivered on a one-to-one basis to participants – six were effective. This finding is consistent with a previous systematic review (Kendrick et al., 2013) which found parenting interventions, most commonly provided on a one-to-one basis in the home as part of a multi-faceted intervention to improve a range of child outcomes, effective in reducing self-reported or medically attended injury in children. In addition, this systematic review found that early interventions delivered to families at the perinatal or immediate postnatal period were effective at reducing the likelihood of injuries in young children. Four of the eight studies reporting interventions delivered during this period, showed positive benefits of the interventions on participating families. The perinatal period offers an ideal opportunity for educating would-be parents on matters relating to their baby before he is born. They may not have the opportunity for learning once the child is born due to the pressures of childcare. In addition, parents are reported to be more receptive to educational messages during this early period (Benjes et al., 2004). The effective studies were evaluated by assessing medical records for injuries (three studies), pre- and post-intervention telephone

interviews (three studies), face-to-face verbal interviews (two studies), and by direct home observation (one study).

Twenty four of the 29 studies reporting child safety practices showed positive effects of the interventions on participating families. The majority of studies reporting effective parenting interventions (22 of the 24) had an educational component and were delivered on a one-to-one basis to study participants. Nine of the effective studies incorporated parental education with free safety equipment, while seven incorporated education with home visitation. Pre- and post-intervention questionnaires were the most frequently used methods of evaluation reported in effective studies. The majority of effective studies were conducted in clinical settings, primarily paediatric and GP practices. In assessing the quality of a child's home environment, five studies showed effects favouring families that received parenting interventions. All five studies evaluated home-visitation programmes and were delivered on a one-to-one basis to study participants. Evaluation methods varied among the effective studies – two studies used face-to-face verbal interviews, while one study each used direct home observation, questionnaires, and telephone interviews.

These findings seem to suggest that parenting interventions with educational, home-visitation, and provision of safety equipment components can be effective at promoting the adoption of child safety behaviour and safety in the home. Due to substantial statistical heterogeneity, as well as variability of the measuring scales and differences in statistical parameters presented, it was not possible to undertake a valid meta-analysis to assess the effectiveness of parenting interventions on child safety practices or the quality of the home environment. This could have implications on the use of the quality of a child's home environment as an outcome measure for an RCT evaluating the effectiveness of parenting interventions in preventing unintentional injury. For instance, in this review, four of the six studies reporting HOME scores presented results as total HOME scores. Only two studies, Kemp et al. (2011) and Armstrong et al. (2000), presented the HOME subscale measuring the organisation of the child's environment.

Measuring this subscale solely would provide a more accurate assessment of the child's environment than would total HOME scores, which would include other subscales unrelated to child safety.

Ten of the fourteen studies reporting parental child safety knowledge showed positive effects of the interventions on participating families. All ten effective studies evaluated parenting interventions that contained an educational component. Eight of the ten were delivered to participants on a one-to-one basis. The majority (seven) were practice-based. The most frequently reported method of study evaluation was by pre- and post-test questionnaire (seven studies). Three of these studies had the post-test questionnaire delivered over the telephone. Three of the effective studies specifically evaluated practice-based tailored interventions delivered by way of computer kiosks. All ten effective studies reported improved parental safety knowledge, as well as improved child safety practices in intervention group families, suggesting a possible association between parental knowledge acquisition and improved safety practices.

### **2.9.2 Comparison with the literature**

The results of this review suggest that parenting interventions are capable of reducing the likelihood of unintentional injury in pre-school children, and improving parental child safety knowledge and practices. These findings are in keeping with an earlier systematic review Kendrick et al. (2013), evaluating the effectiveness of parenting interventions for children aged 0 – 18 years. Both reviews were able to demonstrate the positive impact that parenting interventions have on reducing unintentional child injuries. Despite the fact that both systematic reviews had similar themes, this current review was able to demonstrate some novel findings. These include:

1. The importance and effectiveness of early interventions (delivered to families at the perinatal or immediate postnatal periods) at reducing the likelihood of injuries in pre-school children. The review by Kendrick et al.

(2013) did not investigate the impact the timing of parenting interventions could have on their study outcomes.

2. The importance of assessing parental knowledge improvement as an outcome measure when evaluating parenting interventions. The findings from this review suggest an association between parental knowledge acquisition and improved child safety practices. This outcome measure was not sought in the Kendrick review, which sought reports of unintentional injury, possession and use of safety equipment, and safety practices. Furthermore, as a consequence of assessing knowledge as an outcome measure, this current review was able to demonstrate the effectiveness of parenting interventions with an educational component at improving parental child safety knowledge.

3. This review was able to determine what methods and forms of programme evaluation are effective when evaluating parenting interventions. The majority of studies reporting positive effects in this review were evaluated using pre- and post-test questionnaires. This information is important in the sense that it informs the design and development of similar interventions as those reported in the review.

Both reviews had slightly different outcomes and addressed children of different ages, however, there was an overlap of ten studies included in both reviews.

This current review also demonstrates the beneficial effect of home visiting on the occurrence of child injury, in keeping with findings by (Roberts et al., 1996). Likewise, a systematic review (Dowswell et al., 1996), evaluating the most effective forms of health promotion interventions to reduce unintentional injuries in children aged 0 – 14 years, found that interventions which provided parental education on household hazards and provision of safety devices were effective at reducing childhood unintentional injury.

### **2.9.3 Strengths and limitations**

This systematic review has the strength that it was conducted and reported in compliance with PRISMA guidelines (Moher et al., 2010), and adhered to key stages of a systematic review recommended in the Cochrane Handbook for Systematic Reviews (Higgins Julian and Green, 2011). The author of this PhD thesis used a thorough search strategy incorporating electronic database searches, searching of other relevant resources, and key author consultation. This search method enhanced the chances of identifying all relevant studies to be included in the review. Quality assessment of included studies was conducted using the Cochrane Collaboration's tool for assessing risk of bias. This tool is supported by empirical evidence and has the advantage of covering potential biases such as allocation concealment (Higgins Julian and Green, 2011).

This systematic review has some limitations. Due to time and resource constraints it was not possible to have more than one reviewer extract data and critically appraise all of the included studies. To enhance the validity of the data extraction and critical appraisal process, 20% of the studies were selected at random and a second review was undertaken independently by a reviewer with expertise in critical appraisal methodology. This review may be limited by publication bias, however, all data and findings were reported and stringent efforts were undertaken to search other sources of information, including websites of injury prevention organisations. This review was also limited to articles published in English. It is possible that non-English language papers meeting the inclusion criteria will have been excluded. However, non-English language papers with English versions were included.

This review included observational studies which were subject to bias. To improve the validity of results, the only studies included in the meta-analysis were RCTs judged as being of low risk of bias using the Cochrane recommended Risk of Bias tool (Higgins Julian and Green, 2011). This review involved parents of young children from diverse

neighbourhoods and socioeconomic backgrounds, and over a wide time period. Most of the included studies were based on families from low income backgrounds. This is justifiable as there is a strong relationship between childhood unintentional injury and social deprivation. However, caution should be exercised before findings are generalised to other socioeconomic groups. Only two studies: Dershewitz and Williamson (1977) and Christopherson et al. (1985), involved families from middle to upper-middle income backgrounds. In addition, some studies were directed at families from specific ethnic groups. The studies by Kitzman et al. (1997) and Hardy and Streett (1989) were directed at African-American women; Alvarez and Jason (1993) and Hendrickson (2005) were directed at Hispanic mothers; while Larson (1980) was directed at French-Canadian or English-Canadian women. This, once again, limits the generalizability of the findings. A number of included studies relied on parental reports of child injuries. This could lead to validity problems as parents may underreport the frequency of injuries. All of the included studies were conducted in high income countries and therefore caution should also be exercised before findings are generalised to lower income countries.

Some studies did not provide enough information (in some cases, suitable data) that could be used for analysis. In all cases, an attempt was made to contact the study authors for missing information, but not all responded. In addition, the intensity and duration of interventions and follow-up in the included studies, varied substantially. Some studies had intervention and follow-up periods as short as 4 months while others ran for up to 36 months. This variability in intervention duration could influence the outcome assessment.

#### **2.9.4 Implications for policy, practice and research in this area**

Home visitation interventions delivered on a one-to-one basis during the perinatal or early postnatal period, are effective at reducing the likelihood of unintentional injury in pre-school children. Parenting interventions with an educational component delivered on a one-to-one

basis are effective at improving parental child safety knowledge and practices. The evidence in support of parenting interventions in relation to unintentional injury prevention in pre-school children is of high quality, however, further research is required to explore this finding in various social, cultural, and socioeconomic contexts. This finding adds to the evidence base around childhood injury prevention and could assist researchers and policy makers in the design of future research in this area. The educational component of parenting interventions was found to be delivered by verbal instruction, print material, or by the use of audio-visual tools. Further research is required to determine the best medium for parental education. Similarly, further research is needed to evaluate what components of a parenting intervention incorporating parental education, home visiting and provision of safety devices, actually work. Additional work is also needed to determine the cost-effectiveness of these interventions. Finally, there is a lack of research to date focusing on a reduction in burn injuries in pre-school children or an improvement in parental burn safety practices. Research targeting childhood burn injuries to date have been addressing burns in combination with other accidents. Considering the mortality and morbidity associated with childhood burns, more research needs to be carried out specifically addressing burns prevention. The *Toddler-Safe* study aims to address this gap in evidence.

### **2.9.5 Informing *Toddler-Safe* design and methodology**

This systematic review was undertaken in order to inform the *Toddler-Safe* methodology, as well as to add to the evidence base around childhood injury prevention. The results of this review provide the necessary evidence required to inform the design and methodology of the *Toddler-Safe* study. The key aspects of *Toddler-Safe* for which the results of this systematic review have helped inform include: 1. The type of intervention; 2. The mode of delivery; 3. The timing of the intervention; 4. The choice of outcome measure; 5. The evaluation techniques; and 6. The study setting

1. Type of intervention: The results of this systematic review showed that interventions targeting parents of pre-school children can be effective at reducing the likelihood of unintentional injury, as well as improving parental child safety knowledge and practices. Home visitation interventions were shown to be effective at reducing the likelihood of unintentional injury in pre-school children, while interventions with an educational component (either in combination with provision of safety devices or home visiting) were shown to be effective at improving parental child safety knowledge and practices. The *Toddler-Safe* intervention will be tailored for and targeted at parents and all primary carers of pre-school children. Home visitation and provision of safety devices are heavily reliant on educational instruction, therefore the *Toddler-Safe* intervention will be focused on parental education.
2. Mode of delivery: This review demonstrated the effectiveness of parenting interventions delivered on a one-to-one basis, as opposed to a group or community basis. The *Toddler-Safe* intervention will therefore be delivered to individual participants by the researcher.
3. Timing of the intervention: Early parenting interventions delivered during the perinatal or immediate postnatal periods, were shown to be effective at reducing the occurrence of childhood injury. The Toddler-Safe study will target parents and carers who are currently pregnant or have recently just had their babies. Settings that offer the best opportunity to come in contact with this desired population will be explored and used for study recruitment.
4. Outcome measure: This review assessed studies reporting self-reported or medically attended injuries, child safety knowledge, and practices. All three outcomes are valid for evaluating a parenting intervention and as such, will be sought after in the *Toddler-Safe* study.
5. Evaluation technique: Most of the effective parenting interventions in this review were evaluated using pre- and post-test interviewing methods. Pre-test interviews were conducted using questionnaires, while post-test interviews were conducted either over the telephone



or with the aid of a follow-up questionnaire. Injury outcomes were measured by assessment of medical records. The *Toddler-Safe* study will be evaluated using a self-completion questionnaire. This questionnaire will be validated and piloted to ensure it is fit for purpose and measures what it is supposed to measure. The ED records of participants' children will be assessed for injuries during the study follow-up period.

6. Study setting: Hospital practice-based interventions, in particular those conducted in paediatric practices and, were shown to be effective at improving parental safety knowledge and behaviour. Based on these findings, various child-related sites within a large tertiary hospital will be explored and used for study recruitment.

## **2.10 SUMMARY OF CHAPTER TWO**

- This systematic review sought to establish whether parenting interventions are effective at preventing unintentional injuries in pre-school children and improving parental child safety knowledge and practices. Outcome measures sought included self-reported or medically attended injuries, and child safety knowledge and practices
- Studies eligible for inclusion into this review engaged parents of children younger than five years of age; addressed childhood unintentional injury; included a comparator; reported either child safety practices, safety knowledge, or self-reported or medically attended unintentional injuries; and were written in English
- Data extraction and quality assessment of included studies were conducted using pre-defined electronic forms. Quality assessment was undertaken using the Cochrane recommended 'risk of bias' approach

- From searches of electronic databases and other sources, 49 studies were found to be relevant to the review. Thirty seven studies were RCTs, two were partially RCTs, and 10 were non-RCTs
- A meta-analysis incorporating eight high quality RCTs found that pre-school children from families who had received parenting interventions, had fewer self-reported or medically attended injuries than control children
- Home visitation interventions, delivered on a one-to-one basis during the perinatal or immediate postnatal periods, were effective at reducing the likelihood of unintentional injury in pre-school children. Parenting interventions with an educational component were effective at improving parental child safety knowledge and practices. Effective interventions were evaluated using pre- and post-test questionnaires
- Further research is required focusing specifically on burn injury reduction in pre-school children and improvement of parental burn safety knowledge and practices.

## CHAPTER THREE

## CHAPTER THREE: DEVELOPMENT AND TESTING OF THE *TODDLER-SAFE* INTERVENTION

### 3.1 INTRODUCTION

This chapter describes the steps taken to develop the *Toddler-Safe* intervention, including its testing prior to use in the main trial. The *Toddler-Safe* study design and methodology were informed by literature search undertaken for the introduction, and the findings of a systematic review of parenting interventions for the prevention of unintentional injuries in pre-school children undertaken in the previous chapter. The key aspects of the *Toddler-Safe* study which the results of this systematic review have helped inform are: the type of intervention; its mode of delivery; timing of the intervention; choice of outcome measures; evaluation methods; and study setting.

Type of intervention: The findings from the systematic review demonstrated that interventions specifically targeting parents of pre-school children were effective at reducing the likelihood of unintentional injury, as well as improving parental child safety knowledge and behaviour. Parenting interventions incorporating home visitation, education, and provision of low cost or discounted safety devices were shown to be effective. Education can be considered pivotal to parenting interventions, as effective interventions such as home visitation and provision of safety devices are heavily reliant on educational instruction. The results of the systematic review showed that in effective parenting interventions, parental education was delivered by verbal instruction, or by the use of print materials such as brochures and leaflets, or multimedia tools. The majority of educational interventions were delivered using verbal instruction, followed by printed materials. Only seven studies reported use of multimedia tools, five of which were effective. Guided by the results of the systematic review, as well as evidence from the literature in relation to theories of behaviour change in injury prevention, theories behind health education, memory retention, uptake of information, cost-effectiveness, and promotion of positive health outcomes, a multi-

media based educational approach was selected as the intervention of choice for the *Toddler-Safe* study. This selection was further informed by evidence in the literature of parental preference and receptivity for multimedia-based presentation of educational information during the early part of their children's lives (Morrongiello et al., 2009, Dunn et al., 1998, Armstrong et al., 2011).

Mode of delivery: This review demonstrated the effectiveness of parenting interventions delivered on a one-to-one basis, as opposed to a group or community basis. Tailored computer-based interventions were shown to be effective at improving parental knowledge of various child safety outcomes. This mode of delivery was therefore selected for the *Toddler-Safe* study.

Timing of the intervention: The systematic review found that early interventions delivered during the perinatal or immediate postnatal periods, were shown to be effective at reducing the likelihood of unintentional injury in pre-school children.

Outcome measures: Studies included in the systematic review used the following as outcome measures: self-reported or medically attended injuries, safety knowledge, and safety practice. The results of the review appear to suggest that improving parental child safety knowledge could lead to behaviour change and improvements in child safety practices. These outcome measures were assessed in the *Toddler-Safe* study. Due to the variability of the different scales used to measure quality of the child's home environment, this outcome measure was not sought in the *Toddler-Safe* study.

Evaluation technique: The effective parenting interventions reported in the systematic review were mainly evaluated using pre- and post-interviewing methods. Pre-test interviews were conducted using questionnaires, while post-test interviews were conducted either over the telephone or by postal questionnaire. Injury outcomes were measured by assessment of medical records. Based on these findings, the *Toddler-Safe* study was evaluated

using a pre-test questionnaire administered by face-to-face interview, and a post-test questionnaire administered over the telephone. Data on medically attended burn injuries were obtained from the ED records of participant's children. These methods have been shown to be cost-effective and capable of achieving both high quality responses and response rates (Wilson et al., 1998, Szolnoki and Hoffmann, 2013, Heerwegh and Loosveldt, 2008). In addition, these methods are flexible and can be adapted to the desired respondents (Szolnoki and Hoffmann, 2013).

Study setting: Hospital practice-based interventions, such as those conducted in the ED or paediatric practice, were shown to be effective at preventing childhood unintentional injury and improving parental safety knowledge and behaviour. Based on these findings, the *Toddler-Safe* study was conducted in various departments of a teaching hospital.

An individually randomised controlled trial (RCT) with a parallel group design was selected as the study design of choice for the *Toddler-Safe* study. This study design is one in which individual participants (as opposed to groups of participants) are randomised and allocated into treatment groups. RCTs are the most rigorous way of determining whether a cause and effect relationship exists between treatment and outcome and for assessing the cost effectiveness of a treatment (Sibbald and Roland, 1998). Furthermore, this particular study design balances out the potential confounding factors which could influence the outcomes of a trial.

### **3.1.1 TODDLER-SAFE STUDY AIMS AND OBJECTIVES**

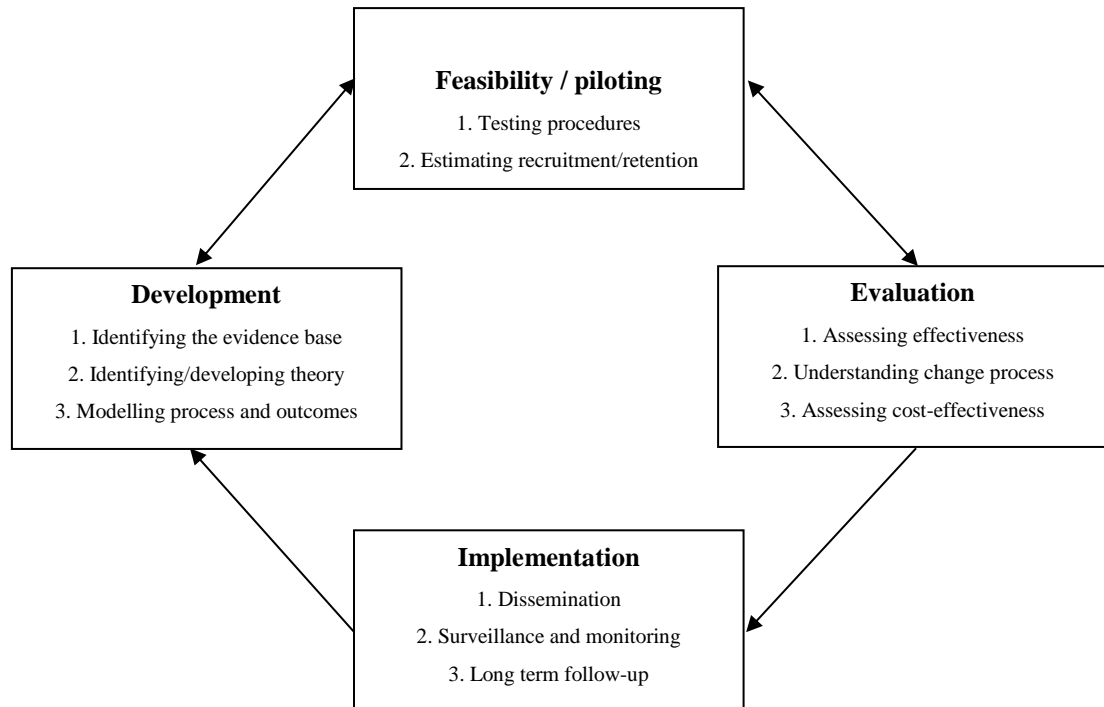
This study aims to determine whether *Toddler-Safe* improves parental childhood burns safety and first aid knowledge and behaviour in the home, and reduces the risk of future burns.

### Objectives

- To design a parenting intervention ‘*Toddler-Safe*’ aimed at improving parental childhood burns safety and first aid knowledge and behaviour
- To conduct a randomised controlled trial:
  - a. To determine if *Toddler-Safe* is effective at promoting change in parental/carer knowledge, attitudes, and practices regarding burns prevention and first aid
  - b. To assess the efficacy of *Toddler-Safe* in reducing the incidence of childhood burns and improving first aid administered to children and family members should they sustain a burn

The *Toddler-Safe* study was registered and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines (Schulz et al., 2010). The methodology governing the trial follows the Medical Research Council’s (MRC) guidelines for the development and evaluation of RCTs for complex interventions (Craig et al., 2008) (see Figure 3.1).

**Figure 3.1: Key elements of the development and evaluation process**



*Adapted from MRC 2008 Developing and evaluating complex interventions: new guidance*

### **3.2 CHAPTER OVERVIEW**

This chapter outlines the study design and methodology governing the *Toddler-Safe* study. A detailed description of the *Toddler-Safe* study, including the theoretical underpinnings and key steps taken in designing the *Toddler-Safe* intervention, as well as the feasibility testing of the intervention prior to its use in the main study, are described. This chapter also contains a full description of the steps taken to obtain research ethics and governance permissions to conduct the study, as well as other ethical considerations necessary for adequate participant confidentiality. Finally, the chapter concludes with a brief summary of all the key points discussed in chapter three.



### **3.3 ETHICAL CONSIDERATIONS**

#### **3.3.1 Ethical approval and study registration**

The *Toddler-Safe* study protocol was submitted for ethical approval via the Integrated Research Application System (IRAS) on 15 May 2012. At the time of protocol submission, the study was known as '*Too Hot to Handle: Prevention of Thermal Injuries in Children by a Targeted Intervention*'. This title was later changed to '*Toddler-Safe: Prevention of Burns and Scalds in Pre-school Children by a Targeted Intervention*' due to the use of the initial title by another injury prevention programme.

Health and Care Research Wales (formerly known as National Institute for Social Care and Health Research - NISCHR) Research Ethics Service is responsible for research ethics policy in Wales. A meeting with the Research Ethics Committee (REC) for Wales was attended on 14 June 2012 and a favourable ethical response was received on 17 July 2012 (Appendix 10). Research governance approval (Appendix 11) was granted on 16 August 2012 by the National Health Service (NHS) Research and Development Directorate of the Cardiff and Vale University Health Board. The author of this PhD thesis was issued an honorary research contract (research passport) by the Cardiff and Vale University Health Board on 13 November 2012 (Appendix 12). The *Toddler-safe* study was registered on the UK Clinical Research Network (UKCRN) portfolio database – UKCRN ID 12456.

#### **3.3.2 Participant consent and confidentiality**

Participants were required to complete an informed consent form (Appendix 5) prior to their involvement in the study. They were assured of confidentiality regarding the information provided during the course of the study. All personally identifiable data collected was anonymised by allocating unique identification numbers to each participant and stored on a secure password-protected Cardiff University computer. Signed consent forms and contact details were kept in a locked filing cabinet within a

locked office in the College of Medicine, Cardiff University. Participants were assured that all personal information collected would not be passed on to any third party unconnected with the study. Participants were also made aware that they were free to withdraw from the study at any time without giving reason. All documentation generated during the study, including delegation logs, was filed in an investigator site file.

### **3.3.3 Perceived risks and benefits of the study**

Potential participants were made aware that there were no known risks to taking part in the *Toddler-Safe* study. Participating in the study on the other hand, could improve their knowledge of burns prevention and first aid. This was stated clearly in the participant information sheet (Appendix 6). Potential participants were also made aware that their decision to take part in the study would not alter their medical care or routine treatment.

## **3.4 TODDLER-SAFE INTERVENTION**

*Toddler-Safe* is a multimedia-based educational parenting intervention which addresses the knowledge gaps around childhood burn injury prevention and burns first aid in parents and carers of children younger than five years of age. An educational intervention was selected based on the findings from the systematic review demonstrating the effectiveness of educational parenting interventions at reducing the likelihood of childhood injury, as well as improving parental injury safety knowledge and behaviour. A multimedia-based educational approach was selected because of the strong evidence base demonstrating the effectiveness of multimedia and audio-visual tools in improving and facilitating parental knowledge of complex paediatric health problems. This selection was further informed by evidence in the literature of parental preference and receptivity for multimedia-based presentation of educational information during the early part of their children's lives. The *Toddler-Safe* intervention consisted of two short educational videos and an injury safety leaflet.

Based on the findings from the systematic review, quantitative research methods were used to evaluate the effectiveness of the *Toddler-Safe* intervention at improving parent/carer burns safety and first aid knowledge and behaviour. Knowledge, Attitudes, and Practice (KAP) questionnaires administered via face-to-face interviews (pre-test), and over the telephone (post-test) were designed for this purpose (Appendices 3 and 4). The pre-test questionnaire was used to collect baseline KAP data as well as demographic information including parental age, gender, ethnicity, highest level of education, and occupation. The post-test questionnaire was administered at two time points after baseline data were obtained (six months and twelve months), to test the effectiveness of the intervention for improving or correcting preconceived ideas, knowledge and behaviour, as well as to check for any medically attended burns that might have occurred over the succeeding year. A thorough description of the pre- and post-test KAP questionnaires, as well as the processes involved in adapting and validating the questionnaires, can be found in chapter four.

### **3.4.1 Theoretical background**

The *Toddler-Safe* intervention has its theoretical underpinnings in theories of information processing and behaviour change. These are:

1. The Elaboration Likelihood Model (Cacioppo and Petty, 1984), which states that people are more likely to actively and thoughtfully process information if they perceive it to be personally relevant.
2. The Health Belief Model (HBM) (Rosenstock et al., 1988), which states that people will adopt a health-related behaviour if: (a) they believe they are vulnerable to a serious health problem or to a perceived threat; (b) the problem they are trying to avoid is serious; and (c) they believe that following a particular health recommendation would be beneficial in reducing the perceived threat.
3. The Cognitive Theory of Multimedia Learning (Mayer, 2002) - which has its origins in the Social Learning and Social Cognitive Theories (Bandura,

1988, Bandura and Walters, 1977), states that optimal learning occurs when visual and verbal materials are presented together simultaneously.

These three theories guided every stage of the development of the *Toddler-safe* intervention.

### **3.4.2 *Toddler-Safe* video and leaflet development**

In developing the *Toddler-Safe* intervention an extensive literature review of childhood burns prevention was carried out along with a review of parenting interventions and multimedia learning. Clinical studies incorporating the use of multimedia-based interventions were also reviewed, and found positive effects on various health outcomes (Brendryen and Kraft, 2008, Bouton et al., 2012, Altman et al., 2011, Arterburn et al., 2011). In addition, the author of this PhD thesis profiled child injury prevention initiatives and made contact with key project management staff to discuss their experiences with similar projects, gaps in injury prevention research, and ideas for improving the current study's design. Some of the organisations consulted include: Flying Start (Cardiff and Caerphilly); Children in Wales; CAPT London; and the Centre for Child and Adolescent Health, University of Bristol. The author also made contact with the clinical videographers at the Department of Media Resources Cardiff University to discuss the design of the *Toddler-Safe* videos and leaflets.

#### **3.4.2.1 *Toddler-Safe* video development**

In order to achieve optimal participant learning and understanding of a given subject, a lot of effort needs to be put into the designing of video-based research interventions. Educational videos need to take into account the target population's demographic and physical characteristics and should contain subject matter capable of keeping the viewer's interest (Steinke, 2001). The video script needs to be well written and should portray the content of the video in a way understandable to the target population. Educational videos should be able to evoke a strong identification between viewers and the images seen on screen – a process known as video/peer

modelling. Video modelling is a key component of the social cognitive theory (Bandura, 1988) and involves demonstration of desired behaviours, outcomes and attitudes through active, visual representations (Krouse, 2001). It can be a very effective technique for promoting behaviour change. The use of video modelling in educational videos has been shown to facilitate knowledge acquisition on various topics while reducing anxiety (Steinke, 2001, Dunn et al., 1998, Clark and Lester, 2000, Walker and Podbilewicz-Schuller, 2005). Furthermore, behaviour change is more likely to be maintained if the visual representation of a new behaviour is perceived as being personally relevant to the recipient (Kwasnicka et al., 2016).

