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# Safe co-sleeping for all babies:

Do infant safer sleep boxes provide a safe and beneficial sleep environment for infants?

By

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October 2016

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*Master of Science*

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# Abstract

This study evaluates the efficacy of providing an 'infant safer sleep box' (ISSB) compared to a standalone cot in the same room to reduce the occurrence of modifiable risk factors associated with SIDS whilst bed-sharing, by providing observational data of mother-infant dyads using ISSBs in the parent-infant sleep lab.

The present study recruited 11 mother-infant dyads who attended the parent-infant sleep lab for two overnight observations. A randomised crossover study design was used to compare the influence of allocating an infant safer sleep box (ISSB) and a standalone cot in the same room on night-time behaviour. Infant safer sleep boxes, modelled on New Zealand's pēpi-pod are aiming to engage parents with safe sleep advice and provide a safe sleep space for infants. Participants were either allocated a standalone cot on the first night and an ISSB on the second night or vice versa. The study aimed to (1) collect observational data relating to the use of infant safer sleep boxes, (2) compare the effects of allocating an ISSB or a standalone cot on night-time caregiving and (3) to understand if ISSBs can provide a safe sleep environment for infants.

The study population consisted of 10 exclusively breastfeeding infants and one formula feeding infant. The average age of infants was 15 weeks with a range of 4-19 weeks and 80% of participants reported bed-sharing at least once a week. None of the sample reported currently smoking or smoking in pregnancy. On nights allocated an ISSB the study population showed a significantly greater number of looking and touching events ( $p=.024$ ) and increased maternal proximity ( $p=.008$ ) in comparison to nights when their infants were settled in a standalone cot in the same room. Results also indicated that allocating an ISSB may be influential in increasing the frequency and duration of breastfeeding, reduce the occurrence of head covering events and create a safer sleep environment compared to a standalone cot in the same room for a preponderance of the study population.

This study contributes to the growing understanding of portable sleep enablers as safe sleep spaces for infants who are contraindicated to bed-sharing. This study has indicated that using an ISSB did not interfere with normal infant care and may enhance parental monitoring and awareness of infants.

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# Introduction

The field of evolutionary paediatrics, developed through the merging of evolutionary medicine and ethno-paediatrics, has focused on using evidence gained from cross-species, cross-cultural, historical and palaeo-anthropological research to critique modern day infant care practices (Ball 2008).

Evolutionary medicine posits that compromises to health may be a consequence of the incompatibility between the lifestyles and environments humans currently live and those under which human biology evolved (Trevathan, Smith and McKenna 1999). Ethno-paediatrics focuses on recognising the influence of culture and cultural beliefs on health, behaviour and illness (Worthman 1995) and uses a cross-cultural approach to study how different caregiving styles may influence infant health and well-being (Ball 2008). Evolutionary paediatrics has been successful in highlighting the effects of Western post-industrial infant care practices on infant health outcomes and has proved effective in influencing behaviour change to mitigate the effects of evolutionary mismatches (McKenna, Ball and Gettler 2007).

An important aspect of contemporary childcare practices that evolutionary paediatrics has deemed to be detrimental to health and wellbeing is the separation of mothers and infants following birth (Ball 2008). Constant mother-infant contact in the postnatal period is present across many societies worldwide as well as being an undisputed feature across non-human primates. Mother-infant separation in the immediate postnatal period and over a number of months is associated with negative outcomes such as colic and excessive crying, maternal postnatal depression, sudden infant death syndrome (McKenna 1986; Konner & Super 1987) and a decline in mothers initiating breastfeeding (Ball 2008) to name just a few. Human infants are poorly neurologically developed at birth requiring close contact for safety, physiological regulation and sustenance (Ball & Russell 2014). Western post-industrial populations are unique in their adoption of a culture of placing infants to sleep in a separate room to sleep. Separation during sleep has historically been recommended by a number of parenting guides and specialists (Ford 2006; Spock 2005) to improve infant sleep quality and promote cultural notions of independence and self-sufficiency (McKenna et al. 2007).

Comparative evolutionary studies have been integral in progressing knowledge surrounding the mechanisms underlying sudden infant death syndrome (SIDS), defined as the unexpected death of an infant which remains unexplained following post-mortem, death scene investigation and review

of the clinical history (Willinger, James & Catz 1991). SIDS has been recognised as a consequence of contemporary sleeping arrangements such as solitary infant sleep and excessive use of soft bedding (Blair et al. 1999; Volpe et al. 2012). As well as this, external factors such as recent parental consumption of alcohol, extreme parental tiredness, smoking during pregnancy and sleeping in the prone position (Blair et al. 1999, Blair et al. 2009, de Jonge 1993) have all been associated with an increased risk of SIDS when same-surface co-sleeping, however individual risk factors are by no means universal and SIDS risk factors vary cross-culturally. Although the mechanisms underlying SIDS are unknown, SIDS is thought to occur through the convergence of 'intrinsic infant vulnerability' (infants who were exposed to parental smoking in utero, low birth weight, premature and male gender) a 'critical development phase' (the first six months of life) and exposure to an external stressor (a feature of the environment that challenges the infant's physiological responses) (Ball & Russell 2014).

Interventions and guidance to mitigate the occurrence of modifiable risk factors for SIDS have previously focused on attempting to reduce the occurrence of same surface co-sleeping recognized as an external stressor for vulnerable infants. In order to reduce risks associated with SIDS from co-sleeping authorities recommend that infants should be placed in a cot in the same room as their parents (The Lullaby Trust 2016). This advice is drawn from SIDS studies that have found a greater risk of SIDS whilst sleeping in a separate room and/or sleeping in the parental bed, compared with sleeping on a separate surface in the parent's room (Blair et al. 1999; Hauck et al. 2003; Carpenter et al. 2004; Blair et al. 2006; Blair et al. 2009). These safe sleep guidelines have avoided confronting complexities surrounding the bed-sharing debate and fail to consider that close mother infant contact is a common if not necessary tactic to negotiate night-time caregiving. Blair & Ball (2004) found that regardless of recommendations that the safest place to put infants to sleep is a standalone cot in the same room, 50% of parents in the UK reported co-sleeping with their babies in the first three months, indicating that these recommendations are inappropriate and result in a knowledge deficit with parents and caregivers uneducated about safe co-sleeping practices.

An emerging discourse in infant sleep education has shifted from a focus on risk elimination to risk minimisation, emphasising the need to educate parents about unsafe sleep practices and encourage open discussion about co-sleeping. A new wave of interventions, such as the *wahakura* and the *pēpi-pod*, have focused on utilising knowledge gained from an evolutionary approach to offer alternative sleep spaces for high-risk infants which can provide the benefits of close parent-infant sleep contact whilst eliminating the risks associated with same-surface co-sleeping. The *wahakura* is a woven basket-like structure in which the infant is intended to sleep, it can be placed in the parental bed in between the parents simulating a co-sleeping environment but providing a safe

sleep space for the infant. The *wahakura* is a culturally embedded intervention using traditional Māori materials and techniques to engage high-risk families with safe sleep messages. Although little is known about the way parents are using these sleep spaces they have been shown to be effective in reducing the rate of SIDS within disadvantaged populations in New Zealand (Cowan 2013).

