# Development and evaluation of a multi-media intervention to enhance the motor development of premature infants

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# Abstract

**Background**: Pregnancy is defined as lasting 40 weeks and birth that occurs before 37 weeks of gestation are classed as preterm, with neonates from as early as 22 weeks gestation surviving, although this is rare. Prematurity is associated with a range of long-term morbidities which negatively influence health and well-being. Infants born at less than 33 weeks gestation are at significantly increased risk for impaired motor development compared with their term peers (Allen, 2008). Deficits in motor skills such as balance, eye-hand co-ordination and manual dexterity have been well documented and are evident in infancy (Wood et al., 2000; Bracewell and Marlow, 2002). Early interventions have demonstrated some success in improving motor skills, but the effective elements were unclear. In addition, interactions between parent and infant can be problematic.

**Aims**: The aim was to develop and evaluate an interactive multimedia parenting intervention, which focuses of motor development of their preterm infant, and to compare parental perceptions of infant capability, parental confidence and parental stress.

**Methods:** The design of the intervention incorporated Social learning theory (Bandura, 1977) as the basis for the parenting intervention. The development of the intervention incorporated findings from a systematic review and a focus group with feedback from relevant healthcare, education professionals and parents of preterm infants. A randomised controlled trial was designed and conducted to evaluate the effectiveness and acceptability of the intervention. In total 168 preterm infants were recruited from five NHS neonatal intensive care units and randomly allocated to an intervention or control arm. The intervention arm consisted of the Helping Our Premature infant ON to better motor skills (HOP-ON) programme and Sharing My Infant's Learning Experiences (SMILES) programme alongside treatment as

usual. The control arm received the SMILES programme alongside treatment as usual. The primary outcome was motor scores on from AIMS and Bayley III developmental assessment. The secondary outcomes were parental perceptions of infant capability, parental confidence and parental stress. Evaluation of the study was conducted following the 12 month assessment.

**Findings:** The primary outcomes of motor scores on the AIMS and Bayley III were not significantly different between the intervention and control groups. Parental perceptions of infant capability were measured with IPIQ and no statistically significant differences were found at 3-4 months corrected age. In relation to parental confidence and stress, these were measured at 3-4 months corrected age and 12 months corrected age using the Parenting Stress Index (PSI) short form. At 12 months corrected age there was a difference between the intervention and control group, with the control group showing significantly higher levels of stress than the intervention group ($p<0.038$).

**Conclusion:** The need for interventions with parents and their preterm infants is well established, and although the HOP-ON programme did not significantly improve the motor skills of the preterm infants, the evaluation suggests that parents found the information valuable. HOP-ON is an easy to use intervention, which would benefit from further exploration, along with the reduction on reported stress levels at 12 months.

# Publications and funding

**Published papers**:

Hughes, A.J., Redsell, S., Glazebrook, C. (2016) Motor Development of Preterm Infants: A Systematic Review and Meta Analysis, **Pediatrics** Sep 2016, e20160147; **DOI**: 10.1542/peds.2016-0147

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Diolch yn fawr.

# Preface

This study forms part of a project funded by Action Medical Research to design and evaluate a motor intervention. The initial design was put together by a research team with Professor Cris Glazebrook as principle investigator. The research team consisted of Dr Helen Budge; Professor Sarah Redsell; Dr Charlotte Beer; Dr Samantha Johnson; Professor Heather Wharrad and Ms Sarah Westwater-Wood.

My involvement began once the funding had been obtained, but prior to final design, development of the intervention and obtaining relevant ethics and research and development approvals. My responsibilities were to complete ethics and trust forms to obtain favourable opinion for the study to be undertaken, and organise application for the study to be accepted on to the UK CLRN portfolio and maintain the accrual database. Involvement in all aspects of development of the intervention and work with research associate and CLRN to recruit onto the study and alongside the research associate conduct the motor assessments wherever possible; agreed scoring; enter and analyse data.

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# Chapter One: Preterm birth and infant development

## 1.1 Introduction

This chapter provides the context and rationale for the study by outlining the epidemiology of preterm birth and its impact on developmental outcomes for children. The need to develop interventions is also highlighted.

## 1.2 Definition of preterm

A term pregnancy is classified as a period of 40 weeks gestation, with the expected due date being calculated 40 weeks from the start of the woman's last menstrual cycle (American College of Obstetricians and Gynecologists, 2013). Given the variation in length and frequency of menstrual cycles, neonates born between 38 and 42 weeks gestation are classified as full term. In maternity care a neonate born less than 37 weeks and six days (<37+6), are classed as preterm, however, when defining prematurity in neonatology and paediatrics, infants born prior to 37 weeks gestation are defined as preterm (Tucker and McGuire, 2004). The Office of National Statistics (2015) state that a foetus is considered to be viable at 24 weeks gestation, as the survival rate for births prior to 24 weeks is rare. Given the extent of developmental change in a foetus between 24 and 37 weeks of gestation, especially during the last weeks of pregnancy, prematurity is further categorised into:

- Extremely preterm (<28 weeks gestation)
- Very preterm (28 to <32 weeks gestation)
- Moderate to late preterm (32 to <37 weeks gestation)

This is due to the increased risk of mortality and morbidity being related to birth at an earlier gestation. There are many factors that influence preterm birth, some of which may have the additional complication of the growth of the preterm infant being restricted. These infants are likely to require additional support, due to being small for gestational age, therefore birth weight is also categorised into:

- Extremely low birth weight (<1000 grams)
- Very low birth weight (<1500 grams)
- Low birth weight (<2500 grams)

There is a correlation with birth weight and outcome, with lower birth weight being related to higher risk of adverse outcome. Neonates categorised as extremely low birth weight are therefore at a greater risk of mortality and morbidity (Anderson et al., 2016).

## 1.3 Rates of preterm birth

In 2012 the World Health Organisation (WHO) produced "Born Too Soon: The Global Action Report on Preterm Birth" (Howsen et al., 2012), as it had been identified that many countries in the world have, in the last two decades, experienced an increase in preterm births. This and the subsequent rise in survival rates, are due to advances in obstetric and neonatal care (Baron and Rey-Casserly, 2010). An estimated 10% of all births worldwide were identified as preterm, with the largest variation being between high and low income countries (Platt, 2014). Blencowe et al (2014) suggest the range is 5-18% with the higher percentage being found in low income countries. In 2012 the Office of National Statistics (ONS) provided the 2010 data for England and Wales, where approximately 53,000 births were preterm, which accounted for 7.3% of live births. The figures provided by ONS for 2012 (ONS, 2014),

and more recently the birth registration statistics in England and Wales for 2013 suggested the number of preterm births and the percentage of live births have remained similar (ONS, 2015).

### 1.3.1 Causes and risk factors for preterm birth

Preterm birth can be classified into two broad categories: Spontaneous or Obstetrician initiated preterm birth. Both of which can be the result of several interacting factors. Obstetrician initiated preterm births are conducted for maternal or fetal indications and involve induction of labour or elective caesarean section (Platt, 2014). Whereas in nearly half of the cases of spontaneous preterm birth, the cause is unidentifiable (Blencowe et al., 2014). This supports previous studies, as Lettieri et al. (1993) found that the majority of cases of preterm labour that resulted in preterm birth were idiopathic.

Preterm labour is viewed as a syndrome initiated by multiple causes which include medical and socio-economic factors. Lettieri et al. (1993) conducted a prospective study to look at possible medical causes of preterm labour and identified the following categories of risk factors: Faulty placentation, intrauterine infection, immunologic factors, cervical incompetence, uterine factors (including multiple births; previous premature birth), maternal factors, trauma and surgery, fetal anomalies, and idiopathic conditions. These have more recently been categorised to areas such as, inflammation or infection, vascular disease and over-distension of the uterus (Goldenberg et al., 2008). Romero et al. (2007) state that despite many suspected causes of preterm labour and birth, in relation to medical risk factors, a causal link has only been established between Inflammation and/or infection and preterm birth.

The evidence for a link between socio-economic factors and premature birth is well established. Oftedal et al (2016) demonstrate how lower socio-economic status is linked to an increased risk of preterm birth, as is ethnicity, maternal age, multiple births, education level. In relation to ethnicity, Black-Caribbean and Black-African women are at increased risk for preterm birth with ONS (2015) stating that in 2013 in the UK, the highest proportion of premature infants were of Black Caribbean ethnicity (10%), although Gray et al. (2009) suggest that these discrepancies may also be due to socio-economic factors, with Pakistani, Black Caribbean and Black African families being more likely to live in areas of high deprivation. Meta-analysis by Weightman et al., (2012) compared deprivation area quintiles and found that preterm birth is more likely in areas of high deprivation (OR = 1.67; 95%CI: 1.42-1.96). There is however, also a suggestion from Patel et al. (2003) that the gestation of pregnancies for Black and Asian women are shorter, which could potentially result in the fetus developing earlier. Maternal age has been demonstrated to factor in preterm birth, with women who are less than 20 years of age, or over 40 years of age being more likely to give birth prematurely, these findings are found in data from England and Wales, and Norway (Platt, 2014, Oftedal et al., 2016), and recent data from the ONS (2015) support this. Multiple births contribute to preterm births figures, as twin, triplet or quadruplet pregnancies are more likely to be born prematurely. Stock and Norman (2010) highlight that >50% of multiple pregnancies are born at <37 weeks gestation. Several factors are inter-related, such as area of deprivation and life-style factors, with health behaviours such as smoking, drinking and drug taking are also linked with preterm labour, as is teenage pregnancy (Smith et al., 2000, Welch-Carre, 2005).

## 1.4 Outcomes of prematurity

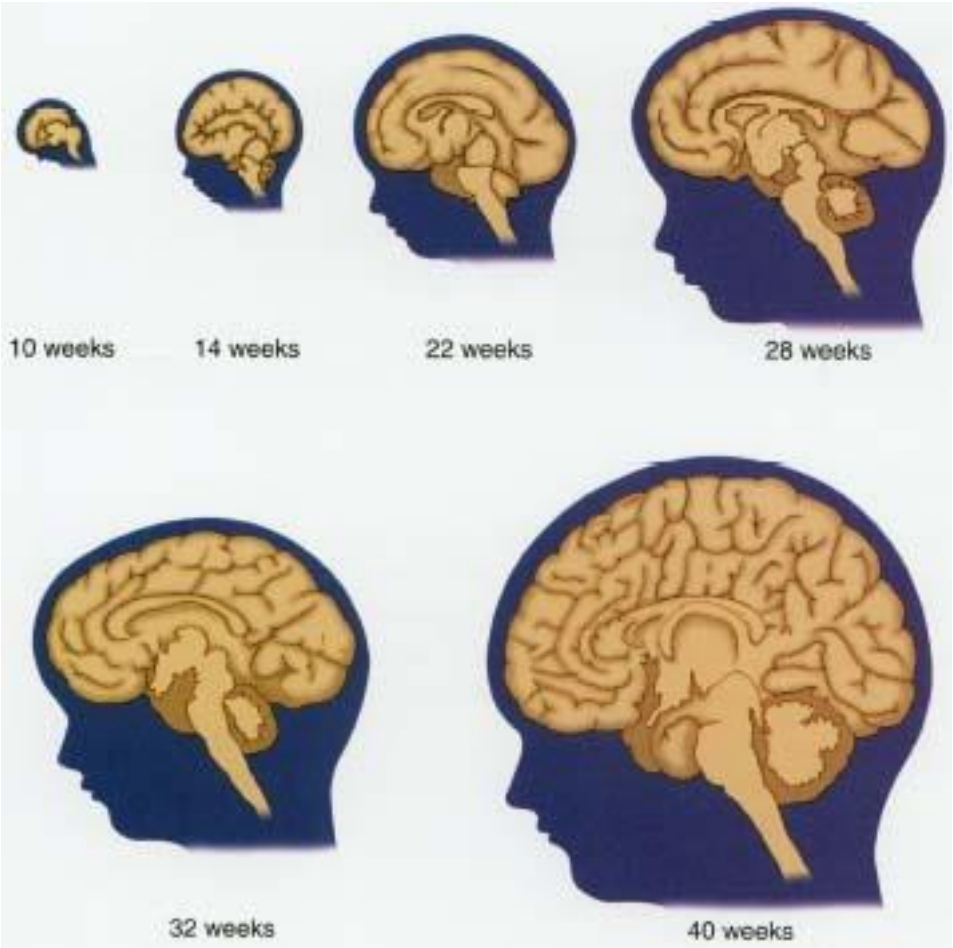
Despite the improvement in survival rates for extremely and very preterm infants over the past three decades, preterm birth is the leading direct cause of neonatal deaths, and also increases the risk of death due to other causes, such as infections (Blencowe et al., 2014). In addition, the Global Action Report on Preterm Birth (Howson et al., 2012) states that it is the second largest direct cause of death in pre-school children worldwide. A recent population-based study was conducted in the United States of America by Anderson et al. (2016), to assess the survival and morbidity of extremely preterm infants (22-28 weeks gestation). Lower gestation is related to survival and level of morbidity, with Anderson et al. (2016) noting a range from 8% survival for infants born at 22 weeks gestation up to 94% survival rates for infants born at 28 weeks gestation. The majority of infants born preterm (>22 and <37 weeks) who survive are at a much greater risk of impairment when compared to full term infants. Those born extremely preterm (22-28 weeks gestation) are at an 80% risk of major morbidity (Anderson et al., 2016). For England and Wales in 2013 the mortality rate for preterm infants was 21.1 per 1000 live births compared to 1.4 per 1000 mortality rate for full-term babies (ONS, 2015).

### 1.4.1 The role of maturation in development

McGrath (2008) states that within the developing embryo, the neurological system is one of the first systems to develop, however, its maturation is not fully completed until adulthood. After 25 weeks of gestation, the growth and complexity of connections are developing (Ajayi-Obe et al., 2000), therefore it is a critical time for brain development. When preterm birth occurs this development is

interrupted (McGrath, 2008, Abbott, 2015), and results in preterm infants having smaller cortical surface area (Ment and Vohr, 2008). Figure 1 depicts the changes that occur in the brain development of the embryo during pregnancy.

**Figure 1: Fetal Brain Development**




©Taken from Beginbeforebirth.org

Abbott (2015) suggests that the preterm neonate brain is forced into dealing with stimuli and sensory inputs for which it is unprepared. In particular the unnatural sensory signals of the neonatal unit, and the medical procedures undertaken (McGrath, 2008, Abbott, 2015). Smith et al. (2011) found an association between exposure to stressors in the NICU with regional alterations in brain structure and function. In addition the extra-uterine environment also impacts on the infant's

motor development, as their muscle movement is effected by gravity (McGrath, 2008). Preterm infants are also at an increased risk of periventricular haemorrhage (PVH), particularly those born prior to 32 weeks of gestation (Ajayi-Obe et al., 2000).

The consequences of prematurity are well documented, with infants significantly more likely to be affected by adverse neurodevelopment (Guralnick, 2012). The evidence of these developmental consequences of preterm birth have been made available via longitudinal observational studies which have been conducted in a variety of countries (Costeloe et al., 2000, Golding et al., 2001, Express Group et al., 2009, Beaino et al., 2010, Moore et al., 2012, Sullivan et al., 2012, Maggi et al., 2014, Soleimani et al., 2014) . In comparison to full-term infants at four years of age, preterm infants performed significantly worse in motor, cognitive and functional performance, even when socio-economic background were similar (Maggi et al., 2014). Mangham et al. (2009) established that the increased economic consequences of preterm birth throughout childhood, mainly impact on the healthcare system with up to 92% of the incremental costs for inpatient hospital care. Howsen et al (2012) agree that the increased risk of impairment exacts a heavy load on health systems, and also on the families.

### 1.4.2 Major impairment

The main neuro-developmental disorders associated with preterm birth are cerebral palsy, especially spastic diplegia; cognitive impairment; visual impairment; developmental coordination disorder and hearing impairments (Arpino et al., 2010). It is important to consider, when looking at longitudinal cohort data, not only gestational age, but also changes in viability and the medical care available at the time of birth

(Baron and Rey-Casserly, 2010). note that this has resulted in a decrease in the number of extremely preterm survivors with severe complications. The level and proportion of preterm infants with major neuro-developmental problems vary although the proportion is argued to be somewhere between 6% (Fawke, 2007) and 15% (Woodward et al., 2009). More recent publications have tended to support the higher rate (Maggi et al., 2014). For example, Platt (2014) notes a 12% rate of cerebral palsy which varies with gestation.

### 1.4.3 Neuro-behavioural impairment

Despite the improvements in neonatal care, neuro-behavioural impairment in childhood for preterm infants has remained relatively constant (Orton et al., 2009b). The majority of preterm infants may not be affected by major neurodevelopmental impairment, however, a high proportion exhibit mild to moderate neuro-behavioural impairment, according to Fawke (2007) between 47% and 64%, although Woodward et al., (2009) suggested a slightly lower percentage of between 25% and 50%. A recent review by Bos et al (2013) found a 40% prevalence of mild to moderate impairment and an additional 20% of preterm infants with moderate impairment. Baron and Rey-Casserly (2010) state that difficulties are likely, as the preterm infant's brain will be very different from a full term infant's, due to the growth being interrupted at a critical stage of neurodevelopment. The evidence demonstrates that preterm children are at a significantly increased risk for impaired development compared with their full term peers.

#### 1.4.3.1 Cognitive impairment

Preterm infants are more likely to need educational support than their full term peers (Johnson et al., 2009) with significant school problems

persisting into adolescence (Luu et al., 2011). Cognitive impairment (IQ<70) is, according to Arpino et al (2010) the most common and severe disability in infants born preterm. Rates of cognitive disability range from 4% to 47% in infants born between 22 and 34 weeks gestation, or low birthweight (750g and 1,500g), with early interruption of brain development playing an important role (Arpino et al., 2010). However, Lee et al (2011) note that even the preterm children who do not appear to have difficulties, such as cerebral injuries, have been shown to have poor verbal working memory and mildly poorer grammatical skills. Luu et al (2011) suggests that this may be due to deficits in executive functioning and memory, which play an important role in learning and school attainment. Adolescents born preterm showed deficits of 0.4 to 0.6 of a standard deviation in tasks of verbal fluency, cognitive flexibility, planning/organisation, inhibition, and verbal, visuo-spatial and working memory, compared with full-term controls (Luu et al., 2011). This deficit remained even when those with neurosensory disabilities and those with <70 intelligence quotient (IQ) were excluded from the analysis (Luu et al., 2011). More recent findings have supported this, with Mohamed Mohamed El-Mazahi et al. (2014) findings that preterm infants displayed deficits in all domains of cognitive and language function, and had lower total score IQ.

#### 1.4.3.2 Motor impairment

Preterm birth has resulted in a high prevalence of survivors with persistent mild neuro-motor dysfunction and poor motor skills (Allen et al., 2008; Arnauld et al., 2007) Deficits in motor planning, sensory-motor integration, speed and quality of movement, gross motor skills such as balance and ball skills, and fine motor skills such as manual dexterity and visuo-spatial abilities in infancy have been widely documented (Wood et al., 2000, Bracewell and Marlow, 2002) and

persist through childhood and adolescence (Mikkola et al., 2005, Allin et al., 2006, Schmidhauser et al., 2006, Davis et al., 2007, Marlow et al., 2007). Meta-analysis of data from infancy to fifteen years of age, for very low birth weight, very preterm infants found that they were on average -0.57 to -0.88 of a standard deviation behind their full-term peers (de Kieviet et al., 2009), with the main types of motor problems being:

- Ball skills
- Balance
- Manual dexterity
- Fine and gross motor skills

These impact on all aspects of schooling, which De Kieviet et al (2009) suggest may exacerbate the motor problems of preterm infants, by placing a constant and greater demand on their motor skills and subsequent development. Moreira et al. (2014) agree that school is a key developmental stage, requiring skills that may not have previously been used, which may be impaired, or unable to cope with the additional demand being placed during this period of development. In their review Moreira et al., (2014) provide evidence that preterm infants demonstrate vulnerability in behaviour, school performance and motor development when assessed between the ages of eight and ten years of age.

## 1.5 Motor development, Developmental Coordination Disorder (DCD) and Attention Deficit Hyperactivity Disorder (ADHD)

The course of motor development during infancy is variable and co-ordination difficulties during childhood can lead to low levels of physical activity, poor cardio-vascular fitness and adiposity (Reithmuller et al., 2009). Difficulties with fine motor skills, such as eye-hand co-ordination and manual dexterity are commonly associated with cognitive deficits, inattention, social and emotional problems and learning difficulties (Jeyaseelan et al., 2006, Arnaud et al., 2007b, Davis et al., 2007, Marlow et al., 2007), which may have a profound impact upon a child's integration and performance in school. Pritchard et al. (2014) assessed the school readiness of very preterm and full term children prior to starting school and at six years of age and nine years of age and found a high proportion of the children born very preterm exhibited neurodevelopmental difficulties that impacted on school performance. At four years of age very preterm born children fared less well than their full-term peers on the domain of physical well-being and motor difficulties in relation to school readiness (Pritchard et al., 2014). Throughout the stages of assessment, difficulties demonstrated by children born very preterm spanned health, physical, social and emotional development, although Pritchard et al (2014) noted when assessing single domain impairment, that it ranged from 24% for socio-emotional adjustment, whilst physical health and motor functioning was identified in 38% of very preterm children. In addition multi domain impairment was much higher for children born very preterm compared with children born at full term (47% vs 16%). Overall, 60% of very preterm born children demonstrated some form of educational delay compared with approximately 25% of full term born children (Pritchard et al., 2014). The high prevalence of motor impairment in extremely and

very preterm children may therefore contribute to the poor academic attainment and high prevalence of special educational needs (SEN) observed in this population (Pinto-Martin et al., 2004, Johnson et al., 2009, Johnson et al., 2011). The Motor co-ordination difficulties that persist from infancy can impact upon a child's integration and performance at school, leading to low levels of self-esteem. Extremely and very preterm birth is associated with a high risk of developmental co-ordination disorder (DCD) later in life (Davis et al., 2007), this has been demonstrated even among preterm infants who have IQ in the normal range and are free of neuro-sensory disability (Goyen and Lui, 2002, Goyen and Lui, 2009). Maggi et al (2014) found that 29% of the scores of preterm children were indicative of DCD.

Developmental coordination disorder has been associated with lower confidence in relation to physical activity and higher rates of obesity. In addition, a higher risk of attention-deficit hyperactivity disorder (ADHD) has been identified not only in extremely/very preterm infants or those with a very low birth weight, but also in late preterm infants and those with weight of only 1 standard deviation (SD) below the mean (Sucksdorff et al., 2015). This has additional implications for motor development, as there is a relationship between hyperactivity/ inattention and obesity in childhood, which can impact on the amount of involvement and level of confidence in relation to physical activity (McWilliams et al., 2013). Arpino et al (2010) noted a high prevalence of DCD in extremely/very preterm infants, which could be isolated or in association with other disorders such as ADHD. The range in the general population is 5-6%, but for preterm infants, the figures ranged between 9.5% and 51% (Arpino et al., 2010). Given the influence that early experience can have on an infant's development, identifying interventions that enhance preterm infant's development has the potential for improving health and psychosocial outcomes.

Children with DCD are less physically fit and significantly more likely to be overweight or obese than their term peers (Schott et al., 2007). Cairney and colleagues also found lower participation in physical activity amongst children with DCD and greater rates of obesity amongst boys with the condition (Cairney et al., 2005). This is a particular concern for preterm infants who are at risk of excess adiposity (Uthaya et al., 2005, Modi et al., 2006). Preterm infants, especially those that are small for gestational age have reduced lean body mass, when compared to infants with birth weight appropriate for their gestational age (Yliharsila et al., 2007). Many of these infants have experienced rapid "catch up growth" during early infancy (Euser et al., 2008) and research exploring maternal beliefs about infant feeding seems to suggest that mothers are anxious for smaller infants to gain weight and feed them accordingly (Reyna et al., 2006). This additional weight tends to be fat rather than lean mass, resulting in low muscle mass which impairs glucose metabolism and thus potentially increases the risk of later cardiovascular disease (Yliharsila et al., 2007).

## 1.6 Development and Early Intervention

It is argued that positive stimuli and interaction are essential for a child's development, as an infant's early experiences influence their emotional, intellectual and physical development. Armstrong et al. (2014) acknowledge that understanding factors which may support or compromise development are key to supporting healthy developmental outcomes. The relationship between a mother and infant begins during pregnancy, and this attachment is argued to be a lifelong process (Armstrong et al., 2014). The quality of early caregiving either assist or impede the infant's ability to regulate inner emotional states (Bowlby, 1978).

It has therefore been argued that interventions aimed at improving health, physical, social and emotional development in infants should be instigated as early as possible (Allen, 2011). There have been many studies assessing the setting and care within the neonatal unit, to reduce the impact of the unnatural environment on the preterm infant. An example of such a programme is the Newborn Individualized Developmental Care and Assessment Program (NIDCAP). NIDCAP interventions only take place in the hospital setting and involve responding to each neonate's behaviour, and adapting care appropriately. Als et al. (1994) developed the program as the environment of the Neonatal Intensive Care Unit (NICU) was believed to inhibit the development of neuronal pathways. It was thought that changing aspects of the environment such as the noise and lighting may help reduce infant distress (Als et al., 1994). There were promising results initially, but there is very little evidence from these studies of any long term benefit in relation to infant development (Als et al., 1994, Kleberg et al., 2000, Maguire et al., 2009, Ullenhag et al., 2009, Wielenga et al., 2009). Wallin and Eriksson (2009) conducted a systematic review on NIDCAP interventions and concluded that scientific evidence for positive effects for NIDCAP are limited. This may be due to the timing and short duration of NIDCAP interventions (Wallin and Eriksson, 2009).

### 1.6.1 Parenting interventions

The NICU setting impacts on amount of movement and interactions between the parents and infant. Evidence has demonstrated that encouraging and providing early movement opportunities can, however, moderate outcomes for extremely and very preterm infants (Treyvaud et al., 2009). Involving parents in providing these opportunities is important, as meta-analysis from a systematic review reported a significant effect of interventions involving parents on motor

outcomes at 12 months of age (Vanderveen et al., 2009b). The vast majority of interventions included in the review were general programmes designed to enhance global neuro-developmental outcomes. A targeted intervention designed to improve motor performance and involve caregivers in implementation with their infants reported significantly enhanced motor outcomes in preterm infants (Lekskulchai and Cole, 2001a). Blauw-Hospers and Hadders-Algra (2005b) review concluded that specific developmental training in which parents learn how to promote their infant's development maximises the effect on motor outcomes (Blauw-Hospers and Hadders-Algra, 2005b). Previous studies also conclude that the efficacy of parenting interventions for extremely and very preterm infants may be optimised in programmes commenced post-discharge (Glazebrook et al., 2007a, Johnson et al., 2009, Johnson et al., 2011), particularly for enhancing motor outcomes (Spittle et al., 2008), when parents have greater opportunity to interact with their infants.

Previous research by Glazebrook et al (2007) suggests that mothers may experience difficulties interacting with their extremely or very preterm infants. Mothers typically perceive their preterm infants as too sleepy or fragile for play in the early months after discharge and are reluctant to rouse sleeping infants (Nicolaou et al., 2009b), resulting in long periods asleep in the supine position. Opportunities for play in the prone position are associated with better motor outcomes (Pin et al., 2007). Majnemer (2007) has argued that stereotyping of premature infants, as fragile and weak, combined with their biological vulnerability, means that preterm infants are particularly disadvantaged by environmental barriers to motor development. For example, studies have found mothers have less early contact with their preterm babies; respond less positively, perceiving the infants as physically weaker; they also chose play programs that were less developmentally appropriate

(Stern et al., 2006, Henderson et al., 2016). Mothers who rated their babies as more vulnerable and who engaged in more prematurity stereotyping at five months, had infants who achieved lower scores on the Mental Scale of the Bayley Scales of Infant and Toddler Development at 32 months old (Stern et al., 2006). These mothers also showed less patience and were less supportive of their infants while interacting with them at nine months of age (Porter et al., 2009). Perceptions of vulnerability have been shown to predict poorer infant developmental outcomes (Allen et al., 2004). Research to date therefore suggests that interventions to address negative perceptions and parental confidence are needed to reduce barriers to motor development and that such interventions need to occur early. Most parenting interventions have focussed on mothers, but there is evidence that paternal engagement is also an important predictor of child development (Sarkadi et al., 2008) in low birth weight, pre-term infants (Yogman et al., 1995).

## 1.7 Conclusion

The risk of neurodevelopmental disabilities is high in preterm children, and impacts on the skills required for readiness for school and learning. Arpino et al. (2010) argue the importance of having a fully defined clinical picture, and a need for effective neuro-behavioural interventions to be identified that have the potential to enhance the outcomes for preterm infants. This is essential as Moreira et al. (2014) found that motor impairment is less assessed than behaviour and academic performance. To identify intervention activities that are effective, a detailed review of the available evidence is needed, and a systematic review of the data conducted. The process of conducting the systematic review and its findings are presented in chapter two.

# Chapter Two: A Systematic Review and Meta-Analysis of Interventions aimed at enhancing the Motor Development of Preterm Infants

## 2.1 Introduction

This chapter will describe the undertaking of a systematic review of interventions designed to enhance the motor development of premature infants. All elements of the interventions identified along with any factors that could impact on the outcomes will be described.

## 2.2 Background

Chapter one demonstrated that motor co-ordination difficulties during childhood can lead to low levels of physical activity, poor cardio-vascular fitness and adiposity (Riethmuller et al., 2009). If motor difficulties persist into the school years, this can impact upon a child's integration and performance at school leading to low levels of self-esteem. Very premature babies are at high risk for poor motor skills and movement problems (Marlow et al., 2007). Even those who are free of major neuro-developmental problems are at higher risk for subtle deficits in eye-hand coordination, sensory-motor integration, manual dexterity and gross motor skills (Arnaud et al., 2007a, Allen, 2008b). Therefore early interventions that enhance motor development have the potential for improving health and psychosocial outcomes.

### 2.2.1. Interventions for preterm infants

A number of interventions have aimed to enhance the neurodevelopment of preterm infants and, although these are predominantly focused on improving cognitive skills, the relationship between motor and cognitive development is well established (Adolph and Berger, 2006, Piek et al., 2008, Grissmer et al., 2010). The majority of studies initiate recruitment whilst the infant is in the neonatal intensive care unit (NICU), and a number of these focus the intervention so that it is conducted solely in the NICU setting. An example of such a programme is the Newborn Individualized Developmental Care and Assessment Program (NIDCAP). The NIDCAP intervention involves trained health professionals observing the infant's behaviour and adapting the care provided, such as positioning the infant and/or altering the environment of the neonatal unit, such as lighting levels. Initial results from the NIDCAP programme were promising, but the longer term impact is unclear (Als et al., 1994, Kleberg et al., 2000, Maguire et al., 2009, Ullenhag et al., 2009, Wielenga et al., 2009). A systematic review on NIDCAP interventions (Ohlsson and Jacobs, 2013) concluded that the evidence for long-term positive neurodevelopmental effects or short-term medical effects is limited. This may reflect restricted opportunities to develop motor skills in the neonatal unit and the importance of the timing and length of intervention, given the complexity and rapidity of developmental changes that occur in the first three years (Zeanah et al., 1997). Evidence suggests that interventions which continue beyond discharge from the neonatal unit, and those that involve parents (Glazebrook et al., 2007b) are more likely to demonstrate benefits (Vanderveen et al., 2009a).

### 2.2.2 Parent-Infant interactions

There is a good rationale for involving parents in intervention delivery as mothers experience difficulties interacting with their extremely or very preterm infants (Glazebrook et al., 2007b). Mothers may perceive their preterm infants as too sleepy or fragile for play in the early months after discharge and are reluctant to rouse sleeping infants (Nicolaou et al., 2008), with the result that infants spend long periods asleep in the supine position restricting opportunities for motor activity. Providing opportunities for time and play in the prone position are associated with better motor outcomes (Pin et al., 2007) and guided play may also increase the confidence of the mother in handling and interacting with their preterm infant.

A recent Cochrane review (Spittle et al., 2015) of early developmental intervention programmes to prevent motor and cognitive impairment, highlighted the impact that even a minor motor impairment can have on a child, and concluded that effective activities to enhance the motor skills of preterm infants need to be identified. This review adds to the Spittle et al (2015) review by identifying activities which can improve infants' motor skills, tested via randomised (RCTs) and non-randomised trials that commenced in the neonatal unit or on discharge from hospital. In addition the analyses will be separated according to the age of the infant at the assessment, thus enhancing the review by Spittle et al (2015).

## 2.3 Objectives

To determine whether early interventions with preterm infants that are commenced in or after discharge from the neonatal unit within the first year of life, improve the development of fine and gross motor skills. A

further objective is to identify the components of effective interventions in order to inform the development of clinical guidelines for early intervention and the delivery of care programmes to reduce motor delay.

### 2.3.1 Research questions

To meet the objectives, the following research questions were identified:

1. What interventions are effective in improving the motor development of preterm infants?

2. What activities are most effective in the short/medium term?

## 2.4 Methods:

### 2.4.1 Inclusion/exclusion criteria

A protocol for the selection of studies was agreed using Cochrane guidance (Higgins and Green, 2011) criteria for health condition/population; intervention and study design. The elements of comparison and outcome were also incorporated into the inclusion and exclusion criteria (Table 1).

**Table 1: Inclusion and Exclusion**

| | Inclusion Criteria | Exclusion Criteria |
|---|---|---|
| **Participant** | Premature Infants born <37 weeks gestation | Full term infants only |
| **Intervention** | Intervention that aims to enhance infants development<br><br>Interventions that continue or start once the infant has been discharged from hospital | No intervention<br><br>Intervention conducted only in the Neonatal Unit prior to initial hospital discharge |
| **Comparison** | Control group from premature population | Comparison group only full term infants |
| **Outcome** | Measure of motor development at ≤5 years | No measure of motor development preschool (≤5 years) |
| **Study Design** | Randomised Controlled Trials<br>Controlled trials<br>Cohort /comparison studies | Review papers – no new data<br>Case Studies or Case Reports<br>Protocol or development publications |

All studies that included preterm infants were eligible for inclusion. Studies reporting outcomes in children >5 years of age were not included in this review. An earlier scoping search revealed limited work in the School age population.

### 2.4.2 Search Strategy

A combination of approaches were incorporated to minimize bias in the review process (Centre for Reviews and Dissemination, 2009). The criteria suggested by Higgins and Green (2011) were utilised based on the participants, intervention and study design. The following terms were identified to meet the objectives of the review:

- **Health condition/Population**: Premature Infants
- **Intervention**: motor development
- **Study design**: Randomised controlled trial/controlled trials/cohort – comparison/intervention studies

To ensure that the most relevant studies were identified, potential alternative terms for each criterion were identified. Table 2 displays the keywords/terms used within the databases.

**Table 2: Keywords/Terms**

| Criteria | Keywords |
|---|---|
| Health Condition/Population | "**premature infant***" OR "**infant premature**" OR "**preterm**" OR "**prematurity**" |
| Intervention | "**motor Development**" OR "**motor skill**" OR "**motor performance**" OR "**motor activity**" OR "**movement**" |
| Study design | "**randomised controlled trial**" OR "**randomized controlled trial**" OR "**controlled trial**" OR "**trial**" OR "**comparative study**" OR "**intervention study**" |

A systematic search of 17 electronic databases, including those containing “grey literature” were conducted using the terms identified (Table 3). Grey literature provides a more complete view, by broadening the scope of the relevant studies, as it includes non-published data, such as reports, dissertations and theses (Mahood et al., 2014).

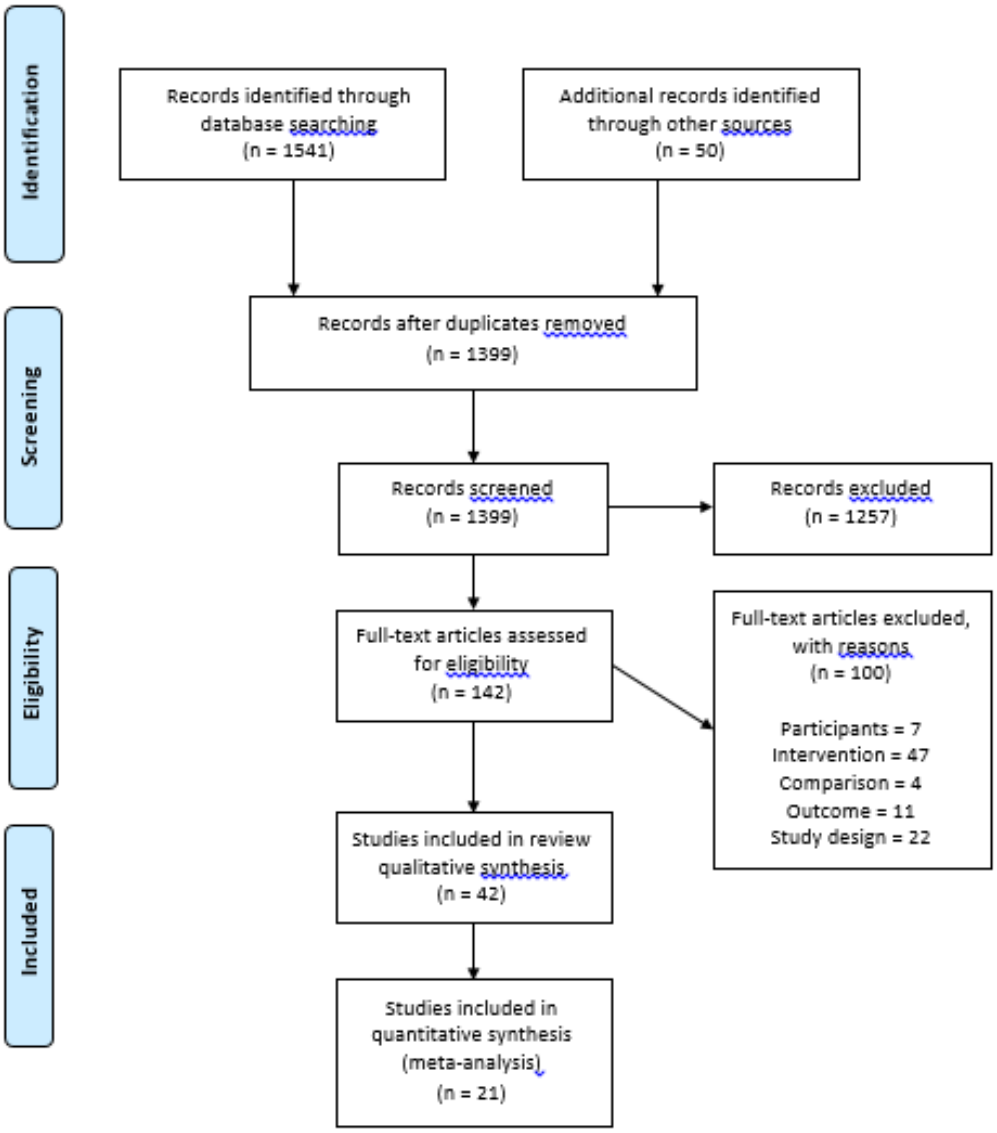
**Table 3: Electronic databases searched**

| Electronic Databases |
| --- |
| AMED |
| CINAHL |
| Cochrane Central Registry |
| EMBASE |
| ERIC |
| Maternity and Infant Care |
| MEDLINE |
| PEDro |
| ProQuest |
| PsycInfo |
| Pubmed |
| Science Direct |
| SCOPUS |
| Web of Knowledge |
| Web of Science |
| EThoS |
| OpenGrey |

In addition hand searches of relevant journals and conference proceedings; reviewing reference lists; and conducting author and citation searches were also utilised. Myers and Ment (2009) suggest when looking at outcomes for preterm infants, advances in neonatal intensive care should be taken into account, and the available treatments for preterm infants born prior to the 1980's need to be considered as confounding variables. The search parameters were therefore from 1980 up to and including April 2015. No other limitations were set to the search strategy, and translations were sought when the full text was not originally in English. Tables displaying each database search record are available in appendix 1 (A1-A16)

The papers from the initial searches (N=1399) were screened by the first author using title and abstract. For the second round the full text of the 142 remaining articles were screened independently by the authors, using the inclusion and exclusion criteria. One hundred papers were excluded for reasons relating to one of the five PICOS elements and are displayed in Figure 2, using the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) (Moher et al., 2009).

**Figure 2: PRISMA diagram**



### 2.4.3 Data Extraction

The data extraction sheet for this review was adapted from the Centre for Reviews and Dissemination (2009) and The Cochrane Collaboration Handbook (Higgins and Green, 2011). Data were checked for appropriateness and quality. Studies were not excluded based on quality and non-RCTs were included to increase the likelihood of identifying appropriate activities to include in an intervention. This resulted in higher heterogeneity therefore a random effects model was used for the meta-analysis.