In designing the *Toddler-Safe* videos, three main focus areas were determined:

1. The approach to take
2. The content of the video
3. The video length

The ideal approach for delivering the *Toddler-Safe* videos had to be one that engaged with the study participants and gave them an opportunity to revisit the videos anytime they wanted, and more importantly, was consistent with the aims of the study and the research plan. It was decided by the study research team (the author of this PhD thesis, his supervisors, and clinical videographers) to design the *Toddler-Safe* videos in three multimedia formats; one to be viewed from a portable electronic device such as a tablet computer or smartphone, the second to be in the form of a Digital Versatile Disc (DVD), and thirdly a web-based version to be viewed from the internet. Participants randomised to the study's intervention group were to receive all three multimedia formats. At recruitment they would watch the videos with the author on a tablet computer, and would be given the DVD to take home along with a web-link to watch the videos online. Based on findings from the systematic review from the previous chapter, the videos were designed to be administered on a one-to-one basis with study participants as opposed to viewing in groups. This approach would enhance

the viewing process and give participants the freedom and opportunity to ask questions.

A script for the *Toddler-Safe* videos was written by the author of this PhD thesis and discussed with the study research team. The videos would address the study's two underlying themes - childhood burns prevention and burns first aid. The videos were designed to evoke in parents a sense of understanding of the severity of burns, the vulnerability of young children to burn injuries, circumstances when burns could occur, how they could be prevented, and what to do in the event of a burn. The burns prevention theme focused on all common childhood burns occurring in the home, with particular emphasis on the age-specific causes of burns, place of occurrence within the home, and the mechanism of injury. The first aid theme would be dramatized to simulate a real burn incident and the subsequent administration of first aid. Both videos would incorporate voice-overs by a narrator and texts on the screen to emphasize key points.

#### **3.4.2.1.1 Patient and public involvement**

To ensure that the content of the script was relevant and appropriate, the author of this PhD thesis put together a patient and public involvement (PPI) group composed of a convenience sample of ten young parents. PPI is defined as the “active participation of citizens, users and carers and their representatives in the development of healthcare services and as partners in their own healthcare” (British Medical Association, 2015). PPI is important in research as it enables lay people to provide valuable perspectives on the way that research is designed and delivered (Stewart et al., 2011). All the parents involved in the PPI group session were satisfied with the content of the script but suggested that the injuries presented in the proposed videos be made less graphic so as not to put off any viewers. The parents also suggested a short but concise video be produced as they felt their attention spans would diminish if the video became too lengthy. The script was then revised using the information from the PPI group session. A decision was made by the research team to separate the burns prevention and first aid videos so as to enhance the viewing experience of the study participants.

### **3.4.2.1.2 Video production**

Filming for both the burns prevention and first aid videos was planned to commence in June 2012. Production was handled by the video unit of the Media Resources Centre, Cardiff University. This unit is based at UHW and primarily produces clinical education and training resources, as well as promotional materials and patient recordings for the Cardiff and Vale University Health Board. Four actors (two adults and two pre-school children) were required for both videos – an adult and a child per video. A female actor was chosen to represent the adult in the video. This decision was made so as to enhance peer/video modelling as we expected the majority of our intended study participants to be female. Actors were required to complete and sign a consent form prior to their involvement in the video shoot. The parents or carers of the pre-school children involved in the video would consent on their behalf. A home environment was selected for filming both videos as a further way of modelling a typical setting, as well as to enhance the safety concepts illustrated in the videos.

The burns first aid video was judged to be the less complicated of the two videos and as such, was chosen for filming first. An adult female (playing the mother) and a pre-school child were recruited as actors for the video shoot. Filming took place at the home of an acquaintance on 19<sup>th</sup> June 2012. The video portrayed the sequence of events from a child pulling down a mug of hot tea from a table onto himself, to the administration of first aid by the mother. The injurious event was simulated and the child was not harmed during the making of the video. Red coloured make-up was used to simulate an actual burn on the skin of the child actor. Filming went on without incident and both actors appeared comfortable with the subject matter and the roles that they were playing.

Filming for the burns prevention video did not commence as planned due to difficulties in recruiting actors to play the designated roles. A decision was then made by the study research team to modify an already existing video to suit the aims of the study. An educational child safety DVD called “Small Steps to Safety” produced by Health Challenge

Caerphilly County Borough and New Tredegar and Fochriw Communities First Partnerships was assessed. This DVD provided injury prevention information on household dangers including poisoning, choking, drowning, burns, and falls. The content of the burns segment of the DVD was judged to be suitable for the *Toddler-Safe* study as it was applicable to the target age group, included the most prevalent burns/scald mechanisms and injury environment, and contained simple effective prevention measures. The author wrote to the organisations involved for permission to use the segment of the DVD that addressed burn injuries for the *Toddler-Safe* study. Permission was granted on 10<sup>th</sup> July 2012.

The burns prevention video portrayed burn accident scenarios in the living room, kitchen and bathroom. It included safety information on keeping hot drinks out of reach of toddlers and safe storage of irons and hair straighteners. Both burns prevention and first aid videos were subsequently edited to include voice-overs by a narrator. Drafts of the videos were reviewed by the study research team with amendments made where necessary. The videos were produced in three formats: DVD, web-based, and electronic for tablet computer (Apple iPad). The final videos had a combined length of 2 minutes 45 seconds (Burns prevention – 1 minute 38 seconds; Burns first aid – 1 minute 7 seconds). Web links to the *Toddler-Safe* videos are provided below:

Burns prevention: <https://www.youtube.com/watch?v=kpPM4lgpAZo>

Burns first aid: <https://www.youtube.com/watch?v=2fwsnOeqUkk>

#### **3.4.2.2 *Toddler-Safe* leaflet development**

To overcome the ethical dilemma of depriving the control group of receiving any beneficial intervention, and to ensure that neither group knew whether they were the intervention or control group, an injury safety leaflet was designed to be administered to parents in the study's control group as well as the intervention group. The script for the leaflet was written by the



author of this PhD thesis and was based on current home injury safety literature. Items included the use of safety gates, safe storage of medicines, recognising choking hazards, and the use of smoke alarms. Special care was taken in writing the script so as not to include too much information on burns prevention or first aid. The format of the leaflet was simple and included pictorial information and simple text of a reading age level of 12 years.

#### **3.4.2.2.1 Patient and public involvement**

A working draft of the *Toddler-Safe* leaflet was tested at the same time as the video script amongst a convenience sample of ten young parents. The parents felt the content of the leaflet was appropriate and relevant. A final draft was reviewed by the study research team and final production carried out by the Graphic Design Unit of the Media Resources Centre, Cardiff University. A copy of the *Toddler-Safe* injury safety leaflet can be seen in appendix 13.

#### **3.4.3 Feasibility testing of the *Toddler-Safe* intervention**

A small feasibility study was undertaken to identify any logistical problems which might hamper the progress of the *Toddler-Safe* study (van Teijlingen and Hundley, 2001, Craig et al., 2008). This feasibility study would assess the likely success of proposed recruitment approaches and determine what resources would be needed for the planned study (van Teijlingen and Hundley, 2001). The author of this PhD thesis intended to conduct a feasibility study of the entire *Toddler-Safe* project, but due to time constraints it was not possible to include a follow-up phase.

The feasibility study was carried out by the author at the University Hospital of Wales (UHW) from 17<sup>th</sup> to 20<sup>th</sup> December 2012. The aims of the study were to;

1. Test the *Toddler-Safe* intervention design
2. Gauge recruitment potential and numbers

### 3. Address in advance any problems that could disrupt the main study

All materials to be used in the main research study were produced for the feasibility study. All the necessary permissions required for subject recruitment and participation were obtained prior to commencement of the study. Five sites were chosen for recruitment in the main study. These were:

- Antenatal clinic
- Maternity ward/Midwifery Led Unit (MLU)
- Children's out-patient clinic
- Children's Accident and Emergency Department
- Mum's exercise/Postnatal physiotherapy class

A total of ten participants (two from each of the sites) were to be recruited for the feasibility study. The parents that took part in the PPI group sessions were exempt from participating in the feasibility study or the main study. The participants taking part in the feasibility study were not to be included in the main research study.

#### **3.4.3.1 Findings from the feasibility study**

All but one of the five study sites were assessed for ease of recruitment on the first day of the feasibility study. The mum's exercise/postnatal physiotherapy class could not be assessed because this class had closed for the Christmas holidays. All other sites were open and subsequently assessed.

There were no difficulties recruiting from the maternity ward, MLU, and the antenatal clinic. However, the manager in charge of the antenatal clinic made the author aware of certain days designated to mothers with 'difficult' pregnancies, including pregnancy loss. It was decided by the

research team that recruitment would not be carried out from the antenatal clinic on these days.

There were difficulties with recruitment and intervention delivery at the Children's Accident and Emergency Department and the Children's out-patient clinic. Both environments were chaotic and it was very challenging attempting to recruit any parents. At the children's ED, three parents were approached – all three agreed to participate but could not concentrate on the intervention because they had to tend to their sick children. In all three, the time frame from recruitment to delivering the intervention far exceeded the 15 minute time frame planned for the delivery of the intervention in the main study. It was a similar occurrence at the children's out-patient clinic, with the two parents approached not able to complete the intervention within the stipulated time frame. Both sites were subsequently dropped from the study.

A total of ten parents (eight mothers and two fathers) were approached and recruited from the other study sites – Antenatal clinic (n =5); maternity ward/MLU (n = 5). Seven of the participants were White-British; two were Asian Pakistani, and one was of mixed race (White and Black African). Four of the participants were educated up to postgraduate level; two had obtained college/university degrees; three had General Certificate of Secondary Education (GCSEs) /equivalent vocational qualifications, while one parent had left school before 16 years of age. Participants were able to give consent, complete the questionnaires, and receive the intervention they were randomised to within the designated 15 minute timeframe. In instances where participants were called in for their appointments while receiving the intervention, they were able to complete the assessment on their return. The intervention was well received by all the participants involved. Modifications were made to the recruitment procedures at the Antenatal clinic.

### 3.5 SUMMARY OF CHAPTER THREE

- The design and methodology of the *Toddler-Safe* study were informed by the findings of a systematic review on parenting interventions for the prevention of unintentional injury in pre-school children undertaken by the author of this PhD thesis.
- The *Toddler-Safe* study was conducted as an individually randomised controlled trial with a parallel design. This method was chosen because RCTs are the most rigorous way of determining whether a cause and effect relationship exists between a treatment and an outcome, and in order to balance out the potential confounding factors which could influence the outcomes of the trial.
- The *Toddler-Safe* intervention was based on three theories: The Elaboration Likelihood Model, The Health Belief Model, and the Cognitive Theory of Multimedia Learning. All three theories guided every stage of the development of the intervention
- The *Toddler-Safe* intervention consisted of a two short educational videos on burn injury prevention and first aid respectively, and an injury safety leaflet. A PPI group composed of a convenience sample of 10 young parents was created to ensure the content of the videos and leaflets were relevant and appropriate.
- The *Toddler-Safe* intervention was feasibility tested on 10 parents (not involved in the PPI group sessions) to assess recruitment and intervention delivery, and to identify in advance any problems that could hamper the progress of the main study.
- The intervention was well received by the participants recruited for the feasibility study. Modifications were made to the study recruitment procedures and two sites were dropped from the study due to difficulties with recruitment and intervention delivery.

## CHAPTER FOUR

## **CHAPTER FOUR: *TODDLER-SAFE* QUESTIONNAIRE DEVELOPMENT**

### **4.1 INTRODUCTION**

The effective parenting interventions reported in the systematic review chapter (chapter two) were mainly evaluated using pre- and post-interviewing methods. Pre-test interviews were conducted using questionnaires, while post-test interviews were conducted either over the telephone or by postal questionnaire. Questionnaires offer an objective means of collecting information, and have been extensively used in injury prevention research to assess people's knowledge, attitudes, and practices (Boynton and Greenhalgh, 2004, Watson et al., 2014). Based on these findings, the *Toddler-Safe* study was evaluated using pre- and post-test knowledge, attitudes, and practice (KAP) questionnaires. Questionnaire-based interviewing methods have been shown to be cost-effective and capable of achieving both high quality responses and response rates (Wilson et al., 1998, Szolnoki and Hoffmann, 2013, Heerwegh and Loosveldt, 2008). In addition, these methods are flexible and can be adapted to the desired respondents (Szolnoki and Hoffmann, 2013).

### **4.2 CHAPTER OVERVIEW**

This chapter gives a detailed description of the identification, justification, adaptation and validation of the *Toddler-Safe* questionnaire, as well as the processes involved in its development. Section 4.3 and its accompanying subsections will describe why the questionnaire and its contents were chosen; how the questionnaire will be administered and delivered to study participants; the processes involved in formulating questions and their accompanying responses; the questionnaire design layout; the questionnaire validation process and pilot testing; and finally, the coding scheme for analysing questionnaire responses. Chapter four ends with a brief summary of all the key points outlined in the chapter.

### **4.3 QUESTIONNAIRE DEVELOPMENT**

Developing a questionnaire is a complex process. Considerable effort is required to ensure that questionnaires are well designed and capable of collecting meaningful information from the desired target population. To ensure that the *Toddler-Safe* questionnaires were suitable for the study population and were able to measure the study's outcomes, the following recommended stages of questionnaire development were undertaken (Williams, 2003):

1. Decide how the questionnaires will be administered
2. Formulate your questions
3. Formulate your responses
4. Design the layout
5. Pilot test your instrument – test validity, reliability, and acceptability
6. Design your coding scheme

#### **4.3.1 Administration of questionnaires**

The decision on how the *Toddler-Safe* questionnaires would be administered and delivered were informed by findings from the systematic review conducted in chapter two, as well as by practicality, ease of delivery, and cost-effectiveness. Self-administration – whereby, the study participants complete the questionnaire on their own, was chosen as the method of administering the *Toddler-Safe* questionnaires. This method is inexpensive and efficient, and allows the administrator to monitor the respondent and answer any questions they may have (Bourque and Fielder, 2003). It also prevents interviewer bias which could distort the outcome of the interview (Burns et al., 2008).

Two methods of questionnaire delivery judged as being both cost-effective and practical were selected: face-to-face interviews using paper

questionnaires, and telephone interviews. These interview methods have been shown to achieve both high quality responses and high response rates (Wilson et al., 1998, Szolnoki and Hoffmann, 2013, Heerwegh and Loosveldt, 2008). In addition, both methods are flexible and can be adapted to the desired respondents (Szolnoki and Hoffmann, 2013). Based on these findings, the *Toddler-Safe* study was evaluated using a pre-test knowledge, attitudes, and practice (KAP) questionnaire delivered by face-to-face interview, and a post-test KAP questionnaire delivered over the telephone.

#### **4.3.2 Formulation of questions**

The structure and content of a questionnaire has been shown to influence quality of responses as well as response rate (Rattray and Jones, 2007, Williams, 2003). Special consideration should be given to the way questions are worded, the language used, as well as the order in which questions are presented (Rattray and Jones, 2007). In order to achieve accurate responses, Williams (2003) suggested that questionnaire questions should be made short (less than 20 words), simple and specific, free from jargon, and should not overtax the respondent's memory. In addition, questions must be phrased appropriately for the target audience and the information required (Boynton and Greenhalgh, 2004). These principles of questionnaire wording guided the developmental stages of the *Toddler-Safe* questionnaires.

In questionnaire development, the use of existing previously validated and published questionnaires is a recommended procedure. Not only does it save time and resources, but it also allows direct comparisons to be made with previous studies (Boynton and Greenhalgh, 2004, Williams, 2003). The *Toddler-Safe* questionnaires were developed from a previously validated questionnaire (see Appendix 7 – Too Hot for Tots Questionnaire) used to evaluate a Canadian paediatric burns prevention programme by Turcotte and Babul-Wellar (2011). This study was one of 48 included studies in the systematic review conducted by the author of this PhD thesis in chapter two. The intervention and means of measuring outcome were



shown to be effective at improving parental burns prevention knowledge and behaviour. The decision to develop the *Toddler-Safe* questionnaires from an already existing questionnaire was made for the following reasons:

- 1.The questionnaire method of evaluating the outcome of the intervention in the study by Turcotte and Babul-Wellar (2011), was feasible and effective within the systematic review.
- 2.Developing and validating (to ensure validity, reproducibility, and applicability) an entirely new questionnaire will be time consuming for a PhD programme and would demand more resources.
- 3.Using a validated questionnaire would enable comparison of results with another study.

An informed decision was therefore made by the author of this PhD thesis, in agreement with his two supervisors, to make use of an existing previously validated questionnaire and modify it to suit the study's target population in a UK setting. The author contacted the British Columbia Injury Research and Prevention Unit (BCIRPU) research team - owners of the Too Hot for Tots questionnaire, and requested permission to modify their questionnaire for the *Toddler-Safe* study. This request was subsequently approved. Due to minor modifications made to the wording of questions in order to suit a British sample, a further round of validation was undertaken to ensure the questionnaire was fit for purpose.

#### **4.3.3 Questionnaire format**

The *Toddler-Safe* pre-test questionnaire (see Appendix 3) was five pages long, consisted of a total of 30 questions (16 core questions and 14 demographic questions), and was the same for both intervention and control groups. The core questions were focused on parental burns prevention knowledge (four questions), attitudes (two questions), practices (nine

questions), and burns first aid knowledge (one question with a and b subsets). Burns prevention knowledge questions such as “What percentage of burns among young children are from hot liquids?” were asked in a multiple-choice format. Attitude questions such as “How preventable do you think burn injuries are among young children?” were asked using a five-point Likert-like scale format. Practice questions such as “Where do you place hot drinks when the children are around?” were asked in a multiple-choice format with additional free text fields. Some practice questions were ‘double-barrelled’ with yes/no and multiple-choice formats, such as “Do you have hair straighteners at home? If yes, where do you store them after use?”. Burns first aid questions such as “What do you do right after a burn happens?” were also asked in a multiple-choice format. All questions were based on key childhood burns prevention and first aid items presented in the *Toddler-Safe* intervention. The demographics section of the questionnaire collected data on the study participant’s age, gender, ethnicity, highest level of education, occupation, and previous attendance at a burns prevention or first aid training course.

The post-test questionnaire (see Appendix 4) contained the same 16 core questions as the pre-test questionnaire, and two additional questions assessing usage of the intervention, and any reported burn injury in the index child or any sibling (younger than five years of age) in the post-intervention period. The post-test questionnaire comprised of four pages, and did not collect any demographic data as these were already collected at baseline with the pre-test questionnaire. Pre- and post-test questionnaires were written at a reading age level of 12 years so as to accommodate participants with relatively low literacy skills. This was deemed appropriate given the educational level of parents participating in a previous study of burns first aid knowledge (Davies et al., 2013), conducted in the same centre as the current study.

#### **4.3.4 Questionnaire responses**

The Toddler-safe questionnaires had a mixture of open-ended and closed questions. The open-ended questions were used particularly in the demographics section of the questionnaire where the responses were expected to be varied. The core questions were mainly closed questions with predetermined answers in multiple tick boxes. Some closed questions had an 'Other' tick box with free text fields, where respondents could state their own answers if they did not agree with any of the predetermined answers. An 'I don't know' option was also provided for respondents who were not sure of the right answers.

#### **4.3.5 Scoring of questionnaire responses**

A scoring system was designed whereby scores were assigned to each of the knowledge, attitude and practice questions so that a higher total mean score indicated a better understanding of burns prevention and first aid. Zero points were awarded for incorrect answers, one point for appropriate but suboptimal answers, and two points for correct answers. Questions left blank or answered inappropriately were assigned zero points. The main outcome measure was the degree of improvement in burns prevention and first aid knowledge, attitudes, and practices as evidenced by improvement in KAP scores. Participants who received the intervention (Group A) were expected to have higher post-test scores and also report increased burns prevention behaviours when compared to participants in the control group (Group B).

The scoring for two practice questions; "Where do you store your hot iron after use?" and "Do you have hair straighteners at home? If yes, where do you store them after use?", was handled differently. This was done so as to take into account participants who did not have irons or hair straighteners at home, and therefore will not be able to answer both questions. Full marks (Two points) were awarded for respondents who answered 'not applicable' to both questions. The rationale for giving full marks was that, if the respondents did not have irons or hair straighteners in

their homes, then their children are not at risk of suffering contact burns from irons or hair straighteners in the home. The author of this PhD thesis was aware of the possibility of this approach falsely inflating practice scores for participants who did not have irons or hair straighteners, so another scoring system awarding one point instead of two was tested, and a comparison made between both scoring systems. No significant differences were noted on practice scores using both scoring systems.

#### **4.3.6 Questionnaire layout**

The layout of a questionnaire can influence the way people respond to the questionnaire (Boynton and Greenhalgh, 2004). To ensure maximal response rates, considerable effort was put into designing the layout of the *Toddler-Safe* questionnaires. The questionnaires were printed in colour on good quality white paper, with official Cardiff University and Cardiff and Vale University Health Board logos affixed at the top of the front page. A font size of 12 with double spacing was used for the individual questions. The questionnaires were printed one sided. The core questions and demographics questions were kept separate, with the core questions presented at the beginning and the demographics questions presented at the end. Clear instructions on how to complete the questionnaires were given at the beginning of each section.

#### **4.3.7 Questionnaire validation**

Prior to using a new or modified questionnaire, it is important to establish whether the instrument is valid, acceptable, and reliable – a procedure known as questionnaire validation. Validation is the process by which any data collection instrument, including questionnaires, is assessed for dependability (Dowrick et al., 2015, Howard 2008). According to Olsen (1989), a validated questionnaire is one which has undergone a formal validation procedure to show that it accurately measures what it aims to do, regardless of who responds, when they respond, and to whom they respond or when self-administered. Questionnaire validation is important as it reduces bias (by detecting ambiguities and misinterpretations), and ensures

that the feasibility, acceptability, time needed to respond etc. are pre-examined (Olsen, 1998).

#### **4.3.7.1 Testing validity, acceptability, and reliability**

Validity is defined as the degree to which an assessment measures what it is supposed to measure (Sushil and Verma, 2010). There are a number of different facets to validity, however, two of the most relevant measures when evaluating a patient-reported outcome assessment instrument are face and content validity (Fitzpatrick et al., 1998). Both facets were therefore tested for the *Toddler-Safe* questionnaires.

Face validity is an assessment which examines whether an instrument appears to measure what it is intended to measure (Guyatt et al., 1993). This assessment is qualitative in nature and is performed by experts, who review the contents of a questionnaire to see if the items seem appropriate. Content validity, on the other hand, refers to the extent to which a measure represents all aspects of a given social concept (Sushil and Verma, 2010). According to Guyatt et al. (1993), it “examines the extent to which the domain of interest is comprehensively sampled by the items, or questions, in the instrument.” Similar to face validity, content validity is a qualitative assessment and consists of a judgement performed by relevant stakeholders (Dowrick et al., 2015). The face validity of the *Toddler-Safe* questionnaires was based on the outcomes of interest (parental burns prevention and first aid knowledge, attitudes, and practices), while the content validity was measured by the extent to which the questionnaire covered key burns prevention and first aid issues identified in the literature. Both face and content validity were performed by the author’s two supervisors and a senior statistician not involved in the *Toddler-Safe* project. The questionnaire was also examined for readability and clarity by twelve of the author’s research and postgraduate colleagues.

Acceptability and reliability of the *Toddler-Safe* questionnaire were tested by conducting a formal pilot study. Acceptability refers to how the intended individual recipients react to the instrument to be tested (Williams,

2003), while reliability refers to the repeatability, stability or internal consistency of a questionnaire (Rattray and Jones, 2007). As a rule, pilot studies should be based on subjects from a similar population to that being examined in the main research study (Williams, 2003). The *Toddler-Safe* questionnaire was therefore pilot tested among a convenience sample of 20 parents, aged between 20 and 40 years, and had at least one child younger than five years of age. Acceptability of the questionnaire was assessed in terms of interpretability and completion rates. Reliability was tested by asking the study participants to complete the questionnaire twice over a three week interval and comparing the responses – a procedure known as test-retest reliability. According to Dowrick et al. (2015), the test-retest reliability test provides information regarding how repeatable the results of an instrument are when instituted at two time points when no change is expected. In this assessment, Cohen's kappa ( $\kappa$ ) coefficients were calculated. Cohen's kappa ( $\kappa$ ) coefficient compares the observed agreement between two assessments made on two different occasions, with the agreement that would be expected simply by chance (Strippoli et al., 2007).  $\kappa$  coefficients  $\leq 0.4$  indicate poor agreement, values of 0.41 – 0.60 indicate moderate agreement, 0.61 – 0.80 indicate good agreement and values  $> 0.8$  indicate excellent agreement (Landis and Koch, 1977). All statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) software version 20 (SPSS Inc. Chicago, IL, USA).

#### **4.3.7.2 Questionnaire validation results**

Face and content validity of the *Toddler-Safe* questionnaires were conducted by both of the author's supervisors and a senior statistician not involved in the project. Face validity was based on the outcomes of interest – parental burns prevention and first aid knowledge, attitudes and practices, while content validity was measured by the extent to which the questionnaire covered key burns prevention and first aid issues identified in the literature. Similar to the face and content validation assessment conducted on the Too Hot for Tots questionnaire (Turcotte and Babul-Wellar, 2011), face and content validity of the *Toddler-Safe* questionnaires

were found to be good by all three assessors. All of the items contained in the questionnaire were appropriate and relevant to current childhood burns prevention and first aid literature. The questionnaire was clear, presented in a readable layout, and questions free from any ambiguities. These findings were echoed by 12 research colleagues who examined the questionnaire for clarity and readability.

Twenty parents participated in the pilot study conducted to assess acceptability and reliability of the *Toddler-Safe* questionnaires. All 20 participants were available throughout the duration of the pilot.

**Acceptability:** The questionnaire was positively perceived by all parents participating in the pilot test. All questions were answered. Subjects found the questions easy to understand and had an average questionnaire completion time of 8.5 minutes. All of the subjects found the items contained in the questionnaire to be appropriate and relevant to current childhood burns prevention and first aid literature. However, some of the participants felt that a demographic question assessing household income may put off potential participants. This point was discussed with the research team, and in order to avoid nonresponse on this item, a decision was made to assess participant socio-economic status using the National Statistics Socio-economic Classification (NS-SEC) (Office for National Statistics, 2010) - which is an occupation-based measure of socio-economic status, rather than by household income.

**Reliability:** All of the subjects were available for the test-retest reliability test. Most of the questionnaire items showed good to excellent agreement (0.61– 1.0). One item showed moderate agreement while two items showed poor agreement. The items showing poor agreement assessed the time taken for hot water to burn a child's skin, and where hot drinks are placed when children are around. The variation in responses in the two items showing poor agreement could be as a result of participants genuinely not knowing the correct answer and therefore attempting to guess the correct option (as in the case of the item on time taken for hot water to burn a child's skin), or

participants attempting to report what they perceive to be the socially desirable response rather than true beliefs or practices (as in the case of the item on where hot drinks are placed when children are around). It could be argued that since both questions showed poor reliability, they should be dropped from the questionnaire. However, since the *Toddler-Safe* intervention aims to improve parental burns safety knowledge and practices, it is necessary to include questionnaire items that could demonstrate effectiveness of the intervention over time. Both questions are capable of showing an effect of the intervention and were therefore retained in the questionnaires despite poor reliability. Nevertheless, the internal consistency of responses was high with ICC greater than 0.70 in 12 questions (71%), and a good overall  $\kappa$  coefficient ( $\kappa = 0.76$ ). The test-retest repeatability test of the *Toddler-safe* questionnaire items is shown in Table 4.1, with SPSS data shown in Appendix 14.

**Table 4.1: Test-retest repeatability of the *Toddler-Safe* questionnaire**

<b>Questionnaire Item</b>	<b>Kappa/ICC</b>	<b>p-value</b>	<b>Agreement</b>
Age group likely to get burn	0.680	0.001	Good
Burn severity	0.886	0.000	Excellent
Burn preventability	0.871	0.000	Excellent
Percentage of burns from hot liquids	0.747	0.000	Good
Child's skin compared to adult skin	0.459	0.042	Moderate
Time taken for hot water to burn a child's skin	0.171	0.472	Poor
First aid after burn	0.904	0.000	Excellent
Cover burn	0.960	0.000	Excellent
Hot drinks while playing with/carrying child	0.853	0.000	Excellent
Where hot drinks are placed	0.375	0.103	Poor
Child in kitchen while someone is	0.979	0.000	Excellent



cooking			
Ring burners used	0.759	0.000	Good
Pot handles turned inward	0.898	0.000	Excellent
Test temperature of bath water	0.746	0.000	Good
When child gets into bath	1.000	0.000	Excellent
Storage of hot iron	0.930	0.000	Excellent
Storage of hot hair straightener	0.679	0.001	Good

### 4.3.8 Coding of questionnaire responses

Coding is the process of converting data derived from questionnaires into meaningful categories so as to facilitate analysis and entry onto databases (Williams, 2003). The *Toddler-Safe* questionnaire responses were coded from 1-5 corresponding to each tick box. A special number (99) was used to denote ‘I don’t know’ options. Free text responses were analysed and recoded into an appropriate code. To facilitate data analysis, all recoding was conducted using syntax commands prepared with the Statistical Package for the Social Sciences (SPSS) software version 20 (SPSS Inc. Chicago, IL, USA). All recoding was conducted by the author and independently checked for accuracy by a statistician not involved in the study.