The present study aims to assess the efficacy of providing parents with a safe sleep space, henceforth referred to as an 'infant safer sleep box' (ISSB) by observing how maternal caregiving and the frequency of modifiable risk factors are affected by the allocation of an ISSB and a standalone cot.

This thesis is divided into five main sections, chapter two uses a comparative evolutionary approach to review existing literature relating to normative infant-care practices, the epidemiology of sudden infant death syndrome (SIDS) and how previous interventions to reduce the occurrence of modifiable risk factors associated with SIDS have been limited because of their failure to consider the biological benefits of close infant and maternal sleep. The chapter will finish by outlining what is currently known about safe sleep enablers and their efficacy in providing safe sleep spaces for high risk infants.

Chapter 3 describes the design, protocol and conduct of a randomised cross-over trial to compare parent-infant interactions and the occurrence of risky events throughout two overnight observations of two allocated conditions: an ISSB and a standalone cot in the same room.

The results from the observational study are presented in chapter 4, including a breakdown of the study population, intention-to-treat (all participants who completed two overnight observations) and per-protocol (participants who used allocated condition used as primary sleep location) analyses. This chapter also describes the occurrence of potential risks, head covering and unsafe sleep environments in the two conditions.

Chapter 5 describes the implications of allocated condition on maternal caregiving and frequency of mitigatable risks by relating the results to published literature of the influence of maternal proximity on maternal caregiving behaviours and factors affecting the prevalence of modifiable risk factors for SIDS.

The final chapter reviews the extent to which the research objectives were met, acknowledges the limitations of the findings and presents suggestions for further research.

# Literature Review

## Evolutionary Perspectives

### The evolution of pregnancy and childbirth

Placental mammals can be distributed into species that produce large litters of small and poorly developed offspring after a short gestation period (*altricial*) and those that produce small litters of large and well-developed offspring after a relatively long gestation period (*precocial*) (Martin & Maclarnon 1982). Of the primates, monkey and ape infants (including humans) fall into a precocial pattern of reproduction exhibiting a relatively long gestation period, with eyes and ears open at birth, a large body size (in relation to maternal body size) and frequent and on demand suckling of milk provided by a primary caregiver (Small 1998; Martin 1992). It has been argued that the pressures imposed by the restrictions of pelvic width on neonatal brain size result in the birth of extremely immature infants who display a number of 'secondarily altricial' characteristics (Trevathan 1987). Known as the 'obstetrical dilemma' (Rosenberg 1992), the evolutionary conflict between the development of large brains and the necessity of narrow pelvises to facilitate efficient bipedal locomotion has been attributed to the development of secondary altriciality in human infants.

The ability to habitually walk on two legs is a unique characteristic that defines humans from other non-human primates (Rosenberg & Trevelyan 2002). The function of bipedalism invariably changed pelvic morphology; human pelvises have short iliac blades that curve around the body and flare outwardly creating a bowl shape, as opposed to non-human primate/quadruped pelvises that are tall flat plates oriented vertically in the coronal plane (Gruss & Schmitt 2015). Humans are also distinguished from all other species for having the largest brain in relation to body size (Rosenberg & Trevelyan 2002). The evolution of larger brained hominins in the genus *Homo* required pelvic shape to facilitate the delivery of well-developed infants with large brains without harm to the mother whilst still maintaining a pelvic morphology to enable efficient bipedal locomotion. These conflicting pressures are believed to have resulted in the birth of underdeveloped offspring constrained by pelvic width and alterations in pelvic morphology which complicated the birth mechanism (Rosenberg & Trevelyan 2002; Trevathan 1996). However, an alternative hypothesis presented by Dundswoth and colleagues (2012) argues that the metabolic strain of gestation limits infant growth in utero, resulting in the birth of immature infants. The authors argue that recent biomechanical evidence fails to support the obstetrical dilemma hypothesis and shows that the pelvis could facilitate widening whilst still providing an efficient form of locomotion. Instead of a conflict

between pelvic width and brain size, secondary altriciality may result from a conflict between foetal energy needs and maternal energy supply, which is finite. Regardless of the evolutionary mechanism that resulted in secondary altriciality, it remains an undeniable and distinct feature of human infants.

Neonatal brain size at birth is around 300-400g, one quarter the size of the average adult brain (Trevathan 1987) and doubles in size during its first year of development (Montagu 1961). This contrasts greatly with other non-human primate species who are born with brains averaging half of their adult brain size (Trevathan 1987). Montagu (1961) refers to the period after birth in which the infant acts more like a foetus than an infant as 'exerogestation', using the adoption of quadrupedal locomotion as the developmental milestone distinguishing foetus' from fully developed infants. This framework for understanding gestation length would double the length of human gestation to 18 months (Montagu 1961, Gould 1977). Martin (1992) compared the gestation length, birth weight and adult body size across a number of mammals and calculated that human gestation should be about 21 months in length, extending the length of exerogestation to one year after birth. The structure of human milk encourages rapid brain growth throughout this critical period of exerogestation; it is low in fat and protein but high in sugar (lactose), which provides essential energy for brain growth (Jellife & Jellife 1978; Ball & Russell 2013). Unlike cache and/or altricial species, whose milk composition is high in fat and protein and serves the purpose of sustaining infants for long periods of separation from their caregivers; human milk provides few calories per feed, indicating that human infants are 'on-demand' feeders, requiring frequent nursing and maternal proximity at all times (Ball 2006).

### Non-Human Primate sleep

Studies of primate behaviour have long been used as an indication of how our early hominid ancestors behaved and can provide context for constructing evolutionary and adaptive scenarios; however there has been very little specific research into non-human primate maternal and infant sleep behaviours (McKenna, Ball and Gettler 2007). Close and constant mother-infant contact throughout sleep is omnipresent in almost all primate species, leading some to hypothesise that it does not compel researchers to seek greater understanding and is overlooked by a focus on more variable sleep behaviours that demand explanation (McKenna, Ball and Gettler 2007), such as the avoidance of predation, the effect of social structure on night-time subgroups and food distribution patterns (Anderson 1984, cited in McKenna, Ball and Gettler 2007). Anderson and McGrew (1984) whilst studying Guinea baboons, noted that they omitted studying infant sleep behaviours because they "always huddled overnight with their presumed mothers" (pg. 7). McKenna and colleagues (2007) refer to the concept of non-human primate mother-infant separation during sleep as

“absurd” (pg. 140) given the vulnerability of primate infants and the protective value of maternal proximity and care.

Great ape species have adapted sleep behaviours to ensure that they can avoid predation throughout the night, primarily by sleeping arboreally. All Great Ape species, in particular Chimpanzee (*Pan troglodytes*), Bonobo (*Pan paniscus*) and Orangutang (*Pongo borneo*) exhibit predominantly arboreal nesting behaviours (Koops et al. 2012; McGrew 2010; Stanford 2006). The ability to build complex sleeping structures or ‘nests’ (either for arboreal or terrestrial sleep) is shown to be a universal trait among Great Apes (McGrew 2010; Sabater Pi et al. 1997), indicating that the complexity involved in planning and building intricate structures for protection may have been present in hominin ancestors. Nesting on cliffs and shallow caves have also been observed in various baboon and macaque (*Papionini*) species (Anderson 1984), Hamilton (1982) notes cliff dwelling as the preferred sleeping site for baboons. Monkeys dwelling in urban areas have also been witnessed sleeping on rooftops (Anderson 1984). By placing sleeping sites high in tress, primates become concealed from floor dwelling predators and difficult to access, further reducing their accessibility by placing their nests towards the terminal ends of branches or choosing ‘hazardous’ sites protected by impenetrable obstacles (Anderson 1984).