## 2.5 Findings

### 2.5.1 Types of study

The 42 remaining publications consisted of 36 trials, five follow-up studies (Barrera et al., 1990, Koldewijn et al., 2010, Spencer-Smith et al., 2012, Verkerk et al., 2012, Jeukens-Visser et al., 2014) from three of the primary studies, and one study that reported different elements over two publications (Heathcock et al., 2008, Heathcock and Galloway, 2009) Of the 36 trials, 25 were RCTs (Widmayer and Field, 1981, Nurcombe et al., 1984, Barrera et al., 1986, Resnick et al., 1988, Weindling et al., 1996, Bao et al., 1999, Lekskulchai and Cole, 2001b, Yigit et al., 2002, Ohgi et al., 2004, Tan et al., 2004, Cameron et al., 2005, Johnson et al., 2005, Gianní et al., 2006, Heathcock et al., 2008, Kaaresen et al., 2008, Johnson et al., 2009, Koldewijn et al., 2009, Spittle et al., 2010, Blauw-Hospers et al., 2011, Kyno et al., 2012, Angulo-Barroso et al., 2013, Soares et al., 2013, Chen et al., 2014, Wu et al., 2014, Ma et al., 2015) and 11 non-randomised comparison trials (Goodman et al., 1985, Mathai et al., 2001, Ogi et al., 2001, Salokorpi et al., 2002, Kanda et al., 2004, Koldewijn et al., 2005a, Wu, 2007, Mazzitelli et al., 2008, Liao et al., 2009, Alvarado-Guerrero et al., 2011,

Li et al., 2013). Studies with follow-up data were all RCTs that reported outcome measures at different time points (6 months to 5.5 years corrected age (ca) (Jeukens-Visser et al., 2014). Duplicated data were excluded, and only the new data were included in the relevant age-based analyses. For the meta-analysis the data were sub-divided by corrected age of the infant, which enabled only one set of data for each time point to be included. Where at least two studies reported outcome measure data at a set age, meta-analysis was conducted within RevMan 5.3 (Collaboration., 2014). The data extracted were continuous: mean and standard deviation; or median and range, with higher scores denoting better motor skills. Moreover the scales used to measure motor outcomes varied, therefore standardised mean differences and random effects were used (Tufanaru et al., 2015). Where median and range were provided the mean and standard deviation were calculated by the first author. Heterogeneity was measured using the $I^2$ test available via the Cochrane Collaboration.

The characteristics of the RCTs are displayed in Table 4 and the characteristics of non-randomised studies presented in Table 5. Both tables are displayed in the order of age at assessment.

**Table 4: Characteristics of RCTs**

| Study | Participants | Intervention | Outcome measure | Age at assessment |
|---|---|---|---|---|
| Lekskulchai 2001 | n=111 (43 I; 41 C) | Motor Development | BSID | Term; 1; 2; 3 & 4 months |
| Chen 2014 | n=117 (63 I; 54 C) | Multidisciplinary | BSID | 2; 3; 6; 12; 18 & 24 months |
| Blauw-Hospers 2011 | n=46 (21 I; 25 C) | Family centred physiotherapy | AIMS | 3; 6 & 18 months |
| Tan 2004 | n=60 (30 I; 30 C) | Early stage upbringing plan | GSID | 3; 6; 9 & 12 months |
| Barrera 1986 | n=59 (40 I; 19 C) | Development or Interaction | BSID | 4 & 16 months |
| Barrera 1990 | | | MSCA & MCDI | 54 months |
| Cameron 2005 | n=72 (34 I; 38 C) | Physiotherapy | AIMS | 4 months |
| Heathcock 2008 | n=26 (13 I; 13 C) | Motor Training | AIMS | 4 months |
| Heathcock 2009 | | | No set scale | |
| Resnick 1988 | n=41 (21 I; 20 C) | Multidisciplinary | BSID | 6 & 12 months |
| Koldewijn 2009 | n=176 (86 I; 90 C) | IBAIP | BSID | 6 months |
| Jeukens-Visser 2014 | | | BSID | 12 & 18 months |
| Koldewijn 2010 | | | BSID | 24 months |
| Verkerk 2012 | | | BSID | 44 months |
| Nurcombe 1984 | n=74 (34 I; 40 C) | Mother Infant Transaction | BSID | 6 months |
| Ohgi 2004 | n=23 (12 I; 11 C) | Early intervention | BSID | 6 months |
| Widmayer 1981 | n = 30 | Brazleton Mother & Neonatal | BSID | 12 months |
| Bao 1999 | n=103 (52 I; 51 C) | Early intervention | BSID | 18 & 24 months |
| Johnson 2009 | n=243 (112 I; 121 C) | Parenting | BSID | 24 months |
| Kaaresen 2008 | n=136 (69 I; 67 C) | Mother-Infant Transaction | BSID | 24 months |
| Spittle 2010 | n=120 (61 I; 59 C) | Preventive care programme | BSID | 24 months |
| Spencer-Smith 2012 | | | Movement ABC | 48 months |
| Weindling 1996 | n=105 (51 I; 54 C) | Early physiotherapy | MAI, LbL & GSID | 24 months |
| Wu 2014 | n=178 (120 I; 58 C) | Clinic or Home based | BSID | 24 months |
| Kyno 2012 | n=118 (62 I; 57 C) | Mother-Infant Transaction | ASQ & MSEL | 36 months |
| Gianni 2006 | n=38 (18 I; 18 C) | Mother-Child intervention | GSID | 36 months |
| Johnson 2005 | n=284 (68 dev I; 84 soc I; 63 C) | Developmental or Social Support | Movement ABC | 60 months |
| Angulo-Barroso 2013 | n=28 (15 I; 13 C) | Treadmill training | No set scale | No set age |
| Ma 2015 | n = 285 | Multidisciplinary | No set scale | No set age |
| Soares 2013 | n=36 (24 I; 12 C) | Practice reaching | No set scale | No set age |
| Yigit 2002 | n=160 (80 I; 80 C) | Early intervention | No set scale | No set age |

I = Intervention C = Control

*Several scales used. Outcome measured using: AIMS = Alberta Infant Motor Scale; ASQ = Ages and Stages; BSID = Bayley Scales of Infant Development; GSID = Griffiths Scales of Infant Development; LbL = Limb-by-Limb; Movement ABC = Movement Assessment Battery for Children; MAI = Movement Assessment of Infant; MCDi = Minnesota Child Development Inventory; MSCA = ; MSEL = Mullen Scales of Early Learning; TIMP = Test of Infant Motor Performance

**Table 5: Characteristics of non-RCTs**

| Study | Participants | Intervention | Outcome measure | Age at assessment |
|---|---|---|---|---|
| Mathai 2001 | n = 48 (25 I; 23 C) | Tactile-Kinesthetic | BNBAS | Term |
| Koldewijn 2005 | n= 40 (20 I; 20 C) | IBAIP | BSID | 3 & 6 months |
| Li 2013 | n = 203 (96 I; 107 C) | Neurodevelopmental training | BSID | 3; 6; 9 & 12 months |
| Liao 2009 | n=140 (65 I; 75 C) | Early intervention | BSID | 3; 6 & 12 months |
| Wu 2007 | n = 83 (43 I; 40 C) | Early intervention | BSID | 6; 12 & 24 months |
| Mazzitelli 2008 | n = 14 (8I; 6 C) | Visuo-Motor Stimulation | GSID | 4; 6; 8; 10 & 12 months |
| Alvarado-Guerrero 2011 | n = 25 (14 I; 11 C) | Multidisciplinary | BSID | 6 months |
| Goodman 1985 | n = 80 (40 I; 40 C) | Home exercise | GSID | 12 months |
| Ogi 2001 | n = 48 (30 I; 18 C) | Early intervention | BSID | 12 months |
| Salokorpi 2002 | n = 126 (63 I; 63 C) | Home based Occupational therapy | MAP | 48 months |
| Kanda 2004 | n = 10 (5 I; 5 C) | Vojte method | No set scale | N/A |

I = Intervention C = Control

BSID = Bayley Scales of Infant Development; BNBAS =Brazelton Neonatal Behavioral Assessment Scale; GSID = Griffiths Scales of Infant Development; MAP = Miller Assessment for Pre-Schoolers.

### 2.5.2 Participants

A total of 3484 preterm infants were enrolled in the 36 studies, with n = 2750 participants in the 25 RCTs and a further 734 participants included in the 11 non-randomised studies. The sample sizes for the included studies varied from 10 participants (Kanda et al., 2004) to 285 (Ma et al., 2015).

The majority of RCTs recruited infants that were less than 34 weeks gestation although the birth weight and gestational age of participants at time of intervention varied within the studies. Almost all studies (34/36) recruited samples of exclusively preterm infants with only 2/34 studies (Weindling et al., 1996, Blauw-Hospers et al., 2011) including both preterm and term infants. Two studies (Nurcombe et al., 1984, Wu, 2007) included an additional control group of infants born exclusively at term, but data from these groups were excluded from the review.

Those with a wide range of gestation age and/or birth weight, tended to stratify the results into early/late preterm and/or very low/low birth weight (Barrera et al., 1986, Barrera et al., 1990, Kaaresen et al., 2008, Koldewijn et al., 2009, Koldewijn et al., 2010, Ravn et al., 2011, Kyno et al., 2012, Verkerk et al., 2012, Jeukens-Visser et al., 2014, Ma et al., 2015). This is appropriate as there is evidence that the lower the gestational age or birth weight, the higher the risk of developmental problems (Anderson et al., 2016). However, stratification criteria were not consistently identified within the included studies.

### 2.5.3 Aim and Focus of interventions

The majority of the studies included interventions aimed at improving both the cognitive and motor development of the preterm infant. Of those 13 studies that aimed specifically at enhancing motor development, nine were RCTs (Weindling et al., 1996, Lekskulchai and Cole, 2001b, Yigit et al., 2002, Cameron et al., 2005, Heathcock et al., 2008, Heathcock and Galloway, 2009, Blauw-Hospers et al., 2011, Angulo-Barroso et al., 2013, Soares et al., 2013, Ma et al., 2015) and a further four were non-randomised studies (Goodman et al., 1985, Salokorpi et al., 2002, Kanda et al., 2004, Mazzitelli et al., 2008). The type of intervention varied as the focus for some of the studies was to enhance the parent-infant relationship as a means to improving infant development, whilst others were additional support or sessions with either a physiotherapist or occupational therapist. This resulted in the theoretical components and implementation of the intervention activities also varying. For all studies the intervention was in addition to usual care. When categorising by type of intervention, 8/13 (61.5%) studies which specifically targeted motor skills demonstrated a significant benefit for motor skills compared to 9/22 (40.9%) of generic interventions.

### 2.5.4 Initiation and implementation of intervention

Studies varied in the age that an intervention started, although the majority commenced whilst the infant was still in the neonatal unit(Resnick et al., 1988, Weindling et al., 1996, Mathai et al., 2001, Ogi et al., 2001, Yigit et al., 2002, Ohgi et al., 2004, Koldewijn et al., 2005a, Wu, 2007, Kaaresen et al., 2008, Johnson et al., 2009, Koldewijn et al., 2009, Liao et al., 2009, Koldewijn et al., 2010). Some interventions did not commence until the infant was three (Kanda et al., 2004, Gianní et al., 2006, Blauw-Hospers et al., 2011) or six months ca (Salokorpi et al.,

2002). The intervention programmes within the majority of the studies comprised of activities which involved both healthcare professionals and parents/carers. In these interventions the activities were demonstrated by the healthcare professionals for parents to engage in with their infant in the home environment.

### 2.5.5 Intervention activities

The majority of studies included activities such as interacting with the infant and some form of handling and positioning in the initial two months after birth. The positioning was adapted according to age and ability, with the amount of support decreasing as the infant's development progresses. The studies which provided the most detail about intervention activities were commenced from term to four/six months ca (Lekskulchai and Cole, 2001b, Cameron et al., 2005, Blauw-Hospers et al., 2011). Activities and suggested appropriate age are displayed in table 6.

**Table 6**: **Example of Activities: term to four months (adapted from Lekskulchai and Cole, 2001 and Cameron et al., 2005)**

| Corrected Age | Activity |
|---|---|
| Term to 4 months | Midline activities in supine and alternate side-lying positions |
| | Promotion of symmetrical head turning – eye and head movement (eg support the infant and use visual/auditory stimulation to encourage eye and head movement) |
| | Facilitate upper limb reaching and midline activities in supine |
| | Facilitate hands to midline, hands to mouth, hands to feet in supine position and supported sitting position in a seat |
| | Play in supine, prone, sitting, side-lying positions |
| | Assisted kicking (eg stroking the infant's legs) |
| 1 to 4 months | Facilitate symmetrical reaching in supine positions |
| 2 to 4 months | Facilitate upper limb reaching and midline activities |
| | Facilitate rolling from supine to side lying to prone positions |
| 3 to 4 months | Facilitate symmetrical reaching in prone position |
| | Facilitate reaching |

Many of the studies where the intervention activities were for ≤12 months, tended to include a basic description of the type of activity included, and discriminated between fine and gross motor exercises. However, most of the studies that delivered longer term interventions provided very little detail of the activities undertaken(Bao et al., 1999, Yigit et al., 2002, Kanda et al., 2004, Tan et al., 2004, Wu, 2007). To identify effective activities, data were extracted and the studies that

reported interventions with a significant effect size ($p<0.05$) scrutinized to determine any recurring stage appropriate activities.

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### 2.5.6 Duration of intervention

Information regarding the duration and frequency of the intervention was described in the majority of studies, and varied from 10 minutes (Heathcock et al., 2008, Heathcock and Galloway, 2009) to sessions which last up to 120 minutes (Spittle et al., 2009). The number of sessions varied from six (Johnson et al., 2009) to 120 sessions (Kanda et al., 2004). The duration of the intervention programme also varied lasting from birth up to term (Mathai et al., 2001) to an intervention which commenced at 3 months ca and lasted until the infant was 39 months ca (Kanda et al., 2004). The majority of included studies continued the intervention beyond three months ca. Most common were interventions that lasted until the infant was six months (Lekskulchai and Cole, 2001b, Ogi et al., 2001, Ohgi et al., 2004, Cameron et al., 2005, Koldewijn et al., 2005b, Kaaresen et al., 2008, Mazzitelli et al., 2008, Koldewijn et al., 2009, Alvarado-Guerrero et al., 2011, Blauw-Hospers et al., 2011, Ma et al., 2015) or 12 months ca (Goodman et al., 1985, Resnick et al., 1988, Weindling et al., 1996, Gianní et al., 2006, Wu, 2007, Liao et al., 2009, Spittle et al., 2009, Li et al., 2013).

### 2.5.7 Outcome measures

A range of assessment tools were used to measure motor function with some studies using more than one scale (Weindling et al., 1996, Liao et al., 2009, Blauw-Hospers et al., 2011), and others assessing motor behaviours rather than using a standardised test (Yigit et al., 2002, Kanda et al., 2004, Heathcock and Galloway, 2009). Nineteen studies used the Bayley Scales for Infant Development (BSID) either the first or

second edition (see tables 3-4). The age at assessment also varied, although the most frequently used corrected age for studies to use the BSID was 6 months and/or 24 months, then 12 months.

### 2.5.8 Meta-analysis

Where motor assessment scores were provided at specific ages by more than two studies, meta-analysis was undertaken. Studies that measured motor function at a time point from term (40-42 weeks gestation) to five years ca were included, although most studies assessed infants up to 24 months. When sufficient intervention and control group data were provided the effectiveness of interventions was assessed. Therefore meta-analysis was conducted on data at eight different ages: term; 2 months; 3 months; 4 months; 6 months; 12 months; 18 months; and 24 months. Table 7 displays the outcome for each of the age ranges.

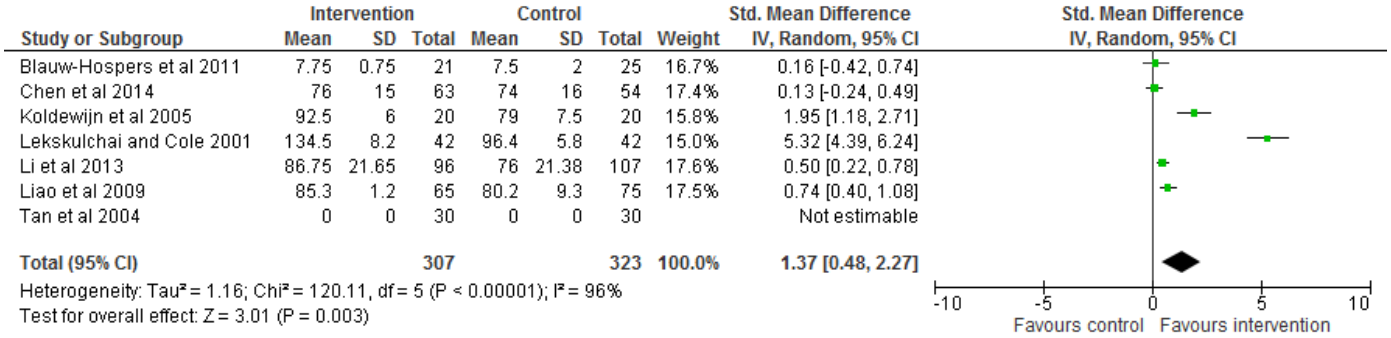
**Table 7: Meta-analysis of outcome for each age range**

| Outcome/ sub-group | Number of studies | Number of participants | Method | Effect |
|---|---|---|---|---|
| Motor score Term | 2 | 117 | Std. Mean Difference (IV, Random, 95% CI) | 0.19 [-0.43, 0.67] |
| Motor score 2 months | 2 | 201 | Std. Mean Difference (IV, Random, 95% CI) | 2.22 [-1.93, 6.37] |
| Motor score 3 months | 7* | 630 | Std. Mean Difference (IV, Random, 95% CI) | 1.37 [0.48, 2.27] |
| Motor score 4 months | 3* | 114 | Std. Mean Difference (IV, Random, 95% CI) | 2.25 [-2.71, 7.20] |
| Motor score 6 months | 13* | 958 | Std. Mean Difference (IV, Random, 95% CI) | 0.34 [0.11, 0.57] |
| Motor score 12 months | 12* | 1042 | Std. Mean Difference (IV, Random, 95% CI) | 0.73 [0.20, 1.26] |
| Motor score 18 months | 3 | 266 | Std. Mean Difference (IV, Random, 95% CI) | 0.32 [-0.02, 0.66] |
| Motor score 24 months | 8 | 1047 | Std. Mean Difference (IV, Random, 95% CI) | 0.28 [0.07, 0.49] |

*includes studies with incomplete data

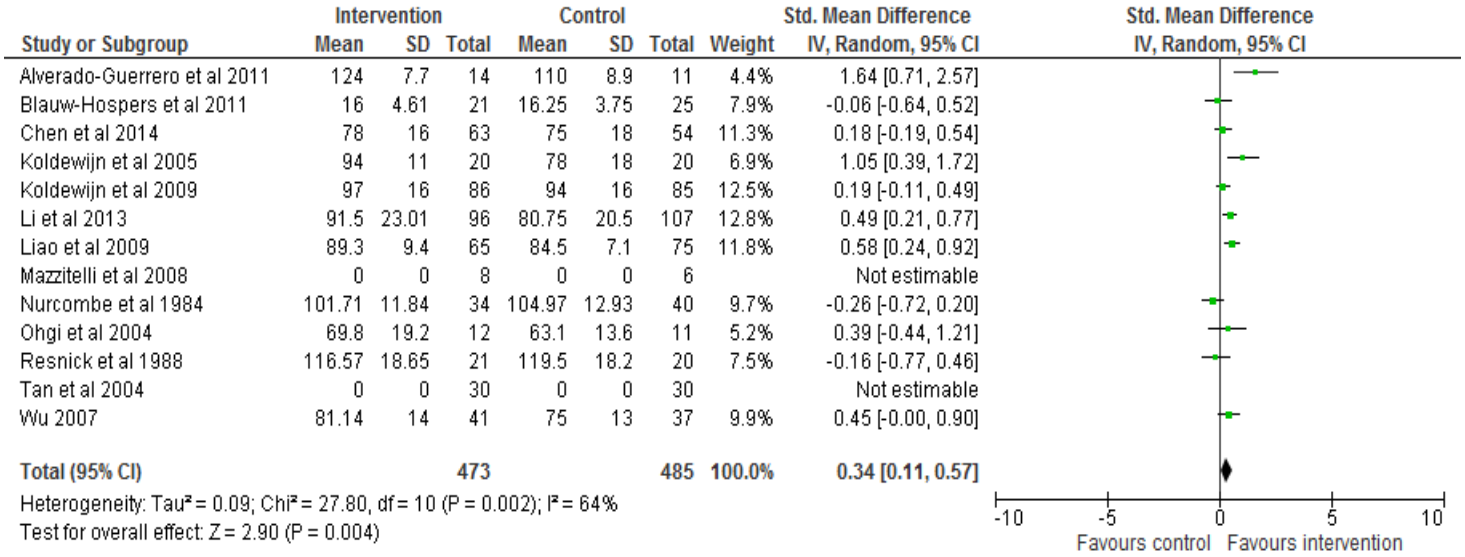
Figures 3-7 display the forest plots for sub-groups where there were data from three or more studies available.

**Figure 3: Meta-analysis for 3 month assessment**




The meta-analysis on data from motor assessments at three months, demonstrated a significant difference, with the intervention groups performing better than the control groups. Studies that assessed infants at 6 months corrected age were included in the analysis wherever practicable (figure 4).

**Figure 4: Meta-analysis for 6 month assessment**



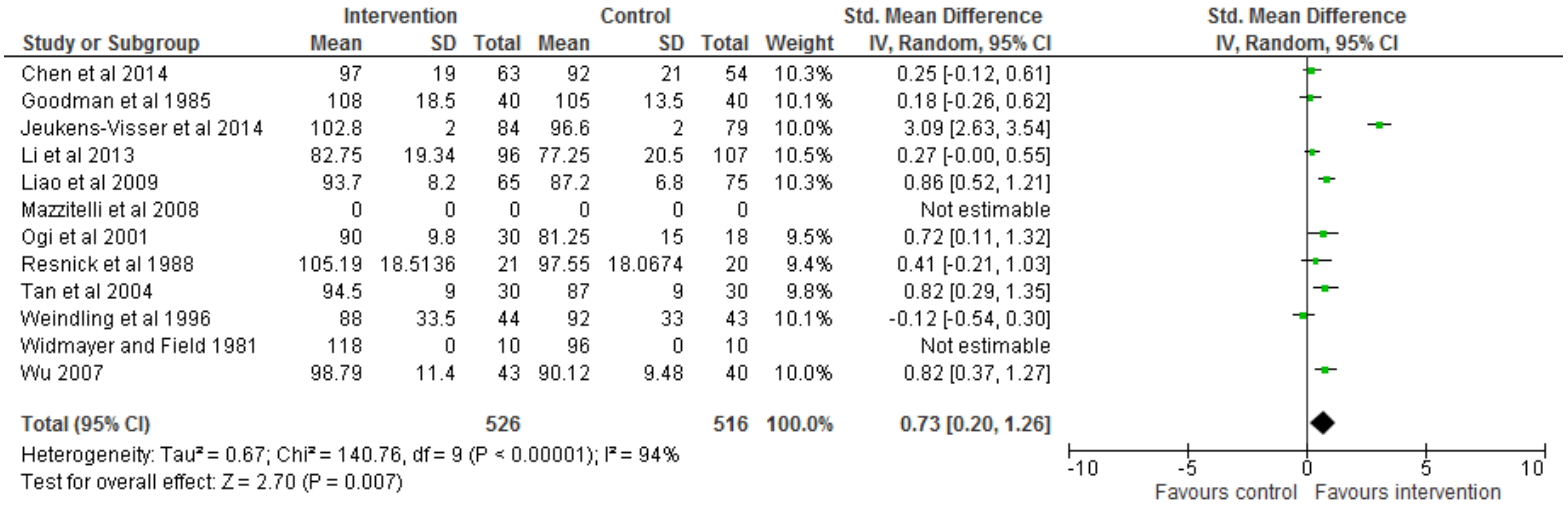
| Study or Subgroup | Intervention Mean | SD | Total | Control Mean | SD | Total | Weight | Std. Mean Difference IV, Random, 95% CI |
|---|---|---|---|---|---|---|---|---|
| Alverado-Guerrero et al 2011 | 124 | 7.7 | 14 | 110 | 8.9 | 11 | 4.4% | 1.64 [0.71, 2.57] |
| Blauw-Hospers et al 2011 | 16 | 4.61 | 21 | 16.25 | 3.75 | 25 | 7.9% | -0.06 [-0.64, 0.52] |
| Chen et al 2014 | 78 | 16 | 63 | 75 | 18 | 54 | 11.3% | 0.18 [-0.19, 0.54] |
| Koldewijn et al 2005 | 94 | 11 | 20 | 78 | 18 | 20 | 6.9% | 1.05 [0.39, 1.72] |
| Koldewijn et al 2009 | 97 | 16 | 86 | 94 | 16 | 85 | 12.5% | 0.19 [-0.11, 0.49] |
| Li et al 2013 | 91.5 | 23.01 | 96 | 80.75 | 20.5 | 107 | 12.8% | 0.49 [0.21, 0.77] |
| Liao et al 2009 | 89.3 | 9.4 | 65 | 84.5 | 7.1 | 75 | 11.8% | 0.58 [0.24, 0.92] |
| Mazzitelli et al 2008 | 0 | 0 | 8 | 0 | 0 | 6 | | Not estimable |
| Nurcombe et al 1984 | 101.71 | 11.84 | 34 | 104.97 | 12.93 | 40 | 9.7% | -0.26 [-0.72, 0.20] |
| Ohgi et al 2004 | 69.8 | 19.2 | 12 | 63.1 | 13.6 | 11 | 5.2% | 0.39 [-0.44, 1.21] |
| Resnick et al 1988 | 116.57 | 18.65 | 21 | 119.5 | 18.2 | 20 | 7.5% | -0.16 [-0.77, 0.46] |
| Tan et al 2004 | 0 | 0 | 30 | 0 | 0 | 30 | | Not estimable |
| Wu 2007 | 81.14 | 14 | 41 | 75 | 13 | 37 | 9.9% | 0.45 [-0.00, 0.90] |
| **Total (95% CI)** | | | **473** | | | **485** | **100.0%** | **0.34 [0.11, 0.57]** |

Heterogeneity: Tau² = 0.09; Chi² = 27.80, df = 10 (P = 0.002); I² = 64%
Test for overall effect: Z = 2.90 (P = 0.004)



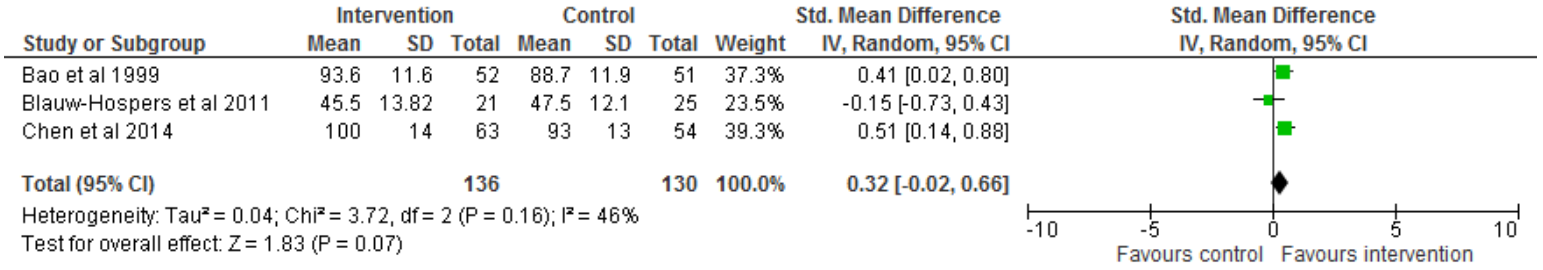
There was a difference present at the 6 months assessment, although the effect was smaller. Figure 5 displays the forest plot for 12 month assessment.

**Figure 5: Meta-analysis for 12 month assessment**



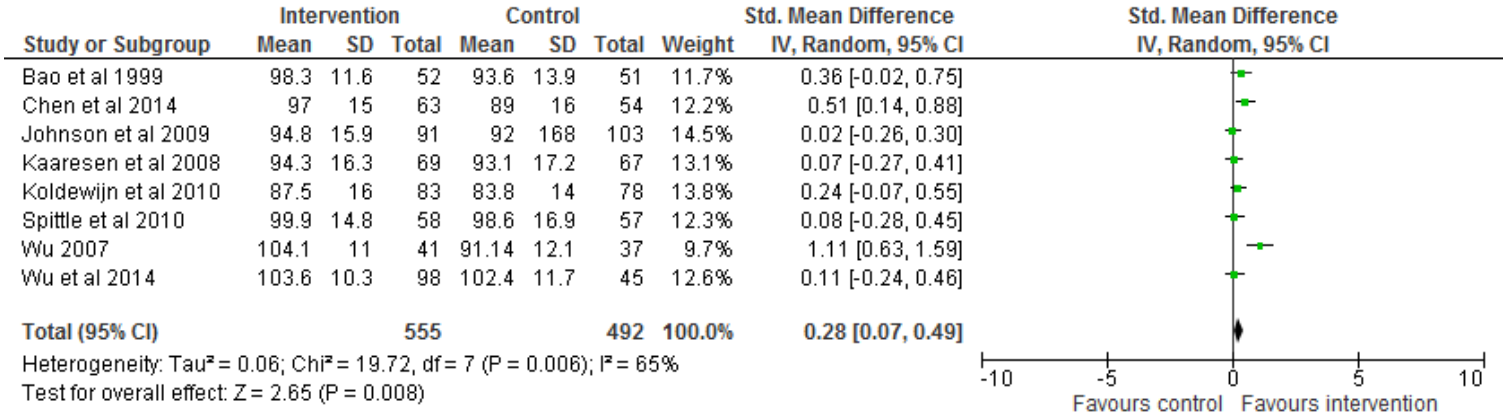

There were 12 studies assessing the motor development of premature infants at 12 months corrected, ten of which provided enough data to be included in the meta-analysis. A significant difference was found between the groups, with the intervention groups performing at a higher level than the control infants. Figure 6 displays the forest plot for 18 month assessment.

**Figure 6: Meta-analysis at 18 month assessment**




The difference between groups were not significant at this stage, however, the data available was limited. Figure 7 displays the forest plot for 24 month assessment.

**Figure 7: Meta-analysis for 24 month assessment**




A significant difference which favours the intervention group was apparent again at the 24 months corrected age. There were too few studies with post 2 year assessment that provided data to be included in a meta-analysis.

The meta-analysis demonstrates that interventions can enhance the motor development of preterm infants, although the effect varies over time. Significant differences were found at three months corrected age (ca) (1.37 [0.48, 2.27]), six months ca (0.34 [0.11, 0.57]), 12 months ca (0.73 [0.20, 1.26]) and at 24 months ca (0.28 [0.07, 0.49), although the effect diminished over time. These time points had a range of sample sizes from 630 (3 months) to 1047 (24 months). There was no significant effect at term; two months; four months and 18 month time points, but this may relate to the limited amount of data at those time points, as there were $\leq$3 studies in these analyses (n=117-266). Data to compare motor specific interventions to generic early intervention was limited. However, looking at interventions with 3 month follow-up data, motor specific interventions (N=4) (Lekskulchai and Cole, 2001b, Koldewijn et al., 2005a, Liao et al., 2009, Blauw-Hospers et al., 2011) showed a large and significant effect size at 3 months adjusted age (2.00 [0.28-3.72]), but generic interventions (N=3) (Tan et al., 2004, Li et al., 2013, Chen et al., 2014) showed no significant benefit for motors skills (0.33 [-0.03-0.69]). The heterogeneity of the pooled data ranged from low to high (Term $I^2$ = 36%; 2 months $I^2$ = 99%; 3 months $I^2$ = 96%; 4 months $I^2$ = 99%; 6 months $I^2$ = 64%; 12 months $I^2$ = 94%; 18 months $I^2$ = 46%; and 24 months $I^2$ = 65%).

### 2.5.9 Data Synthesis

Meta-analysis was not conducted for assessments beyond 24 months due to the limited amount of data available at set time points beyond this age. Seven studies (N=704) assessed preterm infants motor development beyond two years (3-5 years), five of which found no significant effect of the intervention on motor outcomes (N=517)(Barrera et al., 1990, Salokorpi et al., 2002, Johnson et al., 2005, Kyno et al., 2012, Spencer-Smith et al., 2012). Gianni et al (2006) found

no significant difference for the locomotor subscale of the Griffiths development assessment, but a statistically significant difference on eye-hand co-ordination subscale. Verkerk et al. (2012) found a significant difference at 44 months ca on the domains of mobility of the Pediatric Evaluation of Disability Inventory-Dutch version (PEDI-NL). Of those that did not find a significant difference, Johnson et al. (2005) stated that there was no difference between groups at five years of age, but highlighted that the intervention stopped when the child was two years of age.

The remaining studies (N=5) were not included in the meta-analysis due to either not providing data for the outcome measure, or no clear details on age of assessment (Yigit et al., 2002, Kanda et al., 2004, Angulo-Barroso et al., 2013, Soares et al., 2013, Ma et al., 2015). However, three (Kanda et al., 2004, Angulo-Barroso et al., 2013, Ma et al., 2015) found a statistically significant difference between the intervention and control group, in favour of the intervention.

## 2.6 Risk of Bias

### 2.6.1 Assessment of risk of bias

Two different assessment tools developed by the Cochrane Collaboration were used to assess risk of bias; Higgins et al. (2011) criteria for risk of bias assessment was conducted on the included RCTs (Table 8), and Reeves et al. (2011) guidance was used for the non-randomised studies, where there is an increased risk of selection bias

## Table 8: Risk of bias assessment on RCTs

| Study | Random sequence generation | Allocation concealment | Blinding of participants & personnel | Blinding of outcome assessment | Incomplete outcome data | Selective reporting |
|---|---|---|---|---|---|---|
| Angulo-Barroso et al 2013 | Low | Low | High | Low | Low | Low |
| Bao et al 1999 | Unclear | Unclear | High | Unclear | Unclear | Low |
| Barrera et al 1986 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Barrera et al 1990 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Blauw-Hospers et al 2011 | Unclear | Unclear | High | Low | Low | Unclear |
| Cameron et al 2005 | Low | High | High | Low | Unclear | Unclear |
| Chen et al 2014 | Low | Unclear | High | Unclear | Unclear | Unclear |
| Gianni 2006 | Unclear | Unclear | High | Low | Low | Unclear |
| Heathcock et al 2008 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Heathcock & Galloway 2009 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Jeukens-Visser et al 2014 | Low | Low | High | Low | Low | Unclear |
| Johnson et al 2005 | Low | Low | Unclear | Low | Low | Unclear |
| Johnson et al 2009 | Unclear | Low | Unclear | Low | Unclear | Low |
| Kaaresen et al 2008 | Low | Low | High | Low | Low | Unclear |
| Koldewijn et al 2009 | Low | Low | High | Low | Low | Unclear |
| Koldewijn et al 2010 | Low | Low | High | Low | Low | Unclear |
| Kyno et al 2012 | Low | Unclear | High | Unclear | Low | Unclear |
| Lekskulchai and Cole 2001 | Low | Unclear | High | Low | Low | Unclear |
| Ma et al 2015 | Low | Low | High | Low | Unclear | Unclear |
| Nurcombe 1984 | Low | Low | | Low | Unclear | Unclear |
| Ohgi et al 2004 | Low | Unclear | High | Unclear | Unclear | Unclear |
| Resnick et al 1988 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Soares et al 2013 | Low | Unclear | Unclear | Low | High | Unclear |
| Spencer et al 2012 | Low | Low | Unclear | Low | Low | Unclear |
| Spittle et al 2010 | Low | Low | Unclear | Low | Low | Unclear |
| Tan et al 2004 | Unclear | Unclear | High | Low | Unclear | Unclear |
| Verkerk et al 2012 | Low | Low | High | Low | Low | Unclear |
| Weindling et al 1996 | Low | Low | High | Low | Unclear | Unclear |
| Widmayer & Field 1981 | Unclear | Unclear | Unclear | Low | High | Unclear |
| Wu 2014 | Low | Low | Unclear | Low | Low | Unclear |
| Yigit et al 2002 | Unclear | Unclear | Unclear | Unclear | Unclear | Unclear |

The highest risk of bias in the RCTs was lack of blinding of participants and researchers. There was also a risk in relation to incomplete outcome data which may reflect duration of intervention or the stratification of participants by weight and gestation. The potential for performance bias is known to be problematic for these types of studies, therefore detection bias is key, which for the majority of studies (RCT and non-randomised studies) were low risk for detection bias, which enhances the quality of the data.

A main concern with non-randomised studies is the risk of selection bias. For the 11 studies that were not randomised, selection onto the trial was either through parent choice, systematically allocated, or in the case of the pilot study of  compared with a cohort from the previous year.

### 2.6.2 Dealing with missing data

The majority of studies provided clear detail on the sample at recruitment or follow-up. There were instances where insufficient data was available in the publication to include in the meta-analysis and attempts were made to obtain any relevant data from the authors.

## 2.7 Discussion

This review set out to determine whether intervention can enhance the motor development of preterm infants, and to identify the most effective activities to include in a future intervention. The overall findings suggest that focused early intervention is of benefit to preterm infants, as there is a positive impact on the motor skills in infants up to 24 months ca, although the strength of the effect reduced over time.

Beyond two years ca the evidence is inconclusive, due to the limited amount of outcome data of motor development skills from studies. This may reflect the focus, as the majority of studies with longer follow-up tended to be general rather than motor specific, incorporating early intervention principles of being multidisciplinary involving parenting skills, cognitive and motor skills. This lack of longer term data together with limited detail regarding the intervention activities result in challenges to developing an intervention for preterm infants that incorporates activities appropriate from birth to school age.

The RCTs and non-randomised studies included within the review were assessed as acceptable quality for the main aspects of comparison group and assessment of outcome. All studies had a comparison/control group of preterm infants and the majority had assessment of the infants conducted by researchers who were unaware of group allocation. The outcome measure for this review was motor activity and most studies used a validated development scale, of which the most frequently used was an edition of the Bayley Scale for Infant Development (table 4 and 5). Several of the studies did not use a validated scale, and instead looked at age when the infant either lost or gained a particular motor behaviour, such as walking.

This review focused particularly on motor development interventions, as a means of ascertaining the types of activities that are most effective and to obtain information on any longer-term effects. To date there has been a stronger focus on interventions aimed at improving cognitive function, as subsequent education performance was deemed reliant on mental processing, due to the nature of assessments and attention requirement (Duncan et al., 2007, Grissmer et al., 2010). However, the interrelatedness of motor and cognitive development is clearly

established (Diamond, 2000, Adolph and Berger, 2006), and motor skills are a proven indicator of future mathematics and reading success (Grissmer et al., 2010).

This review attempted to add to the available data by analysing findings at specific ca, rather than combine them as previous reviews had (Orton et al., 2009a, Spittle et al., 2015), thus allowing for potential continual effectiveness to be explored. The main trend was for a positive effect up to 24 months ca. The time points of less than 24 months that were analysed but showed no significant differences, were most likely due to limited data being available. Studies that conducted assessment at several time points were included, but duplication of data removed. Koldewijn and colleagues consistently found a statistically significant difference with their intervention group up to 42 months corrected age (Verkerk et al., 2012). However, not enough data were available from the studies assessing beyond 24 months to conduct meta-analysis.

### 2.7.1 Identifying activities

Orton and colleagues (2009) found that significant levels of heterogeneity when pooling outcomes made it problematic to assess the intervention activities which were most beneficial. Despite a similar issue for this review, the number of studies included and the inclusion of non-randomised studies ensured that some general activities and movements which were common between studies could be identified, and their effectiveness assessed, especially from birth to six months ca. These included providing opportunities for movement in supine, prone and sidelying with appropriate support, and facilitating hands to midline in a variety of supported positions. This is important as the most recent update of the Cochrane review on intervention programmes on preterm

infants (Spittle et al., 2015) emphasised the need to identify effective early development interventions.

### 2.7.2 Conducting the activities

The findings suggest that interventions conducted by parents can have positive effects on motor skills. Providing advice and ways of interacting with their infant may help reduce the perception of preterm infants as too fragile for play in the early months after discharge. Parents may have more confidence to for example, provide opportunities for play in the prone position which is associated with better motor outcomes. There is evidence that interventions that specifically target the infant's motor development produce substantial benefits for motor skills at least in the short term. Nearly two-thirds of studies of motor specific inventions produced significant effects compared to 40% of generic interventions.

### 2.7.3 Strengths and limitations

There were limitations in relation to obtaining full data to include in the meta-analysis, as despite attempts to obtain data, only published data was available. However, wherever possible data was incorporated into the review via qualitative data synthesis. The strengths of the process include citation searches for authors of dissertations and theses, and translation of studies not published in English. In addition the number of duplications during the search indicates that an exhaustive search of the databases was conducted. Despite issues of potential bias, especially with including non-randomised studies, the included trials were all of an acceptable quality for inclusion in the review. This is mainly due to the majority of motor skill assessments being conducted

by trained professionals, who were unaware of the group allocation of the infant being assessed.

### 2.7.4 Conclusion

The findings of the review suggest that interventions which are continued beyond the period of neonatal care can have an impact on the motor development of preterm infants with strongest effects noted before 6 months of age, particularly where interventions specifically targeted motor skills. Stage appropriate activities for the first six months and some additional activities for around 6-12 months ca were identified. However, it is important that future studies provide clearer detail of intervention activities to enable replication. This would help in identifying effective activities that could be used to prevent poor motor skills and Developmental Co-ordination Disorder (DCD). Data on length of interventions and long-term impact is also needed to assess if positive outcomes can be maintained beyond 24 months.

The next chapter will detail the development of the motor intervention and the elements of the systematic review findings that were incorporated.

# Chapter Three: Development of an intervention to promote motor development in infants born very preterm: Helping Our Premature infants ON to better motor skills (HOP-ON)

## 3.1 Introduction

This Chapter describes how the "Helping Our Premature infants ON to better motor skills" (HOP-ON) intervention was developed. HOP-ON was designed to provide activities for parents/ carers to undertake with their preterm infant.