## 4.4 SUMMARY OF CHAPTER FOUR

- The development of the *Toddler-Safe* questionnaire took into consideration, the administration and delivery of the questionnaire; the formulation of questions and responses; the questionnaire design layout; questionnaire validation and pilot testing; and coding scheme for analysing questionnaire responses.
- Pre- and post-test KAP questionnaires were used to evaluate the effectiveness of the *Toddler-Safe* intervention as well as to collect

participant demographic data. The pre-test questionnaire was delivered by face-to-face interviews while the post-test questionnaire was delivered over the telephone.

- The *Toddler-Safe* questionnaire was developed from a previously validated questionnaire. Minor modifications were made to the wording of questions in order to suit a British sample. A further round of validation was conducted to ensure the questionnaire was fit for purpose.
- Face and content validity were performed by the author's supervisors and a senior statistician not involved in the *Toddler-Safe* study. These were found to be good by all three assessors. All of the items contained in the questionnaire were judged as being appropriate and relevant to current childhood burns prevention and first aid literature.
- A convenience sample of 20 young parents took part in a formal pilot study, undertaken to test for acceptability and reliability of the *Toddler-Safe* questionnaire. The questionnaire was positively perceived and following a test-retest reliability procedure, most of the questionnaire items showed good to excellent agreement.

## CHAPTER FIVE

## **CHAPTER FIVE: METHODOLOGY OF THE *TODDLER-SAFE* STUDY**

### **5.1 INTRODUCTION AND CHAPTER OVERVIEW**

This chapter describes the methods used for the *Toddler-Safe* study. The design and methodology of the *Toddler-Safe* study were informed by the findings of the systematic review of parenting interventions for the prevention of unintentional injury in pre-school children (see chapters two and three). A RCT design was selected as the study design of choice for the *Toddler-Safe* study. This is because RCTs are the ‘gold standard’ for proof of efficacy and are the most rigorous way of determining whether a cause and effect relationship exists between a specified treatment and an outcome (Sibbald and Roland, 1998).

This chapter begins with a detailed description of the *Toddler-Safe* study setting and target population (sections 5.2.1 and 5.2.2 respectively). This is followed by a description of the eligibility criteria required for inclusion and exclusion into the study (5.2.3 and 5.2.4). Section 5.2.5 describes how the study’s sample size and power were calculated, while sections 5.2.6 and 5.2.7 describe RCT procedures – randomisation, allocation concealment and blinding. The study recruitment procedures are detailed in section 5.2.8 and its accompanying sub-sections, while section 5.2.9 outlines the study’s primary and secondary outcome measures. The procedure for analysing all the data collected in the study is described in detail in section 5.2.10, while sections 5.2.11 and its accompanying subsections describe how participant attrition and missing data are managed. Finally, the chapter ends with a short summary of all key points.

### **5.2 METHODS**

#### **5.2.1 Setting**

In line with the findings from the systematic review in chapter two, reflecting the effectiveness of hospital practice-based parenting

interventions, the *Toddler-Safe* study was undertaken at the University Hospital of Wales (UHW) Cardiff. The UHW, commonly referred to as ‘the Heath’ or ‘Heath hospital’ (reflecting the district of Cardiff in which the hospital is situated) was officially opened by Queen Elizabeth II on 19 November 1971 (WalesOnline, 2011) and is a teaching hospital of the Cardiff University School of Medicine. The UHW is a major hospital, the largest of its kind in Wales and the third largest in the UK (WalesOnline, 2011). A total of 8,028 people work at the UHW, including 1,040 medical and dental staff and 2,348 nurses (Griffith, 2011). More than 400,000 people from various socio-demographic backgrounds attend the hospital each year as in-patients, out-patients, emergencies, and to give birth (Griffith, 2011).

### **5.2.2 Study population**

The target population for the *Toddler-safe* study were parents and carers of pre-school children resident in the Cardiff and Vale of Glamorgan area. Children younger than five years of age being most at risk of childhood burns. It was anticipated that the subjects participating in this study would be mostly mothers, however, participation in the *Toddler-safe* study was open to fathers, grandparents, and any other primary caregivers (A primary care giver was defined as a person, at least 16 years of age, who has the greatest responsibility for the daily care and rearing of the child). For the purpose of this study pre-school children included all children younger than five years of age.

Guided by the findings from the systematic review, the *Toddler-Safe* study was delivered to parents during the perinatal or early postnatal periods. Three sites within UHW were selected for participant recruitment:

1. Antenatal clinic
2. Maternity ward/Midwifery Led Unit (MLU)
3. Mum’s exercise/Postnatal physiotherapy class

These sites were selected because they offered the best opportunity to come in contact with the desired study population, and also to obtain a sample broadly representative of the local community demographics. In addition, one of the sites (Antenatal clinic) had previously been used for participant recruitment in a study assessing parental knowledge of burns first aid (Davies et al., 2013) – a study in which the author of this PhD thesis was involved in and co-authored. The experience gathered during the course of the first aid study informed the decision to include the Antenatal clinic as a recruitment site for the *Toddler-Safe* study.

### **5.2.3 Study inclusion criteria**

To be eligible for inclusion into the *Toddler-Safe* study, the parent/carer must;

1. Have at least one child less than five years of age
2. Be living in the same household as the child
3. Be the primary caregiver of the child

### **5.2.4 Study exclusion criteria**

Parents/carers were ineligible for enrolment into the *Toddler-Safe* study if they;

1. Were unable to understand the written and verbal instructions provided in English and required for completing questionnaires
2. Were not residents of either Cardiff or the Vale of Glamorgan
3. Could not provide a means of communication for follow-up correspondence (telephone, E-mail)

### 5.2.5 Sample size and power

Estimates for sample size calculations were taken from two similar child injury prevention studies, (Turcotte and Babul-Wellar, 2011) and (Turcotte et al., 2011). Turcotte and Babul-Wellar (2011) carried out their sample size calculations in order to detect a ‘moderate’ effect size of 0.5. Effect size is a way of quantifying the size of the difference between two groups, and is a true measure of the significance of the difference, as opposed to the statistical significance of a research result (Coe, 2002, Carson, 2012). This same effect size of 0.5 was adopted for sample size calculations for the *Toddler-Safe* study. A standard deviation (SD) of scores of 10% (0.1) was derived from the two injury prevention studies mentioned above [smallest SD = 5% (0.05) and largest SD = 15% (0.15)], and was used to compute a difference in mean score of 0.05 (5%) using the formula below;

$$\text{Effect size} = \frac{\text{Difference in mean score}}{\text{Standard Deviation}}$$

$$0.5 = \frac{0.05}{0.1}$$

Based on these calculations, a 5% difference in mean scores was therefore assumed to be clinically significant. To detect this mean difference in knowledge, attitudes, and practice scores between study arms at six months, using 90% power and a significance level of 0.05, 86 participants would be required in each study arm. A 90% level of power was chosen because this offered the study a higher chance (in this case a 90% chance) of detecting a 5% difference in KAP scores at a 95% confidence level if one existed (Whitley and Ball, 2002). Allowing for up to 20% losses during follow up, an additional 20 participants were added to each study arm making a total of 212 participants. An anticipated loss to follow-up rate of 20% was chosen for two reasons: 1. It is generally believed that attrition rates of up to 20 percent are acceptable in clinical research (The 20 percent

rule). A loss to follow-up of greater than 20% would downgrade an otherwise tier 1 study (effective) to a tier 2 study (promising) (Amico, 2009, Stinner and Tennent, 2012); 2. A 20% loss to follow-up rate was used in a similar peer-reviewed study (Turcotte and Babul-Wellar 2011). The statistical software nQuery (version 4.0) was used in calculating the sample size. All sample size calculations were checked for accuracy by a senior statistician not involved in the *Toddler-Safe* study.

### **5.2.6 Randomisation and allocation concealment**

In clinical trials, randomisation offers the most robust method of preventing selection bias and improves comparability between study groups (Craig et al., 2008). Parents and carers who consented to taking part in the *Toddler-Safe* study and met the study's inclusion criteria were allocated unique identification numbers and randomly assigned to one of two groups – Group A (intervention) or Group B (control). A computerized random-number generator (Microsoft Excel version 14) was used to produce a set of allocations using block randomisation with a block size of four. Block randomisation ensured that there were equal numbers of consenting participants in each group. The random number generation was carried out by a statistician not involved in the *Toddler-Safe* study. No stratification was used. Allocations were placed in sequentially numbered, opaque, sealed envelopes. Participants were then randomised by the author by opening the corresponding envelope containing the allocation. Randomisation into intervention and control groups was carried out after collection of baseline data.

### **5.2.7 Blinding**

As is common with most RCTs of educational interventions, it was not possible to blind participants or study personnel to treatment arm allocation. Blinding serves to eliminate bias resulting from the expectations of the study participant or the provider regarding outcomes (Medical Research Council, 2000). At the pre-test assessment, the author was blinded to treatment arm allocation because baseline data were collected prior to



group allocation. Post intervention data were collected by two independent research nurses. It was not possible to blind the research nurses to treatment arm allocation as the post-test questionnaires contained some questions assessing the usage of the interventions given to the participants. The author was however, blinded to treatment arm allocation during data analysis.

### 5.2.8 Study recruitment

Recruitment for the *Toddler-Safe* study commenced on 15<sup>th</sup> January 2013. Based on findings from the feasibility study described in chapter three, three sites were confirmed for participant recruitment;

1. Antenatal clinic
2. Maternity ward/Midwife Led Unit
3. Mum’s exercise/Postnatal physiotherapy class

Relevant staff working in the sites for recruitment were informed in advance of the study. A timetable (see Table 5.1) was designed, outlining the days of the week and sites for recruitment. Parents who took part in the *Toddler-Safe* feasibility study were not permitted to take part in the main study. Recruitment of participants was carried out solely by the author of this PhD thesis.

**Table 5.1: Timetable for study participant recruitment**

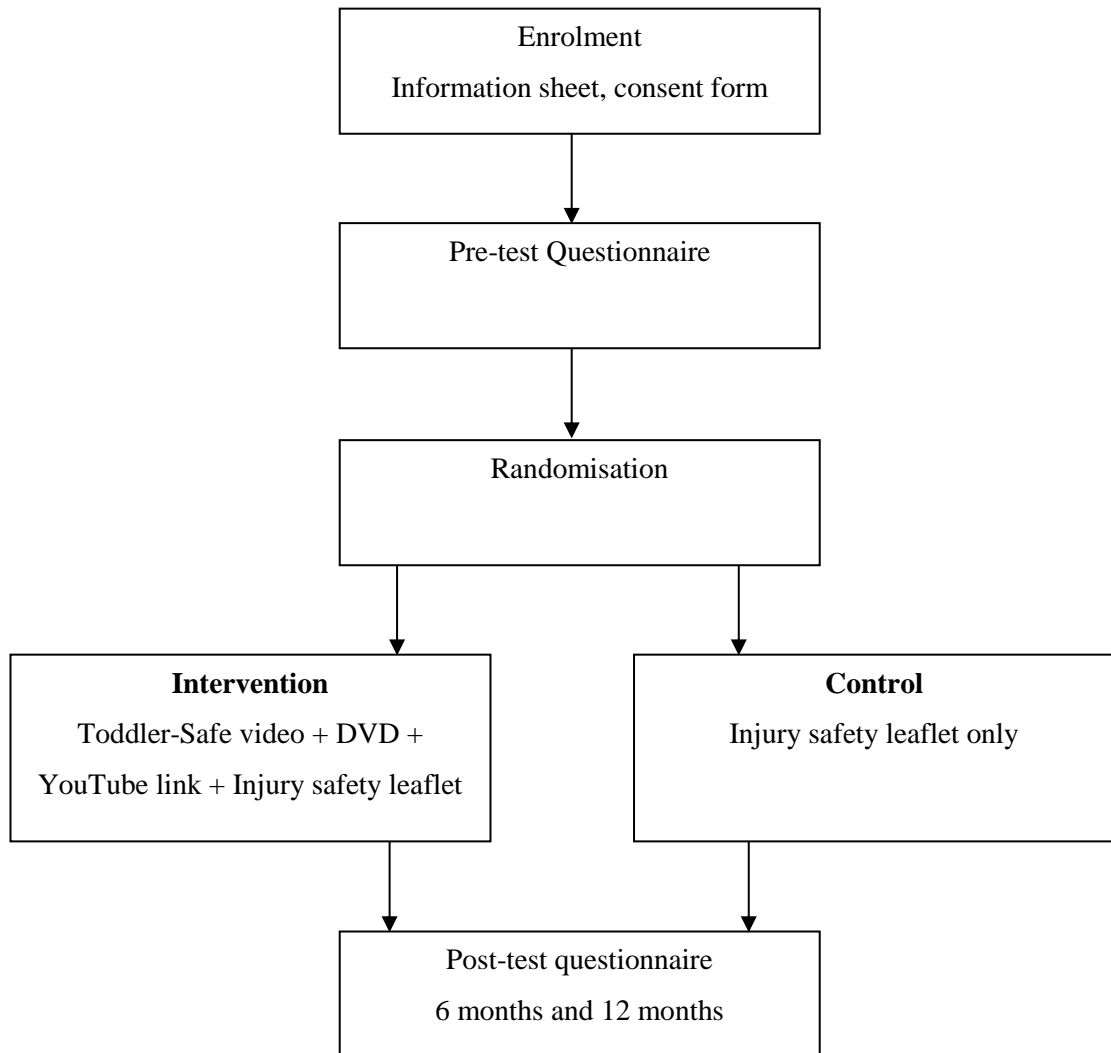
<b>Day</b>	<b>Morning</b>	<b>Afternoon</b>
Monday	Antenatal clinic	Mum’s exercise class
Tuesday	Antenatal clinic	Maternity ward and MLU
Wednesday	Maternity ward and MLU	Postnatal physiotherapy
Thursday	Antenatal clinic	Maternity ward and MLU
Friday	Maternity ward and MLU	Maternity ward and MLU

### **5.2.8.1 Recruitment procedure**

Recruitment of participants into the study followed a standardised protocol (Figure 5.2). However, some adjustments needed to be made in the way eligible subjects were identified due to the variability of the recruitment sites. In the antenatal clinic, maternity ward and MLU for instance, subjects eligible for enrolment into the study were identified by midwives and then approached by the author. In the mum's exercise and postnatal physiotherapy classes, the parents were informed of the study just before their class started and anyone interested in taking part was asked to see the author at the end of the class.

Participant recruitment was carried out on a one-to-one basis. Eligible subjects were approached by the author and given a brief description of the study. They were then asked to read an information sheet (Appendix 6) containing all the details about the study including the contact details of the research team. Parents agreeing to participate in the study were then asked to sign an informed consent form (Appendix 5) and were given unique identification numbers. Participants were also given a copy of the information sheet to keep, along with a copy of the signed consent form. A copy of the information sheet was attached to the medical notes of the participants. Consent was obtained from participants for access to an index child's medical records during the duration of the study. Any child under the age of five years and living in the same household as the participant was eligible for selection as an index child. This enabled monitoring of any attendances with burn injury for the child during the study period. Primary and alternate telephone numbers were collected for post intervention follow up assessments. Participants were then asked to complete the pre-test questionnaire after which they were randomly allocated to either an intervention group (Group A) or a control group (Group B).

**Figure 5.1: Toddler-Safe study flowchart**



### **5.2.8.2 Intervention group**

Participants randomised to the intervention group were asked to watch the *Toddler-Safe* videos on a tablet computer with the author. After watching the videos, the participants were asked what their perceptions were about the intervention they were given, and if they had any comments about the study. They then received a ‘take-home’ pack containing a DVD of the same videos, a web link to watch the videos online (on YouTube), and an injury safety leaflet. A privacy feature unique to YouTube was activated for the online videos so that only study participants with the video web link

address would have access to the videos. This was done in order to prevent contamination between study groups.

### **5.2.8.3 Control group**

Participants randomised to the control group received only the injury safety leaflet. After receiving the leaflet, the control group participants were asked what their perceptions were about the intervention they were given, and if they had any comments about the study.

All participants were allowed a 24 hour ‘cooling off’ period to decide if they still wanted to continue with the study, after which they were called on the telephone by the author of this PhD thesis to confirm their ongoing participation. Any participant not wanting to continue with the study was asked if they were happy for their pre-test data to be retained in the study. If they did not want their pre-test data to be included in the study, the author of the PhD thesis had these destroyed and the participant discontinued from the study.

### **5.2.8.4 Post intervention assessments**

To assess the effectiveness of the *Toddler-Safe* intervention, participants were contacted by telephone at six and twelve months after recruitment to complete the post-test KAP questionnaires. Since the *Toddler-Safe* study was eligible for Health and Care Research Wales research support, two independent research nurses, not involved in the study recruitment or pre-test assessment, were employed to carry out the post intervention telephone interviews. The post-test questionnaire comprised of the same 16 core questions in the pre-test questionnaire, and two additional questions that assessed usage of the intervention given to the participant, and any reported burn injury in the index child or any sibling (younger than five years of age) in the post-intervention period. After completing the questionnaire, the research nurses asked the participants for a second time what their perceptions were about the intervention they were given, and if they had any comments about the study. Each telephone interview was scheduled for a time of the day convenient for the study participant. In line

with current Good Clinical Practice (GCP) guidelines and ethical behaviour in research (Medical Research Council, 1998), only three attempts were made at contacting the study participants. Contact was considered unsuccessful if the primary and alternate telephone numbers provided by the participants at study enrolment were unusable or disconnected, or when three unsuccessful attempts at calling the participants were made.

### **5.2.9 Outcome measures**

Outcome measures for the *Toddler-Safe* study were informed by the findings from the systematic review on parenting interventions for the prevention of unintentional injuries in pre-school children, conducted by the author in the previous chapter. The primary outcome measure of the study was first aid knowledge, and burns prevention knowledge, attitudes, and practices as evidenced by KAP scores. A sub analysis of this primary outcome was a correlation analysis between baseline KAP scores and a number of explanatory variables including: parental socioeconomic status, level of education, age, ethnicity, and previous first aid training. Secondary outcome measures included parent-reported or medically attended burn injury in the pre-school children (index children or any sibling younger than five years of age) of participating parents at six and twelve months post intervention, post-intervention usage of the intervention, and participant perceptions of the *Toddler-Safe* study and intervention. Primary outcome measures were evaluated using the pre- and post-test questionnaires. Data on parent-reported burn injuries in participant's children (both index children and siblings younger than five years of age) were obtained during the post intervention telephone interviews. Data on medically attended burn injuries were obtained from the ED records of participant's index children.

### **5.2.10 Data analysis**

Data analysis was conducted on an intention to treat (ITT) basis. ITT is a strategy for the analysis of RCTs that compares patients in the groups to which they were randomised, regardless of whether they received the allocated intervention (Elkins and Moseley, 2015). ITT is described as being

a pragmatic approach that reflects what is likely to happen in actual clinical practice (Sedgwick, 2015). The CONSORT statement (Schulz et al., 2010) recommends the use of ITT analysis as standard practice for RCTs.

Data analysis for the *Toddler-Safe* study was conducted on all randomised participants. All questionnaire data collected were entered into a password protected Microsoft Excel spread sheet. The data were arranged in rows and columns in a table format and ‘cleaned’ in order to prevent any errors that could undermine the process of analysis. The socio-demographic characteristics of both study groups were assessed at baseline to check for equivalence in both groups. Changes in KAP scores were measured using the data collected from the pre- and post-test questionnaires. Total KAP scores were calculated by summing the individual question scores in each category and dividing these by the number of relevant questions multiplied by two (the maximum number of points available per question). The statistical software SPSS version 20 (SPSS Inc. Chicago, IL, USA) was employed for analysing questionnaire data. The non-parametric Wilcoxon signed rank test for the median difference was used to detect any statistical differences between intervention and control post-test KAP scores. The Wilcoxon signed rank test was chosen because it makes fewer and less stringent assumptions, is more sensitive, and is more powerful in detecting the existence of significant differences (Statistics and Research Methodology, 2010). Significance was assessed at the 0.05 level. Relationships were sought between baseline KAP scores and a number of explanatory variables including: parental socioeconomic status, level of education, age, ethnicity, and previous first aid training. The Spearman’s rank correlation coefficient test was applied to assess the relationships between each of the variables and KAP scores. A series of multiple linear regressions were conducted to allow all the above explanatory variables to be considered together. These regression models were used to assess for any statistically significant relationships between parental socioeconomic status, education and age on their knowledge of burns prevention and first aid, attitudes towards burns prevention and safety practices. A dummy variable regression model approach was employed and statistical significance was

set at 0.05 and 0.1 level. Data from the feasibility study were not included in the final analysis model. The entire data analyses for this PhD project was conducted following the advice of a senior statistician at the Institute of Primary Care and Public Health, Cardiff University.

### **5.2.11 Management of missing data**

RCTs often suffer from two major complications – noncompliance and non-response (Gupta, 2011). Non-response can seriously affect the overall outcome of a trial. There are two kinds of non-response: unit non-response (attrition) and item non-response. Unit non-response arises when a sampled unit does not respond to an entire survey, whereas item non-response refers to the absence of answers to specific questions in the survey (Yan and Curtin, 2010, Andridge and Little, 2010).

Missing data can occur in three ways: 1. Missing completely at random (MCAR) - participants with complete data cannot be distinguished from participants with incomplete data; 2. Missing at random (MAR) – participants with incomplete data differ from participants with complete data, but the pattern of ‘missingness’ is predictable from other variables in the dataset, rather than being due to the specific variable on which the data are missing; and 3. Missing not at random (MNAR) – the pattern of ‘missingness’ is not predictable from other variables in the dataset (Bennett, 2001).

#### **5.2.11.1 Management of unit non-response**

Unit non-response is often considered to pose a greater threat to survey research because failure to retain participants could introduce attrition bias and lead to loss of statistical power (due to the diminution of the achieved sample) and concerns for internal validity (Goldstein, 2009, Hindmarch et al., 2015, Yan and Curtin, 2010). In addition, this loss of participants may not occur at random, thereby leading to a situation where the remaining sample may be biased with respect to the variables being analysed (Goldstein, 2009).

A number of factors have been shown to affect response rates of health-related surveys. A study by Korkeila et al (2001) found that women, especially those in the youngest age group, men in the oldest age group, and being highly educated were associated with high survey response rates. Non-responders were more likely to be male, those with less education, divorced and widowed, and disabled (Korkeila et al., 2001).

As is common in RCTs, losses to follow-up are inevitable. Therefore, based on findings from the current child injury prevention literature (Turcotte and Babul-Wellar, 2011), the *Toddler-Safe* study was powered to allow for up to 20% losses during follow-up. Despite this, efforts were taken to limit non-response in the *Toddler-Safe* study. These included collection of additional contact details; pre-notifications by way of text message reminders; and leaving of voice messages on answering machines of participants when unsuccessful phone call attempts were made. In the *Toddler-Safe* study, unit non-response was handled by recruiting a second sample of study participants and merging with the first sample, once they had been deemed comparable in all of their demographic characteristics. Only the available data were analysed

#### **5.2.11.2 Management of item non-response**

Item non-response is common in clinical trials, and can occur when a sampled unit does not respond to a particular question in a survey (Andridge and Little, 2010). It reduces the representativeness of a sample if only completed cases are used in an analysis, and can therefore distort inferences about the population (Yan and Curtin, 2010). As with attrition, efforts were taken to prevent the occurrence of item non-response in the *Toddler-Safe* study. The author of the PhD thesis was present when participants completed baseline questionnaires, and made sure all items on the questionnaire were answered. The same attention to detail was observed by the research nurses conducting follow-up telephone interviews. These nurses made sure each question was answered before moving on to the next question.



A common technique for handling missing data in a survey is by imputation - a process whereby missing values are replaced with substituted values and treated as if they were observed (Andridge and Little, 2010). Imputation techniques were employed in the *Toddler-Safe* study to impute for missing data. These included replacing missing values with values imputed from the observed data - for instance, item non-response on participant demographic variables such as socioeconomic status (using NS-SEC), was handled by imputing the mode NS-SEC category; and replacing missing values with the last measured value – a method called ‘Last Observation Carried Forward’ (LOCF). In the LOCF method, the last available measurement for each item at the point prior to non-response is retained in the analysis (Gupta, 2011).

### 5.3 SUMMARY OF CHAPTER FIVE

- The design and methodology of the *Toddler-Safe* study were informed by the findings of a systematic review of parenting interventions for the prevention of unintentional injury in pre-school children, undertaken by the author of the thesis in chapter two.
- The *Toddler-Safe* study was conducted as an individually randomised controlled trial with a parallel design. Eligible participants were randomly assigned to intervention and control groups. The intervention group watched the *Toddler-Safe* videos and received the injury safety leaflet while the control group received only the injury safety leaflet. Participants in the intervention group also received a take-home pack containing a DVD of the same videos and a web link to watch the videos online at their own convenience
- Recruitment of study participants took place at three sites within the University Hospital of Wales (UHW) Cardiff. The

target population were parents and carers of pre-school children resident in the Cardiff and Vale of Glamorgan area. A total of 212 participants (106 participants in each treatment group) were required to detect a mean difference of 5% in mean scores after six months.

- Post intervention interviews were conducted over the telephone six and twelve months after baseline data were collected. Telephone interviews were undertaken by two independent research nurses not involved in the study recruitment or pre-test assessments. Any burns that the index children (or siblings younger than five years of age) sustained over the following six and twelve months were determined by parental report and ED attendances.
- Primary outcome measures included: first aid knowledge, and burns prevention knowledge, attitudes, and practices as evidenced by KAP scores, and a correlation analysis between baseline KAP scores and the key explanatory variables - parental socioeconomic status, level of education, age, ethnicity, and previous first aid training. Secondary outcome measures included: parent-reported or medically attended burn injury in index children or siblings younger than five years of age, post-intervention usage of the *Toddler-Safe* intervention, and participant perceptions of the study and intervention.
- Data analyses were conducted using the statistical software SPSS version 20 (SPSS Inc. Chicago, IL, USA). Specific statistical tests were used to detect any statistical differences between baseline and post-intervention KAP scores, and any differences between post-intervention scores for both study groups, as well as to assess the relationships between explanatory variables and KAP scores. A series of multiple

linear regression models was used to assess for any statistically significant relationships between each of the variables and KAP scores.

- Participant attrition was handled by recruiting a second sample of study participants and merging with the first sample, once they had been deemed comparable in all of their demographic characteristics. Imputation techniques were used to handle missing data.

## CHAPTER SIX

## **CHAPTER SIX: RESULTS OF THE TODDLER-SAFE STUDY**

### **6.1 CHAPTER OVERVIEW**

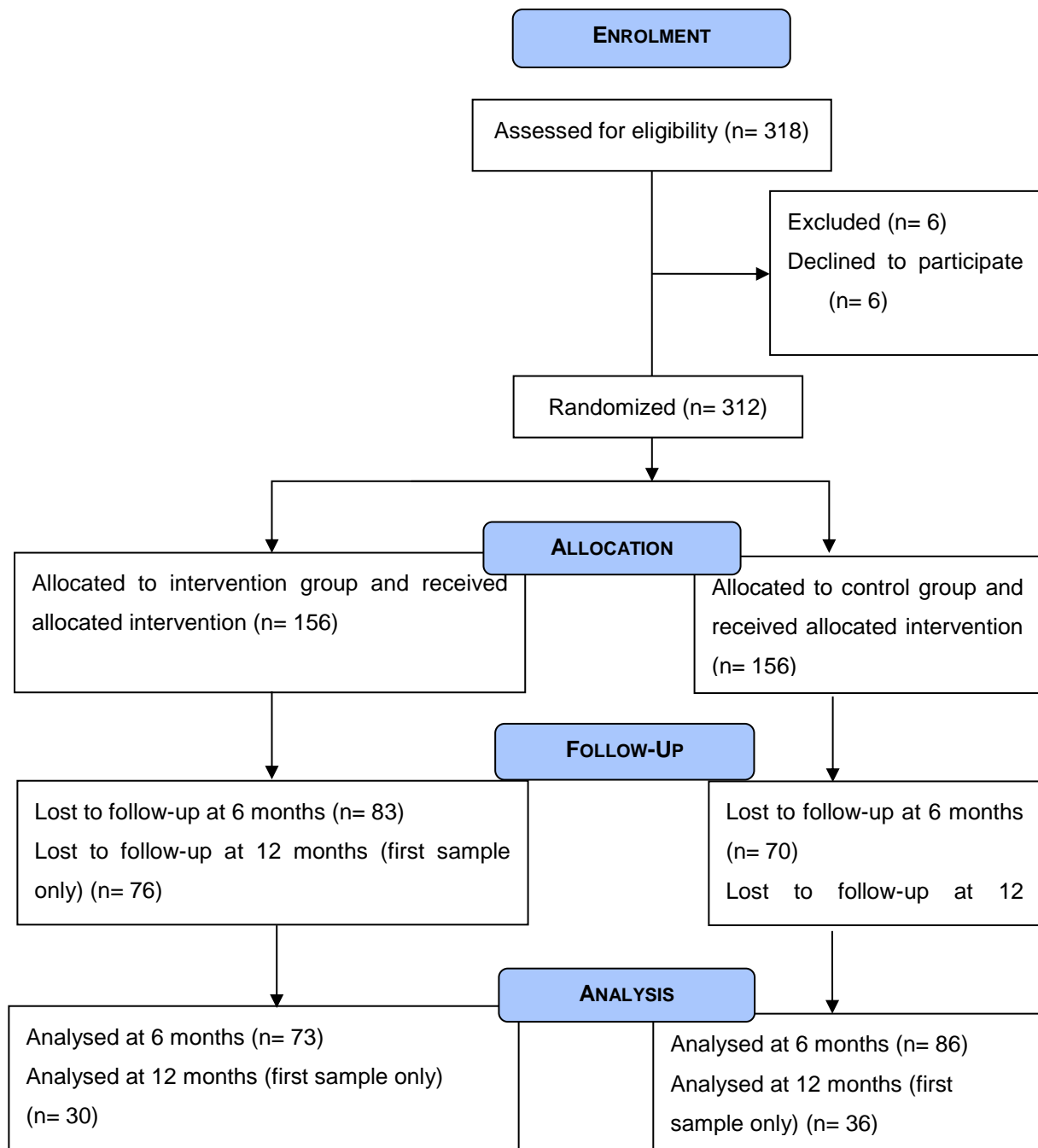
Chapter six presents the results of the *Toddler-Safe* study. This chapter begins with a narrative and graphic description of the flow of participants through the trial (section 6.2), followed by a detailed description of how missing data were handled (section 6.3). Section 6.4 describes the baseline data collected during the course of the trial. These include; demographic data on all the study participants (including previous incidents of burn injuries in participants' pre-school children), baseline comparisons of the primary outcome measure in both study groups, and relationships between key demographic variables and baseline KAP scores. Sections 6.5 and 6.6 describe the post intervention findings at six and 12 months for both primary and secondary outcome measures. An assessment of participant usage and perceptions of the *Toddler-Safe* intervention is described in sections 6.7 and 6.8 respectively. Finally, chapter six concludes with a summary of all key findings.