The adoption of a diurnal sleeping pattern has also been associated with the avoidance of predation; many of the predators of primates are nocturnal (Anderson 1984). By sleeping, primates become quiet and discreet throughout the key period of danger (Meddis 1979) reducing their chances of being spotted by predators. However, a reduction in awareness throughout ‘deep’ sleep cycles increases vulnerability to predation which can be partly mitigated by occupying inaccessible sleeping sites.

Social sleep is common, with most groups of monkeys sleeping in physical contact with one or more of their group enabling thermoregulation and physical stability (Anderson 2000). Mother-infant dyads are an example of a typical huddling subgroup, with maturing infants moving away from their mothers in the daytime, but returning to sleep with them at night; Great Ape infants have been shown to share their mother’s nest for the first 5 years of life. Huddling allows infants to utilise their mother’s metabolic resources, as well as protecting them from infanticide pursuits from competitive males (Nunn et al. 2009). Juvenile chimpanzees that no longer share their mother’s nest have been shown to construct nests near to their mothers. Although social grouping is common, night-time activity is rare, with little direct social interaction. Mothers and their offspring are the exception, with continued interaction throughout the night (Anderson 2000). Specific studies exploring the night-time behaviour of mother-infant pairs in wild primate populations are non-existent, however

Fite and colleagues (2003) conducted a laboratory based study assessing the impact of co-sleeping with infants on the sleep patterns and night-time behaviour of Weild's black-tufted-ear marmosets (*Callithrix kuhlii*). By recording the night-time activity of four family groups without infants and eight groups with infants they found increased night-time wakefulness in mothers caring for young infants, these mothers woke more than three times more than mothers without infants. Infant caregiving for marmoset mothers is energetically costly and daytime caregiving is frequently relinquished to fathers or alloparents, however the disproportionate frequency of maternal waking throughout the night indicates that night-time arousals were due to exclusive maternal behaviours such as nursing (Fite et al. 2003).

Laboratory studies have also been utilised to observe the effects of non-human primate mother-infant separation, demonstrating the devastating physiological consequences of mother-infant separation. Pioneering studies by Harlow (1958) which involved separating macaque infants from their mothers 6 to 12 hours after birth and raising them on surrogate mothers were significant in defining the importance of parent-infant contact. Harlow's studies demonstrated the value of 'contact comfort' in the development of macaque infants, with infants showing a continuing preference for cloth covered surrogate mothers over wire mothers (Harlow & Suomi 1970). In 'fear tests', where the infants were placed in unfamiliar situations, cloth mothers were seen to be a source of comfort with infants showing signs of considerable distress such as vocalization, crouching, rocking and sucking when mothers were absent (Harlow 1958). Studies of maternal separation in pigtail monkeys (*Macaca nemestrina*) by Reite and colleagues (1978; 1982; Reite and Short 1978) showed initial accelerations in heart rate and body temperature, followed by subsequent decreases (Reite et al. 1978), disrupted circadian rhythms (Reite et al. 1978), more frequent sleep disturbances with more awake time and less spent in REM sleep (Reite & Short 1978) for separated infants. Similar results were found from separation studies of bonnet monkey infants (*Macaca radiate*), with the separated infants displaying a 'depressed' body posture, declines in heart rate and body temperature; increases in cardiac arrhythmias and altered sleep patterns (Reite & Snyder 1982). Coe and colleagues (1985) carried out physiological studies of maternal-infant separation in squirrel monkeys and note that even after 30 minutes of separation there were significant increases in the infants' cortisol levels. These studies demonstrate that for primate infants even short periods of separation from a caregiver result in extreme behavioural and physiological changes which could potentially have long term consequences. It seems of note that as a primate species, humans, particularly in Western industrialised societies put their infants to sleep away from a caregiver for long periods of time particularly given the extreme immaturity of human infants.

## The Paleoecology of Human Sleep

Reconstructions of hominid sleep are almost impossible to recreate using evidence from the fossil record. Sleep behaviours do not manifest on skeletal remains and understandings of our ancestor's sleep are speculative. However, factors such as the evolution of bipedalism which facilitated a drastic shift in the environment and ecology of hominid ancestors can help to evidence what may have been influencing changes in sleep behaviour throughout evolutionary history.

Evolutionary changes in sleep ecology have been attributed to the shift from tree dwelling to floor dwelling (Worthman 2008). The evolution of bipedalism would have reduced dexterity in arboreal settings thus reducing the accessibility of arboreal sleeping sites. Loss of hair would also have been an important evolutionary shift that would have made tree dwelling dangerous for young infants by eliminating their ability to cling to their mothers. The use of heat covering materials, such as animal skins and blankets would also become necessary with the loss of hair in order to regulate body temperature during the night. Without the protection from predation provided by arboreal sleeping; tools, social groupings, fire and physical structures would have been used as alternative protection in order to ensure group safety when ground sleeping was adopted. Given the risks involved in terrestrial sleep, human sleep behaviour would have been selected for a high risk environment. Worthman (2008) suggests that the architecture of human sleep is adapted to enable vigilance and responsivity during sleep through the incorporation of sleep cycles with various stages ranging in depth and responsiveness. Sleep bouts consolidated in 90-min cycles with considerable proportions spent in shallower, more reversible sleep states (Stage 1 and Stage 2) and little time spent in deep, inattentive slow wave sleep (stage 3 and stage 4) allow for decreased arousal thresholds and increased sensitivity to sensory cues throughout sleep. McKenna, Ball and Gettler (2007) argue that the sleep architecture of breastfeeding bed-sharing mothers with greater episodes of light sleep, heightened sensitivity and responsiveness reflects ancestral sleep as described by Worthman (2008). Although this trait has largely become redundant due to Western, industrialised sleeping arrangements which are arguably free from risk, it still appears to manifest in cases of mother-infant co-sleeping increasing responsivity to infant cues.

## Cross-cultural sleep practices

Understanding cross-cultural sleeping practices, particularly among nonindustrial populations can be useful in building a more comprehensive picture of the distinctions between evolved and culturally influenced maternal and infant sleep behaviours.