## 3.2 Need for the intervention

The birth of a very preterm baby is viewed as a traumatic and stressful time for parents. Arnold et al. (2013) explored parent's first experiences of their very preterm infant in the neonatal intensive care unit (NICU), and found that for many the NICU was overpowering, and despite the importance of touch those who were nervous, worried that they would interfere with care or transmit infection. This adds to research by Nicolaou et al (2009) which found maternal uncertainty, lack of confidence and low expectations of preterm infants (Barlow et al., 2016), and emerging evidence of disorganised attachment (Wolke et al., 2014). Wolke et al., (2014) highlight the increased risk of neuro-development impairments and note a link with predisposition to disorganisation, resulting in attachment and relationship problems. The increased risk of developmental difficulties and delays for infants born prematurely (Davis et al., 2007), and potential interaction difficulties

suggest a need for activities to be undertaken by parents with their premature infant to enhance their motor development and parent-infant interactions (Spittle et al., 2015, Hughes et al., 2016). There is therefore a need for interventions to break this potential cycle of disadvantage at an early stage, by providing parents with activities that encourage interaction and demonstrate how to build their infant's sense of motor competence through support and the provision of opportunities to practise skills. When designing an intervention, the Medical Research Council (MRC) highlight the need to be clear in the outcome and how change will be brought about (Craig et al., 2008). In addition, there is a requirement for the intervention to have a clear theoretical basis, and be used systematically (Craig et al., 2008).

## 3.3 Theoretical foundation of the intervention

To enable and encourage parent-infant interaction and parent's confidence in supporting their infant the content and structure of the intervention was guided by social learning theory which emphasises observational learning and self-efficacy as important influences on behaviour change (Bandura, 1977).

### 3.3.1 Social learning theory and self-efficacy

Bandura's (1971) social learning theory posited that humans are active information processors, and can think about the relationship between behaviour and consequences. He stated that new patterns of behaviour can be acquired by either direct experience or observing the behaviour of others. The consequences that accompany different actions provide feedback on the types of behaviour likely to succeed, and these reinforcements have a strong incentive-motivational effect. Therefore future consequences can be converted into current motivators that

influence behaviour. Bandura's work to explain and predict behavioural changes were integrated, as the theory of "self-efficacy" which was conceptualised in an attempt to reconcile theory and practice (Bandura, 1977). Self-efficacy refers to the individual's belief in their capacity to undertake behaviours that are necessary to produce specific achievements. It reflects confidence in the ability to exert control over one's own behaviour, motivation and social environment. Bandura (1977) argues that changes achieved by different methods are derived from a common cognitive mechanism. The implications of efficacy expectations were integrated, as expectations were viewed as impacting on the initiation and persistence of a behaviour/activity (Bandura, 1977). Four major sources of efficacy expectations were identified by Bandura (1977), these were:

- ***Performance accomplishments***: are based on personal mastery experiences. Success raises mastery expectations, whereas repeated failures lower them. The timing and pattern of experiences are influential, as if success is repeated early in the course of events, strong efficacy expectations are developed, which can reduce the impact of occasional failures.

- ***Vicarious experience***: are inferences based on awareness of others performing activities without adverse consequences. This modelling of behaviour is more vulnerable to change, as the efficacy expectations will be weaker. However, observing activities that have clear outcomes, that are successful, can produce greater behavioural improvements.

- ***Verbal persuasion****:* are attempts to influence behaviour by telling people what to expect/do. This is widely used due to its ease,

although efficacy expectations induced are likely to be weaker than those induced through personal experience.

- ***Emotional arousal**:* is a source of information that can impact on perceived self-efficacy in coping with threatening situations. High arousal such as anxiety can debilitate performance, with fear-provoking thoughts elevating anxiety levels in excess of what would be experienced in an actual threatening situation.

Interventions which promote ways of interacting can increase confidence and enhance a sense of empowerment and control, which are important when utilising social learning theory. The HOP-ON intervention was presented in several formats, for those with computer access an interactive CD-ROM was provided, whilst for those without computer access, booklets and DVDs were provided. Throughout the intervention the efficacy expectations were encompassed in several ways (see Table 9).

**Table 9: Efficacy Expectations and HOP-ON Intervention**

| Efficacy Expectations | HOP-ON Intervention |
|---|---|
| Performance accomplishments | Provided advice on ways to identify when an infant is ready for each activity and questions for parents to check their understanding |
| Vicarious experience | Provided via recordings and images of parents undertaking the activities with their infant |
| Verbal persuasion | Provided via the narration of the recordings |
| Emotional arousal | Reducing negative feedback in the question and answer section. If an incorrect response was selected, a prompt for checking the section was provided along with the correct response. |

The principles of this theory were deemed appropriate for the interventions to model and reinforce parental strategies to promote gross and fine motor skills. To achieve this, the benefits of parental interactions for promoting infant motor skills are emphasised and fear-inducing messages avoided as strong negative arousal can hinder performance instead of promoting it (Bandura, 1977).

### 3.3.2 Format of the Intervention

Computer access has risen rapidly within Great Britain and by 2011, over 79% of households owned a computer and 73% had access to the internet at home (Kayenne Martins Roberto Formiga and Linhares, 2011). Additional access through the work place and public areas such as libraries and schools means that multimedia, web-based information is a feasible method of health promotion. O'Halloran et al (2015) notes that multimedia is an increasingly popular choice for providing health information, due to having the potential to provide high quality information in an accessible format. In addition multimedia interventions can be easily shared with others, such as grandparents and even older siblings, therefore ensuring a wider reach than traditional parent support programmes. This is particularly important as although most parenting interventions have focused on mothers, there is evidence that paternal engagement is also an important predictor of child development in low birth weight, preterm infants (Yogman et al., 1995).

In their review Raaff et al. (2014) found that multimedia interventions can lead to health-related improvements and highlight the importance of making information not just available, but organised in interactive formats. Interactive functions provide feedback to the user which can improve feelings of competence in relation to the targeted behaviour.

Riley et al. (2015) note the increasing evidence of the advantages of using multimedia formats for interventions, especially those aimed at influencing behaviour. Interactive multimedia has proved to be an effective and engaging method of patient education in clinical settings, and is associated with greater improvements in knowledge compared to non-interactive information provision (Glazebrook et al., 2006, McPherson et al., 2006). Nicolaou et al. (2008) utilised multimedia to promote parental interactions with preterm infants in their programme "Sharing My Infants Learning Experiences" (SMILES), which illustrated aspects of effective parent–infant interaction using photos, interactive questions and answers and video clips. The pilot study found mothers of very premature infants who were given the SMILES programme responded to the Interacting with my Premature Infant Questionnaire (IPIQ) demonstrating more confidence about interacting with their infants compared with controls (mean 28.4 vs 17.14) and perceived their infant as being more capable during social interactions (27.0 vs 22.14) (Nicolaou, 2008).

Given the evidence of the advantages of incorporating multimedia resources, the HOP-ON intervention was developed as an interactive CD-ROM containing videos of interactions and activities along with a supporting information pack. To ensure those who did not have home access to a computer were still able to participate, a DVD version demonstrating the activities was made available, as it has been acknowledged that use of videos can be more engaging (Reznar et al., 2014). The intervention programme/DVD therefore includes video clips of real parents (mothers and fathers) and their infants, simple evidence-based information and interactive features to facilitate deeper learning and to personalise information.

## 3.4 Designing the Intervention Activities

The process of identifying activities and movements to include in a motor intervention began with research team discussions. The research team included clinicians, researchers and educationalists. Raaff et al (2014) highlight the importance of including clinicians when designing multimedia interventions, as the content must be clinically relevant as well as appropriate for the targeted participants. The team discussion and the findings of the systematic review (now published - Hughes et al., 2016) were incorporated into a draft programme for presenting to a focus group.

The activities identified were to encourage opportunities for supervised play for infants in a variety of positions (including prone and sidelying) and to provide developmentally appropriate strategies to stimulate motor functions. For example lying on stomach (prone), elbow propped, with encouragement to promote tracking and reaching for objects (promoting eye hand co-ordination and shoulder stability) progressing through various positions advancing the level of instability by reducing incrementally the base of support, and promote activation of multi axial core muscle activity.

### 3.4.1 Focus groups

One technique of obtaining specialist input is via focus groups. These are a form of group interview whose method allows people to clarify views (Kitzinger, 1995), and enables a mix of participants to explore issues (Green and Thorogood, 2004). A focus group allows for a naturalistic discussion of experiences (Tobin and Begley, 2004), therefore providing contextual data. Focus groups can facilitate the exploration of different potential solutions (Kitzinger, 1995) They can help to investigate or generate hypotheses (Powell and Single, 1996)

and develop questions or concepts for questionnaires and interview guides, to ensure the appropriateness of suggested activities at each developmental stage and on the safety of any advice provided (Lankshear, 1993, Hoppe et al., 1995).

There are many definitions of a focus group in the literature, but features like organised discussion (Kitzinger, 1994), collective activity (Powell et al., 1996), social events (Goss JD and TR., 1996) and interaction (Kitzinger, 1995) identify the contribution that focus groups make to research. Powell et al. (1996) define a focus group as a group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research.

A form of organised discussion was deemed appropriate for aiding the development of the intervention. Given the requirement for consensus to finalise the intervention additional methods that utilise focus groups to obtain information were explored, taking into consideration the range of professionals who would be involved in working with premature infants and the amount of time available for the process. Jones and Hunter (1995) suggest that consensus methods provide a means of synthesising information and obtaining insights of appropriate experts. Two consensus methods that are commonly used in health services research are the Delphi process and the nominal group technique (Jones and Hunter, 1995). The Delphi process utilises surveys to obtain a consensus, whereas the nominal group technique uses a structured meeting to gather information from relevant experts about a given issue. The nominal group technique has at least seven set phases (Horton, 1980):

1) Introduction
2) Participants presented with paper containing a carefully worded question

3) Individual generation of ideas to answer question
4) Share ideas into a list
5) Discussion of list
6) Participants rank the ideas (i.e. most important to least important)
7) Vote on top ideas

The last three phases can be repeated if required.

The focus group set-up allows for gathering and identifying relevant information and activities for the motor intervention. To be effective some form of running order was required to ensure all participants were involved and agreement achieved. Given the type of activities and the range of participants, the full process of nominal group technique was not feasible. However, some elements of the process were incorporated to ensure that the group remained on task.

### 3.4.2 Study focus group workshop

To ensure participation from members of all the appropriate groups involved in the care and support of preterm infants, the following participants attended a focus group workshop:

- developmental psychologists
- a paediatric physiotherapist
- a physiotherapist educator
- a neonatologist
- an occupational therapist
- healthcare researchers
- a specialist in educational technology
- parents of premature infants.

The aim of the initial focus group was to identify activities and advice for the first 12 months of the premature infant's life. All potential participants were contacted and a suitable date to hold a focus group was agreed. The focus group consisted of 12 participants and was scheduled for 3-4 hours with refreshments included. The format of the session was as follows:

- An introduction made by three of the research team who were facilitating the group
- Each participant then given a basic storyboard containing a range of motor skills/activities which had been identified in the systematic review and research team discussions
- Participants provided ideas which were written onto Flip chart sheets
- Discussion on ideas
- Refreshment Break
- Highlight activities and information where there was agreement
- Arrange for further feedback

Table 10 displays the "finding my hands and feet" section of the initial storyboard of activities identified via the systematic review and discussions. The full storyboard which cover the remaining sections are included in Appendix 3.

**Table 10: Finding my hands and feet – birth to 3-4 months corrected age**

| HOP-ON Section | Visuals/Exercises/Videos | References |
|---|---|---|
| Finding my hands and feet | Hands:<br>• Bringing hands to mid-point using a variety of positions – side-lying; over arm.<br>• Variety of materials for touching<br>• Use infants hands to touch face, ears, shoulders, heads, knees | Research team discussion - Lekskulchai and Cole (2001b) (also used in the systematic review)<br>*Cameron et al. (2005)<br>*Heathcock et al. (2008) |
| | Feet:<br>• Opportunities for infant to touch and reach for their own feet – supine on parent's lap.<br>• Assisted kicking – use hands to provide a gentle push<br>• Variety of materials for touching | Research team discussion - Lekskulchai and Cole (2001b) (also used in the systematic review)<br>*Cameron et al. (2005)<br>*Heathcock et al. (2005)<br>*Heathcock and Galloway (2009) |

*References identified by systematic review

### 3.4.3 Findings of the focus group

During the initial discussion the focus group participants suggested that providing 12 months of activities in one programme to a parent might be overwhelming. They recommended splitting the activities into broad age groups to avoid any potential for parents to conduct activities that were developmentally inappropriate. Therefore the information on activities for the first 12 months was split into information which would be distributed to parents at two time points. The initial pack would be

sent once the participant had been randomised and would provide information on activities from around birth to three months (corrected age); and the second pack sent at 3-4 months which would cover activities for the infant from four to 12 months corrected age.

The use of social learning theory was viewed as appropriate, as focus group participants agreed that the information needed to be both encouraging, and include information on why such movements were helpful. In addition, it was noted that it must be clear that the activities were to be encouraged when the infant was physically able to complete the skills. Therefore information to parents on when to deliver the activities by identifying when their infant is developmentally ready, and advice regarding conducting the activities in short sessions was provided. To enhance the potential for success and mastery of experience, a question and answer section for parents was agreed, and the options of wording for the multiple choice responses were discussed. In line with the principles of social learning theory, the importance of avoiding negative feedback was emphasised therefore the wording of the sections would be provided to the group for comment at each stage. Following the focus group the storyboard was updated and forwarded to all for agreement, prior to any filming of infants to demonstrate the motor activities for the intervention. This process was continued via email discussions for each of the stages of activities.

## 3.5 Filming the intervention videos

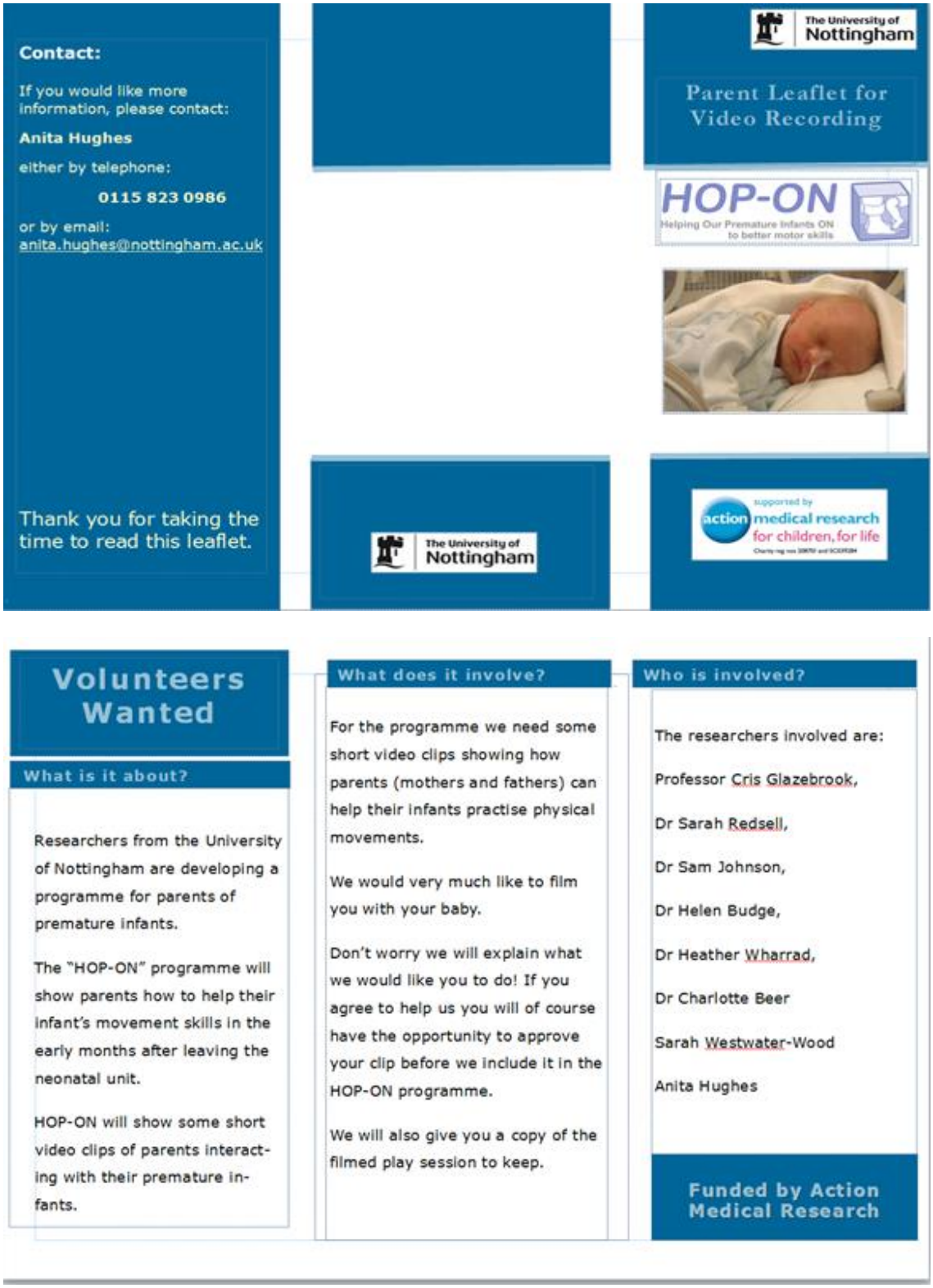
Once the activities were identified and agreed, video recordings of parents undertaking the activity with their infants were used, to provide vicarious experience for parents. This is in line with the role-modelling element of social learning, as participants are provided with infant-parent interactions in real-time. This also allowed a form of piloting of

the activities, as it provided information on whether parents were able to do the activities with their infant, and the usability of the intervention. To ensure the appropriate activities were filmed a storyboard was created, which provided a list of movements to record. To recruit infants for the filming of intervention activities, posters were displayed in a local neonatal unit (figure 8) and a leaflet designed and disseminated to elicit interest in involvement of parents and their infants (figure 9).

**Figure 8: Poster for filming participants**



**Figure 9: Leaflet for video recording**



Parents of preterm and full term neonates were invited to participate in the filming. Those who were interested in being involved were advised to contact the researcher and a mutually agreed time and date arranged to record them and their infants. Parents who consented to be involved were invited to bring their infants along to a video suite within the University. Subsequent filming took place in several venues; a room within a hospital; room attached to a NICU, and the home of the infants being recorded. For each recording, the activities were discussed and demonstrated by researchers/physiotherapist prior to the parent conducting the activity with their infant.

## 3.6 Finalising the intervention activities

A large number of recordings and photographs were required to enable the array of activities and holds identified for inclusion in the programme to be demonstrated with infants from a range of ages. Once the filming was completed, discussions and meetings were held initially with the members of the research team to select options for each section. Participants of the focus group were then invited to comment on the appropriateness of the images and footage for the HOP-ON CD-ROM videos. Throughout the process a consensus was achieved on all the images, videos and wording that were used within the programme. The activities were separated into three different sections for the parents to work through. Prior to finalisation, the video clips and images that had been selected were sent to the parent and infant involved to provide an opportunity for the parent to withdraw consent for use if they were not happy with the footage or image. This also allowed for comment on the acceptability of the videos and images. All parents responded to confirm they were happy with their involvement. Table 11 displays the sections for each of the stages.

**Table 11: Sections for each stage of the HOP-ON intervention**

| Approximate corrected age | Sections/Activities |
|---|---|
| Birth to 3 months | Holding and Playing |
| | Finding my Hands and Feet |
| | Tummy Time |
| 3 – 12 months | Rocking to Rolling |
| | Sitting |
| | Kneeling to Walking |
| 1 year onwards | Side Sitting and Crawling |
| | Kicking and Catching |
| | Walking and Climbing |

The images and footage required for the intervention activities of each section were identified by the researchers from each of the recordings. The health education technologists incorporated these into a computer programme for presentation to parents in a variety of formats such as CD-ROM, DVD, booklet, and/or website.

## 3.7 Conclusion

Following agreement of the activities and wording for the intervention, paediatric physiotherapists and occupational therapists who were not involved in the development externally reviewed the content. The appropriateness of the information and activities were agreed and the final version compiled using Images and video recordings. Each of the three sections were assessed by the wider research team, prior to being recorded onto CD-ROM, DVD and set-up for inclusion on a programme website under development. The study designed to evaluate the HOP-ON intervention is covered in chapter four.

# Chapter Four: Randomised controlled trial of the HOP-ON intervention

## 4.1 Introduction

Infants born very preterm are more likely to experience a delay in the development of their fine and gross motor skills (see Chapter 1 for details). There is evidence that interventions to improve motor skills in preterm infants, which continue beyond discharge from the neonatal unit, are effective in improving motors skills. Interventions which specifically target motor skills are more effective then generic developmental programmes, however, physiotherapy is not offered unless they have marked delay in motor skills. Developmental coordination disorder (DCD) may not be picked up until the child starts school and even subtle motor skills deficits can have marked consequences for their social and educational development. There is evidence that children with DCD are less confident about participating in physical activity and less active. Lower levels of physical activity can predispose to being overweight with negative consequences for future health. Therefore early intervention by parents of very preterm infants to promote motor skills have the potential to improve morbidity, whilst being a cost effective strategy.

Multimedia education for parents has the potential to deliver those specifically focussed motor components which have been shown to produce improvements in development (See Chapter 2). The HOP-ON intervention was developed by a multidisciplinary team to address the need for a safe, evidence based intervention to empower parents to support their infant's motor development (see Chapter 3). It was designed to build parents' confidence in providing active play for their preterm infants since this has been identified by as a barrier (Nicolaou

et al., 2008). Parents of preterm infants experience high levels of parenting stress and it is hypothesised that the intervention will reduce stress by increasing parents' self-efficacy. Reducing motor deficits may also impact directly on the infant's behaviour reducing perceptions that the child is difficult. However, since evidence suggests that parents can stereotype preterm infants as being developmentally less competent than their terms peers it is important to assess whether raising parental expectations of their infant's abilities to engage in active play increases parenting stress levels.

In order to evaluate the effectiveness of the HOP-ON intervention it was necessary to conduct a randomised controlled trial to compare motor outcomes for infants whose parents receive the intervention to those mothers allocated to the active control condition.

## 4.2 Primary and secondary aims and outcomes

The study aimed to evaluate a multimedia, computer-based parenting intervention to promote motor skills in very preterm infants. Scores on the Bayley III motor scale and Alberta Infant Motor Scale were the primary outcome measures for motor development. Secondary outcomes are Bayley's (III) fine and gross motor subscale scores, parental perceptions of infant capability, parental confidence, infant growth and parenting stress.

### 4.2.1 Overall objectives of the study

To compare motor development, parental perceptions of infant capability, parental confidence, and parental stress between the intervention group and control group.

### 4.2.2 Research question and hypotheses for primary outcome

Aslam and Emmanuel (2010) state that a well-formulated research question should identify the variables and population of interest and be precise enough to guide the study. To set the question for the primary aim the PICO headings can be used to achieve this. For this study:

**Participants**: Premature infants

**Intervention**: Interactive, digital technology-based multimedia delivering motor specific activities along with general interaction information.

**Comparison**: Digital technology-based multimedia delivering general interaction information only

**Outcome**: Motor scale scores (Bayley III and AIMS)

To provide precision the format and who would provide the intervention was added, therefore the main research question was:

***Can a multimedia motor specific intervention conducted by parents, enhance the motor development of preterm infants?***

To answer this the null and experimental hypothesis are assessed, and research is carried out to support the experimental hypothesis ($H_1$), by rejecting the null hypothesis ($H_0$) (Driscoll and Lecky, 2001).

For this study:

- $H_1$ states that there will be a statistically significant difference between the motor scores of the intervention and control group, in favour of the intervention group.
- $H_0$ states that there will be no statistically significant difference

between the motor scores of the intervention and control group.

### 4.2.3 Research question and hypotheses for secondary outcomes

PICO headings were again utilised to focus the key elements of the question for the secondary outcomes

**Participants**: Parents of premature infants

**Intervention**: Motor specific interaction activities along with general interaction information

**Comparison**: General interaction information only

**Outcome**: Interaction, confidence and stress measures (IPIQ and PSI)

The question elicited from these elements is:

***Does specific information on activities for parent-infant interaction impact on their level of stress or confidence?***

The null ($H^0$) and alternative ( $H^1$) hypotheses for the secondary outcomes are:

- $H_1$ states that there will be a statistically significant difference in stress and confidence scores of parents from the intervention and control group, with parents from the intervention group having lower stress scores and higher confidence scores than the parents in the control group.
- $H_0$ states that there will be no statistically significant difference between the stress and confidence scores of parents from the intervention and control group.

## 4.3 Methodology

Interventions in healthcare are designed to improve a particular outcome for a group of patients. However, not all interventions prove to be of benefit to the participant, and some can cause harm (Landefeld et al., 2008). Therefore to be incorporated into practice an intervention must be assessed to ensure it is of benefit. When evaluating an intervention aimed at improving health, it is essential to take into consideration any factors or interacting components. The Medical Research Council (MRC) provide a framework for complex interventions, that contain several interacting components and are aimed at improving health outcomes (Craig et al., 2008). The HOP-ON intervention could be described as a complex intervention in its broadest sense, as although it does not have interacting components, it requires that parents adopt a number of different behaviours. Therefore the MRC framework (Craig et al., 2008) was explored and wherever possible followed when designing the intervention and evaluation. For the evaluation of health care interventions, the gold standard of experimental design is the randomised controlled trial (Bowling and Ebrahim, 2005). In its most straightforward form, the experimental design consists of two conditions or groups of participants. One group receives an intervention whilst the other does not. The variable or intervention is the aspect of the study which is manipulated (Howitt and Cramer, 2008). It is argued, that this manipulation of one variable, results in any significant differences found between the two groups, to be most likely due to the intervention (Howitt and Cramer, 2008). Random allocation controls for unanticipated confounding variables. Furthermore randomisation allows for concealed allocation of group which removes an important source of potential bias.

### 4.3.1 Study design

Stolberg et al. (2004) describes randomised controlled trials (RCT) as a powerful tool of research, and identified as the highest quality research design. RCTs are used to examine the effectiveness of an intervention or treatment on a specified outcome. Levin (2007) state that the main features of the RCT are that they are comparative and are designed to minimise bias. The comparative feature relates to the groups, as the control group receive either no treatment or usual care and their outcome measures are compared to the intervention group. It is possible to conduct studies where the control group cohort data can be retrospective, with intervention group outcomes compared to data from previous cohorts. However, this may increase the likelihood of confounding variables, so must be taken into account when considering quality and appropriate comparison. Previous cohorts may have experienced different conditions and medical care following birth. It is therefore preferable if the control group is contemporaneous, and randomised from the same setting.

Despite the RCT design being aimed at reducing bias, Jadad (1998) suggested that to enhance rigour additional methodological strategies need to be incorporated to reduce specific types of bias which can impact on the findings of a RCT. When attempting to minimise bias, there are several aspects to be considered: selection/allocation bias, performance bias, assessment bias, attrition bias and allocation concealment. Kendall (2003) suggests that a well-designed randomised controlled trial should have an appropriate sample to ensure that any results are generalizable to the population; the sample should be randomised to either the intervention or control group, and be treated identically expect for the intervention, reducing the potential for selection bias. Jadad (1998) notes that selection bias is especially important in studies in healthcare. Randomisation is therefore conducted to ensure that the intervention and control groups do not

differ systematically (Bowling and Ebrahim, 2005). However, for studies involving premature infants there are characteristics that have been found to be confounding factors, such as gender and age of gestation. When there is variability within a group which may interfere with the outcome, for example gender or age, it is necessary to divide a population into subgroups or strata then take a random proportionate sample from each subgroup or strata. Therefore stratified randomisation was needed to ensure an equal number of males and females were in both control and intervention groups and an equal number of infants who were born at less than 28 weeks of gestation, which should allow for the groups to be balanced in relation to the factors that can impact on development.

Several forms of bias can be reduced through masking (blinding), although the type of blinding available is dependent on the intervention being compared (Jadad 1998). Allocation and performer bias can be reduced by double-blinding, with the participant and assessor of the outcome being unaware of whether the participant is in the intervention or control group (Bowling and Ebrahim, 2005). Within this study the parents were involved in providing the intervention therefore double blinding was not feasible, as parents could not be masked to their infant's group allocation. Researcher blinding would therefore be the only means of allocation concealment possible. The researcher conducting the motor outcome assessment was therefore unaware of which group the infant had been allocated, thus reducing the potential for allocation or observer bias (Jadad 1998). This is appropriate as it is commonly used in interventions which have some form of education component (Jadad 1998).

Bias can also be introduced when analysing the data, as inappropriate handing of withdrawals and loss to follow-up can result in overestimation of benefits of an intervention (Gupta, 2011). It is therefore essential to take these elements into consideration prior to

conducting the study. In this instance the statistical concept of intention to treat will be incorporated which includes all randomised participants being included in the analysis, even when no final outcome data was collected (Gupta, 2011).

#### 4.3.1.1 Groups

The most appropriate design for this study was an experimental design utilising a single-masked RCT to assess whether the HOP-ON intervention enhances the motor development of premature infants. However, as previous research has demonstrated that general interaction with preterm infants is of benefit (Nicolaou et al. 2008), it was agreed that providing such information to the intervention and control groups would be appropriate. This allows for any differences in motor skills to be due to the addition of an intervention specifically aimed at motor development, rather than general interaction with parents. Nicolaou et al (2008) designed and evaluated a multimedia educational intervention to support parent interactions with their premature infant, Sharing My Infants Learning Experiences (SMILES). This information was provided to all participants (intervention and control groups), whilst the intervention group also received the Helping Our Premature infant ON to better motor skills (HOP-ON). In addition to improving the likelihood of identifying if HOP-ON specifically has any potential benefits to motor skills, providing SMILES was deemed appropriate ethically as any information which has the potential to help should not be withheld.

## 4.4 Ethics and Trust Approval

All studies should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles

of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005. The British Psychological Society (BPS) identify key principles when conducting research with human participants. These are: respect for the autonomy, privacy and dignity of individuals and communities; scientific integrity; social responsibility; and maximising benefit and minimising harm (British Psychological Society, 2014). These principles were adhered to throughout and assessed prior to initiating the study. This was confirmed by obtaining a favourable opinion from a NHS Research Ethics Committee (REC) and approval from the Research and Development departments of each NHS Trust involved with the study.

### 4.4.1 National Research Ethics Service (NRES)

Application was made via the national research ethics service to conduct the research within the NHS. For this the following documents were prepared and submitted for review:

- Integrated research ethics system form (appendix 4)
- Protocol (appendix 5)
- Poster (appendix 6)
- Participant information sheet (appendix 7)
- Expression of interest form (appendix 8)
- Consent form (appendix 9)
- Continued consent form (appendix 10)
- GP letter (appendix 11)
- Health visitor letter (appendix 12)
- Data collection sheet from medical notes (appendix 13)
- Discharge from hospital - Questionnaire 1 (appendix 14)
- 3-4 months corrected age - Questionnaire 2 (appendix 15)
- 12 months corrected age - Questionnaire 3 (appendix 16)
- Parent evaluation of intervention - Questionnaire 4 (appendix 17)

- HOP-ON booklet 1 (boy version) (appendix xx)
- HOP-ON booklet 2 (girl version) (appendix xx)
- SMILES booklet (appendix 20)

The study obtained a favourable opinion from Nottingham 1 Research Ethics Committee on 13th May 2010 (REC reference: 10/H0403/35).

### 4.4.2 NHS Trust Research and Development

Following a favourable opinion from the NHS ethics committee, application was made to the Research and Development (R&D) departments of three NHS Trusts within the East Midlands. All Trusts required copies of the documentation sent to ethics, along with confirmation of a favourable opinion. In addition researchers required a research passport and letter of access to undertake recruitment. For this evidence of recent completion of good clinical practice module; a criminal records bureau search; and one NHS Trust required any researcher who would be recruiting participants to undertake a face to face assessment on taking consent. This was completed prior to obtaining agreement and letter of access to each of the NHS Trusts.

### 4.4.3 Project management

The research team met at regular intervals throughout the study, and provided advice and support to ensure safety of participants and researchers were paramount.

### 4.4.4 Informed consent

The taking consent assessment covered ethical principles, such as ensuring that the potential participant was aware that involvement in the study was entirely voluntary, and that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which they would otherwise be entitled. Sufficient time was given to parents to consider participation, and the opportunity to ask any questions was provided. During recruitment the researcher was required to ensure that parents understood what participation would involve; the potential for being allocated to the control arm (SMILES information only), and to remind the parents that the researcher was not part of the medical team, so any questions or concerns regarding the infant's medical treatment would need to be referred to the medical team.

The initial Informed Consent Form (ICF) was signed and dated by the participant and researcher before the parent and infant entered the study. Copies of the signed consent form were made, one copy given to the participant and one kept securely in the main site file.

### 4.4.5 Participants and inclusion/exclusion criteria

Participants include parents of preterm infants who are born at less than 33 weeks gestation (very preterm) and admitted to one of five participating hospitals across the East Midlands. The full inclusion and exclusion criteria are displayed in Table 12.

**Table 12: Inclusion and exclusion criteria for the HOP-ON study**

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Parents (consenting) aged between 16-60 years of age who have a preterm infant | Parents of preterm infants who are still receiving inpatient hospital care at 3 months adjusted age |
| Preterm infants born at less than 33 weeks gestation | Preterm infants who are still receiving inpatient neonatal hospital care at 3 months adjusted age |
| Preterm infants recently discharged from hospital, or with an anticipated discharge date within the next two weeks | Parents of multiple births, where the number of infants is greater than two (i.e. three or more infants) |
| | Parents and infants residing outside the predefined catchment area |

The rationale for excluding parents and their infant if they had not been discharged from the neonatal unit by three months corrected age, related to the delay starting the intervention. Given the importance of the intervention being introduced as early as possible, it was agreed that three months corrected age was an appropriate cut off for initiating involvement. The catchment exclusion was pragmatic, based on distance to travel to complete assessment.

### 4.4.6 Sample size

To establish the number of infants required for the study a sample size was calculated based on findings reported in very premature infants in an Australian sample (Anderson et al., 2009). This established that a minimum of 138 participants (69 in each group) would be required, giving 90% power to detect a 9.0-point difference in the primary outcome measure (Bayley II) based on a mean of 101.5 (SD 18.1). However, to allow for a 16% loss to follow-up (similar to that experienced in previous studies) a minimum target of 160 premature infants was set.

### 4.4.7 Recruitment

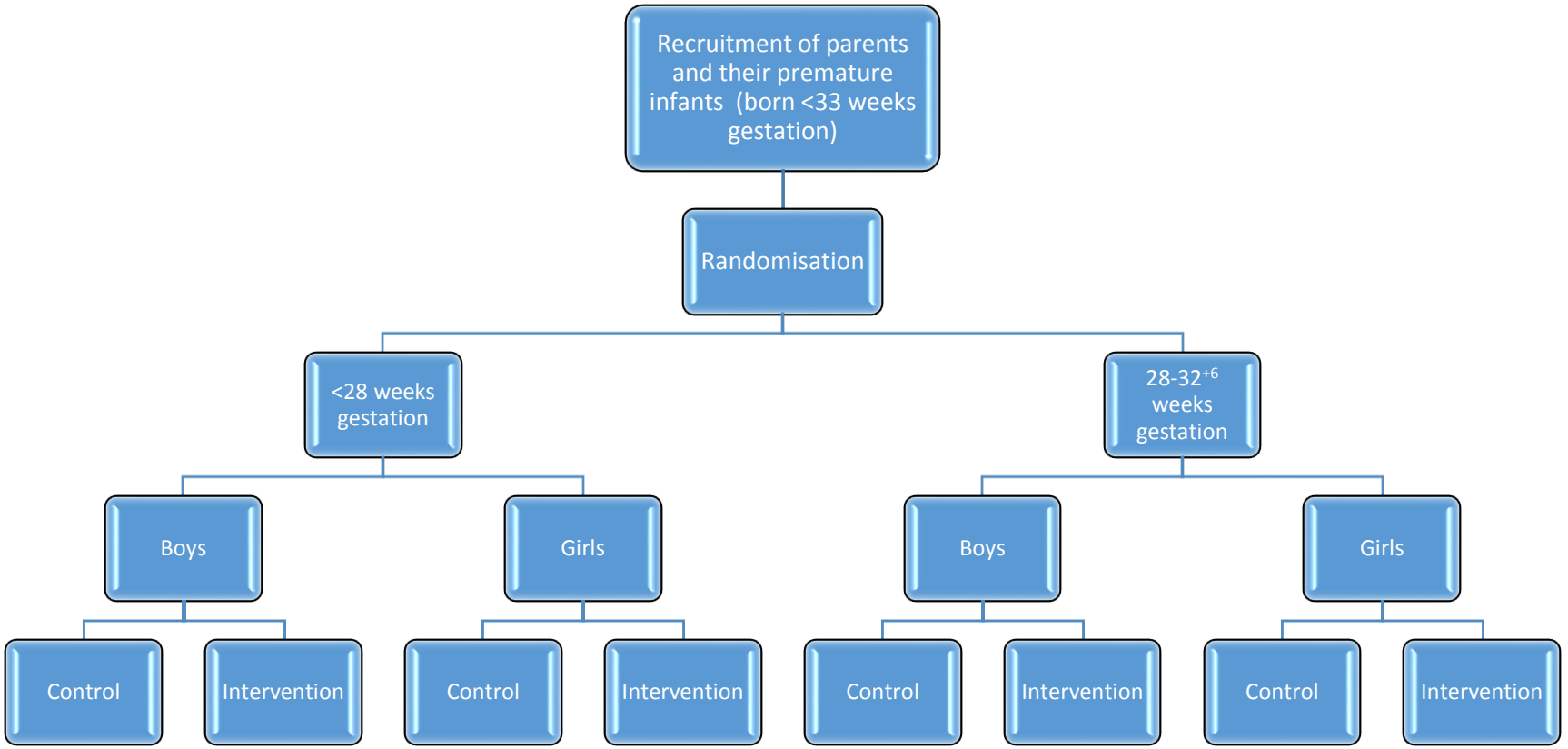
Participants were recruited from five neonatal units in the East of England, which serve a varied population in terms of mix of ethnicity and levels of social deprivation. Researchers visited each unit and provided information for staff and documentation for eligible parents to read, along with posters outlining the study. Posters were displayed in each of the neonatal units. In accordance with ethics, members of the participants' usual care team acted as gatekeepers for the study by providing the initial information to potential participants. Participant information sheets (PIS) were distributed to interested parents along with expression of interest forms allowing them to inform the research team of their interest. Upon receiving an expression of interest, a member of the research team or a research nurse met with the potential participant to discuss the study, answer any questions and, where appropriate, obtain informed consent.

### 4.4.8 Randomisation and Blinding

After consenting to the study, participants were randomly allocated to either the intervention or control group via sequentially numbered sealed envelopes. The randomisation was stratified by gestational age (<28 weeks and ≥28 weeks) and gender (male and female), with a computerised randomisation programme being used to generate blocked ABAB randomisation sequences (blocks of 4) for each group (Figure 10). Sequences were passed onto a member of administrative staff who was responsible for preparing the envelopes in which group allocation was concealed. This member of staff was also responsible for assigning A and B to the intervention or control groups. Once sealed, four boxes of envelopes were handed to a member of the research team

along with the consent forms for each participant and information regarding their gestational age and gender. Envelopes were only opened once participant consent and discharge from hospital were confirmed. In line with previous studies (Kaaresen et al., 2008), when twins were recruited, both were allocated to the same group as it would be problematic for parents to provide the intervention to just one twin. To reduce the risk of allocation or assessor bias, the researcher responsible for allocating participants to their groups and sending out relevant information packs via post was not involved in recruitment or collecting outcome data.

**Figure 10: Recruitment and randomisation process**



### 4.4.9 Data Collection Tools and Baseline Data

During the consent process parents of the premature infant were asked for permission to access the infant's medical records, so that baseline data could be obtained and to allow checks with the medical profession to ascertain if the infant was alive prior to contact being made with the parents. Parents were sent surveys at several time points along with intervention or control packs which provided relevant socio-demographic characteristics, as well as responses to the secondary outcome scales related to confidence and stress.

## 4.5 Primary outcome measures

Development assessments are a means of mapping a child's performance compared with children of a similar age (Bellman et al., 2013). Psychomotor development, the growth and development of the brain and nervous system, are divided into four domains: gross and fine motor skills; speech and language; social and personal; and performance and cognition (Bellman et al., 2013). Assessment scales may focus on one domain, or incorporate all the developmental domains, and as they depend on the age of the infant, the scale used in studies vary (as highlighted in chapter 2). Scales that incorporate all developmental domains are able to identify delay in a specific domain, as well as "global developmental delay" which Bellman et al., (2013) note is a significant delay in two or more of the four domains. For a difference to be classified as significant, the performance requires a score of two or more standard deviations of the mean of an age appropriate norm-referenced scale. Despite the number of scales available not all have been validated for use with preterm infants. Several of the scales available were highlighted in chapter two, and one of the main assessment scales used within the preterm population is the

Bayley Scales of Infant Development, which is now on its third edition, and the Alberta Infant Motor Scale (AIMS) is a single domain scale and has also been validated for use with the preterm population. Scores on the Bayley III motor scale and AIMS were therefore selected as the most appropriate primary outcome measures for motor development.