### **6.2 FLOW OF PARTICIPANTS THROUGH THE TODDLER-SAFE STUDY**

Recruitment of participants into the *Toddler-Safe* study was undertaken at two time points: a first sample of 212 participants was recruited between 15<sup>th</sup> of January 2013 and 20<sup>th</sup> of March 2013; and a second sample of 100 participants was recruited between 21<sup>st</sup> of August 2013 and 21<sup>st</sup> of November 2013. The second sample was recruited to make up for a high attrition of study participants from the first sample at the six-month post-intervention assessment. Of the 212 participants recruited into the first sample, only 52% (n = 110) were available for follow-up at six months. In order to avoid loss of power in the data analysis, a further 100 participants (second sample) were recruited into the study, following the exact same procedure as was employed in recruiting the first sample. Both samples were assessed for any differences and merged to create a total

dataset of 312 participants. A CONSORT diagram detailing the flow of study participants through the *Toddler-Safe* study can be seen in Figure 6.1.

**Figure 6.1: CONSORT diagram demonstrating the flow of participants through the Toddler-Safe trial**



**First sample (n = 212)**

Two hundred and eighteen eligible parents/caregivers were approached to participate in the *Toddler-Safe* study. Six refused to participate, citing the following reasons for refusal: “I’m too tired” (n = 2), “not interested” (n = 1), “I already know enough about burns prevention” (n = 1), “I won’t be in the country during the follow-up period” (n = 1), “I’m too busy” (n = 1). Two hundred and twelve participants were therefore enrolled into the study following the first round of recruitment. The only data available for parents/caregivers who were approached but refused to participate in the study was gender and this did not differ from the study participants.

The 212 participants enrolled were randomised - 106 to the intervention group and 106 to the control group. Recruitment occurred over a nine week period (15<sup>th</sup> of January 2013 to 20<sup>th</sup> of March 2013). Of the 212 participants, 170 (80%) were recruited from the Maternity ward and MLU, 15 (7%) from the Antenatal clinic, and 27 (13%) from the Mum’s exercise/postnatal physiotherapy class. All 212 recruited participants completed the pre-test questionnaire at baseline assessment.

**Second sample (n = 100)**

A second sample of 100 participants was recruited into the study over a 13 week period (21<sup>st</sup> of August 2013 to 21<sup>st</sup> of November 2013). All 100 participants were recruited from the Maternity ward and MLU. There were no refusals from all eligible parents/caregivers approached to participate in the study. The 100 participants recruited were randomly allocated into intervention and control groups (50 participants in each group). The demographic characteristics of the participants recruited into the second sample were compared with those of the participants recruited into the first sample (see Table 6.1). No statistically significant differences in demographics were found between both samples. There was no evidence of widespread media campaign on burns prevention, first aid or any other



local burns prevention programme at the time of recruitment of the second sample.

Having demonstrated sameness between the two samples, both their baseline data were merged to create a total dataset of 312 cases. Six-month post intervention outcomes were sought for all cases. Due to time and resource restrictions, the twelve-month post-intervention outcomes were sought only for the 212 cases recruited in the first sample.

**Table 6.1: Comparison of demographic characteristics of samples 1 and 2 (n = 312)**

<b>Participant demographics</b>	<b>Sample 1 (n = 212) N (%)</b>	<b>Sample 2 (n = 100) N (%)</b>	<b>P-value*</b>
<u>Parent</u>			0.49
Mother	184 (86.8)	78 (78.0)	
Father	28 (13.2)	22 (22.0)	
<u>Age group</u>			0.189
< 20 years	9 (4.2)	1 (1.0)	
20-29 years	87 (41.0)	38 (38.0)	
30-39 years	109 (51.4)	56 (56.0)	
40-49 years	6 (2.8)	5 (5.0)	
> 49 years	1 (0.5)	0 (0.0)	
<u>Education</u>			0.907
Left school before 16 years	7 (3.3)	5 (5.0)	
GCSEs/equivalent vocational qualification	40 (18.9)	16 (16.0)	
A-levels	17 (8.0)	8 (8.0)	
College/University	91 (42.9)	46 (46.0)	
Postgraduate	57 (26.9)	25 (25.0)	
<u>Ethnicity</u>			0.779
White British	177 (83.5)	85 (85)	
Other White	8 (3.8)	4 (4.0)	

<b>Participant demographics</b>	<b>Sample 1 (n = 212) N (%)</b>	<b>Sample 2 (n = 100) N (%)</b>	<b>P-value*</b>
background	8 (3.8)	3 (3.0)	0.319
Mixed background	7 (3.3)	2 (2.0)	
Black or Black British	11 (5.2)	4 (4.0)	
Asian or Asian British	1 (0.5)	2 (2.0)	
Chinese/other ethnic group			
<u>Socioeconomic status (NS-SEC)</u>			0.702
1	51 (24.1)	15 (15.0)	
2	72 (34.0)	44 (44.0)	
3	45 (21.2)	14 (14.0)	
4	44 (20.8)	27 (27.0)	
<u>Number of children in household</u>			0.65
1	112 (52.8)	53 (53.0)	
2	64 (30.2)	25 (25.0)	
3	23 (10.8)	12 (12.0)	
4	9 (4.2)	9 (9.0)	
5	3 (1.4)	1 (1.0)	
6	0 (0.0)	0 (0.0)	
7	1 (0.5)	0 (0.0)	
<u>Number of adults in household</u>			0.65
1	13 (6.1)	12 (12.0)	
2	178 (84.0)	83 (83.0)	
3	13 (6.1)	4 (4.0)	
4	5 (2.4)	0 (0.0)	
5	2 (0.9)	1 (1.0)	
6	0 (0.0)	0 (0.0)	
7	1 (0.5)	0 (0.0)	

\*P-values reported refer to the level significance when comparing both samples

### 6.3 MISSING DATA

Missing data at baseline were due to item non-response. All but two questionnaires were fully completed at baseline. One questionnaire belonged to an intervention participant and the other belonged to a control participant. In both cases the questionnaires had incomplete demographic data. One questionnaire did not have data on the participant's occupation (socioeconomic status) or the number of adults in the household, while the other did not have data on the participant's occupation. There were no major differences between the two study participants with incomplete baseline data and the rest of the sample with complete baseline data, suggesting that the 'missing completely at random' assumption remained tenable. Item non-response at baseline was handled by imputing missing data with replacement values and treating these as if they were observed. Due to the low frequency of missing data, single imputation methods were selected as the imputation method of choice. For occupation, the mode NS-SEC category was imputed (NS-SEC category 2), while for number of adults in the household, a value of 'two' was deemed practical and imputed to represent the participant and a partner.

Missing data at six months follow-up were due to both unit and item non-response. The total attrition rate at six months was 49%. Of the 312 participants randomised at baseline, only 51% (n = 159) [intervention group n = 73 (47%); control group n = 86 (55%)] were available for follow up assessments six months after baseline data were collected. There was differential attrition between study groups with more non-responders coming from the intervention group (Non-responders: Intervention group n = 83 versus control group n = 70). The demographic characteristics of study participants who were available for the six-month follow-up assessment and those who were not available for the assessment, were studied to identify any differences between both groups (see Table 6.2). No significant differences were found between study responders and non-responders on ethnicity, number of children within the household, highest educational attainment, gender of parent recruited, and the number of adults within the

household. Responders and non-responders differed on participant age group and socioeconomic status. The majority of participants who were not available for 6 month follow-up belonged to the 20-29 year age group (n = 70/153; 45.8%) in contrast to responders who were mostly from the 30-39 year age group (n = 55/159; 34.6%). This difference in age group was found to be statistically significant when analysed using the Mann-Whitney U test (p = 0.002). As regards participant socioeconomic status, the majority of non-responders were found to be in the lowest socioeconomic category - NS-SEC category 4, n = 54/153; 35.3%, compared to responders who were mostly from NS-SEC category 2 (n = 62/159; 39%). This disparity between responders and non-responders on socioeconomic status was found to be statistically significant (p = 0.001).

Item non-response was observed on three questionnaires, one questionnaire belonging to an intervention participant and the other two belonging to control participants. The intervention participant did not answer two questions - one on severity of burn injuries in young children (question 2), and the other on the preventability of burn injuries in young children (question 3). Both control participants left one question blank - a question on burns first aid (question 7) and one enquiring if the temperature of a child's bath water is tested (question 13). All three participants with incomplete questionnaires at six months had complete baseline questionnaires. Item non-response was therefore handled by applying the single imputation method - Last observation carried forward (LOCF), in which the missing data were imputed with answers collected at baseline.

**Table 6.2: Comparison of demographic characteristics of responders and non-responders at six month follow-up (n = 312; responders n = 159; non-responders n = 153)**

<b>Demographic characteristics</b>	<b>Responders (n = 159) N (%)</b>	<b>Non responders (n = 153) N (%)</b>	<b>P-value</b>
Intervention	73 (46.8)	83 (53.2)	
Control	86 (55.1)	70 (44.9)	
<u>Parent</u>			
Mother	134 (84.3)	128 (83.7)	0.882
Father	25 (15.7)	25 (16.3)	
<u>Age group</u>			
< 20 years	1 (0.6)	9 (5.9)	0.002
20-29 years	55 (34.6)	70 (45.8)	
30-39 years	96 (60.4)	69 (45.1)	
40-49 years	6 (3.8)	5 (3.3)	
> 49 years	1 (0.6)	0 (0.0)	
<u>Education</u>			
Left school before 16 years of age	7 (4.4)	5 (3.3)	0.104
GCSEs/equivalent	25 (15.7)	31 (20.3)	
A-levels	11 (6.9)	14 (9.2)	
College/University	67 (42.1)	70 (45.8)	
Postgraduate	49 (30.8)	33 (21.6)	
<u>Number of children in the household</u>			0.938
1	83 (52.2)	83 (54.3)	
2	50 (31.4)	38 (24.8)	
3	15 (9.4)	20 (13.1)	
4	7 (4.4)	11 (7.2)	
5	3 (1.9)	1 (0.7)	
6	0 (0.0)	0 (0.0)	

<b>Demographic characteristics</b>	<b>Responders (n = 159) N (%)</b>	<b>Non responders (n = 153) N (%)</b>	<b>P-value</b>
7	1 (0.6)	0 (0.0)	
<u>Socioeconomic status</u>			0.001
1	43 (27.0)	23 (15.0)	
2	62 (39.0)	45 (29.4)	
3	28 (17.6)	31 (20.3)	
4	26 (16.4)	54 (35.3)	
<u>Ethnicity</u>			0.447
White British	131 (82.4)	131 (85.6)	
Other White	8 (5.0)	4 (2.6)	
Background	5 (3.2)	6 (3.9)	
Mixed background	3 (1.9)	6 (3.9)	
Black or Black British	10 (6.3)	5 (3.3)	
Asian or Asian British	2 (1.3)	1 (0.7)	
Chinese or other ethnic group			
<u>Number of adults in household</u>			0.111
8	8 (5.0)	17 (11.1)	
1	137 (86.2)	124 (81.0)	
2	7 (4.4)	10 (6.5)	
3	3 (1.9)	2 (1.3)	
4	3 (1.9)	0 (0.0)	
5	0 (0.0)	0 (0.0)	
6	1 (0.6)	0 (0.0)	
7			

\*P-values reported refer to the level significance when comparing both groups

## 6.4 BASELINE (PRE-INTERVENTION) DATA

### 6.4.1 Demographic characteristics of study participants

All participants recruited into the study were parents of children younger than 5 years of age. Mothers were overrepresented in the evaluation sample  $n = 262$  (84%). Fathers made up the remaining 16% ( $n = 50$ ). Index children were predominantly neonates  $n = 290$  (93%). At baseline, the intervention and control group parents were similar on all demographic characteristics and reflected a wide range of socioeconomic and education levels (see Table 6.3).

**Table 6.3: Baseline demographic characteristics of participants in both study groups (N = 312; intervention group  $n = 156$ ; control group  $n = 156$ )**

<b>Participant demographics</b>	<b>Intervention group (<math>n = 156</math>) N (%)</b>	<b>Control group (<math>n = 156</math>) N (%)</b>	<b>P-value*</b>
<u>Parent</u>			0.758
Mother	130 (83.3)	132 (84.6)	
Father	26 (16.7)	24 (15.4)	
<u>Age group</u>			0.938
< 20 years	6 (3.8)	4 (2.6)	
20-29 years	62 (39.7)	63 (40.4)	
30-39 years	81 (51.9)	84 (53.8)	
40-49 years	7 (4.5)	4 (2.6)	
> 49 years	0 (0.0)	1 (0.6)	
<u>Education</u>			0.226
Left school before 16 years of age	11 (7.1)	1 (0.6)	
GCSEs/equivalent	29 (18.6)	27 (17.3)	
A-levels	14 (9.0)	11 (7.1)	
College/University	60 (38.5)	77 (49.4)	
Postgraduate	42 (26.9)	40 (25.6)	

<b>Participant demographics</b>	<b>Intervention group (n = 156) N (%)</b>	<b>Control group (n = 156) N (%)</b>	<b>P-value*</b>
<u>Ethnicity</u>			0.752
White British	132 (84.6)	130 (83.3)	
Other White Background	6 (3.9)	6 (3.9)	
Mixed background	4 (2.6)	7 (4.5)	
Black or Black British	5 (3.2)	4 (2.6)	
Asian or Asian British	8 (5.1)	7 (4.5)	
Chinese or other ethnic group	1 (0.6)	2 (1.3)	
			0.430
<u>Socioeconomic status</u>	32 (20.5)	34 (21.8)	
1	55 (35.3)	61 (39.1)	
2	31 (19.9)	28 (17.9)	
3	38 (24.4)	33 (21.2)	
4			
<u>Number of children in household</u>			0.309
1	61 (39.1)	52 (33.3)	
2	69 (44.2)	72 (46.2)	
3	12 (7.7)	23 (14.7)	
4	10 (6.4)	8 (5.1)	
5	3 (1.9)	1 (0.6)	
6	0 (0.0)	0 (0.0)	
7	1 (0.6)	0 (0.0)	
<u>Number of adults in household</u>	15 (9.6)	10 (6.4)	0.867
1	126 (80.8)	135 (86.5)	
2	11 (7.1)	6 (3.8)	
3	2 (1.3)	3 (1.9)	
4	2 (1.3)	1 (0.6)	
5	0 (0.0)	0 (0.0)	
6	0 (0.0)	1 (0.6)	
7			



\*P-values reported refer to the level significance when comparing both samples

The majority of parents in both intervention and control groups were mothers aged between 30 and 39 years of age with single children. Most of the households had two adults [intervention group n = 126 (80.8%) versus control group n = 135 (86.5%)]. The majority of parents in both groups were White British [intervention group n = 132 (84.6%) versus control group n = 130 (83.3%)], while the remainder were a mixture of other ethnic groups, the proportion of which is representative of the local Welsh population (Office for National Statistics, 2012). As regards educational attainment, four percent (n = 12) of the respondents had left school before the age of sixteen; 26% (n = 81) had attained their A-levels or had GCSEs or equivalent vocational qualifications; 44% (n = 137) had college/university degrees; and 26% (n = 82) had postgraduate degrees. This finding is not in keeping with the current levels of higher qualification held by working age adults in Wales, which reports the majority (77%) of working age adults having at least level 2 qualifications (GCSEs or A-levels) (Welsh Government, 2016). Parental socioeconomic status was reported using the National Statistics Socio-economic classification (NS-SEC) which is an occupationally based measure of employment relations and conditions of occupations (Office for National Statistics, 2010) (see Table 6.4).

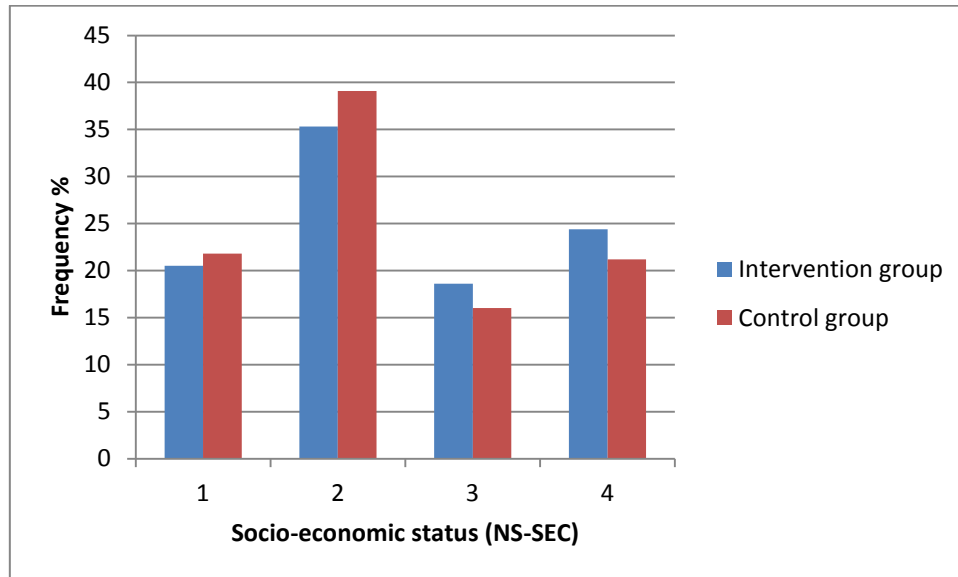
**Table 6.4: National Statistics Socio-economic Classification  
(NS-SEC)**

<b>EIGHT CLASSES</b>	<b>FIVE CLASSES</b>	<b>THREE CLASSES</b>
1. Higher managerial, administrative and professional occupations	1. Higher managerial, administrative and professional occupations	1. Higher managerial, administrative and professional occupations
1.1. Large employers and higher managerial and administrative occupations		
1.2. Higher professional occupations		
2. Lower managerial, administrative and professional occupations		
3. Intermediate occupations	2. Intermediate occupations	2. Intermediate occupations
4. Small employers and own account workers	3. Small employers and own account workers	3. Routine and manual occupations
5. Lower supervisory and technical occupations	4. Lower supervisory and technical occupations	
6. Semi-routine occupations	5. Semi-routine and routine occupations	
7. Routine occupations		
8. Never worked and long-term unemployed	* Never worked and long-term unemployed	* Never worked and long-term unemployed

The NS-SEC is currently the primary socioeconomic classification used in the UK for both official statistics and academic research (Office for National Statistics, 2010). The full version consists of eight classes. This can further be broken down to five and three classes respectively (see Table 6.4). For the purpose of statistical analysis, the eight, five, and three classes of the NS-SEC were modified to four classes in the *Toddler-Safe* study (see Figure 6.2). This was done so as to have a concise, yet compact, classification taking into account study participants who had never worked or who had been unemployed for long periods of time.

The majority of parents in both study groups belonged to NS-SEC class 2 (intermediate occupations): intervention group n = 55 (35.3%) versus control group n = 61 (39.1%).

**Figure 6.2: Distribution of study participants according to socio-economic status (n = 312)**



**National Statistics Socio-economic Classification (NS-SEC)**

- 1 Higher managerial, administrative and professional occupations
- 2 Intermediate occupations
- 3 Routine and manual occupations
- 4 Never worked and long-term unemployed

More than half of the parents taking part in the study had undertaken previous first aid training [n = 188 (60.3%); intervention group n = 87 (55.8%); control group n = 101 (64.7%)]. Only 97 (31.1%) participants: intervention group n = 45 (28.8%); control group n = 52 (33.3%) reported receiving burns first aid training. Fifty three parents (17%) reported receiving burns prevention information in the past [intervention group n = 25 (16%); control group n = 28 (17.9%)]. Twenty two parents (7.1%) had had a burn injury in the past [Intervention group n = 10 (6.4%); control group n = 12 (7.7%)]. Only a minority of parents reported having a social

worker n = 7 (2.2%); intervention group n = 4 (2.6%); control group n = 3 (1.9%).

#### **6.4.2 Children with previous burn incidents**

Only a small proportion of study participant's pre-school children had suffered a previous burn injury prior to the start of the *Toddler-Safe* study n = 22 (7.1%) [Intervention group n = 8 (5.1%); control group n = 14 (9%)]. Scalds accounted for more than half of all burn incidents n = 12/22 (see Figure 6.3). Of the 12 scald incidents, 10 were caused by hot beverages. The other two scald incidents were caused by hot water and steam respectively. All scalding incidents were reported to have occurred as accidents within the home when at least one adult family member was present. The accident scenario most frequently reported was one in which the child pulled down a cup containing a hot beverage from a table or from the parent's hands (n = 9/12).

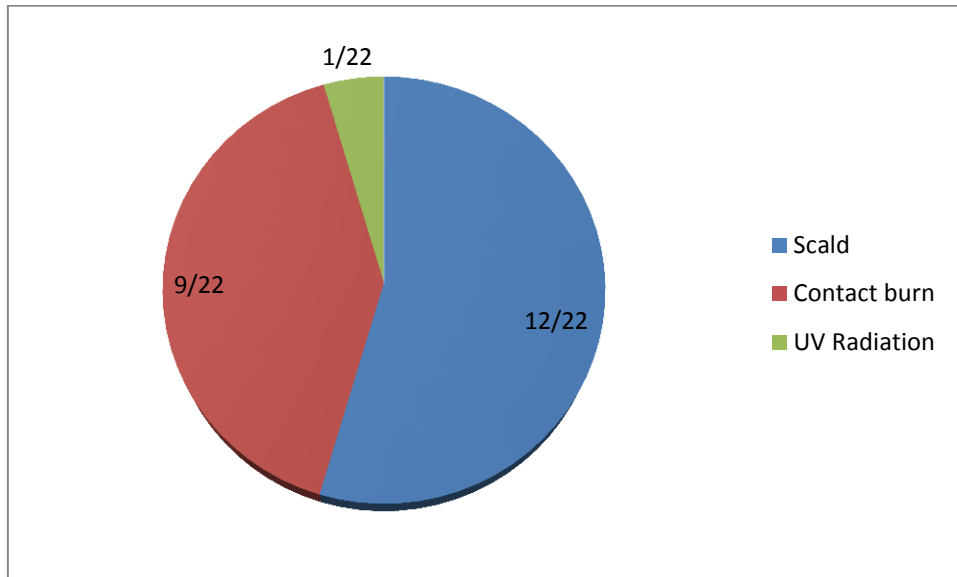
Contact burns were the second most frequent type of burn injuries reported (n = 9/22). The most frequent contact burn agents reported were hair straighteners (n = 5/9). The most frequent mechanism of injury reported for hair straightener burns was one in which the child touched or stepped on the hot hair straightener while it was left on the floor to cool down. Other contact burn agents reported included hot electric iron (n = 2/9), baking tray (1/9), and fire guard (1/9).

Burns due to overexposure to UV radiation (sunburn) was reported by just one parent. The child involved was 3 years old and the burn occurred during a day out to the beach in the middle of summer.

The majority of burn incidents occurred in siblings of index children n = 19 (86%). The three incidents that occurred in the index children happened when the children were 20 months (hot hair straightener), 36 months (hot coffee), and 24 months (hot water) of age respectively.

The distribution of burns highlighting the child characteristics, different burn types, burn agents, and mechanisms of injury can be seen in Figures 6.3 and 6.4, and Table 6.5.

**Figure 6.3: Pie chart showing types of burns reported in study participants' children prior to Toddler-Safe enrolment (n = 22)**

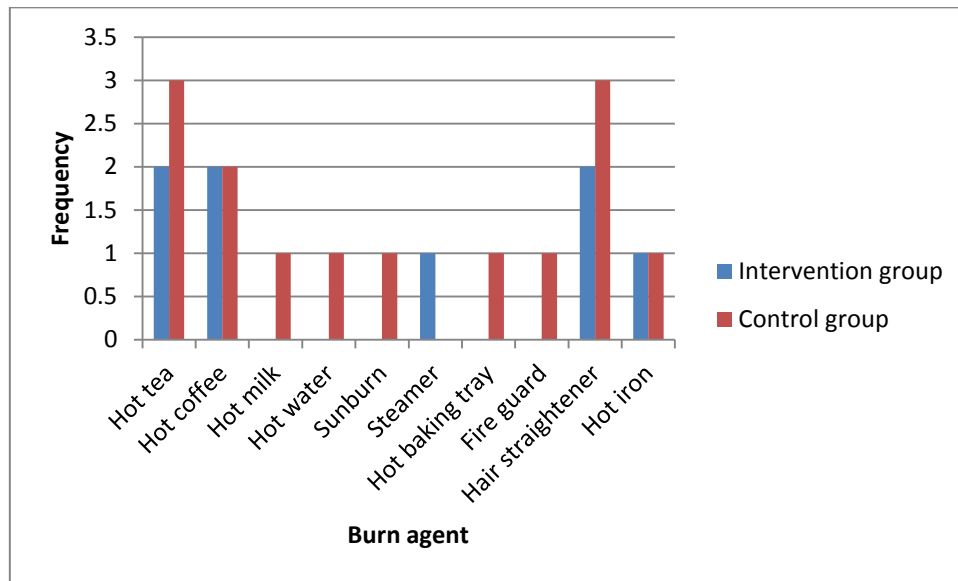


**Table 6.5: Distribution of burns prior to Toddler-Safe enrolment highlighting child burn characteristics and burn mechanisms in children with previous burns (n = 22)**

Burn cases	Age of child at time of burn	Gender	Burn type	Burn agent	Mechanism of injury
Case 1	24 months	Male	Scald	Hot tea	Pull down from table
Case 2	17 months	Male	Scald	Hot tea	Knocked cup out of mum's hands
Case 3	20 months	Female	Contact	Hair straightener	Touched hot hair straightener with hand while it was cooling down
Case 4	36 months	Female	Scald	Hot coffee	Pull down from table
Case 5	24 months	Male	Scald	Hot water	Put hands under hot tap
Case 6	15 months	Male	Contact	Hair straightener	Touched hot hair straightener with hand

<b>Burn cases</b>	<b>Age of child at time of burn</b>	<b>Gender</b>	<b>Burn type</b>	<b>Burn agent</b>	<b>Mechanism of injury</b>
					while it was cooling down
Case 7	18 months	Male	Scald	Hot coffee	Pull down from parent's hands
Case 8	36 months	Female	Radiation	Sunburn	Parent did not apply sunscreen on child
Case 9	36 months	Female	Scald	Steamer	Put face too close to steam coming out of food steamer
Case 10	24 months	Female	Scald	Hot coffee	Pull down from table
Case 11	24 months	Male	Contact	Hot baking tray	Touched tray while mum was bringing it out from oven
Case 12	18 months	Female	Contact	Hair straightener	Touched hot hair straightener with hand while it was cooling down
Case 13	36 months	Male	Contact	Hair straightener	Stepped on hot hair straightener
Case 14	24 months	Male	Contact	Fire guard	Touched fire guard with hand
Case 15	18 months	Male	Scald	Hot milk	Knocked over cereal bowl containing hot milk left on floor
Case 16	24 months	Male	Scald	Hot tea	Pull down from high surface
Case 17	20 months	Male	Contact	Hair straightener	Touched hot hair straightener with hand while it was cooling down
Case 18	24 months	Male	Scald	Hot tea	Pull down from table
Case 19	12 months	Male	Scald	Hot coffee	Pull down from parent's hands
Case 20	24 months	Female	Scald	Hot tea	Pull down from table
Case 21	18 months	Male	Contact	Hot electric iron	Touched hot iron with hands while iron was cooling down
Case 22	24 months	Female	Contact	Hot electric iron	Touched hot iron with hands while parent was ironing

**Figure 6.4: Distribution of burn incidents prior to Toddler-Safe enrolment according to study group**



#### 6.4.2.1 Gender and age distribution

Amongst those who had sustained a burn prior to study commencement, boys were found to have experienced more burns than girls: [Male  $n = 14/22$  (64%) versus female  $n = 8/22$  (36%)] (see Table 6.4). The majority of burn accidents occurred in children aged 24 months or younger ( $n = 18/22$ ; 82%). The highest frequency of burns occurred when the children were twenty four months of age ( $n = 9/22$ ; 41%); mean 23.45 months; standard deviation 6.97 months.