Recognized as one of the key studies in defining the normative pattern of cross-cultural infant sleep (Ball 2006), Barry and Paxson (1971) conducted a large scale cross-cultural comparison of infancy

and childhood behaviour in nonindustrial societies. The review, which considered 127 cultural groups whose infant care practices were recorded in ethnographic reports, showed that in 44% of the societies infants shared a bed or sleeping surface with a caregiver and 79% slept in the same room as their parents. A more recent cross-cultural study conducted by Nelson and colleagues (2000) used the Human Relations Area Files (HRAF) to search the childcare practices of 60 societies in the 19<sup>th</sup> and 20<sup>th</sup> century. Of the sixty societies searched, 53 described childcare practices with bed-sharing referenced in 25 of those. Although only three societies specifically indicated that no separate bed was used for children, none of the sample reported infants sleeping in separate rooms. Ball (2006) has previously criticized cross cultural surveys as 'limited in scope and unsystematic' given the speculation involved in many of the ethnographic reports of sleeping arrangements; many have overlooked or not been able to reliably record private sleeping arrangements. Ethnographic reports are dependent on the ethnographers' personal biases and selectivity in recording, it is important to consider that unusual cultural practices may be recorded rather than normal or commonplace behaviours (Nelson et al. 2000). The absence of any standardized rating scheme for sleeping arrangements means that data between authors is varied, with just under half of the ethnographic sample rated as reliable. Ball however defends the studies as useful in providing a representation of general infant care practices, which demonstrate that mother-infant sleep contact is common throughout the world and separate sleeping arrangements are the exception.

Mauss (1973) distinguishes humans into 'people with cradles and people without' (pg. 79); specifying the entire Northern hemisphere, the Andean region and particular Central African cultural groups as cradle users. Whiting (1981) attributed differences in infant care practices across the world to climatic variation; showing that mother-infant co-sleeping is more common in areas where the winter climate is warm or hot, with 85/91 mothers sleeping with their infants on shared beds or mats. In areas with cool or cold winters (<10°) only 29/45 mothers appear to sleep with their infants, with the remaining cultures displaying separate parent-infant sleep, either in a crib or cradle. Whiting describes African infants as typically carried around on someone's back in a sling throughout the day or in constant bodily contact with a caregiver, sleeping beside the mother on a cloth at night (Konner 1976 cited in Whiting 1982). Ethnographic data of the !Kung has shown that it is universal for !Kung infants to sleep with their mothers on the same skin mat at least until weaning. Konner (2004) reported that of 21 mothers of infants under 3 years, 20 of them reported waking to nurse at least once each night and all stated that their infants nursed without waking them up from two to "many" times or "all night".

Contrasting with African societies, the 'cradle culture' of Eurasia results in infants getting significantly less direct bodily contact, Lewis and Ban (1977, cited in Whiting 1981) observed that 3-

month old Yugoslav infants were in direct contact with their mothers 27 percent of the time contrasting with Kipsigis who carry their infants in shawls and were recorded as being in direct contact 70 percent of the time. Carried by caregivers or pack animals, cradles are also used as devices for napping and sleeping infants. Native North American cultures use cradle boards to carry infants that are heavily swaddled and bound to an upright erect board, usually carried on the back of the mother with the baby facing outwards. Central and South American societies use a sling or a shawl instead of a cradle board to carry infants, with hammocks or mats commonly used for sleep, with some cultures using a “boxlike cradles” for infant sleep (Whiting 1981: 161). Infants have also been observed sleeping in the mother’s bed; Morelli et al. (1992) describe the sleeping arrangements of 14 Mayan mothers living in a rural Guatemalan community and note that almost all slept in the same bed as their infants through the first year of life and onto the 2<sup>nd</sup> year, usually until the birth of their next child. Throughout the night they nursed on demand with the mothers reporting that they did not notice waking to feed their babies. Bedtime routines were absent, with babies falling asleep in someone’s arms when they felt sleepy and going to bed with their parents. The Aché people of Paraguay have been observed holding their infants in their laps throughout the night until weaning (4 years) to protect against dangerous creatures on the forest floor (Worthman and Melby 2002) and to promote thermoregulation of the infant by the mother.

In Middle East societies hammocks are used in place of or in addition to cradles, enabling the infant to be rocked or swung to sleep (Whiting 1981). In many Eastern societies it is commonplace for infants to sleep in the family bed, Korean parents are known to co-sleep with their infants for 3-6 years, with no specific word for bed-sharing, room-sharing or co-sleeping in Korea it is seen as an essential part of parenting. The architecture of Korean homes with heated floors removes the necessity of beds and results in families sleeping on the floor together (Chung & An 2014). Alongside Korea; Japan, Okinawa, Southern China and some of Southern India have been recorded as using the family bed or a sleeping platform for the infant to rest, nap and sleep (Whiting 1981).

The Indian and Pacific islands have been described as using sling and shawls, or no device at all for carrying infants and mats for sleeping. Similar to African infants, Pacific infants spend a majority of their time in close skin-to-skin contact with a caregiver both day and night (Whiting 1981). Alexetteff (2013) describes same-bed co-sleeping for Cook Islanders as an “unremarkable occurrence” (p. 114), not just common among parents and infants, but the whole family - reflecting traditional values of family, sociality and community.

## Western-Industrial sleep practices

*“The only societies where infant co-sleeping is not widely practiced are Western predominantly Anglo-Saxon countries such as US, UK, NZ, Australia and some European countries (Worthman & Melby 2002; Owens 2004).”*

(Alexeteff 2013, pg. 113)

Worthman and Melby (2002) outline four distinctive sleep practices among Western, industrialised populations that are not present in pre-industrial, subsistence populations; Solitary sleep from early infancy with a focus on infant independence with a need for sexual decorum and sleeping in a single long bout; scheduled and distinct bedtimes particularly imposed in childhood, reinforced by scheduled daytime hours with devices for waking and quiet, controlled environments which are visually and acoustically isolated with minimal sensory information. These particular features contrast highly with the previously discussed sleeping behaviours of primate, hominid and non-industrialised societies, representing a mismatch between the ‘environment of evolutionary adaptedness’ (EEA) (Bowlby 1969) and modern day industrial sleeping environments. Ball and Russell (2013) argue that a rethinking of EEA (Figure 1.), which considers shifting selection pressure over time and integrates ancestral cultural adaptations as well as new cultural environments, is necessary to contextualise modern-day parent-infant sleep behaviour. This allows for a more culturally specific understanding of sleep behaviours that can be adapted to particular cultural contexts. It also considers the impact of novel infant care practices, such as the medicalisation of childbirth and scientific infant care, two fundamentally significant factors that have influenced parenting behaviours today that would be overlooked by an EEA perspective.

AE-1: Placental Mammals, viviparity, lactation



AE-2: Precocial mammals, primates, low-fat/high-sugar content milk



AE-3: Hominin mammals: narrow bipedal pelvis, expanding brains, secondarily altricial



NCE-1: Medicalisation of Childbirth

- a) Delivery anaesthesia
- b) Infection control



NCE-2: Scientific Infant Care

- a) Invention of infant formula
- b) Science of infant sleep

NICP-1: Separation of mother and infant post-delivery

NICP-2: Artificial feeding

NICP-3: Sleep training & early settling



NCE-3: UNICEF/WHO Baby-Friendly Hospital Initiative



NICPs identified as undermining breastfeeding

*Skin-to-skin contact post-delivery*

*Rooming-in on postnatal ward*

*Feeding on demand encouraged*



NCE-4: Re-emergence of Ancient Infant Care

Practices in 21<sup>st</sup>-century Western environments

Parent-Infant Sleep Contact

Prolonged breastfeeding

Ancestral environments (AEs)

New cultural environments (NCEs)

Novel infant care practice (NICP)

Figure 1. Ball and Russell's rethinking of Bowlby's 'Environment of Evolutionary Adaptedness' in relation to infant care practices, which considers shifting selection pressures over time and integrates ancestral cultural adaptations (Source: Ball & Russell 2013. Pg. 243, Figure 9.1.)