### 4.5.1 The Bayley Scales of Infant and Toddler Development Third Edition (Bayley III)

The Bayley Scales are the most frequently used of the developmental scales (Johnson et al., 2014). Bayley's is a norm referenced multi-domain developmental tool designed to identify early developmental delay in infants and toddlers aged between 1-42 months of age. The first two editions of the Bayley scale produced two scores, a mental developmental index (MDI) which incorporated cognitive and language scores, and the psychomotor developmental index (PDI) which evaluated motor skills (Moore et al., 2012). The most recent edition of the Bayley Scales of Infant and Toddler Development Third Edition (Bayley-III) (Bayley, 2006) restructured the scales and changed the standardisation process (Moore et al., 2012) Using a number of test items, the Bayley-III produces standardised scores for cognitive, language (receptive and expressive) and motor (fine and gross) development. Each item is designed as a short activity for the child and is marked as either a pass or fail by the assessor. The Bayley is used to assess the current developmental functioning of the infant and to identify developmental delays or disabilities. It is frequently used in research and clinical practice to describe the developmental status of children with particular medical conditions and developmental disabilities. The changes between the 2nd and 3rd editions have made the comparison of scores difficult. Moore et al (2012) notes a more

problematic issue, in that mean scores appear to be higher, with scores of 109 in children developing as expected and 90-97 in high-risk populations. Despite these issues the assessment has been used within a number of studies examining preterm populations and is currently considered the 'gold standard' for assessing early development. The third edition includes measures of five domains, although for analysis the composite score of the Bayley-III fine and gross motor scales were used as the primary outcome measure.

### 4.5.2 Alberta Infant Motor Scales (AIMS)

Alberta Infant Motor Scales (AIMS) (Piper et al., 1992) is an observational scale used to identify delayed and abnormal gross motor patterns in infants aged between 0-18 months of age (40 weeks post-conception to independent walking). It is a norm-referenced scale compromising of 58 items organised into four subscales (prone, supine, sitting and standing) focusing on the domain of gross motor development. The assessment is relatively short in duration and requires minimal handling, with the assessor observing the infant's movement to assess their current window of development. AIMS has been validated for use on infants under 18 months of age (Piper and Darrah, 1994) and has been shown to discriminate between full- and pre-term infants (van Haastert et al., 2006, Pin et al., 2010). The scoring is based on whether a movement has been observed or not observed at the time of the assessment, and as is typical of screening scales has a cut-off of -2SD to identify significant delayed motor skills, and -1SD for mild or suspicious delay. Alongside the Bayley-III, AIMS was used as a primary outcome measure.

Bayley and AIMS assessments complement each other, as Bayley's is conducted by an assessor providing a set of activities for the infant to complete, whereas the AIMS observes spontaneous activity, and is marked as observed or not observed. To ensure accuracy of scoring, all assessments were video recorded. Prior to conducting the development assessment training was undertaken to ensure all assessors conducted the tests appropriately. Furthermore all developmental assessments were recorded to allow for confirmation of scoring/rating to be agreed.

### 4.5.3 Parent questionnaires

Parents who consented to participate in the trial were sent questionnaires at several time points. The questionnaires incorporated general health questions and validated scales to explore parent-infant interaction, confidence and stress. The questionnaires were posted at previously agreed stages based on the corrected age of their infant, these were:

- Discharge from hospital
- Three-four months corrected age
    - Interacting with my Premature Infant Questionnaire (IPIQ) (Nicolaou et al., 2008)
    - Parenting Stress Index (PSI) (Abidin, 1983)
- Twelve months corrected age
    - Parenting Stress Index (PSI) (Abidin, 1983)
    - Evaluation of trial

### 4.5.4 Interacting with my Premature Infant Questionnaire (IPIQ) (Nicolaou et al., 2008)

The interacting with my premature infant questionnaire (IPIQ) was developed by Nicolaou et al., (2008), using qualitative data from interviews with parents of preterm infants, which highlighted maternal perceptions of interactions with their premature infant as a potential area for targeting interventions. The initial scale consisted of 15 items, however, this was refined with each item analysed resulting in a 12 item scale. The aim of the questionnaire is to examine the experience of the parent/caregiver interacting with the preterm infant, and the perceived quality of the interactions (Nicolaou, 2008). The IPIQ demonstrated good face and content validity and reliability (Nicolaou, 2008), in addition to being easy and quick to use. The IPIQ consists of two subscales: "*perceived infant capability*" and "*caregiver confidence*". The perceived infant capability subscale focuses on infant characteristics during interactions, such as sleepiness, interest and responsiveness, whilst the caregiver confidence subscale examines possible confidence and anxiety feelings of the parent/caregiver when interacting or caring for the preterm infant. A strength of using this scale is that it is validated and designed specifically for the preterm population, although not widely used at present.

### 4.5.5 Parenting stress index – version 3 (PSI) (Abidin, 1995)

The parenting stress index (PSI) was developed by Abidin (1983), as a means of early identification of stressful parent-child systems. Abidin (1983) argued the need for interventions to reduce stress, which may subsequently reduce the frequency and intensity of behavioural and emotional disturbance in children. The initial parent-child sources of stress were identified as: "*child characteristics*"; "*parent characteristics*"

and "*situational/demographic life stress*", and the scale developed using available research evidence. There have been several editions of PSI, it is widely used and validated for use with a variety of different groups. The initial full version of the PSI consisted on 120 items (Reitman et al., 2002) which made it time consuming to complete, therefore Abidin (1983) performed factor analysis on the items. This resulted in the current short-form version containing 36 items which measure the domains of: anxiety/mood (Internalizing Symptoms); relationships and attachment; parent, caregiver, family mental health and functioning. The PSI has been found to be negatively associated with parenting self-efficacy and positively related to the number of family risk factors (Raikes and Thompson, 2005). The scale provides a total stress score and covers four separate domains which are:

- Defensive responding
- Parental distress
- Parent-child dysfunctional interaction
- Difficult child

The scale scores normal range as =15th-80th percentile, with scores at or above the 85th percentile considered high and Defensive Responding scores at 10 or below are considered extremely low.

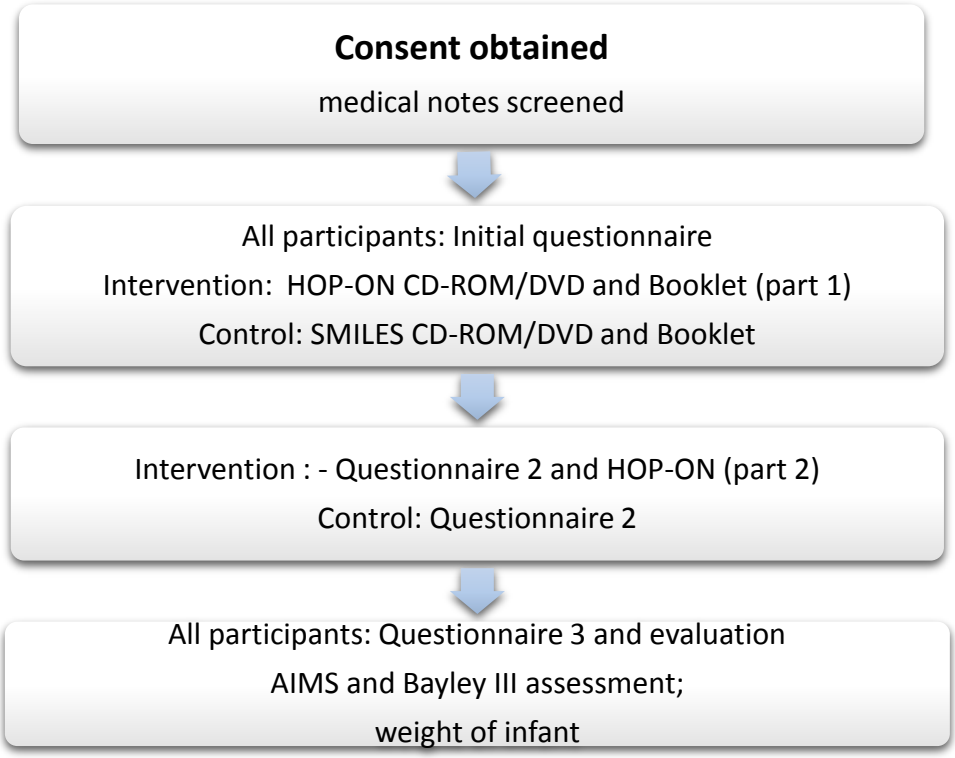
Maternal scores on the PSI-SF have also been found to be related to increased risk for developing insecure attachment in a sample of premature infants (Laganiere et al., 2003). In addition, maternal parenting concerns during pregnancy have also been found to be related to later PSI scores. Calkins et al. (2004) found that difficult child scores correlated with observations of maternal intrusiveness and sensitivity in a sample of mothers and 6-month-old infants.

There is a suggestion that a parenting intervention can have an impact on PSI scores, as Abidin (1995) highlights a significant decrease in scores pre-to-post intervention with a high-risk, predominantly African American sample (DePanfilis and Dubowitz, 2005). Glazebrook et al., (2007) did not find a difference between the intervention and control group scores of the mothers when their preterm infants were three months corrected age, although these were between group comparisons rather than within group.

## 4.6 Study Procedure

The intervention was to commence on discharge from hospital, once this had been confirmed participants were sent a pack containing either the HOP-ON intervention and the SMILES programme (intervention group) or just the SMILES programme (control group). These were provided on a CD-ROM for those with access to a computer and on a DVD and information booklet for those who did not have access to a computer. The initial pack contained information about the study, a questionnaire to establish some baseline and demographic data, a stamped addressed envelope, and a letter for their GP and Health Visitor to inform them of their participation. At this stage, basic information regarding the infant's birth and neonatal history (e.g. birth weight, gestational age, feeding, neurology, cranial ultrasound findings and ROP screening) was collected from the infant's medical notes and online records. Figure 11 displays the flow through the study for the participants.

**Figure 11: Study flow**

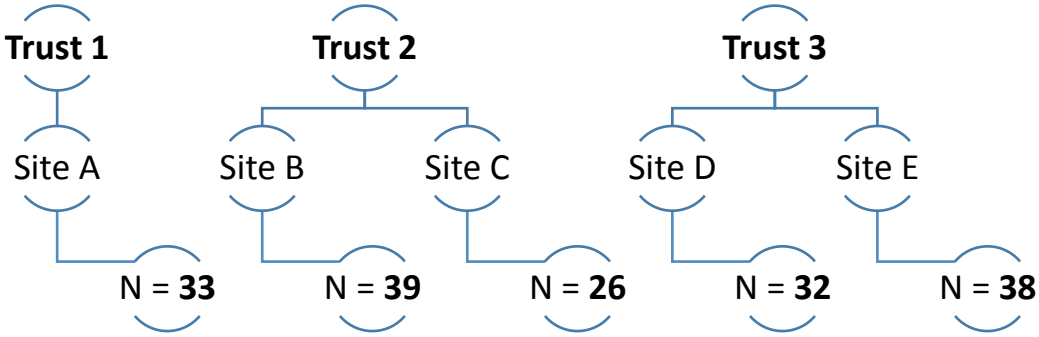



The initial and 3-4 month questionnaire packs, along with the intervention/control information was posted out to the parent. The final questionnaire and evaluation survey were left with parents at the main assessment visit. The developmental assessment conducted when the infant was 12 months corrected age, took place at the family home. The researchers were unaware of the group that the infant had been allocated to, to reduce observer bias. In addition the assessments were recorded for rating by other members of the research team. At this visit the parents were provided with a questionnaire asking for some brief feedback on the CD-ROM(s)/DVD(s) and information booklet(s) they had received as part of the study.

## 4.7 Recruitment of participants

Recruitment took place at three NHS Trusts which consisted of five neonatal intensive care units (NICUs) as two of the trusts had NICUs in each of their two hospitals. The study was accepted onto the Clinical Research Network (CRN) portfolio, which provides the time of research nurses/midwives to aid recruitment. In total 168 infants were recruited for the study. Figure 12 displays initial recruitment from each hospital.

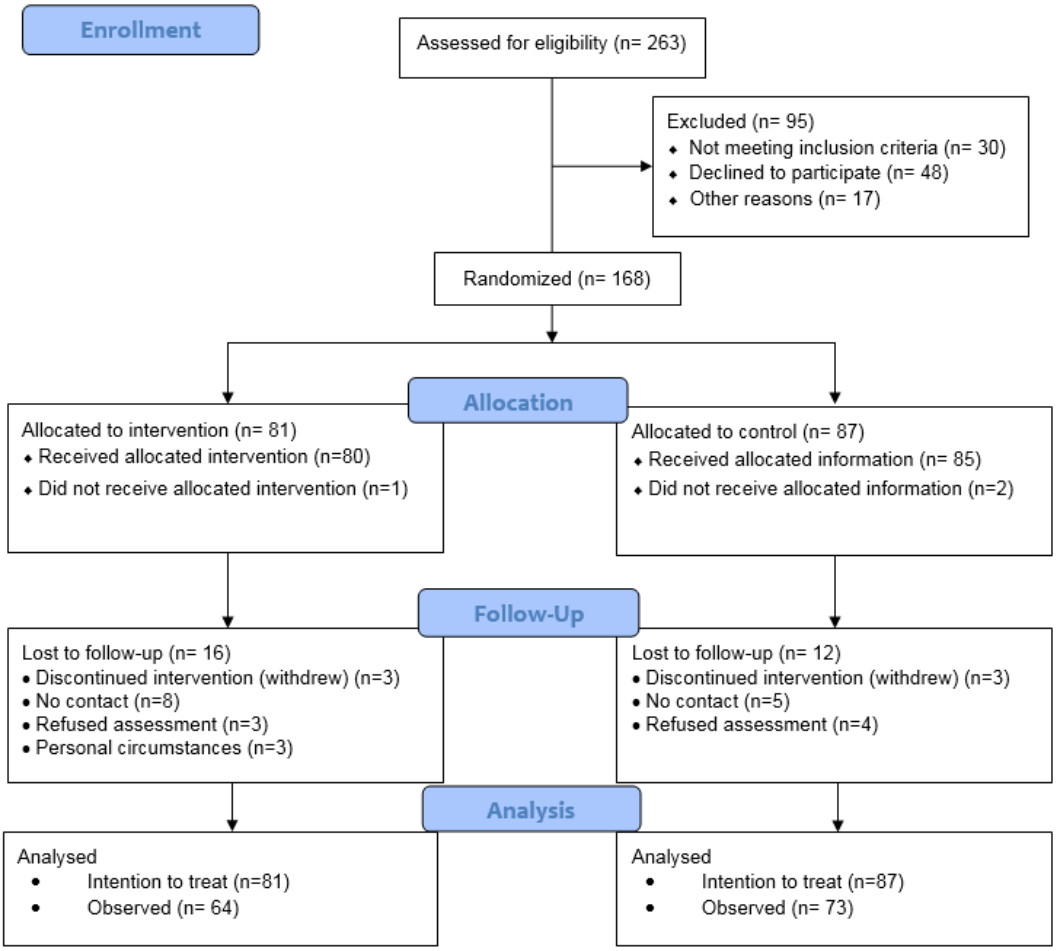
**Figure 12: Initial recruitment across sites**




The NHS Trust with one NICU (Trust 1) recruited 33 neonates (19.6%), Trust 2 recruited 65 neonates (38.7%) over two NICUs (n=39; 23.2%) (n=26; 15.5%), and Trust 3 recruited 70 neonates (41.7%) over their two NICUs (n=32; 19%) (n=38; 22.7%).

It is important when conducting a RCT to note any withdrawal from the study and reasons for this, in addition any information on participants who are lost to follow-up should be included. Figure 13 displays the CONSORT (Moher et al., 2010) flow diagram of recruitment for the study and the number of participants included in the main outcome assessment and analysis.

**Figure 13: CONSORT flow diagram of recruitment**



## 4.8 Findings

Eighty-one infants were randomised to the intervention group and eighty-seven to the control group. All data were inputted into IBM SPSS v22.0 (IBM Corp, 2013) and descriptive statistics calculated. To check whether the health and socio-demographics were similar across the intervention and control groups, crosstabulations were conducted. All tables and figures are displayed by group allocation.

### 4.8.1 Response rates for questionnaires

The initial questionnaire was sent to parents of all infants who were discharged from hospitals to their home (n=165); 120 were returned (72.7%). The 3-4 month questionnaire was posted to 137 parents, and 92 were returned completed (67.1%). At 12 months 137 questionnaires were sent out with 119 returned (86.9%). The two year onwards questionnaire was sent out to 137 families and 42 questionnaires were returned complete (26.6%). However, an additional 12 were returned incomplete due to the family no longer being at the address held on the database. The pattern of response rates varied at each time point, with a slight increase in the number of returns from the 3-4 months to the 12 month point, which may be due to the link with the developmental assessment being conducted.

### 4.8.2 Participant demographics

Data were extracted from the medical notes of all preterm infants whose parents provided signed consent. For this a data collection form that had been approved by NHS ethics and Trust Research and

Development was used. However, not all sites recorded the data in the same format, and not all neonates would require the same range of neurological/medical tests, therefore the number of responses will vary. To obtain/confirm socio-demographic information, questionnaires were sent to parents for completion.

#### 4.8.2.1 Parent characteristics

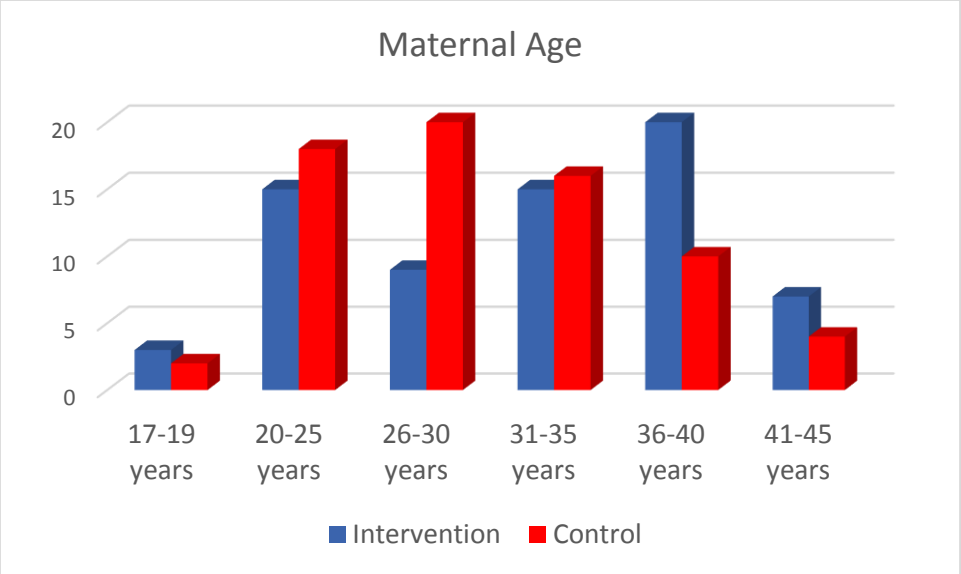
Basic demographic data wherever possible was obtained from the medical records, or from questionnaires that were included with the pack containing the Control or/and Intervention information. The response rates for the initial questionnaire was returned by 71.6% (n=58) of the intervention group and 71.3% (n=62) of the control group. Parents with twins completed a separate questionnaire for each infant, however, duplicated data for demographic details relating to marital status; previous children; ethnic origin; education level; current employment; and age were removed. Table 13 presents the demographic characteristics for the parents of the premature infants. They are presented by group allocation to assess any differences in demographics between the intervention and control group.

**Table 13: Parent demographic data**

| Characteristic | | Intervention N=69 | Control N=70 |
|---|---|---|---|
| Maternal age | Mean | 32.04 | 29.70 |
| | Median | 34 | 29 |
| | Standard deviation | 7.224 | 6.080 |
| Marital status | Married/Co-habiting | 53 (77%) | 54 (77%) |
| | Single | 13 (19%) | 12 (17%) |
| | Partner (not co-habiting) | 0 | 1 |
| | Separated/Divorced | 1 | 1 |
| | Missing | 2 | 2 |
| Other children | Yes | 26 (38%) | 26 (37%) |
| | No | 29 (42%) | 35 (50%) |
| | Missing | 14 (20%) | 9 (13%) |
| Ethnic origin | White British | 50 (73%) | 56 (80%) |
| | Black-African | 6 (8.7%) | 3 (4.3%) |
| | Black-Caribbean | 2 (3%) | 3 (4.3%) |
| | Indian | 4 (5.8%) | 3 (4.3%) |
| | Pakistani | 3 (4.4%) | 1 (1.4%) |
| Highest education level | Graduate education | 19 (27.5%) | 15 (21.4%) |
| | Further education | 12 (17.4%) | 20 (28.6%) |
| | GCSEs | 16 (23.2%) | 13 (19%) |
| | No educational qualifications | 6 (8.7%) | 5 (7%) |
| | Missing | 16 (23.2%) | 17 (24%) |
| Employment status | Employed/Self-employed | 30 (43.5%) | 34 (49%) |
| | Unemployed | 19 (27.5%) | 18 (26%) |
| | Other | 4 (5.8%) | 1 (1.4%) |
| | Missing | 13 (19%) | 17 (24%) |

The randomisation process resulted in more participants being assigned to the control group, reflecting the higher number of twins allocated to that group. In total 23 sets of twins were recruited onto the study, 15 sets (65%) were randomised in to the control group. Overall, the majority of characteristics for which data were collected were similar for both the intervention and control groups. Therefore specific characteristics of the participant and their family would not be confounders in any intervention differences found. One area of note, is that the mothers in the intervention group were slightly older (mean 32; median 34) than the mothers in the control group (mean 30; median 29) (table 13). The range of maternal ages are displayed in figure 14.

**Figure 14: Maternal age range by group**




The difference in maternal ages were not significant between groups, although there were slightly more mothers in the intervention group that were between 36-40 years of age, whereas the control group had slightly more mothers aged between 26-30 years.

The relationship status for parents in both groups were predominantly either married or co-habiting (intervention n=53 (%); control n=54 (%)), and characteristics such as highest education level were similar with the majority having completed further or higher education and employment status had more respondents stating they were employed or self-employed. Parents were asked what their first language was, Table 14 displays their responses.

**Table 14: Parent's first language**

| Parent's first language | Intervention n= 69 | Control n= 70 |
|---|---|---|
| English (+ other) | 52 | 54 |
| Swahilli/Twi/Ndebele (Africa) | 2 | 1 |
| Urdu (Pakistan) | 3 | 0 |
| Gujarati (India) | 1 | 1 |
| Latvian | 0 | 1 |
| Polish | 0 | 2 |
| Tagalog (Philippines) | 0 | 2 |
| Danish | 0 | 1 |
| Missing/Unclear | 11 | 8 |

The majority of parents spoke English, which may be expected within studies where the information and informed consent are predominantly in English. There is a small percentage of other languages and ethnicities in both groups.

#### 4.8.1.2 Infants characteristics

The following figures display the gender, gestational age at birth, weight at birth and type of birth for the infants who participated in the study. These characteristics have been demonstrated to have a potential impact on a preterm infant's development therefore the study stratified the randomisation to allow for equivalence between the groups. Table 15 displays the basic birth characteristics of participating infants grouped under study allocation.

**Table 15: Infant birth characteristics**

| **Characteristic** | | **Intervention N=81** | **Control N=87** |
|---|---|---|---|
| Gender | Male | 41 (51%) | 44 (51%) |
| | Female | 40 (49%) | 43 (49%) |
| Gestation | <28 weeks | 32 (40%) | 30 (35%) |
| | >28 weeks<33 weeks | 49 (60%) | 57 (65%) |
| Birthweight | <1000g | 32 (40%) | 30 (35%) |
| | 1000g-1499g | 32 (40%) | 34 (39%) |
| | 1500g-2500g | 17 (20%) | 23 (26%) |

There were 85 male (51%) infants and 83 female (49%) infants who were randomly allocated to either the intervention or control group.

Weeks of gestation were stratified as less than 28 weeks and 28 to 33 weeks gestation (n=106; 63%), although there were much fewer infants that were born less than 28 weeks gestation (n=62; 37%), these were roughly equal across intervention and control groups (n=25; 16%; n=19;

13%). The neonates in the study who were born at less than 28 weeks of gestation, ranged from 24+1 (24 weeks and 1 day) and 27+6 (27 weeks and 6 days), and 106 neonates (born between 28 weeks and 33 weeks gestation, these ranged from 28+0 (28 weeks and 0 days) and 32+4 (32 weeks and 4 days).

Birthweight of the sample ranged from 511 grams up to 2100 grams, although the majority of infants weighed between 750 and 1250 grams at birth. Birthweight categories (extremely/very/low) were calculated by treatment group. The number of infants in each group is displayed in table 15 by group allocation.

For baseline, the type of birth was obtained however, this was not always recorded in the neonatal notes. No type of birth was stated for 49 participants (29%). For those where data were available, there were slightly more Caesarean section births (N = 61; 36%) than normal vaginal births (N = 54; 32%), and only four (3%) instrumental births using forceps stated. The intervention and control groups had similar numbers of infants born by caesarean section or vaginal birth, whereas those who had an instrumental birth with forceps were all in the control group.

Method of feeding the preterm infant was a similar rate for both groups, although not all provided this information. Fifty-five parents from the intervention group provided data and 63 from the control group. The majority of infants were fed with expressed breast milk, 65% of the intervention group were exclusively fed breast milk and an additional 7% (n=4) were given some expressed breast milk. In the control group 76% (n=48) were exclusively fed breast milk.

#### 4.8.1.3 Infant Health and Screening

General information on the health of the infant and any treatments received were recorded. In addition data from screening conducted in the neonatal unit were obtained. Table 16 displays the results of screening and initial treatment received for both the intervention and control infants.

**Table 16: Screening and Treatment**

| **Treatment or Results of Screening** | | **Intervention N=81** | | **Control N=87** | |
|---|---|---|---|---|---|
| Congenital abnormality | Yes | 10 (12%) | | 10 (11.5%) | |
| | No | 60 (74%) | | 67 (77%) | |
| | Missing | 11 (14%) | | 10 (11.5%) | |
| Fits | Yes | 3 (3.7%) | | 1 (1.2%) | |
| | No | 66 (81.5%) | | 75 (86.2%) | |
| | Missing | 12 (14.8%) | | 11 (12.6%) | |
| Encephalopathy | Yes | 0 | | 0 | |
| | No | 69 (85.2%) | | 75 (86.2%) | |
| | Missing | 12 (14.8%) | | 12 (13.8%) | |
| Haemorrhage in first week | | Left | Right | Left | Right |
| | None | 56 (69%) | 50 (63%) | 55 (63%) | 58 (67%) |
| | Subpendymal | 4 (5%) | 7 (8%) | 7 (8%) | 5 (6%) |
| | Intraventricular | 11 (14%) | 14 (17%) | 14 (16.4%) | 13 (14.4%) |
| | Missing | 10 (12%) | | 11 (12.6%) | |
| Ventricular size at any time | Normal | 53 (66%) | 54 (67%) | 59 (67.8%) | 60 (69%) |
| | Dilated | 18 (22%) | 17 (21%) | 17 (19.6%) | 16 (18.4%) |
| | Missing | 10 (12%) | | 11 (12.6%) | |
| Parenchymal appearances | Normal | 63 (79%) | 62 (77%) | 66 (76%) | 68 (78.2%) |
| | Cystic PVL | 2 (3%) | 3 (5%) | 2 (2.2%) | 0 |
| | Other | 5 (6%) | 5 (6%) | 8 (9.2%) | 8 (9.2%) |
| | Missing | 10 (12%) | | 11 (12.6%) | |
| Steroids | Yes | 6 (7.2%) | | 3 (3.4%) | |
| | No | 63 (78%) | | 73 (84%) | |
| | Missing | 12 (14.8%) | | 11 (12.6%) | |
| Home Oxygen | Yes | 11 (14.8%) | | 13 (14.4%) | |
| | No | 59 (70.4%) | | 62 (71.8%) | |
| | Missing | 11 (14.8%) | | 12 (13.8%) | |

Many of the preterm infants were also screened for visual (retinopathy of prematurity) or hearing impairment. The majority of neonates (n=98; 58%) were screened for retinopathy of prematurity (ROP) in both eyes, and the majority of those screened showed no ROP (n=48 (49%)) or mild/moderate levels of ROP (stage I (n=33 (34%) and II (n=15 (15%)). Stage I and II ROP in most instances resolve on its own without treatment, whilst stage 4 and 5 refer to partial and total detachment of the retina (Wheatley et al., 2002).

Information on whether the infant had a congenital anomaly was available for 147 of the participants, and not available for 21 of the infants who were initially recruited. No congenital anomalies were identified in the majority of the preterm infants (n=127), whilst 20 infants who had a diagnosis, an equal number were allocated to each group. The majority of infants did not have any fits recorded in their medical notes (n-141; 97%), and none of those for whom data was available had a diagnosis of encephalopathy. Therefore the majority of the preterm infants recruited did not have a congenital abnormality, or deemed high risk for neuro-developmental disorders.

Table 17 displays by group allocation the length of treatment and hospital stay for infants.

**Table 17: Length of Treatment and Hospital Stay**

| Characteristic | | Intervention N=81 | Control N=87 |
|---|---|---|---|
| Days ventilated | Mean | 8.07 | 6.87 |
| | Median | 2 | 2 |
| | Standard deviation | 13.67 | 11.25 |
| Days on Continuous positive airway pressure (CPAC) | Mean | 19.41 | 19.91 |
| | Median | 8 | 9 |
| | Standard deviation | 23.98 | 22.48 |
| Days on Oxygen | Mean | 21.99 | 13.25 |
| | Median | 5 | 2 |
| | Standard deviation | 31.58 | 18.83 |
| Length of Stay | Mean | 65.14 | 60.82 |
| | Median | 60 | 54.50 |
| | Range | 207 | 161 |

*

From the medical notes data were collected on whether the neonate had required ventilation, and if so how many days they were ventilated. For those neonates that required oxygen whilst in the NICU, the number of days that oxygen was necessary ranged from 1 to 157 days, although the majority of neonates either did not require any (n=57; 34%) or needed oxygen for up to one week (n=41; 24%). Few infants still required oxygen when they were discharged home (n=24; 17%). The majority of treatments were similar for most groups, although on average the intervention group were on oxygen longer than the control group. The length of stay was similar for both intervention and control groups, however, the range was much larger for the intervention group.

There were no data available on whether the infant received kangaroo care whilst on the NICU.

These data were collected to ensure that any potential confounding factors could be explored, especially any that may impact on the main outcome measures that were assessed at 12 months.

### 4.8.3 Three-Four month corrected age questionnaire

When the infant had reached 3-4 months corrected age, questionnaires were sent out to all those recruited and had not been withdrawn due to an adverse outcome. The questionnaire incorporated questions which confirmed some demographic data and checked current health of the infant. In addition two validated scales were included, one which provides data on parent infant interaction (Infant Parent Interaction Questionnaire (IPIQ) – Nicolau et al, 2008) and parental stress (Parental Stress Index (PSI) (Abidin, 1995).

The responses from each group for the IPIQ are displayed in table 18. Any differences in response rates for an item is highlighted within the table.

**Table 18: Responses to 12 item IPIQ at 3-4 months ca**

| Statement | Intervention group N=43 | | Control group N=54* | |
|---|---|---|---|---|
| | Mean | SD | Mean | SD |
| 1. My baby is too sleepy to interact with | 6.12 | 1.12 | 6.52 | 1.15 |
| 2. My baby responds to me during interactions | 1.40 | 0.58 | 1.31 | 0.58 |
| 3. I feel anxious about playing with my baby | 5.93 | 1.61 | 6.40* (n=52) | 1.21* (n=52) |
| 4. I am confident about interacting with my baby | 1.42 | 0.63 | 1.40 | 0.68 |
| 5. I am worried about my baby's health | 4.30 | 2.02 | 5.13 | 1.72 |
| 6. I am worried that my baby is not strong enough yet for play | 6.23 | 1.19 | 5.85 (n=53) | 1.76 (n=53) |
| 7. My baby is too small to interact and play with | 6.51 | 0.74 | 6.28 | 1.41 |
| 8. I am worried I might do something wrong | 5.77 | 1.67 | 5.60 (n=53) | 1.72 (n=53) |
| 9. My baby is interested in playing | 1.70 | 0.99 | 1.78 | 1.06 |
| 10. I don't know what I should be doing with my baby | 5.84 | 1.43 | 6.04 | 1.20 |
| 11. My baby is alert during interactions | 1.51 | 0.63 | 1.28 (n=53) | 0.45 (n=53) |
| 12. I don't know how to play with my baby | 5.74 | 1.66 | 6.43 | 1.02 |

The IPIQ items are split into domains for which the scoring were calculated for mothers of each group and displayed in table 19.

**Table 19: Scores for IPIQ domains at 3-4 months ca**

| | Intervention group | Control group | Cohen's d |
|---|---|---|---|
| **Perceived infant capability subscale** | **N=43** | **N=52** | 0.0275 |
| Mean | 33.65 | 33.73 | |
| Median | 34 | 35 | |
| Standard deviation | 2.09 | 3.55 | |
| **Maternal confidence subscale** | **N=42** | **N=52** | 0.0033 |
| Mean | 34.38 | 36.25 | |
| Median | 36 | 37 | |
| Standard deviation | 6.44 | 4.61 | |
| **Total IPIQ** | **N=42** | **N=51** | 0.2682 |
| Mean | 68.07 | 70.00 | |
| Median | 69 | 71 | |
| Standard deviation | 7.70 | 6.75 | |

The subscale scores and total IPIQ scores were similar for both groups, suggesting that maternal confidence and parent's perception of their infant's ability were not affected by the intervention at 3-4 months.

The PSI scale was completed at 3-4 and 12 months. The responses at 3-4 months were calculated for the four domains and are displayed along with the overall stress score in table 20.

**Table 20: PSI Scale scores at 3-4 months ca**

| | Intervention group | Control group | Cohen's d |
|---|---|---|---|
| **PSI Defensive Responding** | **N=42** | **N=54** | 0.2288 |
| Mean | 14.95 | 13.85 | |
| Median | 15 | 14 | |
| Standard deviation | 4.63 | 4.98 | |
| **PSI Parental Distress** | **N=42** | **N=53** | 0.3038 |
| Mean | 26.19 | 23.87 | |
| Median | 26 | 23 | |
| Standard deviation | 7.32 | 7.94 | |
| **PSI Parent-Child Dysfunctional Interaction** | **N=37** | **N=54** | 0.1924 |
| Mean | 19.59 | 18.46 | |
| Median | 18 | 18 | |
| Standard deviation | 6.51 | 5.16 | |
| **PSI Difficult Child** | **N=36** | **N=51** | 0.3338 |
| Mean | 21.39 | 18.98 | |
| Median | 20 | 17 | |
| Standard deviation | 8.27 | 5.99 | |
| **PSI Total** | **N=32** | **N=50** | 0.2826 |
| Mean | 66.16 | 60.98 | |
| Median | 66.5 | 58.5 | |
| Standard deviation | 19.33 | 17.27 | |

The domain scores for both groups were similar, although the parents in the intervention group scored slightly higher on all domains, resulting in their PSI total score being higher than the control group. To explore if these differences were significant, these scores were coded for those that scored above the 85% threshold and analysed by group using a chi-square. The difference at 3-4 months did not reach statistical significance (p=0.098), although there was a trend with parents in the intervention group scoring higher on stress domains.

### 4.8.4 Twelve month corrected age questionnaire

When the infant was 12 months corrected age, along with the developmental assessment, a questionnaire was provided to all parents. The questionnaire confirmed current health and incorporated the validated parent stress index questionnaire (PSI). The responses for the parent stress index when their infant was 12 months corrected age are displayed in table 21.

**Table 21: PSI Scale scores at 12 months ca**

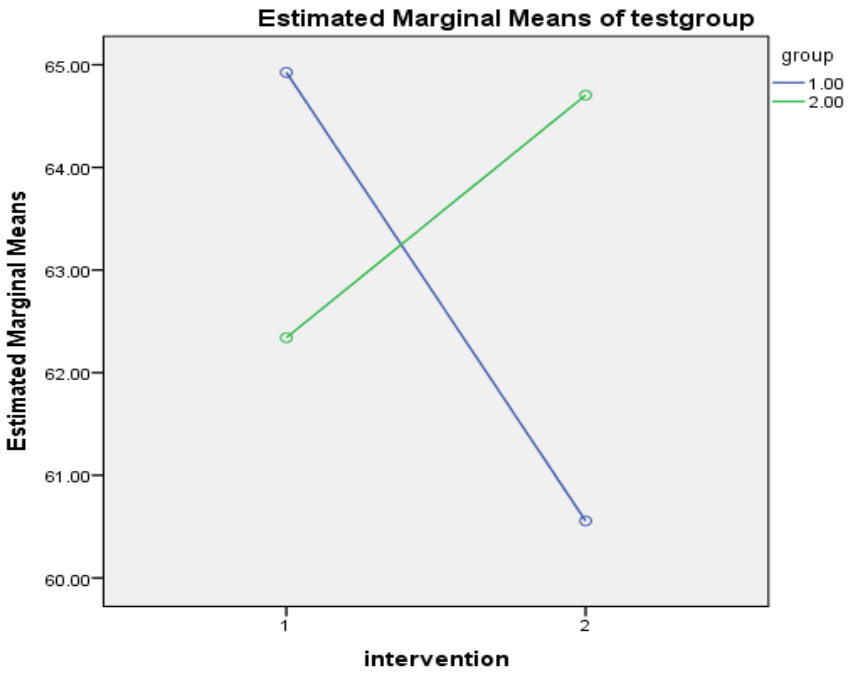
| | **Intervention group** | **Control group** | **Cohen's d** |
|---|---|---|---|
| **PSI Defensive Responding** | **N=54** | **N=62** | 0.2928 |
| Mean | 13.22 | 14.61 | |
| Median | 14 | 14.5 | |
| Standard deviation | 4.58 | 4.91 | |
| **PSI Parental Distress** | **N=54** | **N=62** | 0.3551 |
| Mean | 22.54 | 25.42 | |
| Median | 23 | 24.5 | |
| Standard deviation | 7.60 | 8.59 | |
| **PSI Parent-Child Dysfunctional Interaction** | **N=55** | **N=61** | 0.2136 |
| Mean | 17.91 | 19.20 | |
| Median | 16 | 17 | |
| Standard deviation | 5.42 | 6.60 | |
| **PSI Difficult Child** | **N=55** | **N=60** | 0.1858 |
| Mean | 21.11 | 22.65 | |
| Median | 20 | 20.5 | |
| Standard deviation | 7.64 | 8.89 | |
| **PSI Total** | **N=53** | **N=60** | 0.3210 |
| Mean | 61.47 | 67.75 | |
| Median | 61 | 64.5 | |
| Standard deviation | 17.87 | 21.13 | |

The domain scores between the intervention and control groups were similar, although the control group scores were slightly higher in all domains. In line with the analysis conducted on the PSI scale at 3-4 months, data were coded to assess if there were differences between

groups in relation to scoring above the threshold (>85$^{th}$ percentile) for clinical significance.

A chi-square was then conducted to assess if there was a difference between the groups, and a statistically significant difference was found between the intervention and control group. At this time point the control group scored higher than the intervention group on parent-child dysfunctional interactions (p=0.038), and a non-significant trend with intervention group parents scoring lower than control group parents on total stress score. The finding that intervention parents scored higher in stress score at 3 months, but lower than the control group parents at 12 months was analysed. A repeated measures analysis of variance (ANOVA) was conducted in Statistical Package for Social Sciences (SPSS) v22 (IBM Corp, 2013), and a statistically significant difference was found. A plot of the analysis is displayed in figure 15, group 1 is the intervention group, and group 2 controls.

**Figure 15: Plot of PSI scores at 3-4 months and 12 months**



Within groups showed a statistically significant difference (F=4.325; p=0.041) for the intervention group at the two time points.

### 4.8.5 Motor assessment at 12 months corrected age

Wherever practicable, two researchers, unaware of group allocation visited the infant and parents in their own home. This was to allow one researcher to undertake the recording of the assessment, whilst the other conducted the assessment. The recording of the assessment allowed for the activities to be rated to obtain agreement. The motor assessment of infants was conducted when the infant had reached 12 months corrected age. The loss to follow-up were 17 infants from the intervention group and 14 from the control group. Table 22 displays the reason for loss to follow-up.

**Table 22: Reasons for loss to follow-up**

| | | Group | | |
|---|---|---|---|---|
| | | Intervention | Control | Total |
| **12 month assessment completed** | Yes | 64 | 73 | 137 |
| | Withdrawn | 3 | 3 | 6 |
| | Died | 1 | 2 | 3 |
| | Could not contact | 3 | 2 | 5 |
| | Refused | 3 | 4 | 7 |
| | DNA | 5 | 3 | 8 |
| | Personal circumstances | 2 | 0 | 2 |
| **Total** | | **81** | **87** | **168** |

The loss-to-follow-up from recruitment to 12 month assessment resulted in data not being available for 17 infants from the intervention group and 14 from the control group. Within these numbers, four withdrawals were from twins; two of those who died were twins, and one set of twins were not contactable. This resulted in the intervention group included seven sets of twins at 12 month assessment, and 12 sets of twins from the control group were assessed at 12 months.

Any loss of participants following recruitment can not only have an impact on the results due to reduction in number to below the level calculated by the power calculation, but increases the potential for overestimation of treatment effect (Gupta, 2011). The statistical concept of intention to treat analysis can be a solution to this potential bias, as it is a concept which states that once randomised always analysed (White et al., 2011). Intention to treat was the method selected for analysing the outcome data for this study. Within SPSS this was achieved by multiple imputation. Relevant characteristics were included and a minimum of five iterations was selected. The new data file which included the multiple imputations

was used for the analysis of the motor assessment scores for both groups. Table 23 displays the observed and pooled scores for the separate fine and gross motor scales.