#### 6.4.2.2 Family characteristics of children with previous burn injuries

Of the 22 incidents of previous childhood burns, 18 occurred in households where two parental figures were present. The majority of incidents occurred in children whose parents were allocated to the control group ( $n = 14$ ). The majority of the parents were White British ( $n = 18$ ) and aged between 30 and 39 years ( $n = 15$ ). Half of the parents ( $n = 11$ ) were educated up to college/university level. The majority of parents ( $n = 13$ ) belonged to the NS-SEC category 4 (never worked or long-term unemployed). More than half of the parents had undertaken previous first

aid training (n = 12). Only three of the families had received burns prevention information in the past. None of the families had a social worker.

### 6.4.3 Baseline KAP comparisons (Intervention vs. Control group)

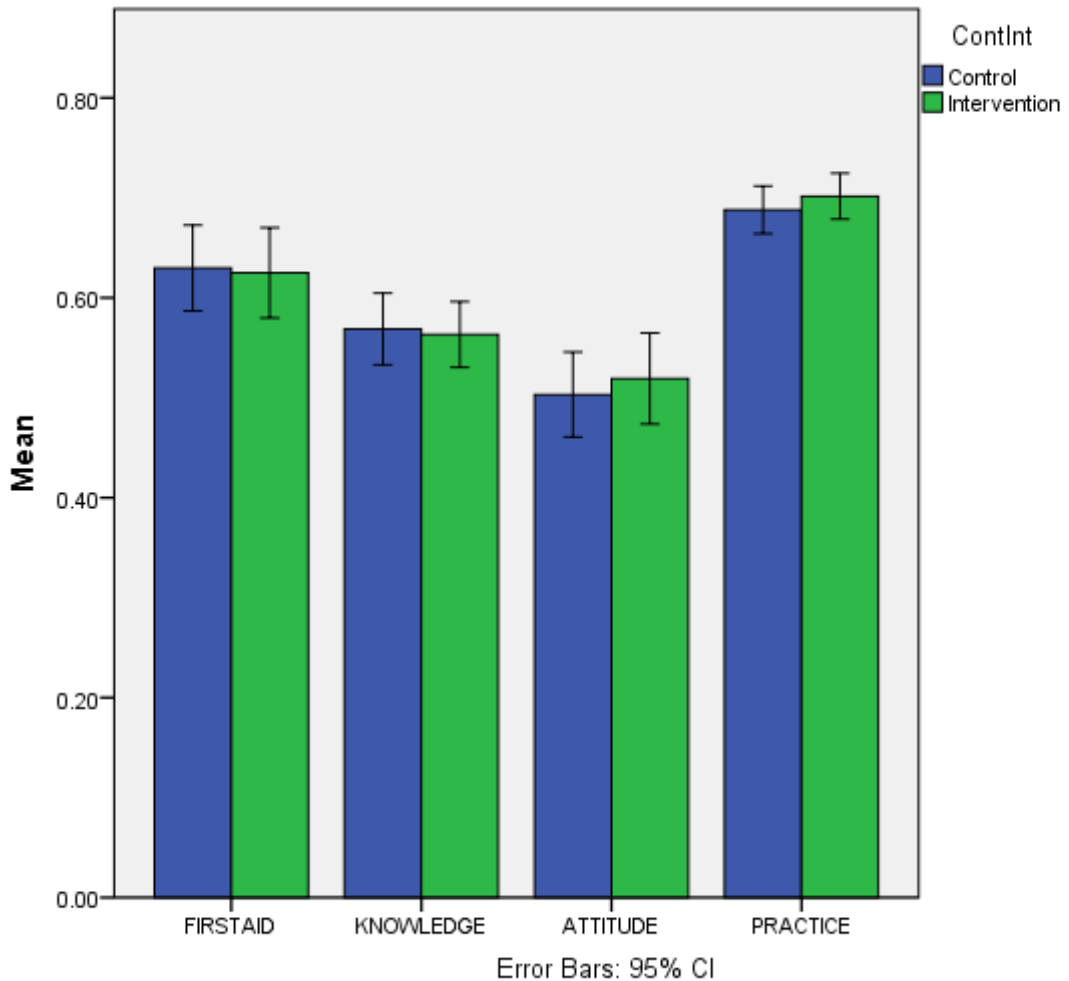
All 312 participants enrolled in the *Toddler-Safe* study received the intervention they were allocated to at baseline. Summary scores were calculated at baseline for each component of KAP (including burns first aid knowledge) in the intervention and control groups. Neither study group showed any statistically significant differences on any of the KAP components. (see Table 6.6 and Figure 6.5).

**Table 6.6: Comparison of intervention and control group baseline KAP scores (n = 312)**

<b>KAP</b>	<b>Study group</b>	<b>Mean score</b>	<b>95% CI</b>	<b>SD</b>	<b>p-value</b>
First aid knowledge	Intervention	62.5%	58.0% to 67.0%	28.6%	0.8744
	Control	63.0%	58.7% to 67.3%	27.2%	
<b>Burns prevention</b>					
Knowledge	Intervention	56.3%	53.0% to 59.6%	20.8%	0.8079
	Control	56.9%	53.3% to 60.5%	22.7%	
Attitude	Intervention	51.9%	47.4% to 56.5%	28.8%	0.6124
	Control	50.3%	46.1% to 54.6%	26.9%	
Practices	Intervention	70.2%	67.9% to 72.5%	14.5%	0.4042
	Control	68.8%	66.4% to 71.2%	15.1%	



**Figure 6.5: Bar chart showing baseline intervention and control group KAP scores**



#### **6.4.4 Assessing relationships between key demographic variables at baseline**

Relationships were sought between baseline burns prevention KAP scores (including burns first aid knowledge scores) and each of the following demographic variables: parental socioeconomic status, level of education, age of parent, and ethnicity. Relationships were also sought between burns first aid knowledge and previous first aid training. A non-parametric measure of statistical dependence between two variables (Spearman's rank correlation coefficient) was used to assess this relationship. This was because the data were not normally distributed. Tables showing these correlations can be seen in Appendix 8.

#### **6.4.4.1 Socioeconomic status**

There was no significant relationship between parental socioeconomic status and burns prevention knowledge ( $p = 0.708$ ) or attitudes ( $p = 0.551$ ). However, there was a significant positive linear relationship between socio-economic status and burns first aid knowledge (Spearman's  $\rho = 0.123$ ;  $p = 0.030$ ) and burns prevention practices (Spearman's  $\rho = 0.232$ ;  $p < 0.001$ ); i.e. the higher the socioeconomic status the greater the chances of adequate burns first aid knowledge and good burns prevention practices.

#### **6.4.4.2 Education**

There was no significant relationship between parental level of education and burns first aid knowledge ( $p = 0.560$ ), burns prevention knowledge ( $p = 0.441$ ) or attitudes ( $p = 0.639$ ). However, there was a significant positive linear relationship between parental level of education and good burns prevention practices (Spearman's  $\rho = 0.332$ ;  $p < 0.001$ ).

#### **6.4.4.3 Parental age**

There was a significant inverse relationship between parental age and burns prevention practices (Spearman's  $\rho = -0.186$ ;  $p = 0.001$ ); i.e. the older the parent the lower the chances of good burns prevention practices. There was no significant relationship between parental age and burns first aid knowledge ( $p = 0.379$ ), burns prevention knowledge ( $p = 0.336$ ), or attitudes ( $p = 0.906$ ).

#### **6.4.4.4 Ethnicity**

There was a significant relationship between ethnicity and both burns first aid knowledge (Spearman's  $\rho = 0.119$ ;  $p = 0.035$ ) and burns prevention knowledge (Spearman's  $\rho = 0.121$ ;  $p = 0.033$ ); i.e. being White British meant one had a greater chance of having adequate burns first aid and burns prevention knowledge. There was no significant relationship between ethnicity and burns prevention attitude ( $p = 0.423$ ) or practices ( $p = 0.323$ ). These findings were based on a correlation analysis performed using

two groups – White British versus other ethnic groups. The numbers of non-White British ethnic groups were too small to be analysed individually and were combined together as one group. White British participants were overrepresented in the analysis, making up 84.6% and 83.3% of participants in the intervention and control groups respectively. This analysis should therefore be interpreted with caution.

#### **6.4.4.5 Previous first aid training**

There was no significant correlation between having undertaken a previous first aid training course and burns first aid knowledge ( $p = 0.134$ ).

#### **6.4.5 Multiple linear regression analysis**

A series of multiple linear regressions with burns first aid knowledge, burns prevention knowledge, attitudes, and practices as outcomes were carried out. The explanatory variables; socioeconomic status, education, and age group of parent, were added to the regression one at a time. As all the explanatory variables are categorical, we used the statistical dummy variable regression model approach.

##### ***Burns first aid knowledge***

According to the coefficient table of the regression analysis (see Appendix 9), only two classes of socioeconomic status (NS-SEC 1 and NS-SEC 2 respectively at 5% and 10% level of significance) seemed to have significant relationships with parental burns first aid knowledge. The  $p$  - values for these two classes were 0.016 and 0.08 respectively. Study participants belonging to NS-SEC class 1 (Higher managerial, administrative and professional occupations) were estimated to have a burns first aid knowledge score 0.13 higher than the participants belonging to NS-SEC class 4 (never worked or long-term unemployed). Those belonging to NS-SEC class 2 (intermediate occupations) were estimated to have a first aid knowledge score 0.083 higher than the participants belonging to NS-SEC class 4. No other variables (parental level of education and age group)

were found to have any significant relationships with burns first aid knowledge. Therefore, for parents enrolled into the *Toddler-Safe* study, socioeconomic status was the most influential variable as regards parental knowledge of burns first aid at baseline.

### ***Burns prevention knowledge, attitudes, and practices***

None of the explanatory variables had a significant relationship with burns prevention knowledge and attitudes.

## **6.5 POST INTERVENTION DATA**

The study's primary outcome measure (burns prevention and first aid knowledge, attitudes, and practices as evidenced by improvement in KAP scores) was assessed at six and twelve months after baseline data was collected. Analysis of data for the primary outcome measure was conducted using an intention to treat (ITT) approach, in which all participants recruited to the trial were compared on the basis of the treatment group to which they were originally randomly assigned. No imputation techniques were performed and only the available data were analysed. There is currently a lack of consensus on how to handle missing data or study drop-outs when conducting an ITT analysis (Alshurafa et al., 2012, Hollis and Campbell, 1999, Herman et al., 2009). Some authors insist that a full application of ITT analysis is only possible when complete outcome data are available for all randomised subjects (Hollis and Campbell, 1999, Gupta, 2011, Armijo-Olivo et al., 2009). Others recommend imputation of missing data only when drop-out rates are less than 20%, but offer no adequate recommendations for larger drop-out rates (Unnebrink and Windeler, 2001). However, in the current literature, researchers are encouraged not to impute missing data in ITT analyses (Elkins and Moseley, 2015). This recommendation is shared by the Cochrane handbook (Higgins Julian and Green, 2011) and the CONSORT statement (Schulz et al., 2010), which describe the ITT analysis as simply collecting data from each participant,

wherever available, and analysing the data on the basis of the treatment group to which the participant was originally assigned regardless of what intervention they received (Elkins and Moseley, 2015). The analysis of data for the *Toddler-Safe* study's primary outcome measure was therefore based on this current stance, with no imputation undertaken to handle study drop-outs.

### 6.5.1 Comparison of mean post-test KAP scores at six-months

Six-month mean KAP scores were compared for only the study participants that were available for follow-up assessments six months after baseline data were collected (intervention group n = 73; control group n = 86) – see Table 6.7.

**Table 6.7: Comparison of intervention and control group post-test KAP scores at six months (n = 159; intervention n = 73; control n = 86)**

<b>KAP</b>	<b>Intervention group post-test mean score</b>	<b>Control group post-test mean score</b>	<b>P - value</b>
First aid knowledge	76.0%	69.2%	0.128
<b>Burns prevention</b>			
Knowledge	61.0%	63.8%	0.446
Attitudes	53.8%	52.0%	0.612
Practices	81.8%	76.0%	0.001*

\*statistically significant at p<0.05

When compared to the control group, the intervention group had higher mean scores for first aid knowledge, burns prevention attitudes, and burns prevention practices. Only the difference in practice scores reached statistical significance (p = 0.001). The control group had a slightly higher mean burns prevention knowledge score.

### 6.5.2 Comparison of mean post-test scores at 12 months

Twelve-month post-test outcomes were sought for only the 212 participants recruited in the first sample. Mean KAP scores were compared for only the study participants that responded at the 12-month follow-up assessment (see Table 6.8). Missing data were due to both unit and item non-response. The total attrition rate at 12 months was 69%. Of the 212 participants recruited into the first sample, only 66 (31%) were available for follow-up assessments 12 months after the baseline data were collected (intervention group n = 30; control group n = 36). Item non-response was observed on six questionnaires. The imputation strategy used was the LOCF method.

**Table 6.8: Comparison of intervention and control group post-test KAP scores at 12 months (n = 66; intervention n = 30; control n = 36)**

<b>KAP</b>	<b>Intervention group post-test mean score</b>	<b>Control group post-test mean score</b>	<b>P - value</b>
First aid knowledge	70.8%	68.8%	0.494
<b>Burns prevention</b>			
Knowledge	60.4%	68.1%	0.127
Attitudes	54.2%	59.7%	0.549
Practices	80.8%	75.4%	0.087

\*statistically significant at p<0.05

The intervention group had higher first aid knowledge and burns prevention practice scores at 12 months. The control group had higher burns prevention knowledge and attitude scores. None of these differences in scores was statistically significant.

## **6.6 SECONDARY OUTCOME: PARENT-REPORTED OR MEDICALLY ATTENDED BURN INJURY**

Data were collected on childhood burn injuries that occurred during the succeeding six and 12 months after the intervention. These included parental reports during follow up phone interviews and medically attended incidents obtained from the children's medical notes. All parents recruited at the start of the study consented to having their children's clinical records assessed for burn attendances.

### **6.6.1 Parent-reported burn injury**

At the six-month follow up, there were four parental reports of burn injuries to pre-school children (intervention group n = 3; control group n = 1). Two incidents were contact burns caused by the children touching hot hair straighteners. The parents of both these children belonged to the intervention group. The children were two years of age at the time of the burn and both incidents occurred in the home environment. The third incident was a contact burn caused by a child touching a hot toaster in the kitchen. The child was 10 months of age at the time of the burn incident and the parents belonged to the intervention group. The fourth incident was a sunburn to the ear of a five year old child, who was in the control group.

There was only one parental report of burn injury between the six and 12 month post-intervention assessments. This involved a child grabbing a hot hair straightener with the hands. The child was 15 months old at the time of the burn and the parents belonged to the control group. This incident occurred in the home environment with one adult present.

### **6.6.2 Medically attended burn injury**

The ED records of index children involved in the study were assessed for burn injury attendance and treatment during the follow-up period. Children of parents in the first sample had their records checked between July 2013 and December 2014. Those in the second sample were

checked between February 2014 and December 2014. There were no reports of burn injury to any of the children in either sample.

### **6.7 POST-INTERVENTION USAGE OF *TODDLER-SAFE* INTERVENTIONS**

The number of times study participants used the interventions allocated to them during the follow-up period, was assessed six months after pre-test data were collected. The majority of study participants in both treatment groups reported using their interventions just once during the six-month follow-up period (DVD 56%; Leaflet 65%). Thirty five percent of study participants in the intervention group reported not watching the DVD at all, while 9% reported watching it more than once. Twelve percent of participants who received the ‘Take-home’ pack reported using the *Toddler-Safe* online resource at least once. In the control group, 13% of the participants reported not using the safety leaflet during the six-month follow-up period, while 22% reported using it more than once.

### **6.8 PARTICIPANT PERCEPTIONS ON THE *TODDLER-SAFE* STUDY AND INTERVENTIONS**

Study participants in both treatment groups were asked what they felt about the interventions they were given and also if they had any comments about the *Toddler-Safe* study. Of the 312 participants that were enrolled into the study at baseline, only 40 (12.8%) responded with comments. Most of the participants felt the *Toddler-Safe* study was “worth taking part in”, and that the questionnaires were “very informative”, “contained common sense questions”, and “made one think”. Two participants said they found the questions difficult to answer, while one participant said she found the questionnaire irrelevant.

When asked about their perceptions on the interventions they were given, most of the participants in the intervention group felt the videos were “very useful and to the point”. When asked about the ‘Take-home’ pack, one participant responded “the DVD may be a barrier to effective utilisation



of the intervention, as it takes more effort to watch a DVD than to read a leaflet”. Another participant responded “the DVD is ineffective - people do not get around to watching them”. One participant said she lost her take-home pack and would have preferred reading a paper leaflet as it takes time to set up a DVD. Only one participant said she found the DVD very useful and instructive, especially for first time parents. When asked about their perceptions on the online resource, one participant felt it was “a novel way of disseminating information, especially in this day and age of smart phones and tablet computers”. Another participant felt the online resource was “a good idea, but people may be discouraged from using it because they had to physically type in the long web link onto a browser”.

Nine participants in the control group responded to comments about the injury safety leaflet. Most of the control participants found the leaflet too basic and of no use to the questionnaire. Four of the participants felt the leaflet had no information on the initial treatment of burns. Two participants felt they already had all the information listed in the leaflet. Only one participant found the leaflet valuable as it made her more aware of hazards within the home.

## **6.9 SUMMARY OF CHAPTER SIX**

Chapter six presented the results of the *Toddler-Safe* study. Below is a summary highlighting the chapter’s key points.

- Study participants were recruited into the *Toddler-Safe* study at two time points. Both samples had similar demographic characteristics and were merged to form a single sample of 312 participants.
- Intervention and control groups did not statistically differ on any demographic characteristics or baseline primary outcome measure, indicating a successful randomisation process.

- Total attrition rate at six months was 49%. Non-responders were found to be younger and from lower socioeconomic backgrounds when compared to responders
- Twenty two study participants' children had suffered previous burn injuries. Most of the children were male and aged 24 months or younger. Scalds accounted for more than half of all burn incidents, with hot beverages the most common burn agent, and 'pull down' from table, the most frequent mechanism of injury. Contact burns were the second most frequent burn injuries reported, with more than half of all cases caused by hot hair straighteners. The most frequent mechanism of injury involved touching or stepping on the hot hair straightener.
- Intervention and control group baseline KAP scores were all above 50%. There were no significant differences in baseline KAP scores between study groups on any of the KAP components.
- Significant positive linear relationships were reported between parental socioeconomic status and burns first aid knowledge, as well as burns prevention practices. Multiple logistic regression analyses confirmed the significance of socioeconomic status and also found it to be the most influential variable in parental knowledge of burns first aid. A significant positive linear relationship was also observed between parental level of education and burns prevention practices.
- At the six month post-test KAP assessments, the intervention group had higher mean scores for first aid knowledge, burns prevention attitudes, and burns prevention practices. Only the difference in practice scores reached statistical significance.

The control group had a slightly higher mean burns prevention knowledge score.

- Twelve month post-test outcomes were sought for only participants recruited in the first sample. The intervention group had higher first aid knowledge and burns prevention practice scores. The control group had higher burns prevention knowledge and attitude scores. None of these differences in scores was statistically significant.
- There were four parental reports of burn injuries at the six month post-test assessment. Three incidents were contact burns (two by hair straighteners and one by toaster) and one incident was a sunburn. There was only one parental report of burn injury at the twelve month post-test assessment – contact burn caused by hair straightener. There were no reports of medically attended burn injuries at follow-up.
- The majority of study participants in both treatment groups reported using the interventions given to them just once during the six-month follow-up period.

## CHAPTER SEVEN

## CHAPTER SEVEN: DISCUSSION

### 7.1 INTRODUCTION AND CHAPTER OVERVIEW

As described in chapter one, unintentional burn injuries in young children are an important public health problem responsible for significant morbidity and mortality worldwide. Tailored educational interventions targeted specifically at parents of young children have been shown to promote behaviour change and facilitate parental knowledge of complex paediatric health problems. This PhD research project was therefore designed to determine whether a targeted preventative intervention improved parental burns safety and first aid knowledge and behaviour in the home and reduced the risk of future childhood burns.

The *Toddler-Safe* study was a multimedia-based educational intervention which addressed the knowledge gap around childhood burn injury prevention and first aid knowledge in parents and carers of children younger than five years of age. A thorough literature review was conducted in order to access current published work in the field of childhood burns prevention. A systematic review of parenting interventions for the prevention of unintentional injury in pre-school children, was undertaken to inform the design and methodology of the *Toddler-Safe* study. The *Toddler-Safe* study was conducted as an RCT with parallel group design. Eligible participants enrolled into the study were randomly assigned to one of two groups: an intervention group receiving the *Toddler-Safe* videos and injury safety leaflet plus a take-home pack; and a comparison group receiving only the injury safety leaflet. This study tested the hypothesis that parents exposed to the *Toddler-Safe* videos and take-home pack will demonstrate better childhood burns-related outcomes when compared to a control group that did not receive the videos and take-home pack.

Chapter seven summarises the principal findings of the *Toddler-Safe* study and provides a discussion of the trial context, its strengths and weaknesses, and a comparison with other studies. The principal findings of

the study's primary and secondary outcomes (KAP scores and self-reported/medically attended burn injuries) are discussed in sections 7.2 and 7.3 respectively. This is immediately followed by the strengths and limitations of the study (sections 7.4 and 7.5 respectively), and an interpretation of the study findings with comparisons with existing literature (section 7.6). The post-intervention usage of the *Toddler-Safe* intervention is described in section 7.7 followed by a discourse on the challenges faced by the author of this PhD thesis during the conduct of the *Toddler-Safe* study (section 7.8). Chapter seven concludes with a summary of all the key points presented in the chapter (section 7.9).

## **7.2 PRINCIPAL FINDINGS – PRIMARY OUTCOME**

### **7.2.1 Baseline findings**

Participation in the *Toddler-Safe* study was high (98%). Of the 318 potential participants approached, only six refused to take part in the study. Intervention and control groups were demographically similar and were representative of the local South Wales population. Pre-test questionnaire data showed that both study groups had a modest level of understanding of key burns prevention and first aid concepts. The highest scores were seen in burns first aid knowledge (intervention group 62.5% and control group 63.0%) and burns prevention practices (intervention group 70.2% and control group 68.8%). Whilst there were no statistically significant differences in mean scores on any of the baseline KAP components between intervention and control groups, the author of this PhD thesis found that study participants from higher socioeconomic backgrounds had higher burns first aid knowledge and prevention practice scores, and there was a significant linear relationship between parental level of education and burns prevention practice scores. A multiple regression analysis confirmed socioeconomic status as the most influential variable regarding burns first aid knowledge at baseline.

### **7.2.2 Post intervention findings**

Just over half of the study participants were available for six month follow up assessments. Non-responders were found to be younger and from lower socioeconomic backgrounds when compared to responders. The *Toddler-Safe* intervention improved parental burns first aid knowledge, and both burns prevention attitudes and practices, as evidenced by improvements in mean scores on the corresponding KAP components at the six month post-test assessment. The intervention effect was powerful enough to show a statistically significant improvement in burns prevention practice scores in the group that received the *Toddler-Safe* intervention ( $p = 0.001$ ). The control group had a slightly higher mean burns prevention knowledge score but this difference was not statistically significant.

Only about a third of participants recruited from the first sample were available for follow-up after 12 months. The improvements in parental burns first aid knowledge and burns prevention practices scores reported in the intervention group at six months were retained up until 12 months post intervention. These improvements however, were not significantly different from those found in the control group.

## **7.3 PRINCIPAL FINDINGS – SECONDARY OUTCOME**

### **7.3.1 Baseline findings**

The results of the *Toddler-Safe* study showed that only a small proportion of study participants' pre-school children had suffered a burn injury prior to the start of the study ( $n = 22$ ). Of this number, only three were index children while the remainder were siblings of the index children younger than five years of age. The majority of incidents occurred in children whose parents were allocated to the control group. Just over half of the total burn incidents were scalds, with hot beverages the most common burn agents. The most frequent mechanism of injury reported was one in which the child pulled down a cup containing a hot beverage from a table or from the hands of the parent carrying them. Most of the injured children

were reported to be male and aged 24 months or younger (mean age 23.45 months). The majority of their parents were White British and belonged to the NS-SEC category 4 (never worked or long-term unemployed).

### **7.3.2 Post intervention findings**

Post intervention findings included parental reports of burn injuries in their children during the follow-up period or medically attended burn injuries obtained from the children's ED notes. At the six month follow-up assessment there were four parental reports of burn injuries. Three of these reports were from parents in the intervention group while the remainder was from a parent in the control group. The three intervention group incidents were contact burns caused by the children touching hair straighteners (two cases) and a hot toaster (one case) with their hands. The children with hair straightener burns were both 24 months of age at the time of the burn, while the child who suffered a burn from a hot toaster was 10 months old. The control group incident was a sunburn suffered on the ear of a five year old child. None of the four children that suffered burn injuries at the six month assessment was reported to have suffered a previous burn prior to the start of the study. There was only one parental report of burn injury at the 12 month post-test assessment. It involved a contact burn to the hand of a 15 month old child caused by a hot hair straightener. The child's parents belonged to the control group. Likewise the four reported cases at six months, the child with the burn at the 12 month assessment had not previously been reported as having suffered a burn prior to the study.

There were no reports of medically attended burn injury in the ED records of any of the children involved in the *Toddler-Safe* study at either of the follow-up time points.

## **7.4 STRENGTHS OF THE STUDY**

A notable strength of the *Toddler-Safe* study is its randomised trial design. RCTs are regarded as the gold standard for clinical trials and are the most rigorous way of determining whether a cause and effect relationship



exists between treatment and outcome. Randomisation of study participants was carried out by a statistician not involved in the *Toddler-Safe* study, using a computerised random number generator and allocations were placed in sequentially numbered, opaque, sealed envelopes. Examination of the demographic characteristics of both study groups at baseline found no significant differences, indicating a successful randomisation process.

Another key strength of the study is the blinding of data collectors at baseline and follow-up. Blinding is important because it eliminates bias resulting from the expectations of the study participant or provider regarding outcomes (Medical Research Council, 2000). Pre-test data was collected solely by the author of this PhD thesis. He was blinded to treatment arm allocation at this stage because pre-test data were collected prior to group allocation. The author was also blinded to treatment allocation at follow-up because data collection at this stage was conducted by research nurses. Blinding of study participants was not possible and this is discussed in section 7.5.3.

The evidence based methodology informing the design of the *Toddler-Safe* intervention is another key strength of this study. Systematic reviews are regarded as the highest level of research evidence and are crucial in identifying and summarising evidence relating to the effectiveness of a given question (Centre for Reviews and Dissemination, 2008). The systematic review reported in chapter two, was conducted in compliance with international PRISMA guidelines, and established which components of parenting interventions were effective at preventing unintentional injury in pre-school children or improving parental child safety knowledge and behaviour. These components were used to inform the *Toddler-Safe* methodology and design.

The *Toddler-Safe* intervention was grounded in behaviour change theory. There is evidence to suggest that interventions developed with the use of such theory are capable of generating larger changes in health behaviour than interventions not developed with theory (Avery et al., 2013,

Protopogerou and Johnson, 2014). Three theories guided every stage of the development of the *Toddler-Safe* intervention. These are the Elaboration Likelihood Model, the Health belief Model, and the Cognitive Theory of Multimedia Learning.

A further strength is the use of a validated questionnaire in evaluating the effectiveness of the *Toddler-Safe* intervention. Validation of a questionnaire ensures that the instrument accurately measures what it aims to do, regardless of who responds, when they respond, and to whom they respond (Boynton and Greenhalgh, 2004). The *Toddler-Safe* study utilised a previously validated questionnaire used in a Canadian burns prevention study (Turcotte and Babul-Wellar, 2011). This questionnaire was modified and re-validated for the *Toddler-Safe* study because of minor modifications made to the wording of questions in order to suit a British sample. The author of this PhD thesis made sure that the pre- and post-test questionnaires were completed by the same parent.