The pursuit of infant independence through parent-infant sleep separation is a common practice in Euro-American societies. Morelli et al. (1992) noted that 69% of the 17 middle class Caucasian US mothers in their study who slept in separate rooms to their infants justified their choices based on fostering independence and self-reliance in their infants. In contrast, Japanese parents consider their infants as independent beings, facilitating the transition to becoming interdependent community members by co-sleeping (Caudill and Plath 1966 in Morelli et al. 1992). Similarly, in Korea, collective needs such as interdependency and conformity are stressed. Co-sleeping is seen as a natural part of this and solitary sleeping is considered a form of neglect. Individual values such as sleep quality and marital intimacy are pushed aside when caring for a baby meaning that parental expectations are altered, resulting in decreased maternal anxiety and a more relaxed attitude to changes in sleep quality (Chung & An 2014).

Psychoanalytic perspectives, driven by Freudian notions of 'infantile sexuality' (Dilman 1983) which envision children as having sexuality (or psychosexuality) even from very early stages in life, altered conceptions of co-sleeping as protective and essential to perverse and sexually exploitative (Tomori 2014). Fear of 'the primal scene' (exposure to parental intercourse) which psychoanalysts link to a number of psychological disorders (Okami 1995), reinforced concerns about co-sleeping and pushed infants out of the 'marital bed' reserved solely for romantic relations between parents.

Psychoanalytic discourses have become deeply ingrained in Western culture to the extent that parenting behaviours such as parental nudity, kissing children on the lips and parent-infant co-sleeping have been dubbed "subtle sexual abuse" (Okami 1995: 52) contrary to a wealth of empirical data showing a lack of short and long term harm associated with related behaviours.

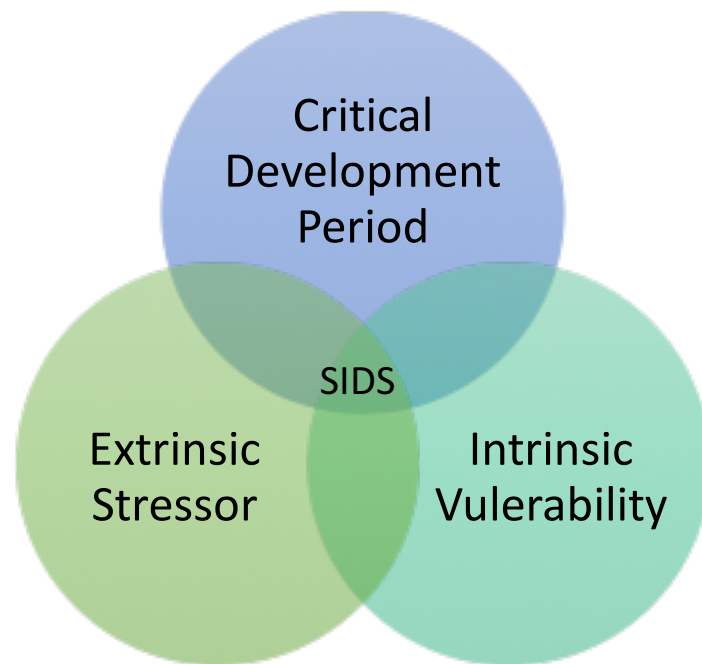
The rise of industrialization and capitalist regimes has necessitated the need for imposed bedtimes and emphasized consolidating sleep into a single bout in order to increase productivity throughout the day. Encouraging infants to 'sleep through' is seen as the aim of many parents in order to allow them to transition back to pre-baby sleeping patterns as soon as possible, something successfully achieved by weaning babies early and providing them with formula. A key study by Moore and Ucko (1957) which analysed the sleep of 160 infants in the UK using self-reported data concluded that 70% of the infants began sleeping through the night by 3 months of age. Although infant location or feeding status was not included in the analyses, it would be realistic to conclude after considering the prevailing infant care fashions at the time that the babies were put to sleep in a separate room and were formula fed. The results led to the formation of an infant sleep model that became adopted as the clinical model of healthy infant sleep and led in the formation of "social folk assumptions" about how and where healthy infants should sleep (McKenna & McDade 2005; 136). More recent research into the development of infant circadian rhythms has shown that infants do

not biologically exhibit diurnal biological rhythms until at least 3 months of age. Taking time to adapt to their environment and establish a consolidated night-time sleep (Joseph et al. 2015). Recent research has shown the difference in sleep patterns of breastfeeding and formula feeding infants; breastfeeding infants are shown to sleep in shorter, more fragmented bouts (Tikotzy et al. 2009; Elias et al. 1986), with formula-fed infants sleeping for longer periods, from an earlier age (Horne et al. 2004). These longer periods of sleep are a consequence of difficulties digesting cow's milk formula (Cavkll 1981) resulting in deeper, longer periods of sleep earlier in life and impaired arousability (Horne et al. 2004). Although breastfed infants have been observed to wake more often, the total sleep duration for breast and formula feeding infants is comparable (Quillin 1997) and the total sleep time of breastfeeding mothers has shown to be equal to, or greater than that of formula feeding mothers (Doan et al. 2007; Dørheim et al.; Montgomery-Downs et al. 2010; Gay, Lee & Lee 2004) contradicting social folk assumptions that formula feeding promotes infant sleep.

### Sudden Infant Death Syndrome

Sudden infant death syndrome (SIDS) is diagnosed following the death of an infant under 1 year of age where all other indications of mortality have been eliminated following a complete autopsy, investigation of the death scene and review of the medical history (Willinger, James & Catz 1991). Sudden infant death syndrome is thus a 'diagnosis by exclusion' (Fleming, Blair & Pease 2015: 1) that encompasses all unexplained infant deaths and may include a variety of pathologies. Studies relating to the mechanisms underlying SIDS are limited to the analysis of such deaths in order to find distinctive recurring traits due to the almost unique feature that death is the first symptom. Anthropology is concerned with the study of SIDS because it is a unique characteristic of human beings, with no equivalent disease apparent in animal species (McKenna 1986). As well as being a species specific phenomenon SIDS is a culturally specific phenomenon, existing most predominantly in Western post-industrial nations and varying between cultural subgroups. Rates of sudden infant death in Asian societies such as Japan and Hong Kong are significantly fewer than those found in Euro-American societies. Lee and colleagues (1989) reported a rate of 0.3 per 1,000 live births in Hong Kong as opposed to 2.01 per 1,000 live births in the UK for that year (Dattani & Cooper 2000). The nature of SIDS as an unexplained phenomenon has led to debates regarding the pathology of the disease. Filiano and Kinney (1994) propose the widely accepted 'triple-risk hypothesis', which posits that the intersection of a critical development period within the first year of life, intrinsic vulnerability in the infant combined with extrinsic stressors which increase vulnerability at time of death, results in SIDS. Given the immaturity of human infants at birth, all infants go through a critical development period in the first year of life where they develop autonomous control of various physiological and homeostatic systems. Trends in the age distribution of SIDS cases reveals that