**Table 23: Fine and Gross Scaled and Raw Scores**

| Scale/Score | Intervention N=64 (N=81 pooled data) | | Control N=73 (N=87 pooled data) | |
|---|---|---|---|---|
| | Mean | Standard deviation | Mean | Standard deviation |
| Fine Motor Scaled | 8.72 (8.77) | 2.64 (2.42) | 8.90 (8.90) | 2.50 (2.34) |
| Gross Motor Scaled | 6.55 (6.58) | 2.76 (2.54) | 6.35 (6.36) | 3.10 (2.92) |
| Fine Motor Raw Score | 27.19 (27.09) | 5.02 (4.53) | 27.92 (27.71) | 2.75 (2.69) |
| Gross Motor Raw Score | 36.48 (36.48) | 6.93 (6.27) | 36.75 (36.63) | 5.88 (5.54) |

The gross and fine motor scores were similar for both intervention and control groups. Analysis was conducted on the AIMS and the Bayley III composite score. The means and standard deviation for the intervention and control group are displayed in table 24.

**Table 24: AIMS and Bayley III means and standard deviation**

| Assessment | Intervention N=64 (N=81 pooled data) | | Control N=73 (N=87 pooled data) | |
|---|---|---|---|---|
| | Mean | Standard deviation | Mean | Standard deviation |
| AIMS total score | 45.91 (45.68) | 10.64 | 44.68 (44.86) | 10.59 |
| Bayley III motor composite score | 85.84 (85.72) | 13.24 | 85.92 (85.92) | 13.74 |

Mean and standard deviation were similar for both groups, and an independent t-test was calculated for the AIMS scores and the composite motor score of the Bayley III. The results for the AIMS assessment at 12 months are presented in table 25, for the original and pooled data, and the results of the Bayley III motor composite scores for the 12 month assessment.

**Table 25: Analysis of AIMS and Bayley III scores – original and pooled data following imputation**

| Assessment | Data | t score | Significance (2 tailed) | Mean difference (95% interval) |
|---|---|---|---|---|
| AIMS | Original | .672 | .503 | 1.22132 (-2.37354 – 4.81618) |
| | Pooled | .533 | .594 | .81887 (-2.19466 – 3.83241) |
| Bayley III | Original | -.031 | .975 | -.7292 (-4.66228 – 4.51644) |
| | Pooled | -.132 | .895 | -.25113 (-3.96804 – 3.46577) |

### 4.8.6 Trial results

The t-test found no significant difference between the intervention and control motor scores on the AIMS (t=.672; p=.503 (original data); t=.0533;

p=0.594 (pooled imputed data)), or Bayley III (t=-.031; p=.975 (original data); t=-.132; p=.895 (pooled imputed data)) in either the original or pooled data for intention-to-treat.

During the assessment all elements of the Bayley III were conducted, however, no significant differences were found in either the cognitive composite scores (intervention group mean 96.64; control group mean 95.00) or the language and social composite scores (intervention group mean 86.48; control group mean 86.87).

The intervention did not enhance the motor performance of the premature infants, and therefore we fail to reject the null hypothesis. There are several issues that may have influenced the results, as although multiple imputation was used to enable analysis to be conducted using the intention to treat principle, the numbers were near the lowest required by the power calculation. In addition detailed information on actual usage of the intervention programme was not available. However, in an attempt to obtain some feedback on usage of the HOP-ON programme, an evaluation questionnaire was given to the parents following the motor assessment.

## 4.9 Parent evaluation of study

Parents in both intervention and control groups were provided with an evaluation questionnaire and a stamped addressed envelope to return once completed.

### 4.9.1 Response rates

Following the 12 month assessment an evaluation questionnaire was provided to 137 participants to obtain their views on the information they received as part of the trial (i.e. SMILES/SMILES and HOP-ON). A total of 99

participants returned completed evaluations (72.3%), 47 from the intervention group and 52 from the control group. In addition a small sub-study was conducted as part of an undergraduate project, and qualitative data obtained separately to the written evaluation was obtained by interviews with HOP-ON participants, however, the response rate was very low, with only 13 responses to the 73 invitation letters (17.8%).

### 4.9.2 Evaluation questionnaire

There were two versions of the evaluation questionnaire, one for those who stated they had computer access, and so were sent CD-ROMs, and a DVD/Booklet version for those who did not have computer access. The CD-ROM version consisted of six statements with a seven point likert scale for parents to rate their level of agreement/disagreement. Table 26 displays parent responses, although only five points of the likert scale are included, as none of the participants used the *somewhat agree*, nor *somewhat disagree* options.

Two questions were also included that attempted to ascertain how often the CD-ROM was viewed, and how often the suggestions were followed. The responses for theses are presented in table 27.

**Table 26: Evaluation responses by group**

| Statement | Strongly agree | | Agree | | Neither agree nor disagree | | Disagree | | Strongly disagree | |
|---|---|---|---|---|---|---|---|---|---|---|
| | I | C | I | C | I | C | I | C | I | C |
| 1. I used the CD(s) | 12 | 8 | 16 | 19 | 1 | 8 | 2 | 2 | 7 | 8 |
| 2. The information on the CD(s) was easy to understand | 16 | 18 | 14 | 18 | 2 | 2 | | | 1 | 0 |
| 3. I found the CD(s) easy to follow | 16 | 18 | 14 | 16 | 4 | 4 | | | 0 | 1 |
| 4. I did not have time to use the CD(s) | 3 | 6 | 4 | 3 | 5 | 8 | 11 | 16 | 11 | 9 |
| 5. I enjoyed using the CD(s) | 8 | 5 | 13 | 8 | 12 | 19 | 1 | 6 | 0 | 1 |
| 6. I would recommend using the CD(s) to a friend with a premature baby | 13 | 8 | 14 | 17 | 5 | 9 | 2 | 4 | 0 | 2 |

**Table 27: Use of CD-ROM responses by group**

| Question | Everyday | | Every other day | | Twice a week | | Once a week | | Once every month | | Every other month | | Once or twice | | Never | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | I | C | I | C | I | C | I | C | I | C | I | C | I | C | I | C |
| How often did you view the CD(s)? | | | 1 | 0 | 4 | 0 | 3 | 0 | 6 | 2 | 0 | 2 | 16 | 32 | 10 | 7 |
| How often did you follow the suggestions? | 10 | 11 | 5 | 3 | 5 | 5 | 1 | 0 | 0 | 2 | 1 | 1 | 5 | 7 | 3 | 3 |

Providing SMILES information to both groups meant that the evaluation could be sent to all without the need to reveal group allocation (masking), whilst providing information on differences in responses between the groups. Any differences could be explored to ascertain the use/helpfulness of the addition of the intervention information provided. The majority of the responses regarding the use of the CD-ROM were similar for the intervention and control group, however, there were some differences in responses between groups for enjoyed using the CD-ROM, with 45% (n=21) of the intervention group agreeing or strongly agreeing, whilst only 25% (n=13) of the control group agreed or strongly agreed with the statement.

Parents were also asked how often they viewed the CD-ROM or followed the suggestions. The majority of parents from the control group (62%; n=32) stated they had only viewed the CD-ROM once or twice, whilst around a third of the intervention group parents stated only viewing the CD-ROM once or twice (34%; n=16). There were some parents from both groups that stated they had never viewed the CD-ROM (10 from the intervention group and seven from the control group), however, as a booklet was also provided, it appears that some used this and followed the suggested activities, as despite 10 parents from the intervention group stating they had not viewed the CD-ROM, only three responded that they had not followed the suggested activities, and four of the seven control group suggested they had followed the suggestions. In relation to frequency of following the activities or interaction information,

Open questions were included in the evaluation survey to allow parents to identify what they thought was good about the CD-ROM/DVD, and what they liked least. There was also space provided for parents to make any other comments on the study.

To obtain additional feedback from the parents in the intervention arm, a sub-study was undertaken as part of an undergraduate medical student's dissertation.

### 4.9.3 Findings of parent interviews

This sub-study received positive responses from 13 of the parents, however, two participants were parents of twins, therefore the findings relate to 15 infants. The inclusion of twins was helpful in that the issues of undertaking the intervention with two infants could be explored. Adding the qualitative element allowed for feedback on both the use of the intervention, and can provide information on impact on parent-infant interaction.

The themes identified by Tobiss (2013) through both inductive and deductive methods were:

- Prompters and reasons for active engagement
- "you can kind of see what to do"
- "it's a good reference tool"
- Concerns around development

A key aspect for parental engagement with the intervention related to an appreciation that their infant would need additional help due to their prematurity. Incorporating footage of activities were therefore important as they provided "*example of things that possibly could help benefit the development of your premature baby" (Interviewee 2).* This

was especially useful in the early stages following discharge from hospital, when it appears that parents were more anxious about handling and caring for their preterm baby.

"*we had absolutely no idea what to do with her*" (interviewee 8)

In addition it was felt to prompt ideas of activities, and could be used with any infant to help interactions.

Despite many of the respondents engaging with the CD, there were parents who stated that they had watched the videos, and appeared to passively take in the information provided. The quote provided as an example of this by Tobiss (2013) is from a parent who had older children. This may be an area which could be explored further, as there may be differences between those who have children and those who are first time parents. In addition, it was noted that parents who felt their infants were developing as expected for their corrected age, also did not engage as actively. An example for this was provided by parent of twins *"because they were actually doing quite well we probably didn't worry about it so much"* (interviewee 9).

Tobiss (2013) suggests that parents were more engaged initially as a means of interacting with and aiding their infant's development, however, their engagement diminishes over time if their infant's development seemed to be going well.

A unique feature of HOP-ON were the videos of parents interacting and undertaking the activities with their infants, which appears to be an aspect of the intervention that appears popular with parents in the study. It was viewed as an effective way of learning and "*a good reference tool*" (interviewee 2) even when the interviewee had described it as "common sense". A sub-theme from the qualitative data related to others being able to view the information, this is a potential

strength of using multimedia as it provides opportunity to share the information with others.

Feedback from parents suggests that there is the potential to be effective on the secondary outcomes, as providing videos and images of activities were described as: "*made us feel confident*" (interviewee 8) and "*let you know…you're doing the right thing*" (interviewee 1).

## 4.10 Summary

This chapter covered the trial of the HOP-ON intervention and analysis of the primary and secondary outcomes, along with the evaluation. The main outcome measures did not show any significant differences between the intervention and control groups, however, there are several areas that require further exploration, and will be discussed in chapter five.

# Chapter five: Discussion

## 5.1 Introduction

This chapter explores the findings of the HOP-ON study and how they contribute to the current body of knowledge. The results of the systematic review, primary and secondary outcomes are explored and contextualised.

## 5.2 Main findings of the study

The findings for the primary outcome measures were not significant, therefore the primary hypothesis ($H^1$) that there would be a statistically significant difference between the motor score of the intervention and control group was unsupported. However, it is important to note that the providing the intervention did not result in any additional harm to the preterm infants or parents. One potential reason for this may relate to the sample size being too small, as the requirement for the power calculation was a minimum of 69 infants in each group, whereas there were 64 participant's data for the intervention group, and 73 for the control group. The method of analysis was designed to reduce the risk posed by missing data, therefore analysis was conducted on an intention to treat basis (White et al., 2011), and data imputed in SPSS. This allows for a value to be calculated for missing data, which were based on relevant characteristics, and to obtain a valid estimate a minimum of five iterations were conducted.

Our findings support previous studies where premature infants exhibit adverse neurodevelopment such as an increased risk of motor impairment (Guralnick, 2012), as they predominantly score below their full-term peers in developmental assessments (Davis et al., 2007,

Marlow et al., 2007, Allen, 2008b). The results show that both the intervention and control group scored below the norm referenced scores on the AIMS and Bayley III scales of development. Once the principle of intention to treat was undertaken and imputed data generated where missing, he mean for AIMS at 12 months for this study was 45.68 for the intervention group and 44.86 for the control group. For the Bayley III the mean motor composite score was 85.72 for the intervention group and 85.98 for the control group. The composite motor scores includes the fine and gross motor scale scores, which were similar for both of the groups, as were the cognitive, language and social items of the Bayley III. None of the scales assessed demonstrated a significant difference between the intervention and control groups. It should be noted that the majority of previous studies included in both chapter one and the systematic review of chapter two, mostly used second edition of Bayley, so issues of potential scoring problems and differences should be interpreted with caution.

The characteristics and demographics that have the potential to influence outcomes were collected and where possible used to stratify the randomisation following recruitment onto the study. This resulted in the baseline characteristics being similar across the intervention and control groups. Gender was equally spread across the intervention and control arms, as this was stratified to avoid any differences being due to a known confounding factor. Age and education level were not found to be dominant in this study. Maternal age has been identified as a risk factor, with young, or older mothers being at an increased risk of giving birth prematurely. The age range of mothers within the study was from 17 years to 45 years of age, although the majority in the sample were aged above 30 years of age. Therefore few of the participants were either classified as young mothers, or over 40 years of age (Stock and

Norman, 2010). In chapter one the risk factors for preterm birth were highlighted, which included socio-demographic characteristics.

The majority of parents had completed further or higher education, which may explain the slightly higher age range for the mothers. There were slightly more of the older mothers in the intervention group, and more twins in the control group.

Gestation for inclusion in the study <33 weeks, with the majority of the recruited infants being born between 28+0 and 32+6 weeks (very premature). Fewer infants recruited were extremely premature (<28 weeks gestation), which reflects the percentage of infants that fit into each category (extremely, very and preterm). Many previous studies highlight the impact of gestation, but do not always stratify based on this characteristic.

The loss to follow-up within the study was explored wherever possible, and the intervention group being lower than the power calculation estimated was problematic, but may be due to lack of engagement with the intervention activities. Those who did not respond to the assessment letter were less likely to have returned the questionnaires throughout the study. This may also reflect the amount of time a parent utilised the activities. During recruitment, one of the reasons given for not participating, were that they already had older children and so would be less likely to participate as timing an issue.

This study identified the need to provide interventions for premature infants which can be delivered by their parents/caregivers. It also highlighted the aspects which can influence the effectiveness in relation to identifying activities for helping motor skills (Hughes et al., 2016); and areas in which the overall study identified novel information in relation to parental stress.

The systematic review (Hughes et al., 2016) demonstrated how the main focus of an intervention is important, especially in regards to improvement in the early months following discharge from hospital. The meta-analysis found a significant difference between the motor scores at 3 months corrected age, when the intervention was focused on motor development, rather than a general developmental intervention (Hughes et al., 2016). The review also added to the available evidence on the need and effectiveness of interventions with preterm infants on motor development, which is still significant at around two years corrected age. The effectiveness appears to diminish over time, however, there is limited data beyond two years, particularly from programmes that are long term.

When designing the intervention, activities identified from the studies included in the systematic review where a significant improvement in motor skills had been demonstrated for infants in the intervention group were utilised. Other elements of effective interventions such as frequency and duration were explored and incorporated with specialist input into the design of the intervention. During development it was agreed that the advice provided should emphasise individuality of infant, therefore moving through the activities should be when the infant was physically ready, rather than at a set age. The rationale was to avoid potential pressure on the parents to move ahead too quickly. The advice would remind at each stage to only move on when their infant was ready. An age range was noted on the information, but the activities were not related to a particular age. In line with social learning theory, videos and images of real parents interacting and conducting the activities with their infant were presented, to allow for role modelling and provided evidence of ease of use of the activities.

Validity of the motor assessment scoring was increased by assessors undertaking appropriate training and the recordings of the assessments being checked and inter-rater reliability checked. This was conducted for both the Bayley III and AIMS assessments.

There are several factors that may have influenced the findings, the activities were aimed at fine and gross motor skills, although the timing of the intervention resulted in the activities focusing more on gross motor skills. The extended sections of the HOP-ON intervention has more fine motor activities due to covering later developmental stages. Therefore additional assessment times would be advantageous for long term effect. It may also have been beneficial to have assessments prior to 12 months ca, which could include basic assessment of reflexes and general movements following discharge from hospital as a baseline. Several previous studies conducted assessments at 6 months, which would be helpful, especially if assessment of parental stress is also conducted. This would allow both primary and secondary outcome measures to be explored given the cross-over of stress scores demonstrated in this study.

It is important to acknowledge that the primary and secondary outcomes, although appropriate for the intervention, are targeting different factors. The activities are providing opportunities for preterm infants to develop co-ordination and motor skills, whilst the guidance for parents aims to increase confidence in interacting with their infant, and reduce negative stereotyping (Majnemer, 2007b).

Gestation was considered within the randomisation process, however, parity was not, and it should be acknowledged as a potential issue which could impact on the time available to conduct the activities with their preterm infant. Limiting recruitment to primiparous women could

however, be problematic in relation to meeting power calculation targets, although it could be considered in subsequent studies.

The length of stay for preterm infants in NICU was considered in relation to recruitment, in that infants who were still in NICU at 3-4 months ca, would not be included. However, the range of time in NICU had quite a large range within the study, and intervention infants had slightly longer in NICU than the control group, suggests the need to categorise based on length of stay as a potential confounding factor.

A further factor which should be considered relates to any potential masking of differences by the control group having the SMILES programme. The rationale was to ensure that the motor activities were the only difference, rather than interactions, however, it would be beneficial to have a control group with usual care only in subsequent studies.

The low participation in the qualitative interviews must be acknowledged, as this may reflect only a sub-group of parents' views, although having additional qualitative data can enhance the rigour of the findings. In addition the evaluation showed that parents who used the HOP-ON information, overall found it helpful, although engagement with the intervention may have been less than required for it to have an impact on motor development. Several aspects could influence which could be clarified and updated in future studies. The format required participants to use a computer with a CD-ROM drive, or use of a DVD player which parents who participated in the evaluation interviews felt was helpful, and did allow sharing the information with others. However, given the changes in technology a CD-ROM format would limit the potential use. Given the importance placed on viewing the videos, the website version of the HOP-ON programme can counter issues with accessing CD or DVD drives. The website can be accessed on

smartphones, and potential for development into an app that can be downloaded. This would provide the opportunity to gather data on frequency of use, which was difficult within the current study to obtain. Diaries were considered as a means of obtaining data on exposure and frequency of activities, but were felt as too time consuming for parents.

The introduction screen of the HOP-ON programme highlights that "all infants are different and will develop at different speeds", however, in the evaluation sub-study, Tobiss (2013) states that some parents were concerned if their infant was having difficulties. Therefore suggests that this needs to be reiterated throughout the programme, and incorporated into the voiceovers provided.

In terms of the secondary outcomes, parental stress levels were higher for the intervention group at 3-4 months, which is similar to previous research findings (Glazebrook et al., 2007b). However, at the 12 month time point, the control group demonstrated higher stress levels. The implication for a parent intervention effect at 12 months needs further exploration. Recommendations based on the findings will be highlighted in chapter six.

# Chapter six: Conclusion and Recommendations

The HOP-ON intervention in this initial study did not find a significant improvement in motor skills of the preterm infants, although no evidence that infants were further impaired through participation was found.

The findings of the systematic review (Hughes et al., 2016) suggest that interventions can have an impact on the motor development of preterm infants with strongest effects noted before 6 months of age. Interventions are more likely to demonstrate a positive effect if they are continued beyond the initial hospital period for the infant and involve the parent or guardian. Stage appropriate activities were identified for the first six months and some additional activities for around 6-12 months corrected age. However, it has also identified the need for further research with preterm infants, and recommends developing longer-term interventions, incorporating motor activities that involve the parent/carer and at least yearly follow-up of outcomes. This would help in identifying effective intervention activities that could be used with children, especially those at risk of Developmental Co-ordination Disorder (DCD).

## 6.1 Strengths and Limitations

Each element of the study identified novel evidence or areas that require further exploration. The design of the intervention incorporated a systematic review with meta-analysis and focus group discussions with participants who had a variety of specialisms related to premature infants.

A limitation when assessing the use of the intervention related to the amount of detail available on actually level of engagement with the activities. However, the findings confirm the need for providing parents with activities that are appropriate for a preterm infant, as these have the potential to both improve the infant's motor skills and increase parent's confidence in handling and interacting with their premature infant. It is particularly helpful to include videos of parents demonstrating the activities. A limitation of the intervention was highlighted in feedback on the intervention, that more guidance on frequency and duration of use would be helpful. The guidance provided suggested that parents attempted activities in frequent but short durations, and to be guided by the infant.

A strength in the design of the intervention was incorporating research evidence, clinical and personal experiences of interacting with preterm infants. All activities were checked with the relevant healthcare professionals including, physiotherapists, occupational therapists and neonatologists. Feedback from the parents provided evidence of the use of the intervention and parents identified the need for this information.

## 6.2 Recommendations

Evaluation of the intervention found that parents, especially in the first few months described the activities as helpful and a means of reducing anxiety. Include more guidance for use of the HOP-ON programme, in relation to frequency and duration.

Advances in technology, especially smartphones and the increase in usage of these, would help increase the potential use of HOP-ON via the website or app and provide the potential to obtain follow-up of use. There is also a need for on-going activities and advice, along with longer follow-up given the implications for impairment.

### 6.2.1 Practice implications

Premature infants undergo regular health and development check-ups, therefore the HOP-ON programme information could be easily distributed and the ongoing impact assessed via audit.

### 6.2.2 Research implications

The main areas for further research are:

- Assessment with preterm and late preterm infants
- Add trial data to meta-analysis.
- More sensitive scale – items identified and elements of asymmetry

The initial work has been undertaken and the intervention has not been shown to be detrimental, and parents found it helpful. Therefore it is possible to build on and explore the benefits in more detail.

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# Appendices

## Appendix 1: Database search records

### A 1: AMED database – Search record

| Item | Searches | Results |
|---|---|---|
| S1 | premature infant*.mp. **or** Infant premature/ | 146 |
| S2 | preterm.mp. | 204 |
| S3 | prematurity.mp. | 25 |
| S4 | S1 **or** S2 **or** S3 | 284 |
| S5 | motor development.mp. | 223 |
| S6 | motor skill* | 1076 |
| S7 | Motor activity | 1272 |
| S8 | Motor performance.mp | 486 |
| S9 | Movement | 4664 |
| S10 | S5 **or** S6 **or** S7 **or** S8 **or** S9 | 7208 |
| S11 | Randomized controlled trial*/ **or** randomised controlled trial.mp | 2199 |
| S12 | Controlled trial* | 3338 |
| S13 | Trial* | 8451 |
| S14 | Comparative study | 4749 |
| S15 | Intervention study | 266 |
| S16 | S11 **or** S12 **or** S13 **or** S14 **or** S15 | 13827 |
| S17 | S4 **and** S10 | 66 |
| S18 | S16 **and** S17 | **9** |

mp = searched as keywords, where there is no .mp suffix, the term was a subject heading.

1. **A 2: CINAHL database – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | (MH "infant premature") **or** "premature Infant" | 14,414 |
| S2 | "preterm" | 14,089 |
| S3 | "prematurity" | 3,507 |
| S4 | S1 **or** S2 **or** S3 | 23,695 |
| S5 | "motor development" | 738 |
| S6 | (MH "motor skills") | 6,435 |
| S7 | (MH "Motor activity") | 8,131 |
| S8 | "Motor performance" | 1,082 |
| S9 | (MH "Movement") | 9.079 |
| S10 | S5 **or** S6 **or** S7 **or** S8 **or** S9 | 23,697 |
| S11 | (MH "Randomized controlled trials") **or** "randomised controlled trial" | 40,252 |
| S12 | "Controlled trial" | 29,113 |
| S13 | (MH "intervention trials") **or** "Trial" | 98,018 |
| S14 | (MH "Comparative studies") | 80,449 |
| S15 | S11 **or** S12 **or** S13 **or** S14 | 191,349 |
| S16 | S4 **and** S10 | 407 |
| S17 | S15 **and** S16 | **62** |

MH=Subject heading within the database.

Terms which are not prefixed with MH were searched as keywords

**A 3: Cochrane library: Trials – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "infant premature" | 1,133 |
| S2 | "preterm" **or** "prematurity" | 4,367 |
| S3 | S1 **or** S2 | 5,014 |
| S4 | "motor development" **or** "motor skills" | 1,364 |
| S5 | "motor performance" **or** "motor activity" | 3,924 |
| S6 | "movement" | 10,374 |
| S7 | S4 **or** S5 **or** S6 | 10,095 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" | 36,204 |
| S9 | "Controlled trial" **or** "trial" | 184,210 |
| S10 | "intervention study" **or** "Comparative study" | 6,100 |
| S11 | S8 **or** S9 **or** S10 | 189,010 |
| S12 | S3 **and** S7 | 178 |
| S13 | S11 **and** S12 | **78** |

**A 4: EMBASE – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "(premature infant" **or** "Prematurity").ab. | 18,071 |
| S2 | ("infant premature" **or** "preterm").ab. | 56,094 |
| S3 | S1 or S2 | 69,181 |
| S4 | "motor development" **or** "Motor activity" | 15,457 |
| S5 | "motor skills.mp" **or** motor performance | 11,461 |
| S6 | "Movement" | 178,334 |
| S7 | S4 **or** S5 **or** S6 | 201,333 |
| S8 | "Randomized controlled trials" **or** ("randomised controlled trial")* | 43,178 |
| S9 | "Controlled trial" **or** "trial" | 427,844 |
| S10 | "Comparative study" **or** "intervention study" | 29,719 |
| S11 | S8 **or** S9 **or** S10 | 456,166 |
| S12 | S3 **and** S7 | 1,094 |
| S13 | S11 **and** S12 | **62** |

MH=searched as keywords, where there is no .mp suffix, the term was a subject heading.

When the terms were searched as keyword, a high number of studies (n=786) were returned. The titles of these were checked and less than 10% were relevant. Above displays the later run of the terms using a streamlined approach, by selecting searching for the terms in the abstract.

**A 5: ERIC – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" | 747 |
| S2 | "infant premature" | 747 |
| S3 | "preterm.mp" | 407 |
| S4 | "prematurity" | 144 |
| S5 | S1 **or** S2 **or** S3 **or** S4 | 888 |
| S6 | "motor development" | 3,327 |
| S7 | "motor skills" | 3,489 |
| S8 | "motor performance" | 708 |
| S9 | "Motor activity" | 743 |
| S10 | "Movement" | 26,703 |
| S11 | S6 **or** S7 **or** S8 **or** S9 **or** S10 | 32,288 |
| S12 | "Randomised controlled trial" | 94 |
| S13 | "randomized controlled trials" | 1,009 |
| S14 | "Controlled trial" | 1,286 |
| S15 | "intervention trial.mp" **or** "intervention study" | 3,816 |
| S16 | "Comparative study" | 5,492 |
| S17 | "trial.mp" | 10,629 |
| S18 | S12 **or** S13 **or** S14 **or** S15 **or** S16 **or** S17 | 19,598 |
| S19 | S5 **and** S11 | 84 |
| S20 | S18 **and** S19 | **6** |

**A 6: Maternity and Infant Care – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant.mp" | 639 |
| S2 | "infant premature.mp" | 7.968 |
| S3 | "preterm.mp" | 18,871 |
| S4 | "prematurity.mp" | 3,575 |
| S5 | S1 **or** S2 **or** S3 **or** S4 | 24,102 |
| S6 | "motor development.mp" | 318 |
| S7 | "motor skills.mp" | 349 |
| S8 | "motor performance.mp" | 70 |
| S9 | "Motor activity.mp" | 87 |
| S10 | "Movement.mp" | 1,426 |
| S11 | S6 **or** S7 **or** S8 **or** S9 **or** S10 | 1,995 |
| S12 | "Randomised controlled trial.mp" | 1,485 |
| S13 | "randomized controlled trials.mp" | 1,867 |
| S14 | "Controlled trial.mp" | 4,030 |
| S15 | "intervention study.mp" | 195 |
| S16 | "Comparative study.mp" | 507 |
| S17 | "trial.mp" | 10,297 |
| S18 | S12 **or** S13 **or** S14 **or** S15 **or** S16 **or** S17 | 10,939 |
| S19 | S5 **and** S11 | 380 |
| S20 | S18 **and** S19 | **32** |

.mp = searched as keywords, where there is no .mp suffix, the term was a subject heading.

**A 7: Medline Ovid – Search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant.mp" **or** Infant premature | 43,812 |
| S2 | "preterm.mp" | 44,197 |
| S3 | "prematurity.mp" | 15,496 |
| S4 | S1 **or** S2 **or** S3 | 79,580 |
| S5 | "Motor Activity" **or** "Motor Skills" **or** "motor development.mp" | 100,463 |
| S6 | "Movement" **or** "motor performance.mp" | 63,146 |
| S7 | S5 **or** S6 | 137,982 |
| S8 | "Randomised controlled trial.mp" | 10,499 |
| S9 | "Randomized controlled trials" | 390,517 |
| S10 | "Controlled trial.mp" | 406,046 |
| S11 | "intervention studies" | 7,523 |
| S12 | "Comparative study" | 1,699,300 |
| S13 | "trial.mp" | 862,946 |
| S14 | S8 **or** S9 **or** S10 **or** S11 **or** S12 **or** S13 | 2,363,431 |
| S15 | S4 **and** S7 | 1,033 |
| S16 | S14 **and** S15 | **247** |

.mp = searched as keywords, where there is no .mp suffix,

the term was a subject heading.

**A 8: PEDro – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | Premature Infant OR Preterm infant | 99 |
| S2 | Motor development OR skills | 223 |
| S3 | Randomised controlled trial | 2,162 |
| S4 | **#S1 AND #S2** | **29** |
| S5 | **#S1 AND #S2 AND #S3** | **1** |

The search facility of the PEDro database meant that the search strategy was adapted to ensure that any relevant studies were identified. The search that combined premature/preterm infant and motor development/skills (S4; N=29) was assessed as when combined with study design, only one study was returned.

**A 9: ProQuest – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | ab(premature infant*) **or** ab(Infant premature) | 19,444 |
| S2 | ab(preterm) | 29,405 |
| S3 | ab(prematurity) | 13,854 |
| S4 | S1 **or** S2 **or** S3 | 55,750 |
| S5 | ab(motor development) | 63,589 |
| S6 | ab(motor skill*) | 20,701 |
| S7 | ab(Motor activity*) | 91,874 |
| S8 | ab(Motor performance) | 76,776 |
| S9 | ab(Movement) | 929,140 |
| S10 | S5 **or** S6 **or** S7 **or** S8 **or** S9 | 1,106,289 |
| S11 | ab(Randomized controlled trial*) **or** ab(randomised controlled trial) | 164,345 |
| S12 | ab(Controlled trial*) | 218,312 |
| S13 | ab(Comparative study) | 57,623 |
| S14 | ab(Intervention study) | 118,910 |
| S15 | S11 **or** S12 **or** S13 **or** S14 | 317,883 |
| S16 | S4 **and** S10 | 2,107 |
| S17 | S15 **and** S16 | **71** |

The ProQuest database consists of 37 separate databases, therefore the limiter of abstract was utilised. In addition duplications are included in the initial searches, but are removed when terms are combined.

**A 10: PsycInfo – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant.mp" | 339 |
| S2 | "Infant premature.mp" | 24 |
| S3 | "preterm.mp" | 4,805 |
| S4 | "prematurity.mp" | 1,337 |
| S5 | S1 **or** S2 **or** S3 **or** S4 | 5,898 |
| S6 | exp "motor development" | 7,455 |
| S7 | exp "motor skills" | 3,456 |
| S8 | exp "motor performance" **or** "motor activity.mp" | 20,147 |
| S9 | "movement.mp" | 82,243 |
| S10 | S6 **or** S7 **or** S8 **or** S9 | 107,236 |
| S11 | "Randomised controlled trial.mp" | 1,980 |
| S12 | "Randomized controlled trial.mp" | 9,668 |
| S13 | "Controlled trial.mp" | 15,238 |
| S14 | "intervention study" | 1,961 |
| S15 | "Comparative study.mp" | 10,148 |
| S16 | "trial.mp" | 75,633 |
| S17 | S11 **or** S12 **or** S13 **or** S14 **or** S15 **or** S16 | 87,447 |
| S18 | S5 **and** S10 | 445 |
| S19 | S14 **and** S15 | **19** |

.mp = searched as keywords, where there is no .mp suffix,

the term was a subject heading.

**A 11: Pubmed – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "infant premature" | 3948 |
| S2 | "preterm" **or** "prematurity" | 59,395 |
| S3 | S1 **or** S2 | 62,598 |
| S4 | "motor development" **or** "motor skills" | 6,066 |
| S5 | "motor performance" **or** "motor activity" | 17,977 |
| S6 | "movement" | 167,765 |
| S7 | S4 **or** S5 **or** S6 | 188,539 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" | 44,795 |
| S9 | "Controlled trial" **or** "trial" | 388,234 |
| S10 | "intervention study" **or** "Comparative study" | 66,813 |
| S11 | S8 **or** S9 **or** S10 | 452,396 |
| S12 | S3 **and** S7 | 878 |
| S13 | S11 **and** S12 | **54** |

Search in Title or Abstract

**A 12: Science direct – nursing and health professions – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "Infant premature" | 387 |
| S2 | "preterm" **or** "prematurity" | 890 |
| S3 | S1 **or** S2 | 1,121 |
| S4 | "motor development" **or** "motor skills" | 546 |
| S5 | "motor activity" **or** "motor performance" | 819 |
| S6 | "movement" | 3,351 |
| S7 | S4 **or** S5 **or** S6 | 4,258 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" | 5,047 |
| S9 | "intervention study" **or** "comparative study" | 11,320 |
| S10 | "Controlled trial" **or** "trial" | 12,329 |
| S11 | S8 **or** S9 **or** S10 | 21,287 |
| S12 | S3 **and** S11 | 54 |
| S13 | S11 **and** S12 | **13** |

*Search selected for abstract, title or keywords

**A 13: SCOPUS – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "infant premature" | 15,531 |
| S2 | "preterm" **or** "prematurity" | 53,257 |
| S3 | S1 **or** S2 | 63,723 |
| S4 | "motor development" **or** "motor skills" | 21,807 |
| S5 | "motor performance" **or** "motor activity" | 40,389 |
| S6 | "movement" | 152,356 |
| S7 | S4 **or** S5 **or** S6 | 197,445 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" | 118,339 |
| S9 | "Controlled trial" **or** "trial" | 540,161 |
| S10 | "intervention study" **or** "Comparative study" | 365,743 |
| S11 | S8 **or** S9 **or** S10 | 841,269 |
| S12 | S3 **and** S7 | 1,806 |
| S13 | S11 **and** S12 | **234** |

**A 14: Web of Science /Knowledge with "Title" limiter selected – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "infant premature" - Title | 6,362 |
| S2 | "preterm" **or** "prematurity" - Title | 31,998 |
| S3 | S1 **or** S2 | 38,219 |
| S4 | "motor development" **or** "motor skills" - Title | 4,654 |
| S5 | "motor performance" **or** "motor activity" - Title | 8,987 |
| S6 | "movement" - Title | 104,617 |
| S7 | S4 **or** S5 **or** S6 | 117,472 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" - Title | 54,426 |
| S9 | "Controlled trial" **or** "trial" - Title | 248,611 |
| S10 | "intervention study" **or** "Comparative study" - Title | 96,308 |
| S11 | S8 **or** S9 **or** S10 | 343,758 |
| S12 | S3 **and** S7 | 228 |
| S13 | S11 **and** S12 | **5** |

The initial search of the Web of Science/Web of Knowledge selected the "Title" limiter however, when the terms were combined the returns were low. Therefore an additional search was conducted using "Topic" in place of "Title" as the limiter.

**A 15: Web of Science /Knowledge with "Topic" limiter selected – search record**

| Item | Searches | Results |
|---|---|---|
| S1 | "premature infant" **or** "infant premature" - Topic | 24,033 |
| S2 | "preterm" **or** "prematurity" - Topic | 72,271 |
| S3 | S1 **or** S2 | 83,164 |
| S4 | "motor development" **or** "motor skills" - Topic | 46,949 |
| S5 | "motor performance" **or** "motor activity" - Topic | 109,669 |
| S6 | "movement" - Topic | 442,788 |
| S7 | S4 **or** S5 **or** S6 | 553,430 |
| S8 | "Randomised controlled trial" **or** "Randomized controlled trial" - Topic | 275,293 |
| S9 | "Controlled trial" **or** "trial" - Topic | 1,084,491 |
| S10 | "intervention study" **or** "Comparative study" - Topic | 571,556 |
| S11 | S8 **or** S9 **or** S10 | 1,547,328 |
| S12 | S3 **and** S7 | 2,686 |
| S13 | S11 **and** S12 | **488** |

**A 16: Grey Literature search terms – search record**

| Database | Item | Terms | Hits | Relevant | Duplication |
|---|---|---|---|---|---|
| **OpenGrey** | 1 | Premature infant*<br>OR<br>Preterm | 62 | 1 | 1 |
| | 2 | Motor Development<br>AND<br>Preterm | 3 | 0 | |
| | 3 | Motor<br>AND<br>Preterm | 5 | 1 | 1 |
| **EThOS** | 1 | Premature infants<br>OR<br>Preterm | 90 | **1** | |
| | 2 | Motor Development<br>AND<br>Preterm | 4 | 0 | |
| | 3 | Motor<br>AND<br>Preterm | 5 | 0 | |

**Appendix 2: Initial HOP-ON storyboard**

### A 17: Initial storyboard for focus group discussion – Introduction to intervention

| HOP-ON Sections | Visuals/Exercises/Videos | Aim/References |
|---|---|---|
| Introduction | Welcome page with basic use information and any primary choices (as with Smiles, boy; girl; twins or other) | Simple introduction to DVD use. What is expected so that parents know how much time they need and/or what the DVD involves. |
| This level is a Q & A format with a linear line of up to 5 Questions with a false/true option which activates a response with information.<br><br>There will be two key topics (sensory and Movement) with a third tab sign posting putting it together.<br><br>• Sensory Input – delineated into touch; sound and vision<br>• Movement Input – possible dialogue with developmental stages NOT in definitive chronology from birth.<br>• Putting it together – here are some examples of other parents putting these ideas into practice with their premature baby. These video clips will be in three sections.<br>i) Finding My Feet – supine, sensory input to feet, feet to hands, etc<br>ii) Tummy Time – prone, tracking<br>Turning Play – rolling activities, vestibular input | Text required for the Q & A's which informs about sensory input including different textures, pressures; looking, fixing and building up to tracking within eye movement range and sound including time for baby to make sounds or baby takes the lead. The movement section would inform about progressive positions/stages preparing for ultimately walking. For example, when baby is practicing moving their head this is the beginning of the skills for walking. Before baby can sit they practice controlling their head and bodies in different lying positions. When baby is ready with these skills they will practice the early skills for changing position like rolling. Once they have become confident with these skills and what they feel like they will be ready practice their existing skills and develop new ones sitting upright. Finally they will be ready to get up off the floor and to practice their first steps. | To advise/inform/affirm parental knowledge/confidence. |

**A 18: Initial storyboard for focus group discussion – "finding my feet" activities**

| HOP-ON Sections | Visuals/Exercises/Videos | Aim/References |
|---|---|---|
| **Finding My Feet video component** | Video no longer than 4 mins of parent/s playing with baby in prone.<br>If possible two examples one with early skills and one showing some level of development with the activities?<br>To include;<br>• Position of ease for baby with rolled towel or cushions to bring shoulders and bottom upward (curled).<br>• Parent posture is important here as this is often done a flat surface with parent bent over. Use the bed to give a soft surface to knees. Use long sitting or try fully supported crook sitting (slightly reclined in a sofa of full arm chair, or on a bed against the wall).<br>• Use a variety of textured objects/toys to 'tickle' babies' feet, apply different levels of pressure.<br>• Encourage legs and feet to be mobile (kicking). Progress with helping baby to touch one foot with their hands, mouth. Vary right to right; left to left and opposites.<br>• Encourage hands to explore body, hand to face, head, ears, shoulder, knee and foot. Vary right and left. Mimic babies sounds in turn and name 'your feet', ' your eyes' etc<br>• Progress by reducing the support for example no towel or cushion, if baby can lift feet up without then do not use towel or cushion but let them practice movements without.<br>• Play with objects - toys so that babys' eye movement range can follow the object/toy. Help them to reach and touch the object/toy. Progress with the range they track the object for so that head turning is encouraged. Later, as baby's head turns fully help their shoulders to follow so that they begin to turn their shoulders and bodies towards each side. | These activities are aiming for ;<br>• Babies sensory motor development with proprioceptive input, joint receptor and tactile stimulation.<br>• Parental confidence with interaction and handling skills<br>• Early disassociation of individual limbs and body parts.<br>• Baby's awareness of self<br><br>Bly, Lois Acquisition of motor skills Therapy Skills Builders.<br><br>Shumway-Cook and Woollacott Motor Control theory and practical applications 2Ed chapter 8.<br><br>Lekskulchai and Cole 2001<br><br>Cameron et al 2005 |

**A 19: Initial storyboard for focus group discussion – "Tummy time" activities**

| HOP-ON Sections | Visuals/Exercises/Videos | Aim/References |
|---|---|---|
| **Tummy Time video component.** | Video no longer than 4 mins of parent/s playing with baby in prone.<br><br>If possible two examples one with early skills and one showing some level of development with the activities?<br>To include;<br><br>• Parent helping baby to avoid lifting their bottom up and having lower limbs flexing underneath them. They should have legs go straight and bottom to be down.<br>• Baby with a roll/towel/soft toy under their armpits to assist lifting shoulders up and thus helping head and arms to be active.<br>• Can be done baby lying chest to chest with parent (parent lying on their backs supported on bed or sofa).<br>• Can be done on a bed with parent comfortably sitting on the floor providing eye to eye contact.<br>• Develop with brushing one arm with toy or different texture; baby may begin to look at object, progress with small movements of toy so that baby moves eyes to follow. Later the toy may move to the side and travel in a 90 degree arc while baby follows it.<br>• Encourage baby to lift head up, developing head on neck and neck on trunk extension (head control). Develop with stimulation (noise, textural stroking or toy movement) to promote bay to turn head to the side (both sides). Progress with activities so that baby is lifting head, turning it and pushing up on arms (can be bent or straight). | These activities are aiming at;<br><br>• Head control<br>• Early eye co-ordination<br>• Early spatial awareness<br>• General extension muscle activity<br>• Early righting reactions with the turning.<br><br>Bly, Lois Acquisition of motor skills Therapy Skills Builders.<br><br>Shumway-Cook and Woollacott Motor Control theory and practical applications 2Ed chapter 8.<br><br>Lekskulchai and Cole 2001<br><br>Cameron et al 2005 |

**A 20: Initial storyboard for focus group discussion – "Turning play" activities**

| HOP-ON Sections | Visuals/Exercises/Videos | Aim/References |
|---|---|---|
| **Turning Play video component**. | Video no longer than 4 mins of parent/s playing with baby in prone.<br>If possible two examples one with early skills and one showing some level of development with the activities?<br>To include;<br>• Carrying or holding baby fully supported with their sides parallel to the floor.<br>• With parent in long sitting on a low seat baby can lay on their lap and be gently rolled up or down the slope of their legs. Begin with rocking movements and not a full roll. As baby responds with some head control to turn with the movement progress to a full roll over.<br>• Later with parent in either sitting or standing baby can be in-side lying fully supported by parents' arms and hands, then moved slowly at first like the big hand of a clock upward to an upright posture and over to side lying on the other side. Progress by letting or helping babies right and left leg to be in different posture i.e. one straight and one bent. | These activities are aiming at;<br>• Progressing head control<br>• Righting reactions<br>• Spatial awareness<br>• Vestibular development/integration<br><br>Bly, Lois Acquisition of motor skills Therapy Skills Builders.<br><br>Shumway-Cook and Woollacott Motor Control theory and practical applications 2Ed chapter 8.<br><br>Lekskulchai and Cole 2001<br><br>Cameron et al 2005 |

## Appendix 3: Data Collection Tool from medical notes

HOP-ON

Nottingham University Hospitals NHS

action medical research for children, for life

Derby Hospitals NHS

The University of Nottingham

University Hospitals of Leicester NHS

**Title: Helping Our Premature infants ON to better motor skills**

**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Ms Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

**Local Study Team:** Dr Helen Budge, Nottingham University Hospitals
Dr Joe Fawke, University Hospitals of Leicester NHS Trust
Dr John McIntyre, Derby Hospitals NHS Foundation Trust

### Data from Medical Notes

Participant ID: Infant's date of birth: / / Infant's gender: Male/Female

Congenital Anomaly detected: Yes ☐ what type? ..... No ☐

Gestation at birth: ☐ Weight at birth: ☐ Head circumference at birth: ☐

APGAR at 1 min: ☐ APGAR at 5 mins: ☐

Days ventilated: ☐ Days on Oxygen: ☐

Days in Intensive Care/ Level 1 Care: ☐ Days in Intensive Care/Level 2 Care: ☐

Days in Intensive Care/Level 3 Care: ☐ Oxygen Dependency at 36/40: Yes ☐ No ☐

**Feeding**

Date first given milk: ☐ Date 150ml per kg per day: ☐

Type of milk first started:
EBM ☐
PT Formula ☐
Other ☐ .....