Prior to the commencement of the *Toddler-Safe* study, a feasibility study was undertaken by the author of this PhD thesis to test the intervention design and address in advance any problems that could disrupt the study. The findings from the feasibility study demonstrated that the participants were receptive to the intervention and also led to a few changes in recruitment procedures. This led to the smooth delivery of the main study, saving time and resources.

While delivering the intervention, the author made sure the intervention group participants watched the entire *Toddler-Safe* video, and the control group participants read the leaflets in his presence. Observing the study participants making use of the intervention given to them at baseline was fundamental to the evaluation process. This was done so as to make sure all study participants made use of their intervention at least once during the study.

The multimedia-based format used for the intervention was informed from the literature and shown to facilitate parental knowledge and understanding of complex child health problems. The intervention came at no cost to the study participants and made emphasis on no or low-cost ways of preventing burn injuries such as, turning saucepan handles towards the back of the cooker. In addition, after watching the *Toddler-Safe* videos with the author, study participants in the intervention group were given a ‘Take-home pack’ containing a DVD and a web link of the *Toddler-Safe* videos to enable them recapitulate on what they had learned at their own convenience. Data from the *Toddler-Safe* questionnaires gave an insight into some of the inappropriate first aid remedies practiced by study participants. These included butter, cream, toothpaste, and ice. According to (Skinner et al., 2004), folk remedies such as these, are often self-perpetuating and generational. Education is therefore required to reverse this trend as well as future research raising awareness of the dangers of inappropriate first aid treatments.

Other strengths include the use of standard statistical comparison methodology such as univariate and linear regression analyses, as well as imputation strategies which minimise the number of subjects eliminated from the data analysis. In addition, proper documentation and participant confidentiality were kept throughout the duration of the study.

## **7.5 LIMITATIONS OF THE STUDY**

The *Toddler-Safe* study had a number of limitations, some of which were due to unforeseen problems encountered at various stages of the study. These limitations could have contributed to the non-significant differences reported in some components of KAP as well as the study’s burn injury outcomes.

### **7.5.1 Attrition**

Failure to retain participants in RCTs can introduce attrition bias and lead to loss of statistical power (due to the diminution of the achieved

sample) and concerns for internal validity (Hindmarch et al., 2015, Goldstein, 2009). In the *Toddler-Safe* study, there was a marked attrition of study participants at the six month post-test assessment. Of the 212 participants (first sample) enrolled into the study at baseline, only 52% (n = 110) were available for assessment at six months. Only two participants formally withdrew from the study. All other participants could not be contacted at the six month post-test assessment. Contact was considered unsuccessful if the primary and alternate telephone numbers provided by the participants at study enrolment were unusable or disconnected or when three unsuccessful attempts at calling the participants were made. In line with current GCP guidelines and ethical behaviour in research (Medical Research Council, 1998), the author limited attempts at contacting participants to three attempts. Participants who could not be contacted by telephone were given an opportunity to call back (voice messages were left on the answering machines of the participants when unsuccessful attempts were made). If the participants did not call back after three unsuccessful attempts at contacting them, it could be considered as harassment if we continued calling, if they chose not to reply.

The exact reasons for high attrition of participants from the first sample are not known, however, a few factors that could have contributed to the attrition include:

1. Neither monetary nor non-monetary incentives were offered for participation in the *Toddler-Safe* study
2. Pre-notifications of the post-test telephone interviews (such as SMS reminders), were not given
3. The majority of our sample were first time mothers. There is a possibility that this population is harder to follow-up due to the added pressures of being new parents
4. The pre-test assessments were conducted when many of the participants were home on maternity/paternity leave from

work. It is possible that they could have returned back to work in the six months after recruitment, making it harder to contact them

5. Some telephone users do not respond to calls from phone numbers they do not recognise. Indeed, some telephone services block calls from phone numbers not previously identified by the user. There is evidence to suggest that the many advances in telephone capabilities have had a negative effect on telephone follow-up rates. According to (Nansel et al., 2008), with the advent of caller ID, call blocking and other phone options, there has been a decrease in response rates of telephone surveys

6. The UK experienced a surprisingly warm summer in 2013. The six month post-test assessment was conducted between 15<sup>th</sup> of June and 20<sup>th</sup> of September 2013. There is a possibility we could not contact our study participants because they were outdoors most of the time and did not respond to voice messages.

In order to make up for the high non-response rate at the six-month follow-up, the author of this PhD thesis recruited an additional 100 participants into the study (sample two). Extra measures were taken to make sure participants in this second sample were retained in the study. These included pre-notifications by way of text message reminders, and collection of additional contact details, such as email addresses and partner/spouse telephone numbers (both primary and alternate). The demographic characteristics of this second sample were similar to those of the first sample (see Table 6.1), and both samples were combined to form a single dataset of 312 participants. Of the 312 participants, only 159 (13 participants short of the sample size for which the study was powered for) were available for six month assessments. Responders and non-responders had largely similar demographic characteristics except for age group and

socioeconomic status. Non-responders were more likely to be younger and from lower socioeconomic backgrounds when compared to responders. An additional consequence of the attrition was the inability of the author to carry out post-test assessments on all the study participants at twelve months. Only the first sample of participants was assessed at twelve month post intervention. This was because the participants in the second sample were recruited months after the first sample and conducting a further twelve month follow-up on this sample would have impacted negatively on the study's timeline.

Attrition was a major limitation in the *Toddler-Safe* study. Some degree of participant dropout is normally expected for studies in which post-test data are collected over time periods. Attrition rates of up to 20 percent are generally acceptable in clinical research (The 20 percent rule). A loss to follow-up of greater than 20 percent downgrades an otherwise tier 1 study (effective) to a tier 2 study (promising) (Amico, 2009, Stinner and Tennent, 2012). However, massive dropouts of study participants in trials – such as was experienced in the *Toddler-Safe* study (49% attrition), can cause significant methodological problems and lead to loss of statistical power to measure outcomes. Retaining parents in programmes can be challenging, therefore an understanding of the barriers to retention of study participants in parenting interventions is necessary to reduce dropout during follow up and prevent unit-non response bias. Consideration should be given to key retention strategies such as the provision of monetary incentives and pre-notifications/SMS reminders, which could aid participant response in programmes, and would need to be incorporated early into the design of health interventions.

### **7.5.2 Omission of topics from the intervention**

Even though the *Toddler-Safe* intervention videos were designed to address all the questions listed in the study questionnaires, there were some questions which the videos did not answer explicitly or implicitly (see subsections below). This was an oversight in the project design and could

have had implications on the study findings. A description of this can be seen below:

#### **7.5.2.1 Burns prevention knowledge**

The *Toddler-Safe* questionnaire had four burns prevention knowledge questions:

**Q1. What age group of children are most likely to get a burn or scald?**

- a. 0 – 1 years b. 1 – 2 years c. 2 – 3 years d. 3 – 4 years e. 4 – 5 years f. I don't know

**Q4. On average, what percentage of burns among young children do you think are from hot liquids?**

- a. 5% b. 20% c. 60% d. 90% e. I don't know

**Q5. Compared to adult skin, a child's skin:**

- a. Burns slower with less damage b. Burns slower with more damage c. Burns the same d. Burns faster with less damage e. Burns faster with more damage f. I don't know

**Q6. How long do you think it takes very hot tap water to burn a child's skin?**

1. Less than 1 second b. 10 seconds c. 30 seconds d. Up to 1 minute e. More than 1 minute f. I don't know

In response to question one, the intervention video did not explicitly state the age group of children most likely to suffer a burn or scald. However, all children represented in the video were aged between one and two years (the age group most likely to suffer burns and scalds). It was

expected that intervention participants watching the video would be able to relate this implied information to the question.

In question four, the intervention video did not explicitly state what percentage of children suffered scalds. Question five and six addressed similar issues regarding the effect of heat on a child's skin. The intervention video did not explicitly answer any of these questions. However, there were a few quotes from the video that were meant to allude to the delicate nature of a child's skin:

**Time frame 00.00 – 00.10**

*“Burns and scalds are common injuries for young children. They are painful and take a long time to heal as children have delicate skin.”* (In reference to an opening scene showing images of paediatric burn injuries)

**Time frame 00.11 – 00.18**

*“...Even something as simple as a hot cup of tea can seriously injure your child, as even after 20 minutes it is still hot enough to scald them.”* (In reference to a scene depicting a parent taking away a potential hazard - a cup of tea, from the reach of a child).

**Time frame 01.22 – 01.28**

*“...remember, a child's skin is thinner than yours, so leave your elbow in a good few seconds.”* (In reference to a scene in which a parent was testing the temperature of her child's bath water with her elbow).

### **7.5.2.2 Burns prevention attitudes**

Parental attitudes towards burns prevention were assessed in two questions (see below). The first question assessed the severity of childhood



burns while the second assessed parents' perceptions of the preventability of burn injuries. Both questions were measured using a 5-point Likert scale ranging from 1 'Not severe' to 5 'Very severe', and 1 'None are preventable' to 5 'All are preventable' respectively.

**Q2. On a scale of 1-5 how severe do you think burn injuries are among young children?**

**Q3. On a scale of 1-5 how preventable do you think burn injuries are among young children?**

In the very first scene of the intervention video, the video had four images depicting real life burn injuries in children. It was assumed that parents watching the video would be able to identify how severe burn injuries were to children by observing these images. Regarding the second attitudes question on the preventability of childhood burn injuries, even though this was not stated in the video, it was assumed parents receiving the intervention will be able to work out the 'take-home' message of the intervention which is that burn injuries can be prevented.

A sub-analysis of the primary outcome, excluding data for questions that the intervention did not address, was considered. However, because all the questions on burns prevention knowledge and attitudes were not explicitly answered by the intervention, this sub-analysis was deemed to be inappropriate as it would not fully assess the study's primary outcome measure.

### **7.5.3 Blinding**

As is common with many educational public health interventions tested in a controlled trial, it was not possible to blind study participants to their treatment allocation. This could have had serious implications on the study's control group such as the 'Hawthorne effect', which can be defined as the phenomenon of improved performance due to an awareness of being scrutinised or tested (McCarney et al., 2007). The Hawthorne effect may

explain the higher scores on some KAP components reported in control group participants, who could have improved their burns safety behaviours because they knew they were taking part in a study. In order to minimise bias at the point of follow-up, the author was blinded to treatment arm allocation - as this was conducted by two research nurses not involved in participant recruitment. Blinding of the research nurses conducting post-test assessments was not possible as they recorded the usage of the interventions given to the study participants. The author was also blinded to treatment arm allocation at baseline because pre-test data were collected prior to group allocation, in a further effort to minimise bias.

#### **7.5.4 Reliance on parent-reported outcomes**

The *Toddler-Safe* study may have been limited by the use of parent-reported outcomes with no objective measure in place to verify parental reports. Data obtained by parent-report may be limited by social desirability bias; a situation whereby study participants report what they perceive to be the socially desirable response rather than true beliefs or practices (Sangvai et al., 2007). Parent-reports were used for both primary and secondary outcomes. To supplement parent-reported data, the author of this PhD thesis monitored the ED records of participants' children for burn injuries that may have occurred during the follow-up period, as an objective measure to verify self-reports for burn injury outcomes.

#### **7.5.5 Contamination of control participants**

Contamination occurs when an intervention administered to an intervention group filters into the control group (Levin, 2005). This could happen either inadvertently or intentionally, and could lead to problems with internal validity. Stringent measures were taken to prevent contamination of control participants, such as the introduction of a privacy feature to the online intervention videos. There is still a possibility that control participants may have been exposed to the intervention if they came into contact with intervention participants. However, participants were recruited over time from the antenatal outpatients and the intervention was in the post

natal wards where the patient turnover is high. This minimise the chances of intervention and control group coming into contact with each other.

#### **7.5.6 Collection of outcome data on only index children from ED records**

Due to the difficulties of family structure, as well as the identification of all children in the same household, and issues that could arise around the estimation of a denominator, permission was sought to access the ED records of only index children and not their siblings younger than five years of age, for burn injuries that could have occurred during the follow-up period. In retrospect, this should not have been done because it weakens the findings of the *Toddler-Safe* study by not demonstrating an accurate representation of burn injuries that occurred during the follow-up phase, and the intervention effect - if any. In addition, not all incidents of burn injuries in children are expected to be treated at the ED. Minor burns are more likely to be treated at home or be referred to health advice and information services such as the National Health Service's (NHS) NHS Direct/NHS 111 service.

#### **7.5.7 Insufficient power to measure study outcomes**

The *Toddler-Safe* study was limited by the fact that it did not have sufficient power to measure the study's secondary outcomes. In addition, the study was not powered to detect differences in the primary outcome (KAP) scores beyond the six month assessment. A very much larger trial, recruiting a larger sample, would be required if these outcomes are to be measured accurately.

#### **7.5.8 Non-generalisability of findings**

There was an overrepresentation of mothers and participants of White British ethnicity in the evaluation sample. The proportion of first degree holders in the sample was larger than could be found in the general Welsh population. Non-responders to the study were found to be younger

and from lower socioeconomic backgrounds when compared to responders. The findings from the *Toddler-Safe* study may therefore not be generalisable to the wider population.

### **7.5.9 Inability to perform a full feasibility study**

When developing research projects, feasibility studies are necessary to identifying any logistical problems that might hamper its progress. A full feasibility study was planned for the *Toddler-Safe* study but this was not possible due to time constraints. The study's follow-up procedures were therefore not assessed prior to use in the main study.

### **7.5.10 Power calculations**

Estimates for power calculations were taken from two previous similar studies (Turcotte and Babul-Wellar, 2011, Turcotte et al., 2011). A 5% improvement in KAP scores was assumed to be clinically significant in the *Toddler-Safe* study, based on the calculations used in Turcotte and Babul-Wellar (2011), however, this study did not explicitly state if this improvement in KAP scores was clinically meaningful. Furthermore, there was no evidence in the wider literature to support the notion that it was. The author felt justified at the time to use this level of improvement because the earlier study had been peer reviewed and accepted within the published childhood injury prevention literature. In addition, an anticipated loss to follow-up of 20% was used for the *Toddler-Safe* study based on the 20% rule, which suggests that attrition rates of up to 20% are acceptable in clinical research and a loss to follow-up of > 20% downgrades an otherwise tier 1 study (effective) to a tier 2 study (promising) (Amico, 2009, Stinner and Tennent, 2012). However, this did not take into account the follow-up methods used and how this could affect follow-up rates.

### **7.5.11 Selection of study participants**

The *Toddler-Safe* results may have been biased by the choice of study participants. First of all, the study participants were selected from

parents attending various departments of a large hospital. These participants may have received injury-related information from their doctors/nurses during their stay in hospital. Secondly, since most of the study participants' index children were new-borns at the time of recruitment, this meant that the children would be just about six months old at the six month post intervention assessment, and would not be able to demonstrate injury outcomes; which begin to manifest at about nine months of age. Thirdly, one of the study's exclusion criteria was the inability to understand the written and verbal instructions required for completing questionnaires (see section 5.2.4). This meant that parents who were unable to understand English or Welsh were automatically excluded from the study. This inadvertently ruled out a considerable number of ethnic minorities, who, as research has shown (Livingston et al., 2006, King et al., 1999, Tan et al., 2012), are in dire need of childhood burns educational interventions. However, the baseline characteristics of both samples recruited into the study were similar, suggesting that recruitment reached people who reflected the populations attending this hospital.

#### **7.5.12 Choice of intervention topic**

The *Toddler-Safe* study compared tailored burns safety and first aid messages (intervention group) with generic injury safety messages (control group), with the expectation of finding differences between study groups exposed to either treatment. Irrespective of the medium through which these messages were delivered to study participants, there is a possibility that giving an injury-based message was enough impetus for the control group to modify their burns safety behaviours. A different topic that had nothing to do with injury might have produced a different outcome. In addition, this study did not collect data on the participant's sources of burn prevention education and first aid information. These data are important for injury prevention research as they can be used to inform the design of future interventions.

## 7.6 INTERPRETATION AND COMPARISON WITH OTHER STUDIES

The results of this research project suggest that the parents enrolled into the *Toddler-Safe* study had a modest level of understanding of key burns prevention and first aid concepts prior to being exposed to the study. It is not clear how the parents enrolled into the study attained their pre-test knowledge of burns prevention and first aid. At the time of recruitment into the study, there was no on-going national or regional campaign on burns prevention or first aid of which the author of this PhD thesis was aware. It is likely that the study participants obtained their pre-test knowledge from a variety of sources such as the internet, print and visual media, radio broadcasts, and word of mouth. More than half of the study participants reported having undertaken previous first aid training. Of this number, 97 (52%) reported having burns first aid included as a component of their first aid training. In addition, seventeen percent (n = 53) of the total participants reported receiving previous burns prevention information prior to enrolment in the study. It is possible that the knowledge derived from these sources of information could have contributed to the level of participants' pre-test KAP scores. However, an analysis of first aid knowledge compared with having undertaken previous first aid training, did not support this as the group who had training did not have a higher first aid knowledge score.

With regards to participant demographics, there was an overrepresentation of mothers in the evaluation sample. Female overrepresentation in child injury prevention research is not uncommon and has been reported in several similar studies (Swartz et al., 2013, Van Beelen et al., 2014, Turcotte and Babul-Wellar, 2011, Gielen et al., 2007). In families, mothers have traditionally had the role of raising children and tending to their day to day needs. This close bond between children and their mothers means they are more likely to be exposed to research opportunities involving their children. Even though this role is somewhat different in modern day societies, it still applies in many settings. Fathers are underrepresented in child injury prevention research and may be the ones in need of child safety education.

There was marked attrition of participants from the *Toddler-Safe* study at six-month follow-up, which necessitated the recruitment of an additional 100 participants into the study. High losses to follow-up have been reported in other similar studies that have evaluated parenting interventions for preventing childhood injuries. Nansel et al (2008) evaluated the effectiveness of a tailored injury prevention intervention to promote parental adoption of safety practices and found that of the 594 parents that completed baseline assessments, only 305 (51%) were available for follow-up after one month. A similar study by Campbell et al (2011), evaluating the effectiveness of a primary prevention intervention aimed at preventing elevated blood lead levels in children, found that only 110 (35%) of the 314 participants enrolled at baseline, were available for follow-up assessments after 12 months. An understanding of the causes of non-response, as well as barriers to retention of study participants in parenting interventions is important in this regard. Non-responders in the *Toddler-Safe* study were more likely to be younger and from lower socioeconomic backgrounds when compared to responders. This finding is consistent with those from a recent systematic review of strategies for improving health research with socially disadvantaged groups (Bonevski et al., 2014), as well as with other studies reporting non-response rates in research (Hindmarch et al., 2015, Nicholson et al., 2011). This could have implications as to the targeting of parenting interventions, suggesting a targeted approach at young parents and those from lower socioeconomic backgrounds.

Despite having relatively good pre-test scores, parents enrolled in the study demonstrated that receiving the *Toddler-Safe* intervention improved their understanding of burns prevention and first aid, as evidenced by improvements in mean scores on first aid knowledge, and burns prevention attitudes and practices at six months, and first aid knowledge and burns prevention practices at 12 months. The principal positive finding of the *Toddler-Safe* study however, was a statistically significant difference in burns prevention practice scores between intervention and control groups at six months. There were modest increases observed in the first aid knowledge and attitude scores of parents who received the *Toddler-Safe*

intervention, however, these were not significantly different from those observed in parents in the control group. These findings are similar to those of the ‘Wakefield District Burns and Scalds Prevention Project’ (Georgieff and Maw, 2004) and the ‘Give Your Child a Safe Start Study’ (Turcotte et al., 2011), which both reported significant improvements in parental behavioural practices but not parental knowledge and/or attitudes towards child safety.

At face value, these findings could suggest that the *Toddler-Safe* intervention, though ineffective at changing knowledge or attitudes, was effective at changing the burns prevention practices of participants who received the intervention. However, revisiting the theoretically underpinnings governing the design of behaviour change interventions described in chapter one of this thesis, as well as the relationships depicted in the study’s logic model (Figure 1.8), this assertion may not hold true. According to the COM-B model of behaviour by Michie et al (2011), for any change in Behaviour (B) to occur, an individual has to be physically and psychologically Capable (C) of performing the necessary actions, have the social and physical Opportunity (O) to do the behaviour, and be Motivated (M) to adopt the new behaviour. The ‘Opportunity’ and ‘Motivation’ components of the COM-B model may have been fulfilled in the *Toddler-Safe* study, but the ‘Capability’ component was not fulfilled. Having the necessary knowledge and skills to perform a new behaviour is included in the ‘Capability’ component of the COM-B model. According to Colver et al (1982), for health education to be effective, it must first change knowledge and attitudes, and finally change behaviour. This means that if study participants’ knowledge and attitudes towards burns prevention and safety were not improved as a result of the *Toddler-Safe* intervention, then it is unlikely that the significant improvement reported in their practices happened as a result of the intervention. Therefore it can be said that the *Toddler-Safe* intervention was not effective at promoting change in parental knowledge, attitudes and practices regarding burns prevention and first aid.

These findings could have arisen because of two main reasons.



1. The omission of key knowledge and attitudes topics from the *Toddler-Safe* intervention may be responsible for the lack of differences in KAP knowledge and attitude scores between study groups. The knowledge and attitude questions contained in the questionnaires were subject specific and needed to be addressed in the intervention. Cues and hints did not help the participants get the correct answers.
2. The *Toddler-Safe* questionnaires were self-administered and relied heavily on parent-reported data. The practices section of the questionnaires collected only parental reports of their safety practices. In both study groups, practice scores were high pre and post intervention. As prevention practices were parent-reported, it is possible that participants in both study groups could have over reported their practices. Unlike the knowledge and attitudes questions in the questionnaire, participants would be more likely to respond to practice questions by giving what they believe is the right response even if that is not what they actually practiced (Georgieff and Maw, 2004). This type of social desirability bias is one of the key drawbacks of using questionnaires to measure self or parent-reported changes. The practice findings could also imply a culture of awareness for burns prevention in the study participants, as was evidenced by high pre-test practice scores. There is also a possibility that the study questionnaire served as a prompt for study participants to seek out more burns prevention information and to carry out the right burns prevention practices.

Despite the negative KAP findings, parental burns prevention practices were shown to correlate with higher socioeconomic status as well as education. This finding is consistent with that reported by Tessier (2010). The study author suggested that parents who are more educated and have a higher income are more likely to seek out programmes that would benefit their family.

With regards to burns first aid knowledge, both study groups had comparable scores at baseline but at follow-up, participants who received the *Toddler-Safe* intervention had higher KAP scores than controls. However, this difference in scores did not reach statistical significance. The burns first aid segment of the *Toddler-Safe* video was very detailed and was presented in a pragmatic instructional manner. Unlike the burns prevention segment of the *Toddler-Safe* video, the first aid segment addressed all first aid questions in the questionnaires. The reason for the non-significant finding between study groups is unclear. However, since the study sample already had high first aid knowledge scores at baseline, it can be assumed that they were already knowledgeable about burns first aid prior to the study, and an added intervention would not have made much difference. In spite of the non-significant findings, parental knowledge of burns first aid was shown to correlate positively with socioeconomic status. Being of a higher socioeconomic status increased the chances of having adequate burns first aid knowledge in the parent, and was found to be the most influential factor determining parental knowledge of burns first aid. This finding is consistent with previous studies (Davies et al., 2013, Bánfai et al., 2015) that have demonstrated the effect of higher socioeconomic status on first aid knowledge. This finding would suggest targeting burns first aid educational efforts at parents from lower socioeconomic backgrounds. Davies et al. (2013) found that first aid knowledge correlated with both higher socioeconomic status and previous completion of a first aid training course. This study, of which the author of this PhD thesis was a co-author, demonstrated that individuals belonging to higher socioeconomic groups were more likely to have gained their first aid knowledge from previous attendance at a first aid training course. Surprisingly, the results of the *Toddler-Safe* study did not show any associations between having undertaken previous first aid training and enhanced parental burns first aid knowledge. This contradicts a number of published studies that have shown the positive effects of previous first aid training on first aid knowledge (Davies et al., 2013, Wallace et al., 2013, Tay et al., 2013, Wei et al., 2013, Li et al., 2012, Tekin and Suskan, 2010, Harvey et al., 2011, Rea et al., 2005). Davies et al. (2013) found that previous first aid training was the

most influential factor on first aid knowledge. In contrast, a Scottish random survey of first aid knowledge in the general population showed no differences in knowledge of general paediatric first aid between those who had attended a first aid course and those who had not (Conrad and Beattie, 1996). The study authors suggested that many first aid courses focus on only adult injuries. More than half of the *Toddler-Safe* study respondents reported having undertaken previous first aid training. It is not clear what the contents of these first aid training courses that they undertook were or how much time had elapsed since completion of the training courses. It is possible that the first aid training courses undertaken by our study participants did not specifically address childhood burn injuries or include a childhood burn injury component. It is also possible that the time elapsed since undertaking first aid training could have had an effect on the study participants' memory and recall. In spite of this, the *Toddler-Safe* intervention improved performance on parental first aid knowledge scores from pre-test to six months post intervention.

With regards to the secondary outcome measure (parent-reported or medically attended burn injury), the study's baseline findings were able to provide valuable epidemiological data on the patterns of burn injury in pre-school children. Not surprisingly, the study found a male predominance of burn injury similar to the pattern reported in previous epidemiological studies (Verey et al., 2014, Hutchings et al., 2010, Tse et al., 2006). The majority of previous burn incidents in this study occurred when the children were aged 24 months or younger, the mean age being 23.45 months. This finding is in keeping with several published studies which report the highest incidence of childhood burns in children younger than five years of age (Mashreky et al., 2008, Mukerji et al., 2001, Edelman et al., 2010, Dokter et al., 2014). A study by Kemp et al (2014) analysing the age bands of children admitted into hospital for unintentional burn injuries found a peak prevalence of around 13 months of age. This finding was not demonstrable in the *Toddler-Safe* study as most of the previous burn incidents were reported in children up to 24 months of age. Only seven burn incidents involved children less than 20 months of age: one child each at 12 months,

15 months, and 17 months of age respectively, and four children at 18 months of age.

The small number of sample children who had sustained previous burns means that our injury findings should be interpreted with caution. These findings were not significantly different and the study was not powered sufficiently to show a difference between control and intervention groups. Furthermore, baseline burn incident figures were collected over a broader time scale than were post-intervention figures. The study also relied on parent-reported data from study participants. Many parents suffer from feelings of guilt following burn injuries to their children (SickKids, 2013). This could have implications when self-reporting burn injuries that might have occurred. The study by Kemp et al (2014) which analysed the age bands of 1,215 children admitted in hospital for burns would give a more accurate and potentially generalizable description of childhood burns prevalence. Nonetheless the *Toddler-Safe* study adds to the epidemiological evidence base around childhood burn injuries and the need to target prevention efforts at children younger than five years of age.

Scalds were reported as the most common type of burn injury in study participants' children. This finding is in keeping with previous studies describing the epidemiology of childhood burns (Verey et al., 2014, Kemp et al., 2014, Kai-Yang et al., 2008). Hot beverages (tea/coffee) were found to be the most common scald agents, reflecting the drinking practices of the study sample. Similar to other previous studies, the most common mechanism of scald injury involved the child reaching for a cup or mug containing a hot beverage and pulling it down over themselves (Kemp et al., 2014, Drago, 2005). Contact burns were found to be the second most common type of burn injury reported in our study. This finding is also in keeping with previous studies (Verey et al., 2014, Teo et al., 2012). Interestingly, the most frequent contact burn agents were hair straighteners. The children involved in the *Toddler-Safe* study, suffered contact burns when they either touched the hot hair straighteners with their hands or stepped on them while they were left to cool down. Hair straighteners have

become increasingly popular in the last decade and childhood burns from these devices have been on the increase. A retrospective study assessing hair straightener burns in children presenting at a tertiary referral centre, reported a steady increase in burn incidence over a five year period (2007 to 2011) (Sarginson et al., 2014). The mean age for injury was 17 months for boys and 21 months for girls, and the commonest mechanism of injury was a ‘touch or grab’ followed by stepping into or onto hot hair straighteners on the floor. The *Toddler-Safe* study findings are similar to those of Sarginson et al. (2014), emphasizing the need for preventative measures targeting users of these devices. The *Toddler-Safe* study did not report any cases of flame, chemical, or friction burns reflecting how less common these types of burns are in the British population. The study, however, reported one case of previous sunburn in a three year old child. Sunburns are beyond the scope of the *Toddler-Safe* intervention which was designed to prevent only household burns. Further research is required to evaluate the effectiveness of multimedia-based interventions on outcomes related specifically to sunburns in children.