there is a consistent period in which infants are vulnerable; with very few deaths in the first month of life and a considerable peak at 2-4 months (Kinney, Filiano and Harper 1992). Intrinsic vulnerability encompasses both biological and familial risk factors such as prematurity (Halloran & Alexander 2006; Blair et al. 2006), low birth weight (Blair et al. 2006), young maternal age and exposure to illegal drug use and maternal smoking in utero (Blair et al. 2009). Studies have indicated that infants who died from SIDS likely possessed an arousal deficiency caused by serotonergic brainstem abnormalities, which leaves infants vulnerable when separated from caregivers to sleep (Kinney et al. 2005). Serotonergic brainstem abnormalities were shown to be more likely in infants that died of SIDS than infants who died of known causes (Paterson et al. 2006; Kinney et al. 2003). Prenatal exposure to cigarette smoke and/or alcohol has also been associated with serotonin receptor binding abnormalities (Kinney et al. 2003) correlating with the relationship between maternal smoking, alcohol intake and SIDS.



*Figure 2. The triple-risk hypothesis as proposed by Filiano and Kinney (1994)*

Rates of sudden infant death syndrome have been strongly biased towards males, Mage and Donner (2014) noted a ~60% male excess of post neonatal SIDS in the United States between 1968 and 2010. It has been hypothesised that the discrepancy between male and female infant mortality is due to the protection provided by the presence of a second X chromosome in XX females, which defends against X-linked conditions putting XY males at a disadvantage (Naeye et al. 1971). Mage and Donner (2014) have extended the hypothesis proposed by Naeye and colleagues by postulating that a state of acute anoxic encephalopathy alongside an X-linked recessive allele that predisposes infants to die from respiratory failure explains the male bias in SIDS and other respiratory diseases.

Although this theory is supported by evidence of gender distinctions in infant respiratory deaths across the US, Australia, Canada, England and Wales and the European Union that show a ~50% male excess, specific genetic studies to determine the X-linked gene have not currently been performed. However, both of the aforementioned studies support the claims that SIDS cases share intrinsic vulnerability.

Also known as, 'modifiable risk factors', extrinsic stressors can arguably be avoided by ensuring that infants are set to sleep in a safe sleeping environment free from risks. Extrinsic risk factors include but are not limited to, head covering (Blair et al. 2008; Posonby et al. 1998), thermal stress or overheating (Gilbert et al. 1992), prone sleep position (Gilbert et al. 2005), co-sleeping on a sofa (Blair et al. 2014; Vennemann et al. 2012), exposure to cigarette smoke (pre- and post-natally)(Klonoff-Cohen et al. 1995; Mitchell et al. 1993; Carpenter et al. 2004), swaddling (Kato et al. 2003; Gilbert et al. 1992), pillow use (Hauck et al. 2003), use of soft bedding (Posonby et al. 1998) and a soft sleep surface (Hauck et al. 2003). It is important to note that in SIDS research 'risk factors' do not assume causation. Many statistical 'risk factors' for SIDS are not causal but are merely associated with an increased risk of SIDS. Extrinsic risk factors vary greatly in prevalence and significance for different cultural groups; bed-sharing and pillow use has been shown to increase the risk of SIDS in a number of populations. However, in Hong Kong bed-sharing and pillow use are common childcare practices and SIDS is uncommon (Nelson & Chan 1996; Lee et al. 1989 cited in Nelson et al. 2000), this is an important consideration when implementing SIDS risk reduction campaigns which aim to reduce the prevalence of modifiable risk factors as attempting to change behaviours that are not risky may result in undesirable outcomes.

Head covering is a significant risk factor for SIDS, with a high proportion of SIDS infants found with their heads covered by bedding. Blair et al. (2008) conducted a systematic review of population-based age-matched controlled studies relating to SIDS and head covering. They concluded that the risk of SIDS associated with head covering was "extremely high" (pg. 781), with the pooled adjusted estimate suggesting a 17-fold increased risk associated with head covering, they treat this result with caution but assume that it represents the importance of acknowledging head covering as a significant risk factor. An increased incidence of head-covering has been found in bed-sharing infants (Baddock et al. 2006; Ball 2009), although Baddock et al. (2006) found that only a quarter of infants who experienced head covering throughout the night woke with their heads covered at the end of sleep. Ball (2009) found that head covering events whilst bed-sharing were frequently terminated either by the mother or the infant before they became potentially risky.

The actual mechanisms relating head covering to SIDS are unknown. SIDS related deaths in infants found prone on a soft surface have been related to hypoxia (Blair et al. 2008), however Thomson and colleagues (2006) demonstrated that SIDS risks from infants found dead prone and supine vary dramatically, with face down, head covered infants associated with a decreased risk for SIDS. The authors propose that infants able to move themselves under duvets due to more advanced motor skills are also able to move their heads out of the face down position mitigating hypoxic risks and resulting in the observed negative association. Duvets have also been shown to be permeable allowing sufficient airflow (Hatch et al. 1982), therefore should not pose a hypoxic risk for normal supine infants.

Alternative explanations propose that head-covering creates a build-up of exhaled air leading to the accumulation and rebreathing of significant amounts of carbon dioxide. Ball (2009) conducted an observational study of airway covering whilst bed-sharing, in which physiological data was collected to monitor the effects of airway covering. The results indicated that when sleeping in the parent's bed infants experienced a much greater prevalence of airway covering than when sleeping in a standalone cot. The physiological data indicated that airway covering did not compromise the infant's ability to maintain normal levels of circulating oxygen and risk mitigation frequently occurred either by the infant or the mother to uncover the airways.

The role of hyperthermia in SIDS has been hypothesized and studies have suggested that it may decrease arousal thresholds (Franco et al. 2002) and disrupt respiratory mechanisms (Brown et al. 1992) increasing vulnerability to SIDS. Head covering could play a role increasing thermal stress resulting in hyperthermia; the head generates 40% of an infant's body heat with 85% of total heat loss through the face or head (Blair et al. 2008). Franco et al. (2002) recorded temperature, breathing and heart rate of 20 healthy infants whose head was covered by a sheet and found increases in heart rate, rectal and pericephalic temperatures and respiration in face covered periods, indicating that head covering risk could be associated with overheating.