Feeding milk at discharge:
Breast/ EBM ☐
PT Follow on Formula ☐
Other ☐ .....

Route of feeding at discharge:
ng/ og/ gastrostomy ☐
Oral (breast/ bottle/ cup) ☐
mixed ☐

Necrotising enterocolitis:
None ☐
High Suspicion ☐
Clinical diagnosis (inc x ray) ☐
Surgical diagnosis ☐

Treated as Necrotising enterocolitis (e.g 5-10 days NBM/antibiotics): Yes ☐ No ☐

Surgical Procedures:
Abdominal (IP) drain ☐
Laparotomy for NEC ☐
Laparatomy for perforation without NEC ☐
Intestinal resection ☐
Stoma ☐
Inguinal hernia repair ☐
Ventrido-peritoneal shunt ☐
Rickman reservoir ☐
Other surgical procedures ..... ☐
None of the above ☐

**Infection**

Positive blood culture at any stage: Yes ☐ No ☐

Positive CSF culture at any stage: Yes ☐ No ☐

Treated for Meningitis at any stage: Yes ☐ No ☐ (2+/52 antibiotics)

**Neurology**

Fits:
None ☐
Brief ☐
Within first 24h ☐
After first 24h ☐
At discharge ☐

Clinical diagnosis ☐
Neurophysiology (CFM/ECG) ☐
Both ☐

Treated seizures: Yes ☐ No ☐

Encephalopathy:
None ☐
Sarnat Stage 1 ☐
Sarnat Stage 2 ☐
Sarnat Stage 3 ☐
Non-hypoxic cause ☐

Other neurological abnormality: ☐

## Appendix 4: IRAS form

**Welcome to the Integrated Research Application System**

**IRAS Project Filter**

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

**Please enter a short title for this project** (maximum 70 characters)
Helping our premature infants on to better motor skills (HOP-ON)

**1. Is your project research?**

(•) Yes ( ) No

**2. Select one category from the list below:**

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
(•) Other clinical trial or clinical investigation
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
( ) Research tissue bank
( ) Research database

**If your work does not fit any of these categories, select the option below:**

( ) Other study

**2a. Please answer the following question(s):**

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

**3. In which countries of the UK will the research sites be located?** *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

**3a. In which country of the UK will the lead NHS R&D office be located:**

(•) England
( ) Scotland



( ) Wales
( ) Northern Ireland
( ) This study does not involve the NHS

**4. Which review bodies are you applying to?**

[x] NHS/HSC Research and Development offices
[ ] Social Care Research Ethics Committee
[x] Research Ethics Committee
[ ] National Information Governance Board for Health and Social Care (NIGB)
[ ] Ministry of Justice (MoJ)

**5. Will any research sites in this study be NHS organisations?**

(•) Yes ( ) No

**5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?**

( ) Yes (•) No

*If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.*

**6. Do you plan to include any participants who are children?**

(•) Yes ( ) No

**7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** *The guidance notes explain how an adult is defined for this purpose.*

( ) Yes (•) No

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?**

( ) Yes (•) No

**9. Is the study, or any part of the study, being undertaken as an educational project?**

(•) Yes ( ) No

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

(•) Yes ( ) No

**10. Is this project financially supported by the United States Department for Health and Human Services?**

( ) Yes (•) No

**11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?**

( ) Yes (•) No

**Integrated Research Application System**
**Application Form for Other clinical trial or investigation**

National Patient Safety Agency
National Research Ethics Service

**Application to NHS/HSC Research Ethics Committee**

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

**Short title and version number:** (maximum 70 characters - this will be inserted as header on all forms)
Helping our premature infants on to better motor skills (HOP-ON)

*Please complete these details after you have booked the REC application for review.*

**REC Name:**
Nottingham 1

**REC Reference Number:**
10/H0403/35

**Submission date:**
25/03/2010

## PART A: Core study information

### 1. ADMINISTRATIVE DETAILS

**A1. Full title of the research:**

Development and evaluation of a parenting intervention to promote development in infants born very premature

**A2-1. Give details of the educational course or degree for which this research is being undertaken:**

Name and level of course/ degree:
PhD

Name of educational establishment:
University of Nottingham

Name and contact details of academic supervisor:

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Professor | Cris | Glazebrook |
| Address | Room S/A 1909 A Floor, South Block | | |
| | Division of Psychiatry, Medical Sch | | |
| | QMC, Nottingham | | |
| Post Code | NG7 2UH | | |
| E-mail | cris.grazebrook@nottingham.ac.uk | | |



| | |
|---|---|
| Telephone | 0115 823 0420 |
| Fax | 0115 823 0433 |

Name and contact details of student:

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mrs | Anita J | Hughes |
| Address | Academic Division of Midwifery | | |
| | QMC, B Floor, East Block | | |
| | Nottingham | | |
| Post Code | NG7 2UH | | |
| E-mail | anita.hughes@nottingham.ac.uk | | |
| Telephone | 01158230986 | | |
| Fax | 01158231207 | | |

*A copy of a current CV for the student (maximum 2 pages of A4) must be submitted with the application.*

**A2-2. Who will act as Chief Investigator for this study?**

- ○ Student
- ◉ Academic supervisor
- ○ Other

**A3-1. Chief Investigator:**

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Professor | Cris | Glazebrook |
| Post | Professor of Health Psychology | | |
| Qualifications | | | |
| Employer | University of Nottingham | | |
| Work Address | Room S/A 1909 A Floor, South Block | | |
| | Division of Psychiatry, Medical Sch | | |
| | QMC, Nottingham | | |
| Post Code | NG7 2UH | | |
| Work E-mail | cris.grazebrook@nottingham.ac.uk | | |
| * Personal E-mail | cris.grazebrook@nottingham.ac.uk | | |
| Work Telephone | 0115 823 0420 | | |
| * Personal Telephone/Mobile | | | |
| Fax | 0115 823 0433 | | |

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
*A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.*

**A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?**
*This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.*

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mr | Paul | Cartledge |
| Address | Research Innovations Service | | |

| | |
|---|---|
| | King's Meadow Campus, Lenton Lane |
| | Nottingham |
| Post Code | NG7 2NR |
| E-mail | paul.cartledge@nottingham.ac.uk |
| Telephone | 01159515679 |
| Fax | |


**A5-1. Research reference numbers.** *Please give any relevant references for your study:*

| | |
|---|---|
| Applicant's/organisation's own reference number, e.g. R & D (if available): | |
| Sponsor's/protocol number: | 10027 |
| Protocol Version: | 1.3 |
| Protocol Date: | 19/03/2010 |
| Funder's reference number: | AP1224 |
| International Standard Randomised Controlled Trial Number (ISRCTN): | |
| ClinicalTrials.gov identifier (NCT number): | |
| European Clinical Trials Database (EudraCT) number: | |
| Project website: | |

| Ref.Number Description | Reference Number |
|---|---|

**A5-2. Is this application linked to a previous study or another current application?**

○ Yes ◉ No

*Please give brief details and reference numbers.*

## 2. OVERVIEW OF THE RESEARCH

***To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.***

**A6-1. Summary of the study.** *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*


Infants born very premature have biological risk factors for later developmental coordination disorder. Parental stereotyping of infants as fragile and other environmental factors, such as spending long periods laying on their backs, also contribute to motor delay. This study aims to develop and evaluate a computer-based intervention (Helping Our Premature Infants ON to better motor skills – HOP-ON) for parents of preterm infants. HOP-ON will model evidence based strategies to develop infants' fine and motor skills, and aims to reduce parental stereotyping. It is hypothesised that infants whose parents receive the HOP-ON CD-ROM and DVD will have better motor skills at 12 months adjusted age compared to those whose parents receive a control CD-ROM and DVD. Parents of infants born at less than 32 weeks gestation (target n = 138) will be recruited prior to discharge from the neonatal unit and randomised to either HOP-ON or control. The primary outcome is motor score (Bayleys III) at 12 months adjusted age. Other outcomes are parental confidence and perceptions of infant capability at 3 months and quality of movement, infant growth, fine and gross motor movement and parenting stress at 12 months. Data will be analysed blind to study condition and on an intention to treat basis.


**A6-2. Summary of main issues.** *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

Ethical considerations have been given to all aspects of the study, especially in regards to recruitment. Firstly, posters will be displayed within the neonatal units, and only those infants who are well enough to have been recently discharged from hospital, or likely to be in the following two weeks would be given information regarding the study.

Although the design is a randomised controlled trial, the control group will also be given information in regards to their interacting with their premature infant.

**A10. What is the principal research question/objective?** *Please put this in language comprehensible to a lay person.*

Develop and evaluate a multimedia intervention to promote motor skills in very preterm infants.

**A11. What are the secondary research questions/objectives if applicable?** *Please put this in language comprehensible to a lay person.*

Develop and validate a short tool to assess quality of movement to compliment Bayley's validated scale.

**A12. What is the scientific justification for the research?** *Please put this in language comprehensible to a lay person.*

Very preterm children, born at less than 32 week gestation, are at significantly increased risk for impaired motor development compared with their term peers. This results in a high prevalence of survivors with persistent mild neuromotor dysfunction and poor motor skills [1, 2]. Deficits in motor planning, sensory-motor integration, speed and quality of movement, gross motor skills such as balance and ball skills, and fine motor skills such as manual dexterity and visuo-spatial abilities have been widely documented. These are evident in infancy [3, 4] and persist through childhood and adolescence [5-9]. Very preterm birth is therefore associated with a high risk of developmental coordination disorder (DCD) later in life [8], even among those children who have IQ in the normal range and are free of neuro-sensory disability [10, 11]. Motor difficulties are associated with cognitive deficits, inattention, social and emotional problems and learning difficulties [2, 7, 8, 12], which have a profound impact upon a child's integration and performance in school. The high prevalence of motor impairment in very preterm children may therefore contribute to the poor academic attainment and high prevalence of special educational needs (SEN) observed in this population [13, 14].

Children with DCD are less physically fit and significantly more likely to be overweight or obese than their term peers [15]. Cairney and colleagues also found lower participation in physical activity amongst children with DCD and greater rates of obesity amongst boys with the condition [16]. This is a particular concern for preterm infants who are at risk of excess adiposity [17, 18]. Preterm infants, especially those that are small for gestational age have reduced lean body mass, when compared to infants with birth weight appropriate for their gestational age [19]. Many of these infants have experienced rapid "catch up growth" during early infancy and our ongoing research exploring maternal beliefs about infant feeding seems to suggest that mothers are anxious for smaller infants to gain weight and feed them accordingly. This additional weight tends to be fat rather than lean mass resulting in low muscle mass which impairs glucose metabolism and thus potentially increases the risk of later cardiovascular disease [19].

Early experience can, however, moderate outcomes for very preterm infants [20]. A recent meta-analysis reported a significant effect of interventions involving parents on motor outcomes at 12 months of age [21]. The vast majority of interventions included in these reviews were general programmes designed to enhance global neuro-developmental outcomes. The authors of a more targeted intervention designed to improve motor performance and involve caregivers in implementing the intervention for their infants reported significantly enhanced motor outcomes in preterm infants [22]. Indeed, the authors of a review of intervention studies conclude that specific developmental training in which parents learn how to promote their infant's development maximises the effect on motor outcomes [23]. Recent reports also conclude that the efficacy of parenting interventions for very preterm infants may be optimised in programmes commenced post-discharge [13, 24], particularly for enhancing motor outcomes [25], when parents have greater opportunity to interact with their infants.

Our previous research suggests that mothers may experience difficulties interacting with their very preterm infants [24]. Mothers typically perceive their preterm infants as too sleepy or fragile for play in the early months after discharge [26] and are reluctant to rouse sleeping infants resulting in long periods asleep in the supine position. Opportunities for play in the prone position are associated with better motor outcomes [27]. Majnemer has argued that stereotyping of premature infants, combined with their biological vulnerability, means that preterm infants are particularly disadvantaged by environmental barriers to motor development [28]. For example, one study found mothers responded more negatively to babies labelled as premature perceiving the infants as weaker physically, they also chose less developmentally appropriate play programs [29]. Mothers who rated their babies as more vulnerable and engaged in more prematurity stereotyping at five months had infants who achieved lower scores on the Mental Scale of the Bayley Scales of Infant Development at 32 months old [29]. These mother also showed less patience and were less supportive of their infants while interacting with them at nine months of age [30]. Perceptions of vulnerability have been shown to predict poorer infant developmental outcomes [31]. Research to date therefore suggests interventions

to address negative perceptions and parental confidence are needed to reduce barriers to motor development and that such interventions need to occur early. Most parenting interventions have focused on mothers but there is evidence that paternal engagement is also an important predictor of child development [32] in low birth weigh, pre-term infants [33]. The proposed intervention will therefore aim to include fathers where possible.

Rationale for developing computer-based multimedia intervention to promote motor skills in preterm infants: Computer access has increased rapidly in the UK and, by 2007, 70% of households owned a home computer and 61% of homes had an internet link [34]. Additional access through the work place and public areas such as libraries and schools means that web-based information is a feasible method of health promotion for mothers of young children. One of the key strengths of multimedia information is that its interactive function can be used to promote a sense of control. Feedback to the user can improve feelings of competence in relation to the targeted behaviour. Interactive multimedia has proved to be an effective and engaging method of patient education in clinical settings and is as associated with greater improvements in knowledge compared to non-interactive information provision [35]. Evidence from randomised-controlled trials suggests that computer-based information can both increase knowledge and influence behaviour. For example, a computer delivered intervention with children and young people with asthma was associated with better knowledge, improved perceived control of asthma compared to written information and improved clinical outcomes at 6 months follow-up [36]. Primary care patients prescribed Skinsafe, a multimedia intervention, had better knowledge about early signs of melanoma and were more likely to be regularly checking their skin compared to controls [37]. The Sharing My Infants Learning Experiences (SMILES) program was developed to promote parental interactions with preterm infants [38] by illustrating aspects of effective parent–infant interaction using photos, interactive question and answers and video clips. It also aimed to address barriers to interaction identified in our previous research [26], such as maternal uncertainty and low expectations of preterm infants. The pilot study found mothers of very premature infants who were given the SMILES program were more confident about interacting with their infants compared with controls (mean 28.4 vs 17.14, Cohen's d = 2.05) and perceived their infant as being more capable during social interactions (27.0 vs 22.14, Cohen's d = 0.74) [38].

**A13. Please give a full summary of your design and methodology.** *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The study is a randomised controlled trial, with randomisation being allocated via sealed envelopes when the expression of interest form is received. Participants will be given either the HOP-ON CD-ROM and DVD (intervention group) or the SMILES CD-ROM and DVD. They will then be sent questionnaires for completion at 3 months, and at 12 months a researcher will visit to assess the infants. This assessment will be conducted by a trained professional and will if consented, be video-taped. Parents will also be asked some questions relating to their infant and an evaluation questionnaire. The evaluation will also assess which was used most the CD-ROM or the DVD as the pack given will include both versions.

**A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?**

- [x] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

*Give details of involvement, or if none please justify the absence of involvement.*
Involvement of parent of preterm infant.

## 4. RISKS AND ETHICAL ISSUES

### RESEARCH PARTICIPANTS

**A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).**

Parent/s aged between 18-60 years of age, who have a preterm infant - born less than 32 weeks of gestation. Preterm infants born less than 32 weeks of gestation, and progressing well enough to have either been recently discharged from hospital, or being discharged from hospital within the next two weeks.
Both parent and infant inclusion criteria must be met for inclusion in the study.

**A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).**

Parent/s of infants who are still receiving hospital care at 3 months adjusted age, and their premature infants who are still receiving hospital care at 3 months adjusted age.

### RESEARCH PROCEDURES, RISKS AND BENEFITS

**A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol.** *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Questionnaire packs | 3 | 0 | 90min | Two questionnaires are to be self-completed. The third questionnaire pack will be administered by a researcher with the participants |
| motor skills assessment of infant at 12 months | 1 | 0 | 60min | the assessments will be conducted by a trained researcher. |
| taking consent | 2 | 0 | 20min | Consent will be taken initially and then revisited again at the 12 month assessment. |

**A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol.** *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

**A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?**

○ Yes ◉ No

**A21. How long do you expect each participant to be in the study in total?**

approximately 18 months

**A22. What are the potential risks and burdens for research participants and how will you minimise them?**

*For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.*

The main burden would be in relation to time commitment. However this would not be onerous, as there are only 3 questionnaire packs. The only other time would be to use CD-ROM or DVD which can be done at a convenient time for the participant.

**A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?**

(•) Yes ( ) No

*If Yes, please give details of procedures in place to deal with these issues:*

There is the potential for parents to be upset when discussing their infant, however, support would be available if required.

**A24. What is the potential for benefit to research participants?**

Promote interaction between parent and infant, and may increase parents confidence of dealing with a premature infant, as well as a reduction in potential stereotyping of premature infants. There will be information regarding providing an age appropriate stimulating environment for the infant. The end point would be the potential for improvement in motor skills, which may in turn impact on school performance.

**A26. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished?** *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

A website will be available to support parents to develop their children's motor skills up to the age of 3 years, and funding will be sought to extend this.

**A28. What are the potential risks for the researchers themselves?** *(if any)*

There should be little risk for the researcher as a safe researcher policy for visits in place.

## RECRUITMENT AND INFORMED CONSENT

***In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.***

**A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?** *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Posters will be displayed in the relevant neonatal units and members of staff within the units will be informed of the study. Information sheets will be made available within each unit with contact details of the research team.

**A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?**

( ) Yes (•) No

*Please give details below:*
Participants will not be identified via reviewing or screening personal information, however, consent will be requested to confirm birth and initial medical treatment from the medical notes.

**A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?**

(•) Yes ( ) No

*If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).*

Posters will be displayed in the participating neonatal units

**A29. How and by whom will potential participants first be approached?**

Posters will be displayed with contact details and information sheets around the unit. However, a member of the participants care team will be involved if potential participants are approached directly.

**A30-1. Will you obtain informed consent from or on behalf of research participants?**

(•) Yes ( ) No

*If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.*

*If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.*

*If you are not obtaining consent, please explain why not.*

*Please enclose a copy of the information sheet(s) and consent form(s).*

**A30-2. Will you record informed consent (or advice from consultees) in writing?**

(•) Yes ( ) No

**A31. How long will you allow potential participants to decide whether or not to take part?**

Participants will have a minimum of 24 hours to decide if they wish to take part

**A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?**

( ) Yes
( ) No
(•) Not Known

*If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?*

It should not impact on the study, however, a question could be included in the baseline data questionnaire to assess this if required.

**A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?** *(e.g. translation, use of interpreters)*

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial, the participant information sheets, and consent forms, but the consent forms and information sheets will not be available printed in other languages in the first instance. It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

## NOTIFICATION OF OTHER PROFESSIONALS

**A48-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

(•) Yes ( ) No

*If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.*

**A48-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?**

(•) Yes ( ) No

*It should be made clear in the participant's information sheet if the GP/health professional will be informed.*

## PUBLICATION AND DISSEMINATION

**A60. Will the research be registered on a public database?**

(•) Yes ( ) No

*Please give details, or justify if not registering the research.*
Action Medical Research UK have provided funding, therefore this information will regarding the research will be available via the funders database.

**A61. How do you intend to report and disseminate the results of the study?** *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [x] Publication on website
- [x] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

PHD Thesis submitted to the University of Nottingham

**A63. Will you inform participants of the results?**

(•) Yes ( ) No

*Please give details of how you will inform participants or justify if not doing so.*
A summary will be sent out to all participants if they request one.

## 6. Scientific and Statistical Review

**A64. How has the scientific quality of the research been assessed?** *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [ ] Review within a multi-centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

*Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:*
Study was reviewed by Action Medical Research as part of the application for funding.

*For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.*

*For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.*

**A68. How have the statistical aspects of the research been reviewed?** *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator's institution
- [x] Review by a statistician within the research team or multi-centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

*In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.*

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Professor | Cris | Glazebrook |
| Department | School of Community Health Sciences | | |
| Institution | University of Nottingham | | |
| Work Address | Room SIA 1909 A Floor, South Block<br>Division of Psychiatry, Medical Sch<br>QMC, Nottingham | | |
| Post Code | NG7 2UH | | |
| Telephone | 0115 823 0420 | | |
| Fax | 0115 823 0433 | | |
| Mobile | | | |
| E-mail | cris.glazebrook@nottingham.ac.uk | | |

*Please enclose a copy of any available comments or reports from a statistician.*

**A67. What is the primary outcome measure for the study?**

Scores on the Bayley III motor scale and Alberta Infant Motor Scale will be the primary outcome measure.

**A68. What are the secondary outcome measures?** *(if any)*

Secondary outcomes are Bayley's (III) fine and gross motor subscale scores, parental perceptions of infant capability, parental confidence, infant quality of movement, infant growth and parenting stress.

**A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?**

In the unlikely event that information became available during the course of the research that may be relevant to continued participation, all participants would be contacted and a new information sheet and consent form would be available highlighting the new information.

**A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study?** *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.

*Further details:*

*If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.*

## CONFIDENTIALITY

**In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.**

### Storage and use of personal data during the study

**A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?** *(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files including X-rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☑ Laptop computers

*Further details:*
Only anonymised data will be kept on the laptop, and laptops are University password protected. All personal data will be stored on password protected databases on University of Nottingham computers.

**A38. How will you ensure the confidentiality of personal data?** *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participants will be given a code which will be used for all documents. The contact details and personal information will be stored on a password protected database and paper copies of consent forms will be stored in a locked filing cabinet in a secured area within the School of Community Health Sciences of the University of Nottingham by the Chief Investigator.

**A40. Who will have access to participants' personal data during the study?** *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The research team will have access to data following written consent from the participants.

### Storage and use of data after the end of the study

**A43. How long will personal data be stored or accessed after the study has ended?**

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

*If longer than 12 months, please justify:*
Data will be stored securely in line with the University of Nottingham Research Code for 7 years after the last publication.

At the end of the study the participants who have shown an interest in participating in any follow-up study, will be asked for ongoing consent to hold onto their contact details. The data protection act would be adhered to in relation to keeping records accurate and up to date.

## INCENTIVES AND PAYMENTS

**A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?**

○ Yes ◉ No

**A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?**

○ Yes ◉ No

**A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?**

○ Yes ◉ No

**A68. What is the sample size for the research?** *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 138
Total international sample size (including UK):
Total in European Economic Area:

*Further details:*

**A80. How was the sample size decided upon?** *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The target sample size is 69 infants in each group, which will give the 90% power to detect a 9.0-point difference in Bayley III motor scales scores based a mean of 101.5 (SD 18.1) reported in very premature infants in an Australian sample [42].

**A81. Will participants be allocated to groups at random?**

(●) Yes ( ) No

*If yes, please give details of the intended method of randomisation:*
Randomisation will be conducted via sealed envelopes when the expression of interest form is received.

**A82. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.**

Analysis will be based on intention to treat basis. Multivariate analysis will be conducted

## 8. MANAGEMENT OF THE RESEARCH

**A83. Other key investigators/collaborators.** *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Sarah | Redsell |
| Post | Principal Research Fellow | | |
| Qualifications | RGN, BSc, PhD. | | |
| Employer | University of Nottingham | | |
| Work Address | Division of Nursing<br>B Floor, Queen's Medical Centre,<br>Nottingham | | |
| Post Code | NG7 2UH | | |
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| Fax | | | |
| Mobile | | | |
| Work Email | sarah.redsell@nottingham.ac.uk | | |

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Samantha | Johnson |
| Post | Non-Clincal Lecturer in Academic Neonatology | | |
| Qualifications | BA, PhD, CPsychol | | |
| Employer | University College London | | |
| Work Address | Institute for Women's Health<br>Division of Academic Neonatology<br>89-96 Chenlew Mews, London | | |
| Post Code | WC1E 6HX | | |
| Telephone | 02076796313 | | |
| Fax | 02073837429 | | |
| Mobile | | | |
| Work Email | s.j.johnson@ucl.ac.uk | | |

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Charlotte | Beer |
| Post | Research and Teaching Fellow | | |
| Qualifications | BSc, PhD | | |
| Employer | University of Nottingham | | |
| Work Address | Behavioural Sciences<br>A Floor, South Block,<br>Queen's Medical Centre, Nottingham | | |
| Post Code | NG7 2UH | | |
| Telephone | 01158230410 | | |
| Fax | 01158230433 | | |
| Mobile | | | |
| Work Email | charlotte.beer@nottingham.ac.uk | | |

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Ms | Sarah | Westwater-Wood |
| Post | Lecturer | | |
| Qualifications | HNC, BSc, PGCHE, MMedSci, MCSP, FHEA | | |
| Employer | University of Nottingham | | |
| Work Address | Division of Physiotherapy Education<br>Clinical Sciences Building,<br>Nottingham City Campus, Nottingham | | |
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| Telephone | 01158231793 | | |
| Fax | 01158321791 | | |
| Mobile | | | |
| Work Email | sarah.westwater-wood@nottingham.ac.uk | | |

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Dr | Helen | Budge |
| Post | Clinical Associate Professor of Neonatal Medicine | | |
| Qualifications | BA, BM BCH, MRCCP, PhD, FRCPCH | | |
| Employer | University Hospital and Nottingham University Hospitals | | |
| Work Address | Academic Child Health<br>Queen's Medical Centre,<br>Nottingham | | |
| Post Code | NG7 2UH | | |
| Telephone | 01158230611 | | |
| Fax | 01158230626 | | |
| Mobile | | | |

| | |
|---|---|
| Family name | Cartledge |
| Address | Research Innovations Service |
| Town/city | King's Meadow Campus, Lenton Lane |
| Post code | NG7 2NR |
| Country | UNITED KINGDOM |
| Telephone | |
| Fax | |
| E-mail | paul.cartledge@nottingham.ac.uk |

**Is the sponsor based outside the UK?**
○ Yes ◉ No

*Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.*

**A87. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?**

○ Yes ◉ No

*Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.*

**A88. Give details of the lead NHS R&D contact for this research:**

| Title | Forename/Initials | Surname |
|---|---|---|
| Ms | Ann | Smith |

| | |
|---|---|
| Organisation | Research & Development Nottingham University Hospitals NHS Trust |
| Address | E11, Curie Court |
| | Queen's Medical Centre |
| | Derby Road, Nottingham |
| Post Code | NG7 2UH |
| Work Email | |
| Telephone | 0115 9709049 |
| Fax | 0115 8493295 |
| Mobile | |

*Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk*

**A88-1. How long do you expect the study to last in the UK?**

Planned start date: 01/05/2010
Planned end date: 01/05/2013
Total duration:
Years: 3 Months: Days:

**A71-1. Is this study?**

○ Single centre
◉ Multicentre

**A71-2. Where will the research take place?** *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 3

**Does this trial involve countries outside the EU?**
○ Yes ◉ No

**A72. What host organisations (NHS or other) in the UK will be responsible for the research sites?** *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

| | |
|---|---|
| ☑ NHS organisations in England | 3 |
| ☐ NHS organisations in Wales | |
| ☐ NHS organisations in Scotland | |
| ☐ HSC organisations in Northern Ireland | |
| ☐ GP practices in England | |
| ☐ GP practices in Wales | |
| ☐ GP practices in Scotland | |
| ☐ GP practices in Northern Ireland | |
| ☐ Social care organisations | |
| ☐ Phase 1 trial units | |
| ☐ Prison establishments | |
| ☐ Probation areas | |
| ☐ Independent hospitals | |
| ☐ Educational establishments | |
| ☐ Independent research units | |
| ☐ Other (give details) | |
| Total UK sites in study: | 3 |

**A76-1. Will a data monitoring committee (DMC) be convened?**

○ Yes ◉ No

*If Yes, please forward details of the membership of the DMC, its standard operating procedures and summary reports of interim analyses to the Research Ethics Committee which gives a favourable opinion of the study (or to GTAC if applicable).*

**A76-2. What are the criteria for electively stopping the trial or other research prematurely?**

No criteria in place.

**A78. Insurance/ indemnity to meet potential legal liabilities**

*Note: In this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

**A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?** *Please tick box(es) as applicable.*

*Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.*

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

University of Nottingham

*Please enclose a copy of relevant documents.*

**A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?** *Please tick box(es) as applicable.*

*Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.*

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

University of Nottingham

*Please enclose a copy of relevant documents.*

**A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?**

*Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.*

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

*Please enclose a copy of relevant documents.*

**A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?**

○ Yes ◉ No

*Please enclose a copy of relevant documents.*

## PART B: Section 7 - Children

**1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.**

It is anticipated that the very premature infants will be several weeks old by the time they will be recruited onto the study. The current study then aims to follow up to just over one year of age.

**2. Indicate whether any children under 16 will be recruited as controls and give further details.**

A control group will be recruited, however, their parents will be given a CD ROM/DVD which will also aid interaction with the infant.

**3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.**

The information sheet will be given to the parents and the opportunity to ask questions provided. The parents will then have a minimum of 24 hours to decide whether they wish to participate. If they wish to participate a member of the research team will then sign the consent form.

**4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.**

It would not be appropriate to have information sheets for the infants, so only the parents would have information and provide consent.

*Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.*

## PART C: Overview of research sites

**Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites.** *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the institution row and insert the research site (e.g. GP practice) in the Department row.*

| Research site | | Investigator/ Collaborator/ Contact |
|---|---|---|
| Institution name | Nottingham University Hospitals NHS Trust | Title |
| Department name | Queen's Medical Centre, Neonatal Unit | First name/ Initials |
| Street address | Derby Road | Surname |
| Town/city | Nottingham | |
| Post Code | NG7 2UH | |
| Institution name | Nottingham University Hospitals NHS Trust | Title |
| Department name | Nottingham City Hospital, Neonatal Unit | First name/ Initials |
| Street address | Hucknall Road | Surname |
| Town/city | Nottingham | |
| Post Code | NG5 1PB | |
| Institution name | Derby Hospitals NHS Foundation Trust, Royal Derby Hospital | Title |
| Department name | Neonatal Unit | First name/ Initials |
| Street address | Uttoxeter Road | Surname |
| Town/city | Derby | |
| Post Code | DE22 3NE | |
| Institution name | University Hospitals of Leicester NHS Trust, Leicester Royal Infirmary | Title |
| Department name | Neonatal Unit | First name/ Initials |
| Street address | Infirmary Square | Surname |
| Town/city | Leicester | |
| Post Code | LE1 5WW | |

## PART D: Declarations

**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs.
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
12. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

**Contact point for publication** *(Not applicable for R&D Forms)*

*NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.*

☑ Chief investigator
☐ Sponsor
☐ Study co-ordinator
☐ Student
☐ Other – please give details
☐ None

**Access to application for training purposes** *(Not applicable for R&D Forms)*
*Optional – please tick as appropriate:*

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name: Cris Glazebrook

Date: 23/03/2010 *(dd/mm/yyyy)*

**D2. Declaration by the sponsor's representative**

*If there is more than one sponsor, this declaration should be signed on behalf of the co–sponsors by a representative of the lead sponsor named at A64-1.*

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature: .....

Print Name: Paul Cartledge

Post:

Organisation: University of Nottingham

Date: *(dd/mm/yyyy)*

**D8. Declaration for student projects by academic supervisor**

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the Chief Investigator and the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Signature: ----------

Print Name: Cris Glazebrook

Post: Professor of Health Psychology

Organisation: University of Nottingham

Date: 23/03/2010 *(dd/mm/yyyy)*

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

# Development and evaluation of a parenting intervention to promote motor development in infants born very preterm

**Version 1.10**

**03/06/13**

**Short title:** Helping Our Premature infants ON to better motor skills (HOP-ON)

**REC reference:** 10/H0403/35

**Trial Sponsor:** University of Nottingham

**Funding Source:** Action Medical Research UK

# STUDY PERSONNEL AND CONTACT DETAILS

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Hannah Tobiss,
Medical Student
University of Nottingham
Medical School

**Study Sites:** Nottingham University Hospitals NHS Trust,
Derby Hospitals Foundation NHS Trust,
University of Leicester Hospitals NHS Trust

# SYNOPSIS

| | |
|---|---|
| Title | Development and evaluation of a parenting intervention to promote motor development in infants born very preterm |
| Acronym | HOP-ON |
| Short title | Helping Our Premature infants ON to better motor skills<br>(HOP-ON) |
| Chief Investigator | Professor Cris Glazebrook |
| Objectives | Develop and evaluate a multimedia, computer based intervention to promote motor skills in very premature infants |
| Study Configuration | Multi-centre randomised controlled trial |
| Setting | Secondary care |
| Sample size estimate | Calculation to give 90% power to detect a 9.0-point difference in the Bayley III motor scales scores based on a mean of 101.5 (SD 18.1) |
| Number of participants | A minimum of 138 required, 69 in the intervention group and 69 in the control group. However, approx 180 recruited to allow for drop out. |
| Eligibility criteria | Infants born at 32 weeks or less gestation. |
| Description of interventions | CD-ROM or DVD and information booklet containing information on interacting with infant and motor development activities. Control group have interaction information only. |
| Duration of study | 5 years |
| Outcome measures | Difference in Bayley III motor scales scores |
| Statistical methods | Analysis will be based on intention to treat basis. Multivariate analysis will be conducted |

# ABBREVIATIONS

| | |
|---|---|
| AE | Adverse Event |
| CI | Chief Investigator overall |
| CRF | Case Report Form |
| DAP | Data Analysis Plan |
| DCD | Developmental Co-ordination Disorder |
| DMC | Data Monitoring Committee |
| GCP | Good Clinical Practice |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| PI | Principal Investigator at a local centre |
| PIS | Participant Information Sheet |
| REC | Research Ethics Committee |
| R&D | Research and Development department |
| SEN | Special Educational Needs |

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# STUDY BACKGROUND INFORMATION AND RATIONALE

Very preterm children, born at less than 32 week gestation, are at significantly increased risk for impaired motor development compared with their term peers. This results in a high prevalence of survivors with persistent mild neuromotor dysfunction and poor motor skills (Arnaud et al., 2007b, Allen, 2008a). Deficits in motor planning, sensory-motor integration, speed and quality of movement, gross motor skills such as balance and ball skills, and fine motor skills such as manual dexterity and visuo-spatial abilities have been widely documented. These are evident in infancy (Wood et al., 2000, Bracewell and Marlow, 2002) and persist through childhood and adolescence (Mikkola et al., 2005, Allin et al., 2006, Schmidhauser et al., 2006, Davis et al., 2007, Marlow et al., 2007). Very preterm birth is therefore associated with a high risk of developmental coordination disorder (DCD) later in life (Davis et al., 2007), even among those children who have IQ in the normal range and are free of neuro-sensory disability (Goyen and Lui, 2002, Goyen and Lui, 2009). Motor difficulties are associated with cognitive deficits, inattention, social and emotional problems and learning difficulties (Jeyaseelan et al., 2006, Arnaud et al., 2007b, Davis et al., 2007, Marlow et al., 2007), which have a profound impact upon a child's integration and performance in school. The high prevalence of motor impairment in very preterm children may therefore contribute to the poor academic attainment and high prevalence of special educational needs (SEN) observed in this population (Pinto-Martin et al., 2004, Johnson et al., In press).

Children with DCD are less physically fit and significantly more likely to be overweight or obese than their term peers (Schott et al., 2007). Cairney and colleagues also found lower participation in physical activity amongst children with DCD and greater rates of obesity amongst boys with the condition (Cairney et al., 2005). This is a particular concern for preterm infants who are at risk of excess adiposity (Uthaya et al., 2005, Modi et al., 2006). Preterm infants, especially those that are small for gestational age have reduced lean body mass, when compared to infants with birth weight appropriate for their gestational age (Yliharsila et al., 2007). Many of these infants have experienced rapid "catch up growth" during early infancy and our ongoing research exploring maternal beliefs about infant feeding seems to suggest that mothers are anxious for smaller infants to gain weight and feed them accordingly. This additional weight tends to be fat rather than lean mass resulting in low muscle mass which impairs glucose metabolism and thus potentially increases the risk of later cardiovascular disease (Yliharsila et al., 2007).

Early experience can, however, moderate outcomes for very preterm infants (Treyvaud et al., 2009). A recent meta-analysis reported a significant effect of interventions involving parents on motor outcomes at 12 months of age (Vanderveen et al., 2009b). The vast majority of interventions included in these reviews were general programmes designed to enhance global neuro-developmental outcomes. The authors of a more targeted intervention designed to improve motor performance and involve caregivers in implementing the intervention for their infants reported

significantly enhanced motor outcomes in preterm infants (Lekskulchai and Cole, 2001a). Indeed, the authors of a review of intervention studies conclude that specific developmental training in which parents learn how to promote their infant's development maximises the effect on motor outcomes (Blauw-Hospers and Hadders-Algra, 2005a). Recent reports also conclude that the efficacy of parenting interventions for very preterm infants may be optimised in programmes commenced post-discharge (Glazebrook et al., 2007a, Johnson et al., In press), particularly for enhancing motor outcomes (Spittle et al., 2008), when parents have greater opportunity to interact with their infants.

Our previous research suggests that mothers may experience difficulties interacting with their very preterm infants (Glazebrook et al., 2007a). Mothers typically perceive their preterm infants as too sleepy or fragile for play in the early months after discharge (Nicolaou et al., 2009a) and are reluctant to rouse sleeping infants resulting in long periods asleep in the supine position. Opportunities for play in the prone position are associated with better motor outcomes (Pin et al., 2007). Majnemer has argued that stereotyping of premature infants, combined with their biological vulnerability, means that preterm infants are particularly disadvantaged by environmental barriers to motor development (Majnemer, 2007a). For example, one study found mothers responded more negatively to babies labelled as premature perceiving the infants as weaker physically, they also chose less developmentally appropriate play programs (Stern et al., 2006). Mothers who rated their babies as more vulnerable and engaged in more prematurity stereotyping at five months had infants who achieved lower scores on the Mental Scale of the Bayley Scales of Infant Development at 32 months old (Stern et al., 2006). These mothers also showed less patience and were less supportive of their infants while interacting with them at nine months of age (Porter et al., 2009). Perceptions of vulnerability have been shown to predict poorer infant developmental outcomes (Allen et al., 2004). Research to date therefore suggests interventions to address negative perceptions and parental confidence are needed to reduce barriers to motor development and that such interventions need to occur early. Most parenting interventions have focused on mothers but there is evidence that paternal engagement is also an important predictor of child development (Sarkadi et al., 2008) in low birth weigh, pre-term infants (Yogman et al., 1995). The proposed intervention will therefore aim to include fathers where possible.