Previous studies have highlighted the risk factors for burn injuries in children. These include low socioeconomic status, low educational levels, being a single parent, living in overcrowded accommodation, and pre-existing impairments in the child (Fukunishi et al., 2000, Glasgow and Graham, 1997, Delgado et al., 2002). The *Toddler-Safe* study successfully demonstrated the effects of some of these risk factors on the burn incidence rates of our study sample. Of the 22 cases of previous burns in participants’ children, 13 occurred in households that belonged to the NS-SEC class 4 (never worked or long-term unemployed). This demonstrates the importance of socioeconomic status as a determinant of burn injury in children and further strengthens the evidence in support of socioeconomic status as the most influential factor in determining parental burn injury outcomes. Contrary to expectations, the *Toddler-Safe* study was not able to fully demonstrate the effect of low educational levels on burn injury rates. Less than half of our injury sample (8/22) was not educated up to college/university level while the remainder had college/university (11/22)

and postgraduate degrees (3/22). This finding would imply that pre-school children from more educated families are more likely to suffer from burn injuries in the home compared to pre-school children from less educated families. Possible explanations for this unusual finding are poor parental recall of injuries, and the small sample size (n = 22) the *Toddler-Safe* study had to infer injury outcomes from. A larger study could demonstrate a more accurate effect of education on injury outcomes.

Furthermore, the four parent-reported burn incidents at the six month assessment (4 in 159 families), would equate to an estimated eight incidents a year, and a suggested prevalence of 1 in 20 children. This would indicate a relatively high prevalence of childhood burns, despite the fact that burns prevention practices were reported to improve in both study groups. These figures cast a doubt as to the effectiveness of the *Toddler-Safe* intervention at preventing burn injuries in study participants' children. Interestingly, three of the four parent-reported incidents of burns at the six month assessment and the only reported incident at 12 months, were contact burns caused by hair straighteners. The children involved were aged 10 months, 24 months, 24 months, and 15 months respectively. Two of the families belonged to NS-SEC class 3 (routine and manual occupations) while the other two belonged to NS-SEC class 4 (never worked or long-term unemployed). This finding is in keeping with the hypothesis supporting low socioeconomic status as a determinant of burn injury in young children. It also highlights the need to repeatedly reiterate the dangers of hair straighteners and the exploration of legislation on the issue.

## **7.7 POST-INTERVENTION USAGE OF INTERVENTIONS**

The majority of study participants reported making use of their interventions at least once during the follow-up period. Referring back to the interventions given to them demonstrates the eagerness of the study participants in wanting to know more about childhood burns prevention and first aid. Most of the participants who received the 'take-home' pack, made use of the DVD component of the pack. Only a few participants watched the

*Toddler-Safe* videos using the online resource. This could imply that the preferred medium for conveying health educational videos is via DVDs rather than by an online resource. Very few studies have been conducted exploring the best medium for presenting health educational videos. Future research should focus on comparing the various video dissemination tools and assess their effect on parental knowledge and behavioural outcomes. Having a resource to fall back to for information from time to time, is necessary to maintain parental levels of knowledge on key childhood burns concepts.

## **7.8 CHALLENGES FACED DURING THE TODDLER-SAFE STUDY**

The author of this PhD thesis encountered two main challenges while conducting the *Toddler-Safe* study. These had to do with obtaining the necessary approvals required to undertake research at the UHW Cardiff, and retention of participants in the study.

The author commenced his PhD programme on the 1<sup>st</sup> of July 2011, and spent most of his first year reviewing childhood burns prevention, and designing the *Toddler-Safe* study. To undertake research at the UHW, the author required favourable research ethics and research and development (R&D) approvals from the Research Ethics Committee for Wales and NHS R&D Directorate of the Cardiff and Vale University Health Board, respectively. The author also required an honorary research contract (research passport) issued by the Cardiff and Vale Health Board. The author submitted the *Toddler-Safe* protocol for ethical and R&D approval on the 15<sup>th</sup> of May 2012. Ethical approval was granted on the 17<sup>th</sup> of July 2012, but R&D approval was delayed for almost a month. R&D approval was eventually granted on the 16<sup>th</sup> of August 2012. The author then had to wait an additional three months (till 13<sup>th</sup> of November 2012) before being granted an honorary research contract. This was only granted after the timely intervention of the author's supervisors. These delays had implications on the start date of the *Toddler-Safe* study and also on the length of follow-up of study participants. The delays were attributed to a

backlog in the system for processing trial applications within the health board.

The *Toddler-Safe* study experienced a high attrition of study participants at the six month post-test assessment, which necessitated an additional round of recruitment of study participants to make up for the losses. The author had to reapply for ethical and R&D approval to recruit these additional participants. These permissions were granted swiftly but the study period then had to be extended from 30<sup>th</sup> of June 2014 to 31<sup>st</sup> of December 2014. The combination of the delays, attrition, and consequent additional participant recruitment, meant that the additional participants could only be followed up for six months and not 12.

## **7.9 SUMMARY OF CHAPTER SEVEN**

- Parents enrolled into the *Toddler-Safe* study had a modest level of understanding of key burns prevention and first aid concepts prior to being exposed to the study. Likely sources of burns safety information include the internet, television and radio broadcasts, and previous training courses.
- The principal positive finding of the *Toddler-Safe* study was a statistically significant difference in burns prevention practice scores between intervention and control groups at six months. There were modest increases observed in knowledge and attitude scores of the intervention group however, these increases were not significantly different from those observed in the control group.
- According to the COM-B model of behaviour (Michie et al., 2011), having the necessary knowledge and skills to perform a new behaviour is required for any change in behaviour. Participants' knowledge and attitudes towards burn safety was not improved by the *Toddler-Safe* intervention, therefore it is unlikely that the



significant improvement reported in burns prevention practice scores occurred as a consequence of the intervention.

- The intervention was successful at improving parental burns first aid knowledge and burns prevention practices after six months. However, burn injuries were reported in four children living with participating families. Modest improvements in burns prevention knowledge and attitudes were demonstrated but these were not significant to show any substantial effect.
- The omission of key knowledge and attitude topics from the *Toddler-Safe* intervention as well as possible over reporting of safety practices, could account for the study's findings
- Key strengths of the *Toddler-Safe* study include its randomised design; the use of an evidence-based approach in informing the study's design and methodology; the use of validated questionnaires for data collection; blinding of data collectors; and the undertaking of a feasibility study prior to commencement of the main study in order to test the intervention design and address and methodological problems in advance.
- The *Toddler-safe* study was limited by high dropout of study participants during follow-up; omission of key topics from the intervention; inability to blind study participants to treatment allocation; use of parent-reported outcomes; insufficient power to measure injury outcomes; and collection of secondary outcome data from only index children.

## CHAPTER EIGHT

## CHAPTER EIGHT: CONCLUSIONS AND RECOMMENDATIONS

### 8.1 CONCLUSIONS

The *Toddler-Safe* study sought to test the hypothesis that parents exposed to a multimedia-based educational intervention would demonstrate better burns prevention and first aid knowledge, attitudes and practices when compared to parents who were not exposed to the intervention. The findings of this study indicate that the *Toddler-Safe* intervention was not effective at confirming this hypothesis. The only component of KAP that appeared to be significantly improved by the *Toddler-Safe* intervention was burns prevention practices. The intervention did not have a significant effect on neither first aid knowledge nor parental burns prevention knowledge and attitudes. Since improved knowledge is a prerequisite for behaviour change, it is unlikely that this improvement in practices occurred as a result of exposure to the *Toddler-Safe* intervention. Non-significant findings may have occurred as a result of the omission of key burns prevention knowledge and attitudes topics from the intervention. Burn injuries were reported in children living with 1 in 20 of the participating families in the intervention group.

The *Toddler-Safe* study design and methodology were informed by findings obtained from a systematic review demonstrating the effectiveness of parenting interventions at preventing unintentional injury in pre-school children and improving parental knowledge and safety practices. The key aspects of the *Toddler-Safe* study for which the systematic review helped inform included:

- Type of intervention – interventions incorporating parental education, home visitation, and provision of safety devices
- Mode of delivery – delivery to participants on a one-to-one basis

- Timing of the intervention – early interventions delivered during the perinatal or immediate postnatal period
- Evaluation techniques – pre- and post-test interviewing methods using face-to-face and telephone questionnaires; assessment of medical records for injury
- Outcome measures – child safety knowledge and practices, self-reported and medically attended injuries
- Study setting – hospital practice

The *Toddler-Safe* study collected rich baseline and post intervention data which adds to the epidemiological evidence base on childhood burn injury prevention. The study also gave an insight into the use of inappropriate burns first aid remedies, suggestive of an opportunity for further burns prevention research.

Participant attrition was a major limitation of the *Toddler-Safe* study. Further research on how to improve participant retention in RCTs is required.

## **8.2 RECOMMENDATIONS**

After the completion of the *Toddler-Safe* study to evaluate the effectiveness of a multimedia-based educational intervention on improving parental burns safety and first aid knowledge and behaviour in the home, the following recommendations have been drawn:

1. The challenge of subject retention in studies, in which post-test data are collected over time, needs to be addressed. Further research is required to determine the barriers and facilitators to retention of parents in parenting interventions. Retention strategies such as, offering monetary incentives, sending out pre-notification text messages, participant tracking, and having

project champions, should be considered before the start of a project.

2. Tools for measuring outcomes should be better designed to match the intervention and vice versa
3. Burns prevention and first aid efforts should be targeted at all parents of children younger than five years of age, prioritising those from younger age groups and lower socioeconomic backgrounds.
4. In order to prevent social desirability bias in studies reliant on self-reported data, objective measures such as house visitation for observation or demonstration of practices, need to be considered in order to verify self-reports.
5. Efforts should be made to incorporate ethnic minorities in burns prevention research programmes. Language barriers may pose difficulties with recruitment, therefore translation and interpretation services should be considered.

### **8.3 AUTHOR'S ROLE**

The *Toddler-Safe* study was designed by the author, Chukwudi Okolie, with the guidance of his PhD supervisors: Professor Alison Kemp and Dr Sabine Maguire. Chukwudi Okolie reviewed the published literature on burn injuries including burn injury prevention in children and first aid (see chapter 1). He conducted a systematic review of parenting interventions for the prevention of unintentional injuries in pre-school children, and used the results to inform the intervention design and methodology. Systematic reviews cannot be completed by a single individual since some steps in the review process require more than one assessment. Chukwudi Okolie carried out the initial screening and data extraction processes while Professor Alison Kemp and Dr Sabine Maguire independently checked 20% of the studies reviewed by Chukwudi Okolie for accuracy and completeness. Two

other trained reviewers, Diane Nuttall and Lesley Sanders were involved in assessing the quality of 20% of the studies included into the review.

Chukwudi Okolie managed the conduct and delivery of the *Toddler-Safe* study. He designed and piloted the *Toddler-Safe* intervention, in addition to validating the study's questionnaire. He wrote the script for the *Toddler-Safe* videos and the injury safety leaflets, and directed the shooting and editing of the videos. The videos were shot by Carl Rogers, a clinical videographer at the Department of Media Resources Cardiff University. Chukwudi Okolie recruited all the study's participants and collected all of their baseline data. He also provided training for two research nurses, Pauline Jones and Linda Phillips, involved in administering the study's post-test telephone questionnaires. Chukwudi Okolie conducted all of the data coding and data entry for the study. He also performed all of the study's data analysis, with specialist advice from a senior statistician not involved in the *Toddler-Safe* study, Dr Daniel Farewell.

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## APPENDICES

### APPENDIX 1: SYSTEMATIC REVIEW SEARCH STRATEGY

1. (infan\$ or child\$ or toddl\$ or bab\$ or pediat\$ or paediat\$ or preschool\$ or pre school\$ or pre-school\$ or neonat\$ or young\$).mp.
2. ((parent\$ adj3 program\$) or (parent\$ adj3 train\$) or (parent\$ adj3 educat\$) or (parent\$ adj3 promot\$) or (parent\$ adj3 skill\$) or (parent\$ adj3 intervent\$) or (parent\$ adj3 group) or (parent\$ adj3 support) or (parent\$ adj3 community) or (parent-child relations or parent-child interaction or object attachment)).mp.
3. parent\$.mp. or Parents/
4. mother\$.mp. or Mothers/
5. father\$.mp. or Fathers/
6. 3 or 4 or 5
7. (injur\$ or unintentional injur\$ or accidental injur\$ or fractur\$ or poison\$ or fall\$ or burn\$ or scald\$ or drown\$ or wound\$ or accident\$ or suffocat\$ or asphyx\$ or lacer\$ or contus\$).mp.
8. ((Home or domestic) adj2 (Accident\$ or Injur\$)).mp.
9. ((Traffic or vehicle or road) adj3 (Accident\$ or Injur\$)).mp.
10. 7 or 8 or 9
11. (randomised controlled trial or randomized controlled trial or random allocation or double blind method or clinical trial or control group or evaluat\$ or intervent\$ or comparative study or case-controlled study or longitudinal study).mp.

12. ((accident\$ adj3 prevent\$) or safety or (safe\$ adj3 device\$) or (safe\$ adj3 equipment\$) or (infan\$ adj3 equipment\$) or (protective adj3 device\$).mp.
13. (injur\$ adj3 prevent\$).mp.
14. (fall\$ adj2 (prevent\$ or avoid\$ or reduc\$)).mp.
15. (choke\$ adj3 (prevent\$ or avoid\$)).mp.
16. ((Burn\$ or scald\$ or fire\$) adj2 (prevent\$ or avoid\$)).mp.
17. 12 or 13 or 14 or 15 or 16
18. 1 and 2 and 6 and 10 and 11 and 17

## APPENDIX 2: DATA EXTRACTION AND CRITICAL APPRAISAL FORMS

### DATA EXTRACTION FORM

#### General Information

Ref ID:

Report title:

Author(s):

Year:

Country:

Reviewer:

Date form completed:

#### Study type:

- Randomised controlled trial
- Case-control study
- Prospective cohort/longitudinal study
- Retrospective cohort/longitudinal study
- Controlled before and after study

<b>Aim of study:</b>
<b>Duration of study:</b>
<b>Type of intervention</b>
<b>Outcome measures:</b> <ul style="list-style-type: none"><li><input type="checkbox"/> Change in parent child safety knowledge</li><li><input type="checkbox"/> Child injury safety practices</li></ul>

<input type="checkbox"/> Self-reported or medically-attended unintentional injury in a child aged 0-5 years
<input type="checkbox"/> Change in unintentional injury incidence in children 0-5 years

<b>Population and setting</b>
Population description:
Age of children:
Number of children/parents:
Ethnicity:
Inclusion criteria:
Exclusion criteria:
Type of environment:
Nature of injury being prevented:

Method(s) of recruiting participants:
Describe any important source of bias:

<b>Main findings</b>

	<b>Yes</b>	<b>No</b>	<b>Unclear</b>
Does the paper address the key question; Are parenting interventions effective at preventing unintentional injuries in children under five years of age?			

<b>Key points meriting inclusion</b>

<b>Weaknesses/limitations of study</b>

	<b>Yes</b>	<b>No</b>	<b>Comment</b>
Is the study included?			

<b>Additional comments</b>

## CRITICAL APPRAISAL FORM

**Ref ID:**

**Author(s):**

**Year:**

**Reviewer:**

**Date:**

### **Section A. EVIDENCE TYPE (STUDY DESIGN)**

**Please tick study type**

- Randomised controlled trial
- Non-randomised controlled study
- Controlled before and after study
- Case-control study
- Prospective cohort/longitudinal study
- Retrospective cohort/longitudinal study

### **Section B. KEY QUESTION**

	<b>Yes</b>	<b>No</b>	<b>Unclear</b>
Does the paper address the key question; <ul style="list-style-type: none"><li>• Are parenting interventions effective at preventing unintentional injuries in children under five years of age?</li></ul>			

**If the paper does not address the key question, please EXCLUDE. (NB – please provide further detail in Section C)**

### **Section C. EXCLUSION CRITERIA**

Please tick any of the following criteria which apply;

- Adult or child older than 5 years old (5 years & 364 days)
- Secondary carer
- Not aimed at parents
- Intentional or inflicted injury

- Management of injury
- Non comparative study
- No evaluation conducted (No outcome measures reported)
- No English language version available

**If you have ticked any of the boxes above, the study should be EXCLUDED (if study is excluded, please go directly to section F)**

**Section D. METHODOLOGICAL QUALITY CRITERIA**

*Questions to assist with the critical appraisal of a RCT*

	Yes	No	Unclear	N/A
1. Is the trial relevant to the needs of the study?				
2. Did the trial address a clearly focused issue in terms of; <ul style="list-style-type: none"> <li>• The population studied?</li> <li>• The intervention given?</li> <li>• The outcomes considered?</li> </ul>				
3. Were the assignments of children/families to intervention randomised?				
4. Were all the participants who entered the trial properly accounted for at its conclusion? <ul style="list-style-type: none"> <li>• Was follow-up complete?</li> <li>• Was follow-up obtained for 80-100% of subjects? (Note % follow-up)</li> <li>• Were participants analysed in the groups to which they were randomised?</li> </ul>				
5. Were the assessors blind to the different groups?				
6. Were the groups similar at the start of the trial?				
7. Aside from the intervention, were the groups treated equally?				
8. Have the results of the study been clearly presented?				



9. Are the data in the tables or graphs and the text consistent?				
10. Were the statistical methods used appropriate?				
11. Were all important outcomes/results considered?				
<b>Overall, do you think this study is significantly flawed?</b>				
Comments				

***Questions to assist with the critical appraisal of a CASE-CONTROL, PROSPECTIVE COHORT/LONGITUDINAL, RETROSPECTIVE COHORT STUDY***

	Yes	No	Unclear	N/A
1. Were the aims of the study clearly stated?				
2. Does the paper address a clearly focused issue? In terms of; <ul style="list-style-type: none"> <li>• The population studied?</li> <li>• (Case-Control study only) Is the case definition explicit and confirmed?</li> </ul>				
3. Was the choice of study method appropriate?				
4. Is the population studied appropriate? <ul style="list-style-type: none"> <li>• Was an appropriate control group used?</li> <li>• (Case-control study) Were the controls selected from the same population as the cases?</li> </ul>				
5. Is confounding and bias considered? <ul style="list-style-type: none"> <li>• Have all possible explanations of the effects been considered?</li> <li>• Were the assessors blind to the different</li> </ul>				

<p>groups?</p> <ul style="list-style-type: none"> <li>• How comparable are the cases and controls with respect to potential confounding factors?</li> <li>• (Case-control study) Were the interventions and other exposures assessed in the same way for cases and controls?</li> </ul>				
6. (Case-control study) Was the comparison group appropriately chosen?				
7. Was the comparison group enrolled in the same time period and assessed in the same way as the intervention group?				
8. (Cohort study) Was follow-up long enough? <ul style="list-style-type: none"> <li>• Was the follow-up of subjects complete/long enough?</li> </ul>				
9. Have the results of the study been clearly presented?				
10. Are the data in the tables or graphs and the text consistent?				
11. Were the statistical methods used appropriate?				
12. Were all important outcomes/results considered?				
<b>Overall, do you think this study is significantly flawed?</b>				
Comments				

**Section E. RISK OF BIAS ASSESSMENT**

	<b>High risk</b>	<b>Low risk</b>	<b>Unclear risk</b>	<b>Unknown risk</b>
Random sequence				

generation (RCTs only)				
Allocation concealment				
Blinding of participants and personnel				
Blinding of outcome assessment				
Incomplete outcome data				
Use of ITT analysis				
Risk of bias due to confounding				

**Section F. FINAL DECISION**

<b>Reviewers conclusions and comments</b>	
Key points meriting inclusion	
Weakness and study limitations (if study is INCLUDED)	

	Yes	No	Comment
Is the study included?			

Additional comments

Adapted from the following sources;

Critical Appraisal Skills Programme (CASP) systematic review checklist 14.10.10 <http://www.casp-uk.net/>

Weightman AL, Mann MK, Sander L and Turley RL Health Evidence Bulletins Wales, A systematic approach to identifying the evidence, Project Methodology 5. Cardiff: Information Services UWCM, January 2004

Undertaking systematic reviews of research on effectiveness. University of York: NHS Centre for Reviews & Dissemination, 2001

Core Info, Cardiff Child Protection Systematic Reviews. <http://www.core-info.cardiff.ac.uk/reviews>



5. Compared to adult skin, a child's skin: (Please check one)

Burns slower with less damage  Burns slower with more damage

Burns the same  Burns faster with less damage

Burns faster with more damage  I don't know

6. How long do you think it takes very hot tap water to burn a child's skin? (Please check one)

Less than 1 second  10 seconds  30 seconds

Up to 1 minute  More than 1 minute  I don't know

7. A. What do you do right after a burn happens? (Please check one)

Cool with ice  Apply butter  Apply cream

Cool with cold water  Apply toothpaste  
Other.....

B. Do you cover the burn? (Please check one)

No  Yes, with Cling film

Yes, with clean dressing  Yes, with Elastoplast

Other.....

8. Do you drink hot drinks while playing with or carrying your child? (Please check one)

All of the time  Most of the time  Some of the time

Rarely  None of the time  Not applicable

9. Where do you place your hot drinks when the children are around? (Please check one)

Low coffee table  On the floor  Kitchen table

Not applicable  Other.....

10. Is your child in the kitchen while someone is cooking? (Please check one)

All of the time     Most of the time     Some of the time

Rarely     None of the time     Not applicable

11. What rings/burners on the cooker do you normally use? (Please check one)

Front     Back     No preference

Not applicable

12. Do you turn pot handles inward while cooking? (Please check one)

All of the time     Most of the time     Some of the time

Rarely     None of the time     Not applicable

13. Do you test the temperature of your child's bath water?

No     Yes, with a floating thermometer

Yes, with my hand     Yes, with my elbow

Other:.....

14. When does your child usually get into the bath? (Please check one)

Before the water starts running     While the water is running

After the bath has been filled     None of the above

15. Where do you store your iron immediately after use? (Please check one)

On the floor     On the ironing board

On a shelf     Other.....

16. Do you have hair straighteners at home ?  Yes  No

If yes, where do you store them after use?

On the floor  On a table  In a heat resistant bag  
on the floor

In a heat resistant bag on a table  
Other.....

***All information provided is strictly confidential and will be used for research purposes only.***

17. What is the age of your youngest child (months/years)?

.....

18. Gender:

Boy  Girl

19. Are you this child's?

Mother  Other: .....

20. A. is this your only child?  Yes  No

B. If no, what are the ages of your other children (please specify in months or

years)?.....

.....

21. Please indicate which age group you belong to:

Less than 20 years  20-29 years  30-39 years

40-49 years  Above 49 year  Prefer not to  
answer

22. What is your highest level of education?

Left school before 16 years of age



GCSEs/equivalent vocational qualification  A-levels

College/University

Postgraduate

Other.....

23. Ethnicity

White:  British   
Irish

Other background..... White

Mixed: White and Black Caribbean  White and Black African

White and Asian

Any other mixed background.....

Black or Black British:  Caribbean   
African

Other background..... Black

Asian or Asian British:  Indian   
Pakistani

Bangladeshi

Other background..... Asian

Chinese or other ethnic group: Chinese

Any other.....

24. Do you have a social worker?  Yes  No

Prefer not to answer

25. Have you had any first aid training?  Yes  No

If yes, did it include burns first aid?  Yes  No

26. What is your occupation?

.....  
.....

27. What is the total number of adults (aged 18 or over) in your household?

.....

28. Has your child had a burn injury in the past?

Yes  No  Prefer not to answer

If yes, from what?.....

29. Have you suffered from a burn injury that required hospital treatment?

Yes  No  Prefer not to answer

30. Have you received any burns prevention information before?

Yes  No

**THANK YOU FOR YOUR PARTICIPATION**



35. Compared to adult skin, a child's skin: (Please check one)

Burns slower with less damage  Burns slower with more damage

Burns the same  Burns faster with less damage

Burns faster with more damage  I don't know

36. How long do you think it takes very hot tap water to burn a child's skin? (Please check one)

Less than 1 second  10 seconds  30 seconds

Up to 1 minute  More than 1 minute  I don't know

37. A. What do you do right after a burn happens? (Please check one)

Cool with ice  Apply butter  Apply cream

Cool with cold water  Apply toothpaste  
Other.....

C. Do you cover the burn? (Please check one)

No  Yes, with Cling film

Yes, with clean dressing  Yes, with Elastoplast

Other.....

38. Do you drink hot drinks while playing with or carrying your child? (Please check one)

All of the time  Most of the time  Some of the time

Rarely  None of the time  Not applicable

39. Where do you place your hot drinks when the children are around? (Please check one)

Low coffee table  On the floor  Kitchen table

Not applicable  Other.....

40. Is your child in the kitchen while someone is cooking? (Please check one)

- All of the time     Most of the time     Some of the time  
 Rarely     None of the time     Not applicable

41. What rings/burners on the cooker do you normally use? (Please check one)

- Front     Back     No preference  
 Not applicable

42. Do you turn pot handles inward while cooking? (Please check one)

- All of the time     Most of the time     Some of the time  
 Rarely     None of the time     Not applicable

43. Do you test the temperature of your child's bath water?

- No     Yes, with a floating thermometer  
 Yes, with my hand     Yes, with my elbow  
 Other:.....

44. When does your child usually get into the bath? (Please check one)

- Before the water starts running     While the water is running  
 After the bath has been filled     None of the above

45. Where do you store your iron immediately after use? (Please check one)

- On the floor     On the ironing board  
 On a shelf     Other:.....

46. Do you have hair straighteners at home ?  Yes  No

If yes, where do you store them after use?

On the floor  On a table  In a heat resistant bag  
on the floor

In a heat resistant bag on a table  
Other.....

47. What intervention was given to you by the researcher?

DVD and leaflet  Leaflet only

If DVD and leaflet;

- How many times have you watched the DVD?  
.....
- How many times have you read the  
leaflet?.....

If Leaflet only;

How many times have you read the leaflet?  
.....

48. Have any of your children had a burn injury in the last 6 months?

Yes  No  Prefer not to answer

If yes;

- How did they get the burn?  
.....  
.....
- Age of  
child.....

Comments

**THANK YOU FOR YOUR PARTICIPATION**

**APPENDIX 5: TODDLER-SAFE CONSENT FORM**



**CONSENT FORM**

**PARTICIPANT STUDY NUMBER:** .....

**Project Title:**

***Toddler-Safe: Prevention of burns and scalds in preschool children by a targeted intervention***

**Researcher:**

**Dr Chukwudi Okolie**

Cochrane Institute of Primary Care and Public Health

Cardiff University School of Medicine

4<sup>th</sup> Floor, Neuadd Meirionnydd

Heath Park

Cardiff

CF14 4YS

Telephone: 02920687176

E-mail: [okolieco@cardiff.ac.uk](mailto:okolieco@cardiff.ac.uk)

**Child's name:**

**Date of birth:**

**Contact details:**

**Please initial box**

1. I confirm that I have read and understand the information sheet (Version 5.4: 03/01/2013) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason
3. I understand that if my child comes in with a burn injury then their Emergency department medical notes will be looked at by the research individuals.
4. I give permission for these individuals to have access to my child's records and that information will be stored on a protected computer.



5. I agree to take part in the above study

\_\_\_\_\_

Name of participant

\_\_\_\_\_

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

Date

Name of researcher  
Signature

## APPENDIX 6: *TODDLER-SAFE* INFORMATION SHEET



### ***TODDLER-SAFE***

#### **PARTICIPANT INFORMATION SHEET**

**Principal investigator:** Dr Chukwudi Okolie

**Contact details:**

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Cardiff University School of Medicine  
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Heath Park  
Cardiff  
CF14 4YS  
Telephone: 02920687176  
E-mail: [okolieco@cardiff.ac.uk](mailto:okolieco@cardiff.ac.uk)

**Project title:**

***Toddler-Safe*:** Prevention of burns and scalds in preschool children by a targeted intervention

#### **Invitation**

##### **Thank you for reading this leaflet**

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss with others if you wish. Please ask the researcher if there is anything that is unclear or if you would like more information.

**What is the study all about?**

Every year in the UK, more than 6,500 children under 5 are injured in burn accidents. With this study, we are hoping to reduce the number of burns in young children and also improve the knowledge of burns first aid in parents.

**Why have I been invited to participate?**

We are inviting you to take part in this study because you are a parent/carer of a child aged 0-5 years

**Do I have to take part?** It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you do take part you are still free to withdraw at any time and without giving a reason. Decision to take part or not will not alter your child's medical care or routine treatment whatsoever.

**What will happen if I take part?**

First you will be asked to complete a questionnaire to find out what you know about burns prevention and first aid. This will only take about 10 minutes and will be done while you are waiting to be seen for your appointment.

You will then be put into one of two groups. The groups will be allocated at random using sealed envelopes and you stand an equal chance of being in either group.

Group A: You will be asked to watch a short video, after which you will be provided with a leaflet containing general home safety information including a link to view the same video online. Or if you prefer, you can have a DVD of the same video.

Group B: You will be given a leaflet containing general home safety information only.

None of this information will replace the information you would have normally been given by clinic staff.