### SIDS Risk Reduction Campaigns

Risk reduction campaigns to reduce rates of SIDS have mainly been focused on attempting to reduce the occurrence of modifiable risk factors such as the prone sleep position, parental smoking, head covering and risky co-sleeping. As a response to findings that the prone sleep position increased the risk of SIDS more than twofold (Willinger, Hoffman & Hartford 1994) the *Back to Sleep* campaign, implemented in 1991 focused on encouraging parents to place their babies on their backs to sleep. The incidence of SIDS during the period following the implementation of the campaign fell dramatically, with unexplained infant deaths decreasing by two thirds between 1989 and 1993

(Dwyer & Ponsonby 1996). The campaign was successful in taking an authoritative public health approach (Beattie 1991), which gave blanket advice to parents outlining 'dos and don'ts' regarding infant sleep safety. Ball and Volpe (2013) define infant sleep position as an 'infant care practice' that has little cultural value and involves minor engagement from parents, allowing it to be easily influenced by authoritative interventions. The success of the campaign shows how easily modifiable infant care practices can be through public health campaigns and education initiatives. Although worldwide back to sleep campaigns were successful in reducing rates of SIDS; the campaigns' success was limited as it only addressed one, easily modifiable infant care practice. The elimination of a major risk factor gave way to the emergence of other prevalent risk factors and although parents were not placing their babies to sleep prone, prevalence of SIDS remained stagnant at reduced levels. The side sleep position became associated with an increased risk of death compared to the supine position following the back to sleep campaign, which had previously been encouraged by health care providers as a safe alternative to prone position (Fleming et al. 1996). The side position is problematic because infants placed on their sides have increased instability and are more likely to fall into the prone position, thus increasing their risk of SIDS. The emergence of the side position as a risk factor has been attributed to more babies being put on their sides rather than prone following advice not to settle infants in the prone position.

Emerging risk factors have proved more difficult to influence by an authoritative, 'top down' approach by virtue of their personal and cultural value. Ball and Volpe (2013) attribute varying effectiveness in SIDS risk reduction interventions to a failure to differentiate between infant care-practices, parenting behaviours and cultural beliefs surrounding sleep, each of which requires specific negotiation in order to effectively influence the caregiving behaviours of parents. Practices, behaviours and beliefs require different approaches, three "levels of parental engagement" (Ball and Volpe 2013: 86) in order to culminate in successful SIDS-risk reduction. Activities parents choose to engage in or 'parenting behaviours' can be more difficult to alter by mere information focused health campaigns as they require a change in attitude and personal commitment to encourage change. Bed-sharing and parental smoking are examples of parental behaviours that offer parents benefits, and can only be altered when the benefits of behaviour change outweigh the costs (Ball and Volpe 2013).

Culturally embedded notions about the nature of infancy, role of the parent and the wider cultural environment infants are raised all contribute to parental beliefs surrounding sleep. Interventions that challenge culturally embedded beliefs are likely to be shunned as not relevant, for example a mother's urge to cuddle her baby when she cries conflicts with the cultural notion that one may 'spoil' infants by cuddling (Ball and Klingaman 2008). Salm Ward and Belfour (2015) conducted a

systematic review of interventions to increase adherence to safe sleep recommendations from 1990-2015 and noted that out of twenty-two of the studies, none of them showed complete adherence to recommended behaviours. In studies that examined sub groups, there was huge variability between groups, suggesting that future safe sleep interventions should consider the cultural, social and ethical subcultures that may be influenced by the interventions. Crane and Ball (2016) interviewed 21 Pakistani and 25 White British women from a bi-cultural urban community in the UK about their perceptions and use of safe sleep guidance and found variation in aspects of advice followed by the two populations. Pakistani mothers felt that guidance was not directed towards them and prioritised traditional Pakistani beliefs when there was conflict between safe sleep guidance and traditional beliefs. Each of these examples demonstrates that a more nuanced approach to public health campaigns that considers the social, cultural and ethical backgrounds of participants can help make SIDS risk reduction campaigns more successful.

Recent interventions have been focused on reducing the prevalence of same surface co-sleeping. Rates of co-sleeping in the UK have been shown to be around 50% (Blair & Ball 2004), with studies indicating that on any particular night for some part of their sleep parents are sleeping in bed with their neonates (Blair & Ball 2004). Some campaigns have attempted to implement prescriptive health persuasion techniques to deter all parents from co-sleeping with their infants by giving blanket advice to avoid same surface co-sleeping (Task force on sudden infant death syndrome 2011) or advise that infants should be placed in a standalone cot in the same room. These campaigns omit to consider the cultural embeddedness of co-sleeping behaviours as well as the social and cultural diversity of populations (Ball and Volpe 2013). Previously described as one of “the key sleep practices most influenced by cultural practices and beliefs” (Owens 2004: 165), co-sleeping is a multifaceted and complex parenting behaviour that can enable parents to negotiate the pressures of night-time infant care. The binary, standardised nature of public health messages which define sleep locations into ‘appropriate’ and ‘inappropriate’ fail to recognise the situation dependent nature of SIDS risks and result in women receiving contradictory advice (Ball & Volpe 2013). McKenna and colleagues (1993) define co-sleeping as “sleeping either in contact with another person (in someones arms, passively touching whilst in bed) or close enough to access, respond to or exchange sensory stimuli such as sound, movement, touch, vision, gas, olfactory stimuli, CO<sub>2</sub> and/or temperature”. This definition of co-sleeping thus considers a plethora of behaviours and can include instances of safe and beneficial co-sleeping as well as risky co-sleeping.

Co-sleeping has been shown to increase the risk of SIDS; Vennemann et al. (2012) conducted a meta-analysis of studies aiming to assess the relationship between bed-sharing and SIDS, including eleven case-controlled studies from the UK (4), US (3), Germany (1), Norway (1), New Zealand (1) and

Ireland (1) conducted between 1987 and 2006. Although all studies found an increased risk of SIDS in bed-sharing infants, the authors conclude that the risk is greatest in infants whose parents smoke or young infants (<12 weeks). They also note that more recent studies show a significant relationship between bed-sharing, parental use of alcohol and drugs and co-sleeping on a sofa. Included in the analysis was the Confidential enquiry into stillbirths and deaths in infancy (CESDI) sudden unexplained deaths in infancy (SUDI) study, a three-year population based case-control study in five regions of England, including 325 SIDS infants, and 1300 age matched controls. The study found that co-sleeping on a sofa was associated with a high and formerly unknown risk of SIDS. They also found no increased risk for older infants who shared the parent's bed, infants of parents who do not smoke or when infants were returned to their cot. A similar study, conducted by the same research team in the South West of England between 2003 and 2006 (Blair et al. 2009) found that just over half (54%) of the SIDS infants were found co-sleeping with an adult either in a bed or on a sofa. Maternal alcohol consumption and co-sleeping were the strongest predictors of SIDS with co-sleeping in the absence of alcohol and drug use showing a significant but decreased risk. However, the proportion of SIDS infants who co-slept in a bed in the absence of drugs and alcohol (>2 units) were no different from the random control group. In a combined analysis of the two studies, Blair et al. (2014) concluded that there was no increased risk for SIDS associated with bed-sharing in the absence of sofa-sharing, alcohol consumption and smoking, even going so far as to claim that bed-sharing in the absence of other hazards was significantly protective for infants older than 3 months. However, co-sleeping on a sofa or next to a parent who had consumed more than 2 units of alcohol carried a particularly high risk of SIDS. A Swedish study analysing the circumstances of unexplained infant deaths between 2005-2011 found that 90% of SIDS cases which had sleep location mentioned involved bed-sharing, however the study did not match with control infants or explore the relationship with smoking, alcohol use and co-sleeping (Möllborg et al. 2015). Carpenter and colleagues (2004) conducted a case control study of sudden unexplained infant death in 20 regions of Europe and found a significant risk of SUDI from bed-sharing in mothers who did not smoke and infants under 8 weeks old. They also note that the risks associated with maternal alcohol consumption was only significant when bed-sharing. These studies show that the risk of SIDS from bed-sharing is very situation dependent and varies among populations.