**Rationale for developing computer-based multimedia intervention to promote motor skills in preterm infants:** Computer access has increased rapidly in the UK and, by 2007, 70% of households owned a home computer and 61% of homes had an internet link (Office of National Statistics, 2008). Additional access through the work place and public areas such as libraries and schools means that web-based information is a feasible method of health promotion for mothers of young children. One of the key strengths of multimedia information is that its interactive function can be used to promote a sense of control. Feedback to the user can improve feelings of competence in relation to the targeted behaviour. Interactive multimedia has proved to be an effective and engaging method of patient education in clinical settings and is associated with greater improvements in knowledge compared to non-interactive information provision (Sefton et al.,

2000). Evidence from randomised-controlled trials suggests that computer-based information can both increase knowledge and influence behaviour. For example, a computer delivered intervention with children and young people with asthma was associated with better knowledge, improved perceived control of asthma compared to written information and improved clinical outcomes at 6 months follow-up (McPherson et al., 2006). Primary care patients prescribed Skinsafe, a multimedia intervention, had better knowledge about early signs of melanoma and were more likely to be regularly checking their skin compared to controls (Glazebrook et al., 2006). The Sharing My Infants Learning Experiences (SMILES) program was developed to promote parental interactions with preterm infants (Nicolaou et al., 2008) by illustrating aspects of effective parent–infant interaction using photos, interactive question and answers and video clips. It also aimed to address barriers to interaction identified in our previous research (Nicolaou et al., 2009a), such as maternal uncertainty and low expectations of preterm infants. The pilot study found mothers of very premature infants who were given the SMILES program were more confident about interacting with their infants compared with controls (mean 28.4 vs 17.14, Cohen's d = 2.05) and perceived their infant as being more capable during social interactions (27.0 vs 22.14, Cohen's d = 0.74) (Nicolaou et al., 2008).

# STUDY AIM AND PURPOSE

## PURPOSE

## PRIMARY AIM AND OUTCOMES

This study aims to develop and evaluate a multimedia, computer-based intervention to promote motor skills in very preterm infants. Scores on the Bayley III motor scale and Alberta Infant Motor Scale will be the primary outcome measure. Secondary outcomes are Bayley's (III) fine and gross motor subscale scores, parental perceptions of infant capability, parental confidence, infant quality of movement, infant growth and parenting stress.

## SECONDARY AIM AND OUTCOMES

To develop and validate a short tool to assess quality of movement, which can be used to compliment the Bayley Scales of Infant Development, which is a validated scale. The secondary aim will be the research outcome of a PhD study for a member of the research team (Anita Hughes).

# STUDY DESIGN

The study is a quantitative experimental design which will utilise a randomised controlled trial to enable the HOP-ON intervention to be evaluated. The participants will be randomisation into either the intervention group or the control group. The randomisation will be done via sealed envelopes which will be picked when expression of interest forms are returned. The participants in the intervention group will receive the

HOP-ON CD-ROM if they have a computer or a DVD and information booklet pack, which contains the SMILES information, and the control group participants will receive the SMILES CD-ROM if they have a computer or a DVD and information booklet pack. All parents will be given an evaluation form to complete at the end of the trial, to evaluate participation. To ensure the intervention has been fully evaluated, the parents from the intervention group will, if they consent, be offered a telephone interview to complete the evaluation.

Those who consent, may be contacted for follow-up studies.

# STUDY MANAGEMENT

The data will be collected by one of the research team and stored by the research team securely at the University of Nottingham during the data collection period, and then by the chief investigator, or their nominated replacement for seven years following the last publication. During the study the research team will meet monthly.

# DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The study will be conducted over five years, however, the study will require the participants to be involved for a maximum period of 30 months.

## End of the Study

The study will end Spring 2015.

# SELECTION AND WITHDRAWAL OF PARTICIPANTS

## Recruitment

The study will involve the parents and their infants. The parents of infants who were born at 32 weeks gestational age or less, admitted to neonatal units in Derby, Nottingham or Leicester and have either recently been discharged, or an anticipated discharge date in the next 2 weeks will be invited to participate in the study.

Posters will be displayed in the five neonatal units involved in the study. At each site members of the participant's usual care team will be informed of the study, and will provide the initial information about the study to the potential participants. The information will contain details about the study

and contact details for the research team for more information if they are interested in participating. An expression of interest form will be available with a stamped addressed envelope for the participant to inform the research team of their interest.

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial, the participant information sheets, and consent forms, but the consent forms and information sheets will not be available printed in other languages in the first instance. It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

## Inclusion criteria

Parent/s aged between 16-60 years of age, who have a preterm infant - born at 32 weeks gestation or less.

Preterm infants born 32 weeks of gestation or less, and progressing well enough to have either been recently discharged from hospital, or being discharged from hospital within the next two weeks.

Both parent and infant inclusion criteria must be met for inclusion in the study.

## Exclusion criteria

Parent/s of infants who are still receiving hospital care at 3 months adjusted age, and their premature infants who are still receiving hospital care at 3 months adjusted age.

Parent/s of multiple births, where the number of infants is greater than two (three of more infants).

To avoid excessive travel costs, infants born outside the defined catchment area will be excluded from the study. There are no other exclusion criteria.

## Expected duration of participant participation

Study participants will be participating in the study for approximately 30 months.

## Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigators. The participants will be made aware that this will not affect their future care. Participants will be made aware (via

the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

## Informed consent

All participants will provide written informed consent. The initial Consent Form will be signed and dated by the participant and researcher before the parent and infant enter the study. The Investigator will, if required, explain the details of the study and Participant Information Sheet, and expression of interest forms will be available on all units. The Investigator will ensure that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the potential participant has concerning study participation.

Initial informed consent will be collected from each participant before they undergo any interventions (including physical examination and history taking) related to the study. One copy of this will be kept by the participant, and one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

In addition, at the 12 month visit, the researcher will discuss and then provide a continuation of consent form, for participants interested in remaining in the study for further follow-up.

# STUDY REGIMEN

It is anticipated that recruitment will take place from November 2010 onwards until the appropriate sample size is obtained. Due to the longitudinal nature of the study it may be necessary to recruit over the target sample size to ensure an adequate sample size at the end of the trial. Once participants have consented they will be provided with a questionnaire to establish some baseline data and enable some basic demographic data to be collected prior to discharge from hospital. If the infant has already been discharged from hospital, then information may be sent out via the clinical team. Participants are also being asked for consent to access the infant's medical notes, to allow for additional data regarding any tests conducted regarding the infant's health and development. On discharge from hospital participants will be sent a pack which contains either the HOP-ON CD-ROM if they have a computer, or a DVD and information booklet with the SMILES information, or the SMILES CD-ROM if they have a computer, or a DVD and information booklet. The packs will include a letter for their Health Visitor and their GP to inform them of their participation. The CD-ROM, DVD and information booklets contain suggestions for parents to help their premature infant learn specific motor skills and interact with their infant, which may help to reduce stereotyping of premature babies. The CD-ROM, DVD and information booklet will contain clear instructions from trained professionals, and highlight appropriate everyday types of activities for each stage of their infant's motor development. The activities on the HOP-ON element of the CD-ROM, DVD and information booklet have been designed by physiotherapists, to

promote movement that is appropriate to the infant's stage of development, and would not require any special equipment. One specific example would be skin to skin hand over hand (parents hand facilitating baby to touch key body areas, hand to hand, hand to foot, foot to foot for example) tactile exploration of body, face and texture in a fully supported (by parent) posture .The SMILES CD-ROM/DVD has been used and validated by members of the researcher team in an earlier study, and contains information and suggestions of interactions with premature infants.

At three months (age adjusted) questionnaires will be sent out to the parent for completion, along with a stamped addressed envelope for return. Then at one year (age adjusted) researchers will visit the parents to conduct a motor assessment, and a researcher lead questionnaire will be completed. The University of Nottingham fieldwork guidelines will be followed by the researchers for home visits. At the visit, the researchers will conduct motor assessments of the infant (Bayley's III; Alberta Infant Motor Scale; and newly developed scale). The researchers will be trained to conduct the motor assessments. To ensure valid assessment it is anticipated that this with be video recorded. To do this consent will be re-visited regarding the recording of the motor assessment of the infant. However, if the parent does not consent for videoing it would not affect their inclusion in the study. If they consent for the recording then they will be informed that their infant's dignity will be respected during the recording of the video, and these would be anonymised where possible, by not including names, and allocating a study code. Parents will be offered a copy of the recording, which will allow them to assess how the infant's dignity is being respected, and to demonstrate that no names were used. If the parent consented for use of the recording for educational purposes, they will be reminded that this is optional and that they still have the option to withdraw consent for use of the recording for this purpose.

Prior to contacting the parent, the infant's medical record would be checked to ensure that the infant is still alive before any questionnaires are sent out. In addition, as the 3 month questionnaire contains a stress index, if the scores revealed any concerns, the mother would be contacted and the appropriate support discussed. i.e. contact GP, Health Visitor, specialist support. This would again be the response if any concerns were raised at the 12 month visit.

The recording will also be stored securely in accordance with the University of Nottingham guidance for storage of source data. At the end of the visit an evaluation questionnaire will be given to parents. The parents from the intervention group, if they have given their consent, will be contacted via telephone for an evaluation interview, which will be audio recorded. Following the assessment the intervention group parents will be sent details of the HOP-ON website which will provide details on activities for their infants up to the age of 3 years. If in the initial consent form the participants have agreed to be contacted for future follow-up, then consent regarding retaining address for this will be sought at this time. For those who sign continuing consent a follow-up questionnaire will be sent when the child reaches 2 years corrected age. The questionnaire will contain an

update of demographic data and incorporate two validated questionnaires regarding the child's motor ability.

**TIMEFRAME**:

November 2010: Start recruitment from three NHS Trust, who in total have five neonatal units

January 2011 onwards: At three months adjusted age for the infant, the parents will be sent a questionnaire pack containing health questions, the interacting with my premature infant questionnaire and the parenting stress index.

November 2011 onwards: At 12 months adjusted age: parents will be contacted and a visit arranged to complete parent questionnaires, and to assess the infant's motor skills. This assessment of motor skills will be filmed to allow for the quality of the data to be assessed and the developed motor scale to be validated. Consent for the video recording will be obtained, but having the assessment video is not an essential element to participating in the study, so is completely voluntary.

Spring 2013 onwards: A summary of the initial findings will be sent out to participants, and if they consented, information regarding any potential follow-up study.

Summer 2013 onwards: A questionnaire will be sent to those who have asked to remain in the study.

# STATISTICS

## Methods

A member of the research team will conduct the statistical analysis, by entering the data into Statistical Package for the Social Sciences (SPSS) v16. Multivariate analysis will be conducted to ascertain predictive variables.

The comments from the questionnaires and evaluation will be transcribed, and coded to elicit any relevant themes.

## Sample size and justification

The target sample size is 69 infants in each group, which will give the 90% power to detect a 9.0-point difference in Bayley III motor scales scores based a mean of 101.5 (SD 18.1) reported in very premature infants in an Australian sample (Anderson et al., 2009). However, approximately 180 will be recruited to allow for drop out.

# ADVERSE EVENTS

The occurrence of adverse as a result of participation within this study is not expected and no adverse event data will be collected.

# ETHICAL AND REGULATORY ASPECTS

There are several ethical issues that must be considered in relation to the study. Parents who have had a very premature infant are at a potentially vulnerable time. Participants will only be approached by a member of the care team, and only when the infant is progressing well and will be being discharged from hospital within the next two weeks. No undue pressure or cohersion to participate will be placed on potential participants.

Another possible ethical issue would be whether during discussions with a parent a child protection issue becomes apparent, if this is the case then it would need to be discussed with the family's health visitor. For both of these issues parents would be made aware of this procedure at the start of the meeting.

# ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

# INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent or assent and parent / guardian informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that

might be introduced. The investigator or their nominee and the participant or other legally authorised representative shall both sign and date the Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled.

If the Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Form by the REC and use of the amended form (including for ongoing participants).

# DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Information about the trial in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

# QUALITY ASSURANCE & AUDIT

## INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham has taken out an insurance policy to provide indemnity in the event of a successful litigious claim for proven non-negligent harm.

# STUDY CONDUCT

Study conduct will be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria); accountability of study materials.

The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

# STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

# RECORD RETENTION AND ARCHIVING

In accordance with the University of Nottingham's Research Code of Conduct, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

# DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

# STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

# PUBLICATION AND DISSEMINATION POLICY

A report will be written up and submitted to Action Medical Research UK at the end of the study, and findings will be written up for submission to academic journals and relevant conferences. In addition a thesis will be submitted to the University of Nottingham which will be available for loan. All participants will be provided with a summary of the findings of the study.

# USER AND PUBLIC INVOLVEMENT

Users are invited to the research meetings and have had input into the content of research documents.

# STUDY FINANCES

## Funding source

Funding for the study is being provided by Action Medical Research UK and The Henry Smith Charity.

## Participant stipends and payments

Participants will not be paid to participate in the study, and it is unlikely that any out of pocket expenses would be incurred by the participant.

# SIGNATURE PAGE

Signatories to Protocol:

**Chief Investigator:** Professor Cris Glazebrook

Signature: 

Date: 03/06/13

**Co-Investigator**: Dr Sarah Redsell

Signature:_____

Date: _____

**Co-Investigator:** Dr Samantha Johnson

Signature:_____

Date: _____

**Co-Investigator:** Dr Charlotte Beer

Signature:_____

Date: _____

**Co-Investigator:** Dr Helen Budge

Signature:_____

Date: _____

**Co-Investigator:** Sarah Westwater-Wood

Signature:_____

Date: _____

**Co-Investigator:** Dr Heather Wharrad

Signature:_____

Date: _____

**Co-Investigator/PhD Student:** Anita Hughes

Signature: 

Date: 19/10/10

**Appendix 6: Poster**

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Nottingham University Hospitals NHS

Derby Hospitals NHS

NHS Foundation Trust

University Hospitals of Leicester NHS

# Helping Our Premature infants ON to better motor skills (HOP-ON)

## We are looking for parents and infants to take part in our study



Please take an information sheet, ask a member of staff for details, or contact one of the researchers






Katy Allen – Researcher
E-mail: katy.allen@nottingham.ac.uk
Tel: 0115 8230431

Anita Hughes – Researcher
E-mail: anita.hughes@nottingham.ac.uk
Tel: 0115 8230986

**Appendix 7: Participant information sheet**



















## Parent Information Leaflet

**Full Title:** Development and evaluation of a parenting intervention to promote motor development in infants born very preterm

**Short title:** Helping Our Premature infants ON to better motor skills (HOP-ON)

**Local Study Team:**

Dr Helen Budge – Nottingham University Hospitals

Dr Joe Fawke – University Hospitals Leicester

Dr John McIntyre – Derby Hospitals

**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

**Invitation**

You are being invited to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully, and talk to others about it if you wish. This information sheet tells you the

purpose of this study, what will happen if you take part and about the conduct of the study.

Please feel free to ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

Research has shown that infants who are born very prematurely (less than 32 weeks) may have a greater risk of problems associated with motor skills (movement development). This can lead to difficulties with handwriting and sport which may be seen during school years. This study aims to show parents how to help their premature infant learn movement (motor) skills from an early age. Information will be provided to parents in a programme which we have called HOP-ON. HOP-ON uses film clips, simple text, diagrams and photos to show parents how to interact with their infants and how to encourage their child's motor skills. The information will be provided as an interactive computer program in two volumes, one around discharge from hospital and a second volume at about 3 months after discharge. The information will also be provided on a DVD and information booklet for parents who do not have access to a computer. At 12 months parents will be given details of a HOP-ON website which will provide suggestions of activities for you to do with your child up to the age of three years.

We wish to look at how parents follow the guidance in the HOP-ON programme, and whether this leads to better movement (motor) skills for their infants.

To do this, we will give some parents the HOP-ON CD or DVD and information booklet (intervention group), and some parents a similar CD or DVD and information booklet called SMILES (control group). SMILES has useful information and guidance on interacting with your premature infant, but not the information about specific motor skills.

**Why have I been invited?**

You have been invited as you are a parent of a premature infant born 32 weeks gestation or less, who has been cared for in one of five participating hospital, and your infant has either just been discharged from hospital or will be discharged within a few weeks.

**Do I have to take part?**

No, participation in this research project is entirely voluntary. It is up to you to decide. If you are interested we will arrange for our researcher to describe the study to you and go through this information sheet, which we will then give to you. If there is anything you do not understand please ask the researcher or contact a member of the research team (information below). If you agree to take part we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive, or your legal rights.

**What will I have to do and what will happen to me if I take part?**

If you decide to take part, you will be asked to complete an expression of interest form and consent form and return it to the researchers in the stamped addressed envelope provided. You will then either be given HOP-ON or SMILES packs, but you will not be able to choose which version you are given. The version you get will be decided by random allocation, like tossing a coin. The allocations will be hidden in sealed envelopes so that no one will know in advance which version any participant will get. You will be given or sent a pack which contains a CD or DVD and information booklet prior to, or following your infant being discharged from hospital. The pack will also contain letters to pass on to your health visitor, and your GP to let them know about the study too.

When your infant is 3 months old you will be sent a pack of questionnaires asking about you and your infant's health and well-being. At 12 months a researcher will contact you to arrange a visit at your home. This visit will

involve an assessment of your infant's movements and include details of their weight and length. To assess their movement, three motor assessments will be conducted by a trained professional, and with your permission these assessment will be video recorded. This recording would respect your infant's dignity and a code given to avoid the use of names. Once the video has been assessed it will be stored securely. Some parents may, at a later date, be asked whether they would give their permission for the video to be used as an educational tool, but again no names would be used. The video recording is to check the quality of the data and aid the development of a quality of movement scale. However, the recording is entirely voluntary, and would not affect your participation in the study. During this visit, you would be asked some questions regarding your infant's development and will be given an evaluation form to find out your experience of using the CD or DVD and information booklet. If you are allocated to the HOP-ON group, you will also be given the opportunity to take part in a telephone interview to discuss use of the HOP-ON CD/DVD. This will be audio-recorded.

At the 12 month visit you will be asked if you are interested in participating in any follow up studies, and if so to confirm that we can hold on to your contact details for this purpose. If you have consented to having the assessment of your infant recorded, you will be asked whether you would like a copy posting to you.

Prior to sending the questionnaire packs we would check your child's health records to ensure that questionnaires are not sent out if it is not appropriate. If at any point the information from the study gives rise to concerns regarding your or your infant's health and wellbeing, we would provide you with information regarding appropriate support. For example we might suggest that you contact your GP, health visitor or other support services.

**What are the possible benefits of taking part?**

If you take part in the study you will receive CD or DVD and information booklet based information about caring for your premature infant, which

you can keep. There is no guarantee however, that these will benefit your infant. You will also be offered information about your infant's performance on tests of physical and mental development at 12 months, and if you agreed to the recording then you will also be sent a copy of the film of your infant participating in the study. You will also be given access at the end of the study to a website which will give you suggestions for activities with your infant up to the age of three years.

**What are the possible disadvantages and risks of taking part?**

The main disadvantage will be giving up your time, as you will be involved in the study for approximately 18 months.

**What will happen if I do not want to carry on with the study?**

Your participation in the study is voluntary and you are free to withdraw at any time, without giving a reason and without your legal rights or medical care being affected. If you withdraw the information collected up to that point cannot be erased and this information may still be included in the findings.

**Will my taking part in the study be kept confidential?**

Yes. Ethical and legal practice will be followed, and all information including videos will be stored in a locked cupboard in the Department of Community Health Sciences, at the University of Nottingham. The videos of the motor assessment will be anonymised. They will only be viewed by the research team listed above. However, we will ask some parents if their infant's video can be used for educational purposes, such as presentations at conferences. If your infant's video is chosen for this purpose we will ask for your consent separately to the consent for this study.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers (Katy Allen or Anita Hughes) who will do their best to answer your questions, or you can speak to Professor Cris Glazebrook tel: 0115 8230420. However, if you are still unhappy and wish to complain

formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

**Who is organising and funding the research?**

This study is being organised and sponsored by the University of Nottingham and is being funded by The Henry Smith Charity and Action Medical Research UK.

**What will happen to the results of the research study?**

The results will be presented in a report to Action Medical Research UK, and will be written up as academic articles in journals. A summary of the findings will be sent to all participants. The movement assessment part of the study is being carried out as an educational qualification, so will be submitted in a study report (thesis) to the University of Nottingham. We may wish to use some direct quotes in the publications, from the evaluation forms received from parents. However, these would be anonymised.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and agreed by Nottingham 1 Research Ethics Committee prior to the research being conducted.

**Contact details**

If you have any further enquiries about this research, please do not hesitate to contact the researchers:

Katy Allen: 0115 8230431 or Anita Hughes: 0115 8230986 or the Chief Investigator: Professor Cris Glazebrook on 0115 8230420

Or another member of the research team:

| | |
|---|---|
| Dr Sarah Redsell | Tel: 0115 8230809 |
| Dr Samantha Johnson | Tel: 0115 8230609 |
| Dr Charlotte Beer | Tel: 0115 8230410 |
| Dr Helen Budge | Tel: 0115 8230611 |
| Sarah Westwater-Wood | Tel: 0115 8231793 |
| Dr Heather Wharrad | Tel: 0115 8230909 |

**Thank you for taking the time to read this information sheet.**

**Appendix 8: Expression of interest**



















Centre Number:
Participant Identification Number for this trial:

## EXPRESSION OF INTEREST FROM PARENT

I am interested in finding out more about the helping our premature infants on to better motor skill (HOP-ON) study, so have included my contact details below.

Title of Project: Helping Our Premature infants ON to better motor skills (HOP-ON)

Name of Researchers: Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

Local Study Team: Dr Helen Budge, Nottingham University Hospitals. Dr Joe Fawke – University Hospitals of Leicester. Dr John McIntyre – Derby Hospitals

Contact Details:

Name: ……..

Address ……..

……..

Contact telephone number: ……..

Do you have a? Boy ☐ Girl ☐

What is your baby's name? .....

Do you have access to a computer? Yes ☐ No ☐

Email address: .....

**Appendix 9: Consent form**

HOP-ON
Helping Our Premature Infants ON to better motor skills



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Nottingham University Hospitals NHS Trust
Derby Hospitals NHS Foundation Trust
University Hospitals of Leicester NHS Trust

Centre Number:
Participant Identification Number for this trial:

## PARENT CONSENT FORM 1

Title of Project: Helping Our Premature infants ON to better motor skills (HOP-ON)

Name of Researchers: Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

Local Collaborators: Dr Helen Budge – Nottingham University Hospitals
Dr Joe Fawke – University Hospitals of Leicester NHS Trust;
Dr John McIntyre – Derby Hospitals NHS Foundation Trust

Please initial box

1. I confirm that I have read and understand the information sheet dated 13th December 2011 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily ☐

2. I understand that my, and my infant's participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my or my infant's medical care or my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand relevant section of my infant's medical notes and data collected during the study may be looked at by individuals from the University of Nottingham, Action Medical Research, and from regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I agree to take part in the above study and to allow my infant to participate. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |

When completed, 1 for participant, 1 for research site file

**Appendix 10: Continued consent form**

HOP-ON
Helping Our Premature Infants ON to better motor skills

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Nottingham University Hospitals NHS Trust
Derby Hospitals NHS Foundation Trust
University Hospitals of Leicester NHS Trust

Centre Number:

Study Number:

Patient Identification Number for this trial:

## PARENT CONTINUED PARTICIPATION CONSENT FORM

Title of Project: Helping Our Premature infant ON to better motor skills (HOP-ON)

Name of Researchers: Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Ms Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

Please initial box

1. I understand that my and my infant's continued participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my or my infant's medical care or my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
2. (optional) I agree to the assessment of my infant to be video-taped ☐
3. (optional) I agree to the video of my infant to be used for educational purposes ☐
4. I have read the information sheet dated 14th June 2012 and have had the opportunity to ask questions. ☐
5. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐
6. (optional) I would be willing to be contacted if a follow-up study was being planned ☐

| ---------- | ---------- | ---------- |
|---|---|---|
| Name of Participant | Date | Signature |
| ---------- | ---------- | ---------- |
| Name of Person taking consent | Date | Signature |

When completed, 1 for participant, 1 for research site file

**Appendix 11: GP letter**

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Nottingham University Hospitals NHS Trust

Derby Hospitals NHS Foundation Trust

University Hospitals of Leicester NHS Trust

School of Community Health
Room S/A 1909, A Floor,
South Block,
Queen's Medical Centre,
Nottingham, NG7 2UH

Today's date to be inserted

**Study title**: Helping Our Premature infants ON to better motor skills (HOP-ON)

**Researchers**: Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

Dear General Practitioner,

Your patient (Parent's Name) and their infant (insert name) are participating in the above study. They will have been provided with a (insert either CD or DVD and information booklet) which contain(s) information and suggestions of how to interact with their premature infant. If they have been allocated to the intervention group, the (insert either CD or DVD and information booklet)will also contain suggestions for motor activities which have been put together by a team which include Paediatric Physiotherapist, Consultant Neonatologist, a health psychologist, an educational technologist and a health visitor. If you would like more information please contact Professor Cris Glazebrook: 0115 8230420.

Yours sincerely,

Professor Cris Glazebrook,
Professor of Health Psychology.

**Appendix 12: Health visitor letter**

School of Community Health
Room S/A 1909, A Floor,
South Block, Queen's Medical Centre,
Nottingham, NG7 2UH

Today's date to be inserted

**Study title**: Helping Our Premature infants ON to better motor skills (HOP-ON)
**Researchers**: Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Sarah Westwater-Wood, Dr Helen Budge, Dr Heather Wharrad, Anita Hughes, Katy Allen

Dear Health Visitor,

Your client (Parent's Name) and their infant (insert name) are participating in the above study. They will have been provided with a (insert either CD or DVD and information booklet) which contain(s) information and suggestions of how to interact with their premature infant. If they have been allocated to the intervention group, the (insert either CD or DVD and information booklet)will also contain suggestions for motor activities which have been put together by a team which include Paediatric Physiotherapist, Consultant Neonatologist, a health psychologist, an educational technologist and a health visitor. If you would like more information please contact Professor Cris Glazebrook: 0115 8230420.

Yours sincerely,

Professor Cris Glazebrook,

Professor of Health Psychology.

**Appendix 13: Data collection sheet for medical notes**

**Appendix 14: Questionnaire 1**

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## Helping Our Premature Infant ON to better motor skills (HOP-ON)

## Hop-on Questionnaire 1



**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

Study Number:

You will have received this questionnaire as you stated you were interested in being involved in the helping our premature infant on to better motor skills. This questionnaire has been designed to obtain information about you, your partner and your infant. Please answer the following questions and return once completed in the stamped addressed envelope provided. If you have any questions regarding this you can contact the chief investigator:

Professor Cris Glazebrook on 0115 8230420

Thank you for taking part in the study.

Please complete by ticking or writing where appropriate.

**Date completed: .....**

**1. Your baby**

My baby's date of birth: ☐

My baby is: Male ☐ Female ☐

My baby's birth weight: ☐

Gestation at birth: weeks ☐ days ☐

What type of birth did you have?

- Vaginal ☐
- Caesarean Section ☐
- Forceps ☐
- Ventouse/Vacuum ☐

Was your baby in intensive care? Yes ☐ No ☐

If yes, for how long? ☐

How are you currently feeding your baby?

- Breast ☐
- Formula ☐
- Mixed (breast and formula) ☐

**2. You**

Age: ☐ Date of Birth: ☐

Your first language: ☐

Your ethnic origin:

- White ☐
- Black-Caribbean ☐
- Black-African ☐
- Black other ☐
- Indian ☐
- Pakistani ☐
- Bangladeshi ☐
- Chinese ☐
- Other/ Mixed ☐ .....

Your marital status:

- Married ☐
- Single ☐
- Co-habiting ☐
- Partner, not co-habiting ☐
- Separated or Divorced ☐

Your home:

- Own home ☐
- Local Authority ☐
- Housing Association ☐
- Private furnished ☐
- Private unfurnished ☐
- Living with parents ☐
- Other (please describe) ☐ .....

Highest education qualification:

- None of the below ☐
- O'Level/GCSE/Scottish Standards ☐
- BTEC/A'Level/Highers/or equivalent ☐
- Diploma/HND ☐
- University degree ☐
- Postgraduate University degree ☐
- Other after A'Level (please describe) ☐ .....

Are you in full time education? Yes ☐ No ☐

Are you currently? Employed ☐
Self-employed ☐
Unemployed ☐
Other (please describe) ☐ .....

Current occupation:
(or last if unemployed)

Number of hours worked per week:

Does/did your job involve supervising other employees? Yes ☐ No ☐

Your health:

Do you have any long-term illnesses? Yes ☐ No ☐
If yes, please describe

**3. Your Partner (if applicable)**

Ethnic origin: White ☐
Black-Caribbean ☐
Black-African ☐
Black other ☐
Indian ☐
Pakistani ☐
Bangladeshi ☐
Chinese ☐
Other/ Mixed (Please describe) ☐ .....

Highest education qualification:

- None of the below ☐
- O'Level/GCSE/Scottish Standards ☐
- BTEC/A'Level/Highers/or equivalent ☐
- Diploma/HND ☐
- University degree ☐
- Postgraduate University degree ☐
- Other after A'Level (please describe) ☐ .....

Is your partner in full time education? Yes ☐ No ☐

Is your partner currently? Employed ☐
Self-employed ☐
Unemployed ☐
Other (please describe) ☐ .....

Current occupation:
(or last if unemployed)

Number of hours worked per week:

Does/did your partner's job involve supervising other employees?

Yes ☐ No ☐

Your partner's health:

Does your partner have any long-term illnesses? Yes ☐ No ☐

If yes, please describe

Please use the space below to make any comments you feel are relevant to the study.

**Thank you for completing this questionnaire.**
**Please return it in the envelope provided.**

**Appendix 15: Questionnaire 2**

HOP-ON

action medical research for children, for life

The University of Nottingham

# Helping Our Premature Infant ON to better motor skills (HOP-ON)

## Questionnaire pack 2



**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

Study Number:

Thank you for completing the first questionnaire. We would now like to ask you to fill in the following questionnaires, which have questions about you and your child. We will treat this information in the strictest confidence and it will not be divulged to anyone outside the HOP-ON study. For confidentiality, neither your child's name nor your own name is anywhere on the questionnaire.

This questionnaire is designed to be completed by the baby's mother, or main caregiver.

Please answer the following questions and return once completed in the stamped addressed envelope provided. If you have any questions regarding this you can contact the chief investigator:
Professor Cris Glazebrook on 0115 8230420

Thank you for taking part in the study.

**Your baby's health and development**

Your baby's date of birth:

1) Has your baby been admitted to hospital after first being discharged home? Yes ☐ No ☐

If yes, how many times has s/he been admitted

How long did your baby stay in hospital at each admission and for what reason:

2) What is your baby's current weight?

Date last weighed:.....

3) Does your baby have any medical problem?

Yes ☐ No ☐ Don't know ☐

If yes, please describe

4) Do you think your baby has any difficulties sleeping?

Yes ☐ No ☐ Don't know ☐

5) How are you currently feeding your baby?

6) Does your baby have problems feeding? Yes ☐ No ☐

If yes, please describe

7) Do you think your baby has any difficulties with his or her vision?

Yes ☐ No ☐ Don't know ☐

If yes, please describe:

8) Do you think your baby has any difficulties with his or her hearing?

Yes ☐ No ☐ Don't know ☐

If yes, please describe:

For the following questionnaire, please rate your agreement with each of the following 12 statements. There are seven options to choose from:

- Strongly agree,
- Agree,
- Agree somewhat,
- Neither agree nor disagree,
- Disagree,
- Disagree somewhat or
- Strongly disagree

| | Strongly agree | Agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Disagree | Strongly disagree |
|---|---|---|---|---|---|---|---|
| 1. My baby is too sleepy to interact with | □ | □ | □ | □ | □ | □ | □ |
| 2. My baby responds to me during interactions | □ | □ | □ | □ | □ | □ | □ |
| 3. I feel anxious about playing with my baby | □ | □ | □ | □ | □ | □ | □ |
| 4. I am confident about interacting with my baby | □ | □ | □ | □ | □ | □ | □ |
| 5. I am worried about my baby's health | □ | □ | □ | □ | □ | □ | □ |
| 6. I am worried that my baby is not strong enough yet for play | □ | □ | □ | □ | □ | □ | □ |
| 7. My baby is too small to interact and play with | □ | □ | □ | □ | □ | □ | □ |
| 8. I am worried I might do something wrong | □ | □ | □ | □ | □ | □ | □ |
| 9. My baby is interested in playing | □ | □ | □ | □ | □ | □ | □ |
| 10. I don't know what I should be doing with my baby | □ | □ | □ | □ | □ | □ | □ |
| 11. My baby is alert during interactions | □ | □ | □ | □ | □ | □ | □ |
| 12. I don't know how to play with my baby | □ | □ | □ | □ | □ | □ | □ |

**Instructions**

There are two parts to this next questionnaire, the first part contains 36 statements. Read each statement carefully. For each statement please circle the response that best represents your opinion.

Circle the SA if you **strongly agree** with the statement
Circle the A if you **agree** with the statement
Circle the NS if you are **not sure**
Circle the D if you **disagree** with the statement
Circle the SD if you **strongly disagree** with the statement

For example, if you sometimes enjoy going to the movies, you would circle A in response to the following statement.

I enjoy going to the movies (SA) A NS D SD

While you may not find a response that exactly states your feelings, please circle the response that comes closest to describing how you feel. YOUR FIRST REACTION TO EACH QUESTION SHOULD BE YOUR ANSWER.

Circle only one response for each statement, and respond to all statements. **DO NOT ERASE!** If you need to change an answer, make an "X" through the incorrect answer and circle the correct response. For example,

I enjoy going to the movies ~~(SA)~~ A (NS) D SD

SA=Strongly Agree A=Agree NS=Not Sure D=Disagree SD=Strongly Disagree

| | | | | | | |
|---|---|---|---|---|---|---|
| 1. | I often have the feeling that I cannot handle things very well | SA | A | NS | D | SD |
| 2. | I find myself giving up more of my life to meet my children's needs than I ever expected. | SA | A | NS | D | SD |
| 3. | I feel trapped by my responsibilities as a parent | SA | A | NS | D | SD |
| 4. | Since having this child, I have been unable to do new and different things | SA | A | NS | D | SD |
| 5. | Since having a child, I feel that I am almost never able to do things that I like to do | SA | A | NS | D | SD |
| 6. | I am unhappy with the last purchase of clothing I made for myself | SA | A | NS | D | SD |
| 7. | There are quite a few things that bother me about my life | SA | A | NS | D | SD |
| 8. | Having a child has caused more problems than I expected in my relationship with my spouse (male/female friend) | SA | A | NS | D | SD |
| 9. | I feel alone and without friends | SA | A | NS | D | SD |
| 10. | When I go to a party, I usually expect not to enjoy myself | SA | A | NS | D | SD |
| 11. | I am not as interested in people as I used to be | SA | A | NS | D | SD |
| 12. | I don't enjoy things as I used to | SA | A | NS | D | SD |
| 13. | My child rarely does things for me that make me feel good | SA | A | NS | D | SD |
| 14. | Most times I feel that my child does not like me and does not want to be close to me | SA | A | NS | D | SD |
| 15. | My child smiles at me much less than I expected | SA | A | NS | D | SD |
| 16. | When I do things for my child, I get the feeling that my efforts are not appreciated very much | SA | A | NS | D | SD |
| 17. | When playing, my child doesn't often giggle or laugh | SA | A | NS | D | SD |
| 18. | My child doesn't seem to learn as quickly as most children | SA | A | NS | D | SD |
| 19. | My child doesn't seem to smile as much as most children | SA | A | NS | D | SD |
| 20. | My child is not able to do as much as I expected | SA | A | NS | D | SD |
| 21. | It takes a long time and it is very hard for my child to get used to new things | SA | A | NS | D | SD |

For the next statement, choose your response from the choices "1" to "5" below

22. I feel that I am: 1 2 3 4 5

1. Not very good at being a parent
2. A person who has some trouble being a parent
3. An average parent
4. A better than average parent
5. A very good parent

| | | | | | | |
|---|---|---|---|---|---|---|
| 23. | I expected to have closer and warmer feelings for my child than I do and this bothers me | SA | A | NS | D | SD |
| 24. | Sometimes my child does things that bother me just to be mean | SA | A | NS | D | SD |
| 25. | My child seems to cry or fuss more often than most children | SA | A | NS | D | SD |
| 26. | My child generally wakes up in a bad mood | SA | A | NS | D | SD |
| 27 | I feel that my child is very moody and easily upset | SA | A | NS | D | SD |
| 28. | My child does a few things which bother me a great deal | SA | A | NS | D | SD |
| 29. | My child reacts very strongly when something happens that my child doesn't like | SA | A | NS | D | SD |
| 30. | My child gets upset easily over the smallest thing | SA | A | NS | D | SD |
| 31. | My child's sleeping or eating schedule was much harder to establish than I expected | SA | A | NS | D | SD |

For the next statement, choose your response from the choices "1" to "5" below

32. I have found that getting my child to do something or stop doing something is:

1 2 3 4 5

1. Much harder than I expected
2. Somewhat harder than I expected
3. About as hard as I expected
4. Somewhat easier than I expected
5. Much easier than I expected

For the next statement, choose your response from the choices "10+" to "1-3"

33. Think carefully and count the number of things your child does that bother you. For example: dawdles, refuses to listen, overactive, cries, interrupts, fights, whines, etc.

10+ 8-9 6-7 4-5 1-3

| | | | | | | |
|---|---|---|---|---|---|---|
| 34. | There are some things my child does that really bother me a lot | SA | A | NS | D | SD |
| 35. | My child turned out to be more of a problem than I had expected | SA | A | NS | D | SD |
| 36. | My child makes more demands on me than most children | SA | A | NS | D | SD |

Please use the space below for any comments you would like to make about your baby's first few months using the box below.

Today's date

**Thank you for completing this questionnaire.**

**Please return in the envelope provided**

## Appendix 16: Questionnaire 3

HOP-ON Helping Our Premature Infants ON to better motor skills

action medical research for children, for life

The University of Nottingham

# Helping Our Premature Infant ON to better motor skills (HOP-ON)

## Face to Face Questionnaire 3



**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

Study Number:

**This will be completed by the researcher during the visit at 1 year.**

**Your child's health and development**

Weight:..... Height:.....

1) Does your baby have any medical problems? Yes ☐ No ☐
If yes, can you describe them?

2) Do you think your baby has any difficulties sleeping?
Yes ☐ No ☐ Don't know ☐

3) Does your baby have any feeding difficulties? Yes ☐ No ☐

a) Does your baby dislike being touched around the mouth?

b) Does your baby dislike having things put into his or her mouth?

c) Does your baby gag or choke on food

d) Does your baby have problems biting biscuits?

e) Does your baby have a poor appetite?

f) Does your baby become upset or have tantrums during meals?

g) Does your baby have difficulty swallowing fluids?

h) Does your baby have difficulty swallowing solids?

i) Does your baby refuse food?

4) Do you think your baby has any difficulties with his or her vision?

Yes ☐ No ☐ Don't know ☐

If yes, please describe:

5) Do you think your baby has any difficulties with his or her hearing?

Yes ☐ No ☐ Don't know ☐

If yes, please describe:

**Instructions**

There are two parts to this questionnaire, the first part contains 36 statements. Read each statement carefully. For each statement please circle the response that best represents your opinion.

Circle the SA if you **strongly agree** with the statement
Circle the A if you **agree** with the statement
Circle the NS if you are **not sure**
Circle the D if you **disagree** with the statement
Circle the SD if you **strongly disagree** with the statement

For example, if you sometimes enjoy going to the movies, you would circle A in response to the following statement.

I enjoy going to the movies SA A NS D SD

While you may not find a response that exactly states your feelings, please circle the response that comes closest to describing how you feel. YOUR FIRST REACTION TO EACH QUESTION SHOULD BE YOUR ANSWER.

Circle only one response for each statement, and respond to all statements. **DO NOT ERASE!** If you need to change an answer, make an "X" through the incorrect answer and circle the correct response. For example,

I enjoy going to the movies SA A NS D SD

SA=Strongly Agree A=Agree NS=Not Sure D=Disagree SD=Strongly Disagree

| | | | | | | |
|---|---|---|---|---|---|---|
| 1. | I often have the feeling that I cannot handle things very well | SA | A | NS | D | SD |
| 2. | I find myself giving up more of my life to meet my children's needs than I ever expected. | SA | A | NS | D | SD |
| 3. | I feel trapped by my responsibilities as a parent | SA | A | NS | D | SD |
| 4. . | Since having this child, I have been unable to do new and different things | SA | A | NS | D | SD |
| 5. | Since having a child, I feel that I am almost never able to do things that I like to do | SA | A | NS | D | SD |
| 6. . | I am unhappy with the last purchase of clothing I made for myself | SA | A | NS | D | SD |
| 7. | There are quite a few things that bother me about my life | SA | A | NS | D | SD |
| 8. | Having a child has caused more problems than I expected in my relationship with my spouse (male/female friend) | SA | A | NS | D | SD |
| 9. . | I feel alone and without friends | SA | A | NS | D | SD |
| 10. | When I go to a party, I usually expect not to enjoy myself | SA | A | NS | D | SD |
| 11. | I am not as interested in people as I used to be | SA | A | NS | D | SD |
| 12. | I don't enjoy things as I used to | SA | A | NS | D | SD |
| 13. | My child rarely does things for me that make me feel good | SA | A | NS | D | SD |
| 14. . | Most times I feel that my child does not like me and does not want to be close to me | SA | A | NS | D | SD |
| 15. . | My child smiles at me much less than I expected | SA | A | NS | D | SD |
| 16. . | When I do things for my child, I get the feeling that my efforts are not appreciated very much | SA | A | NS | D | SD |
| 17. | When playing, my child doesn't often giggle or laugh | SA | A | NS | D | SD |
| 18. . | My child doesn't seem to learn as quickly as most children | SA | A | NS | D | SD |
| 19. . | My child doesn't seem to smile as much as most children | SA | A | NS | D | SD |
| 20. . | My child is not able to do as much as I expected | SA | A | NS | D | SD |
| 21. | It takes a long time and it is very hard for my child to get used to new things | SA | A | NS | D | SD |

For the next statement, choose your response from the choices "1" to "5" below

22. I feel that I am: 1 2 3 4 5

1. Not very good at being a parent
2. A person who has some trouble being a parent
3. An average parent
4. A better than average parent
5. A very good parent

| | | | | | | |
|---|---|---|---|---|---|---|
| 23. | I expected to have closer and warmer feelings for my child than I do and this bothers me | SA | A | NS | D | SD |
| 24. . | Sometimes my child does things that bother me just to be mean | SA | A | NS | D | SD |
| 25. | My child seems to cry or fuss more often than most children | SA | A | NS | D | SD |
| 26. | My child generally wakes up in a bad mood | SA | A | NS | D | SD |
| 27. | I feel that my child is very moody and easily upset | SA | A | NS | D | SD |
| 28. . | My child does a few things which bother me a great deal | SA | A | NS | D | SD |
| 29. | My child reacts very strongly when something happens that my child doesn't like | SA | A | NS | D | SD |
| 30. | My child gets upset easily over the smallest thing | SA | A | NS | D | SD |
| 31. | My child's sleeping or eating schedule was much harder to establish than I expected | SA | A | NS | D | SD |

For the next statement, choose your response from the choices "1" to "5" below

32. I have found that getting my child to do something or stop doing something is:

1 2 3 4 5

1. Much harder than I expected
2. Somewhat harder than I expected
3. About as hard as I expected
4. Somewhat easier than I expected
5. Much easier than I expected

For the next statement, choose your response from the choices "10+" to "1-3"

33. Think carefully and count the number of things your child does that bother you. For example: dawdles, refuses to listen, overactive, cries, interrupts, fights, whines, etc.