You will be asked for your contact details so you can be contacted after 24 hours to see if you are still happy to help with this study. If you decide to continue, we will be in touch at 6 months and 12 months to complete a short series of questions. This will take about 10 minutes and will be done over the phone at a time that is best for you.

Your child's emergency department medical notes will be assessed for attendance, admissions or treatment during this period. Although we will have your child's name to locate details of such admissions, their name will not be stored on any computers and will not appear on any forms we use to collect this information.

**What are the risks of taking part?**

There are no known risks to participating in this research.

**What are the benefits of taking part?**

Taking part in this study could improve on your knowledge of burns prevention and first aid.

**What happens with my personal details?**

All information which is collected about you during the course of this research will be kept strictly confidential. Data will be stored on secure, password protected Cardiff University computers and personal details will be deleted once the study is completed. Your contact details will not be passed onto anyone else.

**What will happen if I don't want to carry on with the study?**

You can withdraw from the study at any time without giving a reason. We would greatly appreciate it if we could use the information that we have already collected but if you don't want that, we will remove all information collected to this point. Should you decide not to enter or to leave the study at any point, it will not alter your medical care or routine treatment whatsoever.

**What if there is a problem?**

We do not expect there to be any problems from taking part in this study, however if you have any concerns you should ask to speak to the researchers who will do their best to answer your questions – Dr Chukwudi Okolie. Tel. 029 2068 7176.

If you remain unhappy and wish to complain formally, you can do this by contacting the Complaints' Department – Tel. 029 2074 2202, and they will be happy to discuss your concerns with you. Alternatively you can send an email to [Angela.Hughes5@wales.nhs.uk](mailto:Angela.Hughes5@wales.nhs.uk)

**What will happen to the results of the study?**

The results of this study will be documented in the researcher's PhD thesis. It will also be published in reputable medical journals and presented at professional meetings. Your child's name and details WILL NOT be revealed at any stage. Please let us know if you would like a copy of the report.

**Who is funding the research?**

The research is funded by the National Institute for Social Care and Health Research (NISCHR)

**Who has reviewed the study?**

This study was reviewed and approved by the Research Ethics Committee for Wales

**Contact for further information:**

Dr Chukwudi Okolie  
Cochrane Institute of Primary Care and Public Health  
Cardiff University School of Medicine  
4<sup>th</sup> Floor, Neuadd Meirionnydd

Heath Park  
Cardiff  
CF14 4YS  
E-mail: [okolieco@cardiff.ac.uk](mailto:okolieco@cardiff.ac.uk)  
Telephone: 02920687176

**Thank you for taking the time to read this information leaflet. Please do not hesitate to ask if you would like to discuss anything further.**



Subject ID: \_\_\_\_\_  
Date: \_\_\_\_\_

7. How long do you think it can take the glass front of a fireplace to become very hot?

- <1 minute
- 6 minutes
- 12 minutes
- 30 minutes
- 60 minutes

8. How long do you think it takes the glass front of a fireplace to cool down?

- Up to 5 minutes
- Up to 15 minutes
- Up to 30 minutes
- Up to 45 minutes
- Up to 60 minutes

9. How long do you think it takes very hot tap water to burn a child's skin?

- Less than 1 second
- 10 seconds
- 30 seconds
- Up to 1 minute
- More than 1 minute

10. What is the first thing that you should do if your child is burned?

- Dial 911
- Cool with ice
- Apply butter
- Treat with cream or ointment
- Cool with cold water

11. When leaving your child in the care of another caregiver, do you review child safety concerns?

- Yes
- No
- Sometimes
- Not Applicable

12. Do you place coffees, teas, hot liquids and hot foods out of your child's reach?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time

13. Do you use mugs with secure lids in the home when drinking hot beverages near children?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not Applicable

Subject ID: \_\_\_\_\_

Date: \_\_\_\_\_

14. Do you drink hot beverages while holding your child?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not Applicable

15. Is your child safely out of the way of burn hazards in the kitchen while someone is cooking?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not Applicable

16. Do you use rear stove burners whenever possible?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not Applicable

17. Do you turn pot handles inward while cooking?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not Applicable

18. How should you test the temperature of your child's bath water?

- With a floating thermometer
- With my hand
- With my wrist
- With my arm/elbow
- Other: \_\_\_\_\_

19. When does your child usually get into the bathtub?

- Before the water starts running
- While the water is running
- After the bathtub has been filled
- All of the above
- None of the above

20. Is there an adult within arm's reach during your child's bath-time?

- All of the time
- Most of the time
- Some of the time
- Rarely
- None of the time
- Not applicable



21 A. Have you tested the temperature of the hot tap water in your home?

- Yes  
 No

B. If not, why?

- Did not know it should be tested  
 Do not know how to test it  
 Just have not done it yet

22 A. Is your home hot tap water adjusted to a safe temperature?

- Yes  
 No  
 Do not know

B. If not, why?

- Do not know if it needs adjusting  
 Do not know how to adjust it  
 Just have not done it yet  
 Cannot adjust the hot water heater (e.g. apartment building)  
 Too expensive to hire a plumber (i.e. install a mixing valve)  
 Other: \_\_\_\_\_

23. Do you have a barrier around your fireplace?

- Yes, a secured barrier  
 Yes, a barrier that is not secured  
 No  
 Not applicable

24. Do you have a cover over the gas fireplace switch to prevent a child from turning it on?

- Yes  
 No  
 Not applicable

**All information provided is strictly confidential and will be used for analysis purposes only.**

25. What is the age of your youngest child? \_\_\_\_\_

26. Gender:

- Boy  
 Girl

27. Are you this child's?

- Mother  
 Father  
 Other: \_\_\_\_\_

28 A. Is this your only child?

- Yes  
 No

B. If no, what are the ages of your other children (please specify in months or years)?

\_\_\_\_\_

Subject ID: \_\_\_\_\_  
Date: \_\_\_\_\_

29. Please indicate which age group you belong to:

- ≤20 years
- 20-29 years
- 30-39 years
- 40-49 years
- ≥49 years

30. What is your current marital status?

- Single
- Married/Common law
- Separated/Divorced/Widowed
- Other \_\_\_\_\_

31. Are you a single parent?

- Yes
- No
- Not applicable

32. What is your highest level of education?

- ≤High School
- High School
- Some College
- College Diploma
- Some University
- Bachelor Degree
- Masters Degree
- Other: \_\_\_\_\_

33. What is the primary language spoken in your home? \_\_\_\_\_

34. Can you estimate your household income?

- ≤ \$20,000
- \$20,000-39,000
- \$40,000-59,000
- \$60,000-79,000
- ≥ \$80,000

35. What is the total number of adults in your household? \_\_\_\_\_

36. Has your child had a burn injury in the past?

- Yes
- No

37. Have you suffered from a serious burn injury?

- Yes
- No

38. Do you know someone who has suffered from a serious burn injury?

- Yes
- No

39. Have you received any burns prevention information before?

- Yes
- No

**THANK YOU FOR YOUR PARTICIPATION @**

**APPENDIX 8: CORRELATIONS BETWEEN VARIABLES AT BASELINE**

**Correlations**

			SE-S	FIRSTAID
Spearman's rho	SE-S	Correlation Coefficient	1.000	.123 <sup>*</sup>
		Sig. (2-tailed)	.	.030
		N	312	312
	FIRSTAID	Correlation Coefficient	.123 <sup>*</sup>	1.000
		Sig. (2-tailed)	.030	.
		N	312	312

\*. Correlation is significant at the 0.05 level (2-tailed).

**Correlations**

			SE-S	KNOWLEDGE
Spearman's rho	SE-S	Correlation Coefficient	1.000	.021
		Sig. (2-tailed)	.	.708
		N	312	312
	KNOWLEDGE	Correlation Coefficient	.021	1.000
		Sig. (2-tailed)	.708	.
		N	312	312

**Correlations**

			SE-S	ATTITUDE
Spearman's rho	SE-S	Correlation Coefficient	1.000	.034
		Sig. (2-tailed)	.	.551
		N	312	312
	ATTITUDE	Correlation Coefficient	.034	1.000
		Sig. (2-tailed)	.551	.
		N	312	312

**Correlations**

		SE-S	PRACTICE
Spearman's rho	Correlation Coefficient	1.000	.232**
	SE-S		
	Sig. (2-tailed)	.	.000
	N	312	312
	Correlation Coefficient	.232**	1.000
	PRACTICE		
Sig. (2-tailed)	.000	.	
N	312	312	

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		EDUCATION	FIRSTAID
Spearman's rho	Correlation Coefficient	1.000	.033
	EDUCATION		
	Sig. (2-tailed)	.	.560
	N	312	312
	Correlation Coefficient	.033	1.000
	FIRSTAID		
Sig. (2-tailed)	.560	.	
N	312	312	

**Correlations**

		EDUCATION	KNOWLEDGE
Spearman's rho	Correlation Coefficient	1.000	.044
	EDUCATION		
	Sig. (2-tailed)	.	.441
	N	312	312
	Correlation Coefficient	.044	1.000
	KNOWLEDGE		
Sig. (2-tailed)	.441	.	
N	312	312	

**Correlations**

			EDUCATION	ATTITUDE
Spearman's rho	EDUCATION	Correlation Coefficient	1.000	.027
		Sig. (2-tailed)	.	.639
		N	312	312
	ATTITUDE	Correlation Coefficient	.027	1.000
		Sig. (2-tailed)	.639	.
		N	312	312

**Correlations**

			EDUCATION	PRACTICE
Spearman's rho	EDUCATION	Correlation Coefficient	1.000	.332**
		Sig. (2-tailed)	.	.000
		N	312	312
	PRACTICE	Correlation Coefficient	.332**	1.000
		Sig. (2-tailed)	.000	.
		N	312	312

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

			FIRSTAIDTRAINING	FIRSTAID
Spearman's rho	FIRSTAIDTRAINING	Correlation Coefficient	1.000	.085
		Sig. (2-tailed)	.	.134
		N	312	312
	FIRSTAID	Correlation Coefficient	.085	1.000
		Sig. (2-tailed)	.134	.
		N	312	312

**Correlations**

		AGEGROUPPA RENT	FIRSTAID
Spearman's rho	AGEGROUPPARENT	Correlation Coefficient	1.000
		Sig. (2-tailed)	.379
		N	312
	FIRSTAID	Correlation Coefficient	-.050
		Sig. (2-tailed)	.379
		N	312

**Correlations**

		AGEGROUPPA RENT	KNOWLEDGE
Spearman's rho	AGEGROUPPARENT	Correlation Coefficient	1.000
		Sig. (2-tailed)	.336
		N	312
	KNOWLEDGE	Correlation Coefficient	.055
		Sig. (2-tailed)	.336
		N	312

**Correlations**

		AGEGROUPPA RENT	ATTITUDE
Spearman's rho	AGEGROUPPARENT	Correlation Coefficient	1.000
		Sig. (2-tailed)	.906
		N	312
	ATTITUDE	Correlation Coefficient	.007
		Sig. (2-tailed)	.906
		N	312

**Correlations**

		AGEGROUPPA RENT	PRACTICE
Spearman's rho	AGEGROUPPARENT	Correlation Coefficient	1.000
		Sig. (2-tailed)	-.186**
		N	.001
		N	312
	PRACTICE	Correlation Coefficient	312
		Sig. (2-tailed)	1.000
		.001	.
		N	312
		N	312

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**APPENDIX 9: MULTIPLE LINEAR REGRESSION – PARENTAL BURNS FIRST**

**AID KNOWLEDGE**

**Coefficients<sup>a</sup>**

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	.396	.292		1.355	.176
SES: Higher managerial, administrative and professional occupations (Dummy1)	.130**	.054	.191	2.434	.016
SES: Intermediate occupations (Dummy 2)	.083*	.047	.144	1.757	.080
SES: Intermediate occupations (Dummy 3)	.011	.051	.016	.217	.828
Education: GCSE, vocational or A level (Dummy1)	.032	.090	.050	.351	.726
Education: College/University or Higher (Dummy 2)	-.026	.089	-.043	-.294	.769
Age category of the patient of <20 (Dummy1)	.181	.296	.115	.612	.541
Age category of the patient of 20-29 years (Dummy2)	.210	.281	.370	.746	.456
Age category of the patient of 30-39 years (Dummy3)	.165	.280	.297	.589	.556
Age category of the patient of 40-49 (Dummy4)	.114	.293	.076	.389	.698

a. Dependent Variable: Burns first aid knowledge  
Significance, p\* < 0.1; p\*\* < 0.05



## APPENDIX 10: TODDLER-SAFE RESEARCH ETHICS APPROVAL

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government  
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru



**Research Ethics Committee (REC) for Wales**  
Sixth Floor, Churchill House  
17 Churchill Way  
Cardiff CF10 2TW  
Telephone : 029 2037 6829  
Fax : 029 2037 6824

E-mail : corinne.scott@wales.nhs.uk

Website : www.nres.nhs.uk

17 July 2012

Professor Alison M Kemp  
Professor in Child Health  
Cardiff University  
Cochrane Institute of Public Health and Primary Care  
Heath Park  
Cardiff CF144XN

Dear Professor Kemp

**Study title:** Toddler-Safe: Prevention of burns and scalds in preschool children by a targeted intervention  
**REC reference:** 12/WA/0162  
**Protocol number:** SPON 1097-12  
**EudraCT number:** 0000000

Thank you for your letter of 06 July 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chairman, Dr. Gordon Taylor.

### Confirmation of ethical opinion

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

### Ethical review of research sites

#### NHS sites

The favourable opinion applies to all NHS sites listed in the application, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Non-NHS sites

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

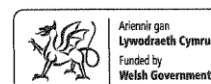
### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.



Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science Collaboration is hosted by Powys Teaching Health Board



Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

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

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

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

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### Approved documents

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

Document	Version	Date
Evidence of insurance or indemnity	Zurich Municipal Certificate of Insurance - Cardiff University - expires 31 July 2012	06 July 2011
Investigator CV	Dr Okolie	01 May 2012
Investigator CV	Professor Kemp	07 May 2012
Investigator CV	Dr Sabine Maguire	08 April 2012
Letter from Sponsor	signed Dr KJ Pittard-Davies, Cardiff University	18 April 2012
Other: Cardiff & Vale UHB, Emergency department Children (0-16 years) Burns and Scalds Assessment Form	5	01 May 2012
Other: Certificate of Attendance - GCP Training	Dr Okolie	20 October 2011
Other: Certificate of Attendance - GCP training	Professor Kemp	01 March 2010
Participant Consent Form	5.2	05 July 2012
Participant Information Sheet	5.2	05 July 2012
Protocol	5	01 May 2012
Questionnaire	5	01 May 2012
REC application	signed in ink by Professor Kemp, electronically by Helen Falconer, sponsor's representative; in ink by Professor Kemp and Dr Sabine Maguire, academic supervisors	

Response to Request for Further Information	Email from Dr. Chukwudi Okolie	22 June 2012
Response to Request for Further Information	Email from D Okolie	06 July 2012
Summary/Synopsis	Flowchart, version 5	01 May 2012

**Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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

**After ethical review**

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

<b>12/WA/0162</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Gordon Taylor**  
**Chairman**

Email: corinne.scott@wales.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Chukwudi Okolie  
Professor J I Bisson, Cardiff and Vale Research Review Service

## APPENDIX 11: TODDLER-SAFE RESEARCH GOVERNANCE APPROVAL



Bwrdd Iechyd Prifysgol  
Caerdydd a'r Fro  
Cardiff and Vale  
University Health Board

Ysbyty Athrofaol Cymru  
University Hospital of Wales

Heath Park,  
Cardiff, CF14 4XW  
Phone 029 2074 7747  
Fax 029 2074 3838  
Minicom 029 2074 3632

Parc Y Mynydd Bychan,  
Caerdydd, CF14 4XW  
Ffôn 029 2074 7747  
Ffacs 029 2074 3838  
Minicom 029 2074 3632

Eich cyf/Your ref  
Ein cyf/Our ref  
Welsh Health Telephone Network 1872  
Direct line/Llinell uniongyrchol

Tel: 029 20746986  
Fax: 029 20745311  
CAV\_Research.Development@wales.nhs.uk

From: Professor JI Bisson  
R&D Director  
R&D Office, 2<sup>nd</sup> Floor TB2  
University Hospital of Wales  
Cardiff  
CF14 4XW

16 August 2012

Professor Alison Kemp  
Department of Child Health  
Cochrane Institute of Primary Care and Public Health  
School of Medicine  
Neuadd Meirionnydd  
Heath Park  
Cardiff  
CF14 4YS

Dear Professor Kemp

**Cardiff and Vale UHB Ref : 12/RPM/5405 : Toddler-Safe: Prevention Of Buns And Scalds In Pre-School Children By A Targeted Intervention**

**NISCHR PCU Ref: 103848**

The above project was forwarded to Cardiff and Vale University Health Board R&D Office by the NISCHR Permissions Coordinating Unit. A Governance Review has now been completed on the project.

Documents approved for use in this study are:

Document	Version	Date
Research protocol	5	01 May 2012
Research participant consent form	5.2	05 July 2012
Research participant information sheet	5.2	05 July 2012
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	5	01 May 2012
Non-validated questionnaire	5	01 May 2012

I am pleased to inform you that the UHB has no objection to your proposal. Please accept this letter as confirmation of permission for the project to begin within this UHB.

You have informed us that Cardiff University is willing to act as Sponsor under the Research Governance Framework for Health and Social Care.

Your study may be eligible for adoption by the NISCHR Clinical Research Portfolio (CRP). You should now apply to have this trial adopted in order for the UHB to receive funding to support this study. If your study is adopted onto the NISCHR CRP, it will be a condition of this NHS research permission, that you will be required to regularly upload recruitment data onto the portfolio database.

To apply for adoption onto the NISCHR CRP, please go to:  
<http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979> Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at:  
<http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571>

If your study is adopted onto the portfolio, please inform NISCHR PCU and the R&D Office of your portfolio ID number.

To upload recruitment data, please follow this link:  
[http://www.crnc.nihr.ac.uk/about\\_us/processes/portfolio/p\\_recruitment](http://www.crnc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment) Uploading recruitment data will enable NISCHR to monitor research activity within NHS organisations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact  
[CAV\\_research.development@wales.nhs.uk](mailto:CAV_research.development@wales.nhs.uk)

May I take this opportunity to wish you success with the project and remind you that as Principal Investigator you are required to:

- Inform the R&D Office if this project has not opened within 12 months of the date of this letter. Failure to do so may invalidate R&D approval.
- Inform NISCHR PCU and the UHB R&D Office if any external or additional funding is awarded for this project in the future
- Submit any substantial amendments relating to the study to NISCHR PCU in order that they can be reviewed and approved prior to implementation
- Ensure NISCHR PCU is notified of the study's closure
- Ensure that the study is conducted in accordance with all relevant policies, procedures and legislation
- Provide information on the project to the UHB R&D Office as requested from time to time, to include participant recruitment figures

Yours sincerely,



**Professor Jonathan I Bisson**  
R&D Director

## APPENDIX 12: HONORARY RESEARCH CONTRACT



**GIG**  
CYMRU  
**NHS**  
WALES

Bwrdd Iechyd Prifysgol  
Caerdydd a'r Fro  
Cardiff and Vale  
University Health Board

**Ysbyty Athrofaol Cymru**  
**University Hospital of Wales**

Heath Park,  
Cardiff, CF14 4XW  
Phone 029 2074 7747  
Fax 029 2074 3838  
Minicom 029 2074 3632

Parc Y Mynydd Bychan,  
Caerdydd, CF14 4XW  
Ffôn 029 2074 7747  
Ffacs 029 20743838  
Minicom 029 2074 3632

Eich cyf/Your ref  
Ein cyf/Our ref  
Welsh Health Telephone Network 1872  
Direct Line/Llinell uniongychol

Chukwudi Okolie  
Flat 10 6B Gwennyth Street  
Cathays  
Cardiff

Date 13<sup>th</sup> November 2012

Dear Mr Okolie

### Honorary research contract issued by Cardiff and Vale University Health Board

I am pleased to offer you an honorary research contract in Cardiff and Vale University Health Board. I should be grateful if you would sign the attached two contracts, keep one yourself and return the other to Kelly Skene, Recruitment Office, Lakeside, UHW Heath Park Cardiff, CF14 4XW. We will send a copy of the contract to your substantive employer.

The contract if accepted by you begins on 13<sup>th</sup> November 2012 and ends on 30<sup>th</sup> June 2014 unless terminated earlier in accordance with the clauses in the contract. Please note that you cannot start the research until the Principal Investigator has received a letter from us giving permission to conduct the project.

We will not reimburse any expenses you incur in the course of your research unless we have agreed to do so by prior arrangement. Similarly, we accept no responsibility for damage to or loss of personal property.

Your Research Passport may be subject to random checks carried out by us within the lifetime of the project. The information it contains must therefore remain up to date and accurate.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform your employer through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Once you have signed and returned one of the attached contracts, you should contact the R&D Department of this organisation, who will arrange for you to be issued with an ID badge.

Yours sincerely

**Pat Tamplin**  
Governance Officer Human Tissue Act  
HR department of the substantive employer  
**Prof Alison Kemp**

## APPENDIX 13: TODDLER-SAFE INJURY SAFETY LEAFLET

**Further information can be found at the following websites:**

[www.rospa.com](http://www.rospa.com) 

[www.capt.org.uk](http://www.capt.org.uk) 

Leaflet compiled by the Toddler-Safe Team,  
Cochrane Institute of Primary Care and Public Health,  
School of Medicine, Cardiff University,  
4th Floor, Hezardd Meirionnydd, Health Park,  
Cardiff CF14 4YS  
Telephone: +44(0)29 20687176  
E-mail: okolleco@cf.ac.uk



**Home safety Information for parents**





 Bwrdd Iechyd Prifysgol  
Caerdydd a'r Fro  
Cardiff and Vale  
University Health Board

**What we know**

- Accidental injury is one of the biggest killers of children in the UK
- Most of these accidents happen in the home environment
- Children aged 0-5 years are most at risk

**Main home safety messages for families**

- CHILDREN AGED LESS THAN 5 NEED SUPERVISION AT ALL TIMES
- Recognise the dangers
- Take action to avoid or remove the danger



**HOME SAFETY INFORMATION**

**Do**

- ✓ Keep small objects such as buttons, beads and marbles out of reach 
- ✓ Install smoke alarms on each floor level and test regularly 
- ✓ Keep secure fire guard screens in front of open fires, heaters and radiators 
- ✓ Store matches and lighters out of reach 
- ✓ Install safety gates at the top and bottom of stairs 
- ✓ Lock up medicines out of children's sight and reach 

**Don't**

- ✗ Leave babies unattended on raised surfaces 
- ✗ Allow children near fireworks 
- ✗ Use baby walkers - children move too quickly without control 
- ✗ Leave young children in the bath unsupervised 
- ✗ Leave young children unattended in the kitchen or near fires and heaters 
- ✗ Put anything under the window that can be climbed on 
- ✗ Allow children near BBQs or garden chemicals 
- ✗ Leave young children out in the sun without sunscreen, hat and T-shirt 

**APPENDIX 14: TEST-RETEST RELIABILITY (PILOT STUDY)**

**Correlations**

		AGEGROUPLI KELYTOGETB URN_M	AGEGROUPLI KELYTOGETB URN_Q
AGEGROUPLIKELYTOGET BURN_M	Pearson Correlation	1	.680**
	Sig. (2-tailed)		.001
	N	20	20
AGEGROUPLIKELYTOGET BURN_Q	Pearson Correlation	.680**	1
	Sig. (2-tailed)	.001	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		PERCENTAGE FROMHOTLIQ UIDS_M	PERCENTAGE FROMHOTLIQ UIDS_Q
PERCENTAGEFROMHOTL IQUIDS_M	Pearson Correlation	1	.747**
	Sig. (2-tailed)		.000
	N	20	20
PERCENTAGEFROMHOTL IQUIDS_Q	Pearson Correlation	.747**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		CHILDSSKIN_ M	CHILDSSKIN_ Q
CHILDSSKIN_M	Pearson Correlation	1	.459*
	Sig. (2-tailed)		.042
	N	20	20
CHILDSSKIN_Q	Pearson Correlation	.459*	1
	Sig. (2-tailed)	.042	
	N	20	20

\*. Correlation is significant at the 0.05 level (2-tailed).



**Correlations**

		TIMEFORVERY HOTWATERTO BURNCHILDSS KIN_M	TIMEFORVERY HOTWATERTO BURNCHILDSS KIN_Q
TIMEFORVERYHOTWATE RTOBURNCHILDSSKIN_M	Pearson Correlation	1	-.171
	Sig. (2-tailed)		.472
	N	20	20
TIMEFORVERYHOTWATE RTOBURNCHILDSSKIN_Q	Pearson Correlation	-.171	1
	Sig. (2-tailed)	.472	
	N	20	20

**Correlations**

		FIRSTAID_M	FIRSTAID_Q
FIRSTAID_M	Pearson Correlation	1	.904**
	Sig. (2-tailed)		.000
	N	20	20
FIRSTAID_Q	Pearson Correlation	.904**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		COVER_M	COVER_Q
COVER_M	Pearson Correlation	1	.960**
	Sig. (2-tailed)		.000
	N	20	20
COVER_Q	Pearson Correlation	.960**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		HOTDRINKSW HILEPLAYING WITHCHILD_M	HOTDRINKSW HILEPLAYING WITHCHILD_Q
HOTDRINKSWHILEPLAYIN GWITHCHILD_M	Pearson Correlation	1	.853**
	Sig. (2-tailed)		.000
	N	20	20
HOTDRINKSWHILEPLAYIN GWITHCHILD_Q	Pearson Correlation	.853**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		WHEREHOTD RINKSAREPLA CED_M	WHEREHOTD RINKSAREPLA CED_Q
WHEREHOTDRINKSAREP LACED_M	Pearson Correlation	1	.375
	Sig. (2-tailed)		.103
	N	20	20
WHEREHOTDRINKSAREP LACED_Q	Pearson Correlation	.375	1
	Sig. (2-tailed)	.103	
	N	20	20

**Correlations**

		CHILDINKITCH ENWHILECOO KING_M	CHILDINKITCH ENWHILECOO KING_Q
CHILDINKITCHENWHILEC OOKING_M	Pearson Correlation	1	.979**
	Sig. (2-tailed)		.000
	N	20	20
CHILDINKITCHENWHILEC OOKING_Q	Pearson Correlation	.979**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		RINGSBURNE RSUSED_M	RINGSBURNE RSUSED_Q
RINGSBURNERSUSED_M	Pearson Correlation	1	.759**
	Sig. (2-tailed)		.000
	N	20	20
RINGSBURNERSUSED_Q	Pearson Correlation	.759**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		POTHANDLESIN WARD_M	POTHANDLESIN WARD_Q
POTHANDLESINWARD_M	Pearson Correlation	1	.898**
	Sig. (2-tailed)		.000
	N	20	20
POTHANDLESINWARD_Q	Pearson Correlation	.898**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		TESTTEMPERAT UREOFBATHW ATER_M	TESTTEMPER ATUREOFBAT HWATER_Q
TESTTEMPERATUREOFBATH HWATER_M	Pearson Correlation	1	.746**
	Sig. (2-tailed)		.000
	N	20	20
TESTTEMPERATUREOFBATH HWATER_Q	Pearson Correlation	.746**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		WHENDOESC HILDENTERBA TH_M	WHENDOESC HILDENTERBA TH_Q
WHENDOESCHILDENTER BATH_M	Pearson Correlation	1	1.000**
	Sig. (2-tailed)		.000
	N	20	20
WHENDOESCHILDENTER BATH_Q	Pearson Correlation	1.000**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		STOREHOTIR ON_M	STOREHOTIR ON_Q
STOREHOTIRON_M	Pearson Correlation	1	.930**
	Sig. (2-tailed)		.000
	N	20	20
STOREHOTIRON_Q	Pearson Correlation	.930**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		STOREHOTHAIR RSTRAIGHTEN ER_M	STOREHOTHAIR RSTRAIGHTEN ER_Q
STOREHOTHAIRSTRAIGH TENER_M	Pearson Correlation	1	.679**
	Sig. (2-tailed)		.001
	N	20	20
STOREHOTHAIRSTRAIGH TENER_Q	Pearson Correlation	.679**	1
	Sig. (2-tailed)	.001	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		SEVERITYSCA LE_M	SEVERITYSCA LE_Q
SEVERITYSCALE_M	Pearson Correlation	1	.886**
	Sig. (2-tailed)		.000
	N	20	20
SEVERITYSCALE_Q	Pearson Correlation	.886**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

**Correlations**

		PREVENTABL ESCALE_M	PREVENTABL ESCALE_Q
PREVENTABLESCALE_M	Pearson Correlation	1	.871**
	Sig. (2-tailed)		.000
	N	20	20
PREVENTABLESCALE_Q	Pearson Correlation	.871**	1
	Sig. (2-tailed)	.000	
	N	20	20

\*\* . Correlation is significant at the 0.01 level (2-tailed).

OVERALL CORRELATION COEFFICIENT = 0.759