10+ 8-9 6-7 4-5 1-3

| | | | | | |
|---|---|---|---|---|---|
| 34. There are some things my child does that really bother me a lot | SA | A | NS | D | SD |
| 35. My child turned out to be more of a problem than I had expected | SA | A | NS | D | SD |
| 36. My child makes more demands on me than most children | SA | A | NS | D | SD |

Comments

Optional

Mother's Height: Mother's weight:

Today's date

**THANK YOU FOR YOUR TIME**

**Appendix 17: Parent evaluation**

HOP-ON

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## Helping Our Premature Infant ON to better motor skills (HOP-ON)

### Hop-on Evaluation



**Researchers:** Professor Cris Glazebrook,
Dr Sarah Redsell, Dr Samantha Johnson,
Dr Charlotte Beer, Dr Helen Budge,
Sarah Westwater-Wood, Dr Heather Wharrad,
Anita Hughes, Research Assistant (to be recruited)

Study Number:

This questionnaire is to assess your experience of participating in the helping our premature infant on to better motor skills. Please answer the following questions and return once completed in the stamped addressed envelope provided. If you have any questions regarding this you can contact the chief investigator: Professor Cris Glazebrook on 0115 8230420

Thank you for taking part in the study.

Please complete by ticking or writing where appropriate.

**Today's Date .....**

Please rate your agreement with each of the following statements.
There are seven options to choose from:
Strongly agree,
Agree,
Agree somewhat,
Neither agree nor disagree,
Disagree,
Disagree somewhat
Strongly disagree

| | Strongly agree | Agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Disagree | Strongly disagree |
|---|---|---|---|---|---|---|---|
| 1.I used the CD | | | | | | | |
| 2. I used the DVD | | | | | | | |
| 3. The activities were clear | | | | | | | |
| 4. The DVD/CD helped me interact with my infant | | | | | | | |
| 5. I found the CD easy to use | | | | | | | |
| 6.I did not have time to use the CD/DVD | | | | | | | |
| 7.I found the stages relevant to my infant | | | | | | | |
| 8. I would recommend using the CD/DVD to a friend | | | | | | | |

9. What was good about the HOP-ON CD/DVD?

10. What did you like least about the CD/DVD?

Please use the space below to make any comments you feel are relevant to the study.

**Thank you for completing this questionnaire.**
**Please return it in the envelope provided.**

HOP-ON

Helping Our Premature Infants ON to better motor skills



# Helping Our Premature infants ON to better motor skills ("HOP-ON")

## Information Booklet 1

### (0-3 months corrected age)

**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

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# Welcome

**All babies are different**
**and will develop at different speeds!**

The HOP-ON programme aims to show you how you can help your baby develop her movement skills.

In this booklet we will show you ways you can help her development through your interactions.

The advice in this booklet offers brief movement-based activities you can use to add variety and different experiences to your interactions with your baby.

## Twins

If you are a parent of twins and wish to use these activities then you will either need to do them with one baby at a time or have another adult to help.

## Girl and Boy Twins

This booklet is for parents of girl babies and so uses "her" and "she" throughout. This is the only difference, but if you would also like a booklet for boy babies which uses "he" and "his" then please contact us and we will send you one.

# Activities

The activities within HOP-ON are designed for you to do with your baby regularly for short periods of time. This is because early on your baby will need lots of sleep and will tire more quickly.

The activities themselves are separated into three different sections:

Holding and Playing

Finding my Hands and
Feet Tummy Time

# Making a support roll from a folded towel

Premature babies can find it difficult to bring their arms and legs towards the centre of their bodies. It is not easy for their muscles to work against the impact of gravity, but the way that you hold and position your premature baby can help to overcome this. One of the ways you can help your baby is by using a supportive roll. This will bring her shoulders and legs upwards, and her arms to the centre of her body. This allows your baby to see her hands and feet and become aware of her body. This is important for two reasons. Firstly, before babies can learn how to grasp an object they need to bring their arms together. Secondly, allowing your baby to look down at her hands will help her practise using her eyes together rather than separately.

Below are some instructions for making a support roll from a folded towel (Picture 1). This can be used to help position your baby and can be useful for some of the activities. Although a support roll can be helpful, you do not have to use a support roll for the activities and it should not be used all the time.

**Picture 1: Support Roll**



A towel or muslin square can be used to make a support roll. You can see in Picture 1 that baby's hands and feet are more towards the middle of the body and the back is flat. It is important when using the support roll that your baby's back remains flat.

To make the support roll you need to:

Place the towel flat (Picture 2)

**Picture 2: Towel**



Starting in one corner, roll the towel diagonally (Picture 3)

**Picture 3: Roll the towel diagonally**



Roll until you have a long rolled sausage shape (Picture 4)

**Picture 4: Rolled towel**



Curve the roll, so you have a horseshoe shape (Picture 5)

**Picture 5: Curve the roll**



It is important to check that her shoulders and legs are supported and her bottom is at the curve in the horseshoe (see Picture 6).

**Picture 6: Baby using support roll**



## Holding and Playing

There are many ways that you can hold and play with your baby. Holding her in a range of positions can help her to exercise different parts of her body and gain muscle control.

## Holding your baby

Your baby can be held on her side with her back to your tummy, and your arm across her stomach. Her head is either supported on your arm (Picture 7), or your hand can cup her face while your arm supports her body (Picture 8). When your baby is facing forward, you can use your hand to gently bend one of her legs. Picture 7 shows this position.

**Picture 7: over arm facing forwards**



**Picture 8: over arm**



## Moving while carrying your baby (Rocking and Rolling)

Varying your movement when you are holding your baby is helpful as this can help your baby develop her awareness of movement and gravity. You can try holding her facing forwards as in Picture 9, or facing you as in Picture 10. **Gently** rock forwards and backwards and side to side at different speeds.

## Picture 9: rocking movement (see arrows)



## Picture 10: rocking

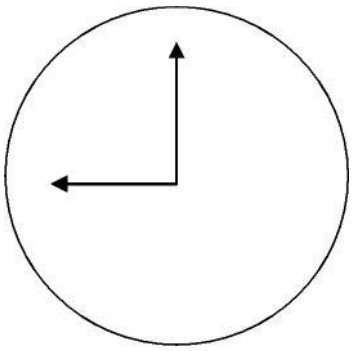


## Tic Toc

One way of varying how you hold your baby is by moving her from arm to arm. This is called tic toc as your baby and you are positioned like the arms of a clock. The positions of the clock are 9 o'clock (Picture 11), 12 o'clock (Picture 12) and 3 o'clock (Picture 13). This can be done whilst you are standing or sitting.

**Picture 11**

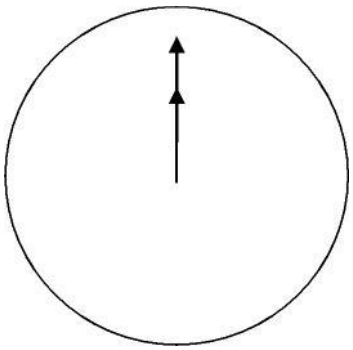




For this hold your baby's head will be at the position of 9 on the clock face

**Picture 12**

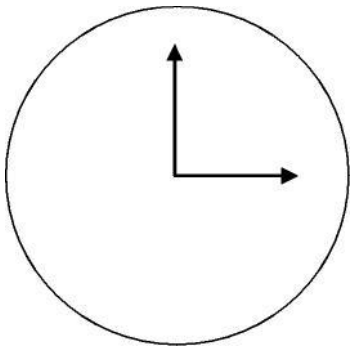




For this hold your baby's head will be at the position of 12 on the clock face

**Picture 13**





For this hold your baby's head will be at the position of 3 on the clock face

Take your time and get used to handling your baby in these different positions.

When you are ready you can move your baby between each position: say from 9 o'clock to 12 o'clock and then back again.

Eventually you and your baby may enjoy moving through the range 9 o'clock to 12 o'clock to 3 o'clock.

All babies and parents are different and you may enjoy moving slowly, or a little quicker. Music and/or singing may add to the fun.

## Playing and Talking

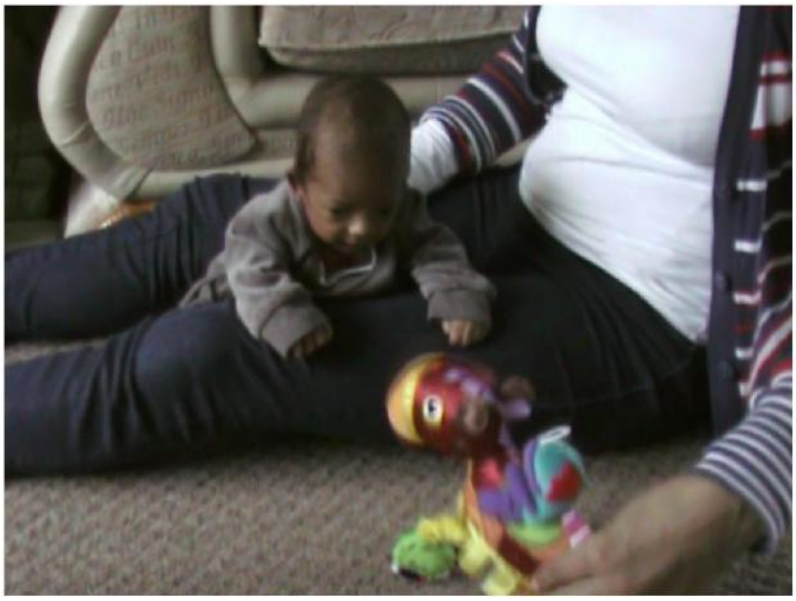
When playing and talking to your baby it is important to have eye contact with her. Once she is able to move her head, you can then start using toys or other items to try and encourage her to follow these objects to develop her head movement (Pictures 14 & 15).

### Picture 14: Eye contact with toy on lap



In Picture 14 you can see that the baby's head, hips and legs are supported into a curl just like when using the support roll.

**Picture 15: Eye contact with toy over knee**



Variety is good. Picture 15 is a different position which will make it easier for your baby to lift her head and look up at the toy.

# Finding my Hands and Feet

## Hands

The first stage of helping your baby to learn how to hold an object is to help her to learn to focus on it. In the early months babies focus best on objects that are around 25- 30cm in front of their eyes. This is about the distance from the mother's face to the baby's face when feeding. Therefore, when interacting with your baby it is helpful to make sure that your face and your baby's hands, feet or toys are about this distance away from her face so that she can focus on them. She will be able to focus on things further away from her as she gets older.

Babies' eyes are attracted by strong contrast in colour. The strongest colour contrast is black and white.

Try to give your baby opportunities to see her hands as this can help her develop greater awareness of her body. You can help your baby do this by:

Laying your baby on her side, with her back supported (Pictures 16 & 17)

**Picture 16: Side-lying**



**Picture 17: Side-lying**



Using a support roll (as in Picture 6)
Laying your baby on your lap (Picture 18)

**Picture 18: Laying on your lap**



When laying your baby on your lap, it is a good idea to sit in a position where you are supported (such as on a sofa) with your knees slightly bent. Your baby's bottom should be up against your tummy and her legs resting up on your chest.

This position is good as it encourages your baby to look at her hands and also allows her to use her hands to explore different textures (soft, fluffy, rough, etc.). You can do this by having some objects or toys with different feels or textures for her to touch. Feeling different textures is helpful for developing sensation (Picture 19).

**Picture 19: Hand to toy**



It is also good to help your baby explore her body. When playing with your baby you can encourage her to put her hands:

to her face

to her head

to her ears

to her shoulders

to her knee

to her foot (Pictures 20 & 21)

Remember to tell her what she is doing.

You can make this into a song or a game. For example, "here's my eyes; here's my ears; here's my nose and here's my hair".

**Picture 20: Hand to foot using support roll**



**Picture 21: Hand to foot**



Try to vary the movement by touching left hand to right foot, right hand to left foot, hands to hands, and feet to feet.

Talk about what you are doing (e.g. "this is your head" Pictures 22 and 23).

**Picture 22: Hands to head**



**Picture 23: Touching head**



## Feet

It is also helpful to encourage your baby to use her feet to explore different textures (soft, fluffy, rough, etc.) as this can help her develop her sense of touch and awareness of the environment around her. You can help her do this by using a variety of textured toys or other items to touch her feet.

Babies need to move their legs and feet, so giving them space to kick their legs is important. Babies begin by kicking both legs out at once, this is natural. After a few weeks you can help your baby to kick out one leg at a time. You can do this by allowing her to kick at one of your hands, and gently pushing against her foot so that her leg is slightly bent. She can push back to straighten her leg. This is assisting her to kick her legs one at a time (Picture 24).

**Picture 24: Assisted Kicking**



When doing these activities your baby should be relaxed so that the movement is gently encouraged and free. It should never be forced.

If she is not enjoying it, leave it for a while and try again another time.

## Tummy Time

It is good for babies to feel what it is like to be on their tummy as this can help them develop control of their head movements and strengthen key muscles. However, you should only put your baby on her tummy for very short periods of time until she is able to hold her head up and turn to the side. You should always stay with your baby during tummy time and take particular care if the surface is above floor height.

**Do not allow your baby to go to sleep whilst on her tummy**.

Placing your baby on her tummy can be done in several ways including:

Laying your baby chest to chest with you (Picture 25)

**Picture 25: Tummy chest to chest**



When you are lying chest to chest with your baby, your head needs to be supported as you lie on your back. You may need to support your baby's chest with your thumbs or hands to help her prop himself up on her elbows. Find a comfortable position and remember it is just as important for you to move little and often as it is for your baby. For new mothers, practising your pelvic floor exercises in any of these positions will create movement for your baby and can be of benefit for both.

At a later stage, if your baby can prop himself up on her elbows, you can help her to learn to lift her chest by supporting her bottom (Picture 26).

### Picture 26: Support when propping themselves up



Tummy time on the bed (Picture 27)

### Picture 27: Tummy Time on the bed



Laying your baby over your knees (Picture 28)

**Picture 28: Tummy Time lying over knees**



Putting a roll or towel under your baby's chest (Picture 29)

**Picture 29: Tummy Time with towel under chest**



As your baby gets used to tummy lying and leaning on her elbows, you can use play to move her more to one side then to the other. When your baby turns her head to look at one side then the other she is learning to co-ordinate all the muscles of her body.

Whilst she is on her tummy you can try and encourage your baby to lift her head by talking to her or attracting her attention with a toy. If she looks at the toy then move it to the left or right. As she turns to follow, she will be putting her weight very slightly more to one side than the other. This is the start of developing her body muscles and her body control. She may try to reach towards the toy at first with crawling or clawing of her fingers. Eventually, she will begin to push up using her elbows or with her arms straight. Either way is good.

Not every baby will enjoy every suggestion in this booklet all the time. If your baby is not enjoying something she may not be ready. Leave it for a few days and try again.

**Thank you for taking the time to read and use this information booklet.**

**We hope this information about ways you may be able to help your baby's development has been useful.**

**Below are some of the sources of information which were used to write this booklet. If you would like a complete list, please let us know.**

Selected sources of information:


Bly L (1994) **Motor skills acquisition in the first year: An illustrated guide to normal development.** San Antonio, Texas, Therapy Skills Builders

Shumway-Cook A, Woollacott MH (2000) **Motor control: Theory and Practical Applications** (2nd Edition). Baltimore, MD, Lippincott Williams and Wilkins.

Spittle A, Orton J, Doyle LW, Boyd R (2007) **Early developmental intervention programs post hospital discharge to prevent motor and cognitive impairments in preterm infants.** *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD005495. DOI: 10.1002/14651858.CD005495.pub2.



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# HOP-ON

Helping Our Premature Infants ON to better motor skills



# Information Booklet 2

## (from around 3 to 12 months corrected age)

**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

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# Welcome

## Now your baby is older you can help him develop new movement skills

The first HOP-ON CD/booklet recommended some movement-based activities you could do with your baby in his early months.

Now that your baby is older, there are some new ways you can help your baby to continue developing his movement skills. This second booklet will show you some of these activities.

The activities in this booklet are designed for you to do with your baby regularly for short periods of time. Remember to stay with your baby during these activities.

All activities should be carried out on the floor.

Don't rush to move your baby onto the next stage. It is better to give him lots of opportunity to practise his movement skills at each stage. That way he will find the next stage easier.

If you have concerns about using any of the HOP-ON activities with your baby, or worries about his movement skills, discuss them with a member of your follow-up team, your GP or your health visitor.

If your baby has physiotherapy please discuss the activities in this booklet with your physiotherapist.

# Rocking to Rolling

Now your baby is a little older, you can give him lots of opportunities to practise shifting his weight from side to side. This will help build the skills he needs to help him to roll over and will help develop his co-ordination and strengthen key muscles.

The following activities involve your baby lying on his tummy and rolling. Always stay with your baby whilst he is playing on his tummy and when he is rolling.

**NEVER ALLOW YOUR BABY TO GO TO SLEEP WHILST HE IS ON HIS TUMMY**

## Reaching on my back and tummy

It is helpful to encourage your baby to reach for toys when he is on his back (Picture 1) or tummy (Picture 2). This is the first step to helping your baby learn to roll and will help develop his arm muscles and co-ordination.

**Picture 1: Reaching for a toy whilst on my back**



**Picture 2: Playing with a toy whilst on my tummy**



## Shifting my weight from side to side

When your baby is on his tummy and using his arms to hold his head up, you can give him the chance to move his weight from one side to the other. Use a toy to attract his attention and then slowly move the toy from one side to the other. As he turns to look at the toy, he will be moving his weight slightly to one side. When he is ready, he may begin to reach out for the toy with one hand whilst supporting himself with the other arm.

You can also encourage your baby to shift his weight from side to side by attracting his attention whilst you sit to one side of him. As he turns to look at you, he will be moving his weight slightly to one side (Picture 3).

**Picture 1: Shifting weight onto one side**



When your baby is confident in pushing up and shifting his weight from one arm to the other, he may start to use his hands to push himself up (e.g. Picture 3). He may rock a little as his balance will not be perfect at first.

When on his tummy he will eventually start moving around to face in other directions.

# Rolling

When your baby can easily shift his weight from side to side and reach for toys he may be ready to practise rolling. Giving him opportunities to practise this will help him strengthen the muscles in his neck, back, arms and legs in preparation for crawling and sitting.

You can encourage your baby to roll from his:

 Side to his tummy  Side to his back  Back to his tummy  Tummy to his back

## Rolling from side to tummy

At first, you can help your baby roll from his side to his tummy.

When your baby is on his side you can attract his attention with a toy and slowly move the toy around him and in front of him. Encourage him to look and reach for the toy. As he turns his head to follow the toy, and reaches for it, his weight will begin to shift and he will roll onto his tummy (Pictures 4 & 5).

**Picture 4: Rolling from side to tummy (1)**



**Picture 5: Rolling from side to tummy (2)**



When rolling onto his tummy your baby may end up with his arm underneath him. If this happens, give him time and encourage him to move his arm out.

## Rolling from side to back

You can also help your baby to roll from his side to his back. Just move the toy slowly around him so that it is behind his head instead of in front of him (Pictures 6 & 7).

**Picture 6: Rolling from side to back (1)**



**Picture 7: Rolling from side to back (2)**



Remember your baby is still developing the strength to control his head so as he rolls back, be ready to protect his head. As he practises, he will gain the strength to control his head himself.

## Putting it all together to roll . . . back to tummy

Once your baby is able to roll from his side your baby may like to try rolling from his back to his tummy (Pictures 8, 9 & 10).

You could talk to him and encourage him to reach for the toy. As he turns to look and reach for the toy he will begin to roll onto his tummy (Picture 10). You do not need to turn him yourself. Just wait for him to join in and when he is ready he will finish the roll.

**Picture 8: Rolling from back to tummy (1)**



**Picture 9: Rolling from back to tummy (2)**



**Picture 2: Rolling from back to tummy (3)**



When he is lying on his back he may bring his legs up and start to grasp his own feet. This can result in him rolling onto his side automatically. It is good for him to be able to grasp his feet and practise rolling back and forth himself as it will help him develop greater body control.

## Putting it all together to roll . . . tummy to back

It can also be helpful for your baby to roll from his tummy onto his back (Picture 11, 12 & 13). This can be done by attracting his attention so that he begins to turn his head to look behind him rather than in front of him.

**Picture 11: Rolling from front front to back (1)**



**Picture 12: Rolling from to back (2)**



**Picture 3: Rolling from front to back (3)**



## Moving on . . .

It is helpful for your baby to develop these skills and practise rolling on his own. You can encourage this by attracting his attention with a toy and slowly moving it to one side. If he is ready, he will use his arms and legs to help him roll (Pictures 14, 15 & 16).

**Picture 14: Rolling without support (1)**



**Picture 15: Rolling without support (2)**



**Picture 4: Rolling without support (3)**



Remember rolling over can be very difficult at first so don't worry if your baby doesn't seem interested in this activity. Leave it for a few days and try again another time.

## Sitting

Giving your baby opportunities to practise sitting can help him develop greater body control and balance. The following activities show you ways you can begin to do this.

### Supported sitting

At first, your baby will need a lot of support when sitting. You can help your baby practise this by sitting him against you so he is facing outwards. You should make sure that you are in a comfortable position with your back well-supported.





When sitting with your baby play with him by using a toy and encourage him to reach forwards (Picture 17) or to either side to grasp it (Picture 18). He may use one hand to support himself as he reaches for the toy. This is good. Doing this will help him develop his balance and his co-ordination.

**Picture 17: Sitting reaching to forward**



**Picture 18: Sitting reaching the side**



Another way to help your baby is by sitting face to face with him. You can do this by sitting your baby in your lap with your legs curled around him (Picture 19). This will act as a support for your baby so you can play with him.

**Picture 19: Sitting face to face**



As your baby gets more confident, he may like to try sitting with less support from you. Give him the opportunity to do this and stay with him to play. This will help him learn how to become more steady and will also develop his body strength.

## Sitting to Crawling

You can help your baby develop greater body control, co-ordination and balance. A good way to do this is to give him lots of opportunities to practise going into sitting and crawling positions and to play with him whilst he is in these positions.

There are many ways you can do this. However, remember that all babies are different. Not all babies will crawl on their hands and knees and some will move in different ways (e.g. bottom shuffle). This is fine. Just see which activities suit you and your baby best.

### Sitting Unsupported

Over time, and with a lot of practice, babies gain more control over their bodies so that they can reach further and move more whilst sitting.

Once your baby is more confident sitting with support, you will find that you can start giving him opportunities to sit unsupported. When doing this make sure that you stay with him to play.

Whilst he is sitting you could play a game such as stacking blocks/cups. Take turns to stack the blocks and encourage him to reach forward to pick them up and place them on top of each other (Picture 20).

**Picture 20: Sitting unsupported**



Whilst your baby is sitting unsupported you can also encourage him to reach for a toy which you are holding to his side. As he reaches for the toy, encourage him to use one hand to support himself as he leans over (Picture 21). When he reaches the toy allow him to grasp it.

**Picture 21: Side reaching**



## Moving from . . . sitting to lying

When reaching forward or to the side for a toy your baby may end up on his tummy in a lying position (Pictures 22 & 23). As your baby gets stronger this movement will become more controlled. It is good to let your baby practise doing this as it will help him develop his co-ordination and body control.

**Picture 22: Going from sitting to lying (1)**



**Picture 23: Going from sitting to lying (2)**



## Moving from . . . lying to sitting

Once your baby is happy sitting unsupported he may start to try to move into a sitting position when he is lying down. This is an important skill to learn as it will help to strengthen his muscles and become more independent with his movement.

You can allow your baby to do this by encouraging him to roll onto his side. When he is ready he will use his elbow to push up from this position into sitting (Pictures 24 & 25). You can give him a little support as he does this but remember to let him practise doing this without support too.

**Pictures 24: Going from lying to sitting (1)**



**Pictures 25: Going from lying to sitting (2)**



Your baby may also try to move into a sitting position by pushing himself up with his arms while he is lying on his tummy. At first, he may accidently move into this position by pushing backwards on his legs and bending his legs as he pushes up with his arms. This is good. Give him time to practise and get used to moving around.

He may find it difficult to move from lying to sitting as there is a lot to organise. Don't worry, give him lots of opportunities to practise and he will start to master this skill.

## Moving on to crawling

At first, you may notice that your baby sits very still. However, as he becomes more confident he will begin to move his legs around to help him to reach for objects more easily. Eventually, he will put one hand down to reach for things further away and come up into a crawling position.

You can give your baby the opportunity to practise coming up into this position by encouraging him to sit with one leg bent (Picture 26) and to reach forward for a toy in front of him. As he does this, he will start putting more weight on his hands and knees (Picture 27).

**Picture 26: Sitting with one leg bent**



**Picture 27: Moving onto hands and knees**



As he takes the toy, encourage him to go back to a sitting position. This will help strengthen his muscles in preparation for crawling.

As your baby gets used to being in a crawling position, he may rock backwards and forwards in this position or begin to crawl.

Rocking backwards and forwards in a crawling position will help strengthen his arms and legs. Even if your baby doesn't crawl on his hands and knees encourage him to move into and spend time playing in this position to help develop his muscles.

## Crawling

If your baby likes crawling you can encourage him by placing toys just out of his reach. Encourage him to move towards the toy and play with him when he reaches it (Picture 28). This will help strengthen the co-ordination between his hand and his eyes.

**Picture 28: Encouraging crawling**



It is also useful to give your baby opportunities to crawl around and over obstacles. You can do this is by placing toys or pillows on the floor for your baby to crawl around or over. You can also encourage him to crawl over or up your legs to reach a toy

(Picture 29). This will help him develop his movement skills and confidence even more.

**Picture 29: Crawling**



It is important, especially when your baby begins crawling around, to be aware of his safety.

## Kneeling to Walking

Try to give your baby lots of opportunities to practise kneeling, standing and walking. This will help develop his leg muscles and, most importantly, his balance and co-ordination.

The Royal Society for the Prevention of Accidents advises parents not to use baby walkers as they increase the risk of accidents and can prevent babies from using their muscles in a variety of different

ways. The activities below show other ways you can help him practise kneeling, standing and walking.

If your baby doesn't enjoy the activities it may mean that he is not ready for this yet. Leave it for a while and try again another time.

## Moving to standing – kneeling

Before your baby learns to stand it is useful to give him opportunities to practise kneeling. Try encouraging your baby to crawl up to a low surface and move into a kneeling position to reach for and play with toys.

He may lower his bottom down to his heels and come back up again to play. This will help strengthen his knee and hip muscles which are important for standing and walking.

**Picture 30: Kneeling and playing**



## Moving to standing – weight bearing

It is also good to give your baby opportunities to practise using his legs and feet to support his own weight. This will help him develop those leg muscles which are important for standing and walking.

One way you can do this is by sitting your baby on one of your legs so that he is straddling it. When doing this, make sure his feet are touching the ground either side of your leg and that you are in a comfortable position. You can then play with your baby using a toy. Encourage him to reach to both sides for the toy and allow him to grasp it to play (Picture 31).

**Picture 31: Sitting on leg**



As he does this he will be putting slightly more weight on one side than the other, using his leg muscles to support himself and balance. As he becomes more confident he may begin to bear more weight through his legs.

## Standing with support

You may have noticed your baby likes standing and using his legs to support his own weight. When you and your baby are ready you can encourage this by supporting your baby in a standing position (Picture 32). This will help him learn what it is like to stand on his feet and develop his balance and body control.

### Picture 32: Supporting baby in a standing position



Babies and parents often enjoy playing this game. At first, a little time in this position is fun but, if you have to support your baby a lot he may not be ready yet. Leave it for a while and try again another time. As your baby gets stronger he will need less support from you and may like playing this game more often.

## Moving from . . . kneeling to standing

Once your baby is confident standing on your lap, he may like to try moving into a standing position and standing with less support from you.

Whilst sitting on the floor, with your baby kneeling against a low solid surface like a coffee table or chair, attract his attention to a toy on the surface that is just out of his reach. When he is ready he will reach for the toy and bring one leg in front of the other so he is kneeling on one knee (Picture 33). He will then use his legs and arms to push/pull himself into a standing position to grasp the toy on the chair (Picture 34).

**Picture 33: Kneeling to standing (1)**



**Picture 34: Kneeling to standing (2)**



Whilst he is in this standing position you can play with him by encouraging him to reach for different toys and grasp them or by playing a game such as stacking blocks. At first, he will rest his chest on the surface for support as you do this (Pictures 35 & 36). However, as he gets better he may just use one hand to hold the surface and support himself.

**Picture 35: Standing and playing**



**Picture 36: Standing and playing**



At first your baby may need some support when he practises moving from kneeling to standing. However, as he progresses try and give him opportunities to do this on his own whilst you sit with him.

Remember to make sure that the surface your baby is pulling up to is stable.

## Standing and turning

As your baby becomes more comfortable with standing and playing, you can begin to encourage him to turn whilst he is standing.

One way you can do this is by encouraging him to reach for a toy to his side. Whilst he is standing at the sofa/chair, attract his attention to a toy you are holding to the side of him and encourage him to turn and reach for the toy (Picture 37). Eventually, he will begin to grasp the toys you hold out for him and bring them round to the play area in front of him.

**Picture 37: Turning whilst standing**

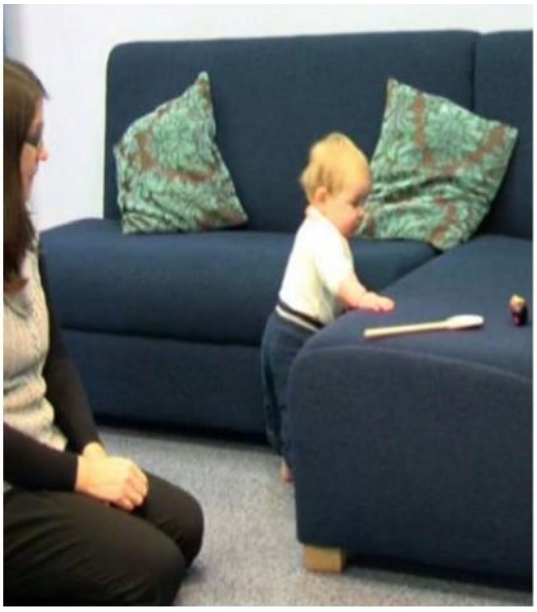


## Cruising and unsupported standing

When your baby is a little older and is comfortable with the activities already described, he may attempt to side step along a low surface. This is known as cruising. It is important to wait until he has really mastered the previous activities before you let him move on to this next stage.

You can encourage his cruising by placing a few toys slightly out of reach and allowing him to reach for them. When he is ready, he will begin to side step towards these toys to play with them, using the surface as support (Picture 38).

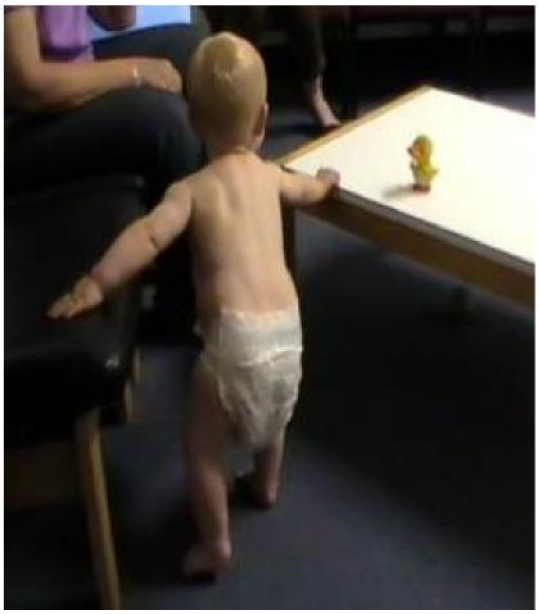
**Picture 38: Cruising**



At first, the toys only need to be a small step away from your baby. However, as he becomes more confident you can give him the opportunity to move several side steps to reach toys further away.

As your baby becomes more confident with cruising he may be ready to try cruising with less support. Try putting toys across a small gap and encouraging him to collect them. By doing this you will be giving him the opportunity to bridge the gap (Picture 39) and take his first steps towards being able to stand, and walk, unsupported.

**Picture 39: Bridging the gap**



As your baby becomes more comfortable bridging small gaps you can try increasing the distance of the gap for him to side step across.

It is important to allow your baby time to become confident and steady doing each new movement. It is also helpful to give him time to think about how to make his next step. Try not to rush him. Putting the movements together takes a lot of practice.

**Thank you for taking the time to read and use this information booklet.**

**We hope this information about ways you could help your baby's development has been useful.**

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Royal Society for the Prevention of Accidents (2000). Baby Walkers [online] Available at: http://www.rospa.com/faqs/detail.aspx?faq=217 [Accessed 07 Feb 2011]

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**This project was supported by grants from The Henry Smith Charity and Action Medical Research**

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The University of Nottingham

smiles
Sharing My Infant's Learning Experiences



# Sharing My Infant's Learning Experiences

# Information Booklet

**Researchers:** Professor Cris Glazebrook, Dr Sarah Redsell, Dr Samantha Johnson, Dr Charlotte Beer, Dr Helen Budge, Sarah Westwater-Wood, Dr Heather Wharrad, Anita Hughes, Katy Allen

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# Welcome

The smiles programme is designed for you and your infant. It will give you information about your baby's development and how you can help this development.

'Smiles' also looks at the interactions that you will have when you go home with your baby. Interactions are when you are talking, touching, holding, looking and playing with your baby. These positive interactions have been found to help the development of babies.

Through the information in this programme you will read about and see how you can help you baby's development through your interactions.

# All about interactions

## The importance of interactions

Early interactions have been found to play an important role in the development of infants. Positive, stimulating interactions can:

- Help intellectual development
- Help the development of language skills
- Help build muscle control
- Help infants learn how things work
- Help infants solve new problems

## How much do they need?

'Premature infants need interactions as much as other babies do.'

Positive interactions and stimulation are even more important for premature infants. This is because premature infants have a higher risk of delays in their development, problems with muscle coordination and learning problems. If premature infants are stimulated and are exposed to positive interactions that help encourage development they have a bigger chance of overcoming these problems.

"I'm at the stage where I'm thinking, right, okay, what do I need to be doing to help her development?' (Mother of baby born 32 weeks)

## How much do parents interact?

'Parents of premature infants do not interact and play with their babies as much as parents of full term infants.'

Although each parent is different, parents of premature infants as a whole have been found to act differently compared to parents of full term infants. They move and hold their babies less, and they talk and look after them less often.

*Why?*

Parents might be afraid that they'll do something wrong or that they will hurt their baby. There is also some evidence that parents of premature infants expect less of their baby. If parents expect that their baby will not develop very quickly and will not be interested in interacting, they in turn might interact, hold and talk less to their baby. This means that the infants who would benefit most from positive interactions may not be receiving them.

'When it came round to just being with him and playing with him we didn't really know what to do.' (Mother of baby born 24 weeks).

‘The two of us kind of sat and looked at each other and thought, well, what do we do now?’

(Mother of baby born 33 weeks).

## Overstimulating

‘Interacting a lot with my baby won’t over stimulate her.’

When premature infants are born they can be very fragile and sensitive. Many parents cannot have a lot of contact with them until they are stronger.

By the time you take your baby home she will be much stronger and you will be able to hold her, talk to her and interact with her.

The more you play with your baby, the older they get and the stronger they get, interactions will last longer and your baby will be able to take part more actively.

‘We were happy to take her out but on the other hand we were really quite scared to anything with her.’ (Mother of baby born 28 weeks).

## Sleeping baby

‘My baby sleeps a lot. It’s ok to wake them up to play with them.’

 Many parents are surprised by how many hours their premature babies sleep when they take them home

 Premature infants tend to be much less active and much more passive compared to full term infants.

 Until your baby gets a little older it is you who will have to make the first move because many infants would sleep most the day if they could.

 While it is important that they get plenty of hours sleep each day, it is also important that they have a chance to interact and play with you.

 Take advantage of the times your baby is awake and don't be afraid of waking them up if they have had a long uninterrupted nap so that you can play together.

'At first to be honest she slept . . . she would literally be fed and changed and would sleep. There wasn't much interaction.' (Mother of baby born 28 weeks)

'He was so little that he didn't really interact with us much at that stage.'

(Mother of baby born 27 weeks).

## How can you help interactions with your infant

*Relax*

You have been through a lot and it is natural that you feel anxious about taking your baby home. Remember that the doctors and nurses would not have sent your baby home if your baby was not ready and if they were not positive that you could look after them.

*Give yourself time*

Babies often cry and fuss for many reasons, for example if they are hungry or tired. It may be confusing in the beginning but give yourself time to get to know your baby's signals.

*Create a routine*

This may take some time with some babies but it will happen. Getting into a routine with feeding and bathing will help both of you. Also, this way you can make the most of the times your baby is awake.

### Talking

Talking to your baby can help them very much because it stimulates their attention and helps them develop their language skills.

When you are playing you can talk about what you are doing, describe toys and give feedback to your baby about what they are seeing or doing.

## Supporting your baby

When you are playing with your baby look out for what things your baby is interested in and try and encourage them.

If your baby is looking for a particular toy help them satisfy their interest: give it to your baby or hold it close to them, let them feel it and talk to them about it.

## Joint attention

When you are playing with your baby episodes of joint attention can be very positive. This is when you are both playing with a toy together, you are both looking at each other and you are talking to your baby about what is happening.

This helps your baby to focus on what you are doing and it also helps stimulate your baby's attention, muscles and language skills.

### Responding to your baby

 Although you may find it hard at first, in time you will learn to understand what your baby is telling you.

 Your baby will give you clues when they want to interact and play with you. These can be looking at you, reaching to you, smiling and vocalising.

 Your baby will also give you clues when they need a break from your interaction. These can be frowning, fussing, looking away or crying.

## All about toys

### Toys

- Your baby's toys can do a lot more than just keep your baby occupied.
- Toys are designed so that they excite and interest infants and provide stimulation in the areas which it is most needed.
- Toys can stimulate your infant's senses of sound, touch, smell and sight, and also help with your infant's development of co-ordination and motor skills.
- Infants who have access to a range of toys are stimulated more often and show quicker physical and intellectual development.

### My baby doesn't play with toys

- Some parents notice that initially their baby does not show a lot of interest in toys.
- In the early days you will have to introduce toys to your baby so that you can start playing. You do not

have to wait for your baby to show an interest in something so you can play with them.

- Showing your baby different toys, talking about them and letting your baby touch them can be a good way of introducing toys.
- Having a range of stimulating toys will help your baby become more interested in time.

## Top qualities for toys

1. Safe
2. Easy to handle
3. Stimulates more than one sense
4. Gives infant feedback
5. Gives infant comfort

### Safe

Manufacturers follow strict guidelines so that their toys are safe. What you can do is make sure that the toys that are available to your baby are safe and do not contain things that could be dangerous (e.g. small pieces that detach from the main toy).

### Easy to handle

At first your baby will simply look at things. Later on, when your baby gets older though they will want toys that they can grasp and hold and which are easy to handle.

### Stimulates senses

The best toys are those which stimulate and excite many different senses at the same time. Infants prefer toys with bright, bold colours, different materials, and toys which make sounds.

Toys like this will make your baby use their touch, their hearing and their eye sight.

## Gives infant feedback

Your baby will like toys which do things. When your baby is old enough to hold and move things they will enjoy toys which make noises or have surprises (e.g. rattle).

Toys like this will also help your infant to realise that they are an active member in the environment and that their actions affect the things around them.

## Gives baby comfort

Your baby should enjoy playing and should feel comfortable and comforted by her toys. Toys which are soft and cuddly will not only comfort your baby but will also reduce anxiety.

# Putting it all together

The following images show parents putting all this information together.

## Example 1

These parents are:

- Talking to their infants
- Introducing new toys to their infants

to get them interested.

- Talking about what the infants might

be feeling or thinking.

## Example 2

These parents are:

- Making time and playing with their infants.
- Describing the toys to their infants.
- Talking about what the baby is looking at.
- Trying to keep eye contact with their infants

while playing.

## Example 3

These parents are:

- Describing what is happening while playing.
- Helping their infants play with toys.
- Encouraging their infants.
- Praising the infants when they are trying or succeeding in doing something.