Studies relating to SIDS risk factors have focused on preventing infant death and increasing knowledge of safe sleeping practices, ultimately safeguarding infants. Ball and Volpe (2013) note that this agenda is in contrast to an alternative public health agenda, that of wellbeing. Wellbeing focuses on improving overall and sustainable health outcomes over the life course such as encouraging breastfeeding, creating secure attachment relationships and facilitating optimal growth

and development. Public health interventions that focus on eliminating risk factors may also be detrimental to overall wellbeing, in particular interventions that discourage same surface co-sleeping. Same surface co-sleeping and breastfeeding have a mutually reinforcing relationship that exists interdependently; mothers who breastfeed are more likely to co-sleep, at least for some part of the night (Ball 2003; Hooker et al. 2001). Among breastfeeding dyads bed-sharing has also been associated with a significantly greater number of feeds per night compared to solitary sleeping mother infant dyads (Ball et al. 2006; Gettler & McKenna 2011; McKenna, Mosko & Richard 1997) which is relevant for milk production and the maintenance of lactation (Ball et al. 2011). It also allows mothers to get better sleep by causing a hypnagogic effect for both mothers and infants and encourages mothers to breastfeed their infants for a greater number of months (when compared to non-bed-sharing mothers) (Ball 2002). Hooker and colleagues (2001) found that parents who had not intended to co-sleep before the birth of their babies found co-sleeping to be more convenient and practical than their anticipated sleep location. Maternal-infant proximity throughout the night has been shown to have a strong effect on the frequency of breastfeeding. Ball, Ward-Platt, Heslop, Leech and Brown (2006) conducted a randomized trial of different sleep locations on the postnatal ward in an attempt to understand the effects of maternal-infant sleep location on breastfeeding initiation. They found that when mothers were provided with unhindered access to their infants (by being allocated a three-sided crib attached to the bed, or bedding-in the mother's bed) they exhibited greater feeding attempts and successful feeds than those physically separated from their infants placed in a standalone cot, out of reach of the bed. More frequent feeds in the immediate period after birth can impact the timing of Lactogenesis II and increase prolactin levels associated with successful long-term lactation. In another study, twenty routinely bed-sharing and fifteen routinely solitary sleeping Latino parent-infant dyads undertook observational polysomnographic monitoring to assess the effect of mother-infant bed-sharing on breastfeeding behaviour (McKenna, Mosko & Richard 1997). Routinely bed-sharing infants breastfed on average three times longer than solitary sleeping infants, showing a two-fold increase in number of breastfeeding episodes.

The importance of breastfeeding for infant and maternal health and well-being demonstrates how vital it is to not discourage behaviours that increase ease and frequency of breastfeeding. High rates of breast cancer in developed countries have been attributed to the lack of or short lifetime duration of breastfeeding; the relative risk of breast cancer has been shown to reduce by 4-5% for each year that a woman breastfeeds (Collaborative Group on Hormonal Factors in Breast Cancer 2002; Kvåle & Heuch 1988). Breastfeeding has also been associated with a reduced risk of ovarian cancer for women who had ever breastfed (Gwinn et al. 1990) and type 2 diabetes (Aune et al. 2013). The role of breastmilk in providing immunological support for neonates cannot be underplayed, described as

an “irreplaceable immunological resource” (Labbok, Clark & Goldman 2004) breastmilk can protect against respiratory infections (Horta et al. 2013), infectious diseases (Sankar et al. 2015), diarrhoea (Horta et al. 2013) and acute otitis media (Bowatte et al. 2015) as well as a plethora of other conditions.

Breastfeeding has been shown to have a protective effect against SIDS (Hauck et al. 2011). Vennemann et al. (2009) conducted a case control study of 333 infants who died of SIDS and 998 age matched controls and found that breastfeeding reduced the risk of SIDS by ~50%. Their results are consistent with a previous study that concluded the overall risk of SIDS was twice as great for formula-fed infants than breastfed infants (McVea, Turner, Peppler 2000). These studies however cannot determine the exact function of breastfeeding in protecting against SIDS. Socio-economic status and breastfeeding rates are strongly associated therefore the protective effects of breastfeeding may be caused by factors related to the behaviour rather than the behaviour itself. Fleming et al. (1996) found a significant relationship between bottle feeding and SIDS, however when adjusted for socio-economic status the effect became non-significant, leading the authors to assume that the relationship was caused by the lifestyle choices of breastfeeding mothers, not biological processes. In a meta-analysis of eighteen studies that explored the relationship between breastfeeding and SIDS, Hauck et al. (2011) concluded that breastfeeding to any extent and duration was protective against SIDS, with a stronger protective effect for exclusively breastfed infants. Their results also indicated that breastfeeding itself was protective when controlled for associated factors such as smoke exposure and socio-economic status.

Breastfeeding, co-sleeping mothers have also been shown to induce arousals in their infants that may have a protective effect against life threatening apneas and SIDS. McKenna (1986) proposed that SIDS occurs as a result of mother-infant separation, common in Western parent-infant dyads. Co-sleeping allows infants to be physiologically regulated by their mother’s body as well as enabling mothers to induce arousals in their infants, either to initiate feeding or to improve infant arousability and protect against arousal deficiencies. Mosko, Richard and McKenna (1997) in a polysomnographic study of twenty routinely bed-sharing and 15 solitary sleeping breastfeeding mother-infant dyads found that 40% of infant arousals were caused by the mother arousing 2s before the infant. For mothers, co-sleeping was related to a reduction in the amount of REM stage 3-4 sleep and an increase in the amount of stage 1-2 sleep. Similar effects have been found in infants with close contact in sleep limiting the amount of deeper, adult like sleep and increasing lighter sleep episodes suggesting that co-sleeping encourages safer infant sleep and increases arousability potentially reducing the risk of dangerous sleep episodes (Mosko et al. 1997).

Co-sleeping has thus been shown to be a potentially risky behaviour increasing the risk of SIDS in certain circumstances however, the benefits of close parent-infant co-sleeping in increasing arousability, encouraging breastfeeding which thus protects the mother and infant against a range of diseases, facilitating infant and maternal bonding and improving sleep quality cannot be underplayed. Co-sleeping is also a culturally significant practice which cannot be influenced by top-down information based interventions.

### Portable Safe Sleep Spaces

Following a new rhetoric in infant sleep interventions which focuses on eliminating blanket recommendations to avoid bed-sharing and emphasises risk minimisation through targeted advice and education to specific populations, portable safe sleeping spaces have been proposed as a method of providing a safe sleeping surface whilst allowing parents to share the same bed as their infants and providing many of the benefits of co-sleeping. Providing parents with portable sleep spaces can also act as a backdrop to engage parents in associated safe sleep education programmes. By providing a device that encourages safe co-sleeping, health care providers and parents are encouraged to openly discuss practices that parents may have previously been condemned for engaging in or feel shame talking about.

In the 1980s New Zealand had the highest SIDS mortality rate in the world which was attributed to a high level of mortality in disadvantaged communities (which tended to be Māori communities), in populations at high latitudes and increased SIDS prevalence in winter months (Mitchell 2009) among other universal risk factors. The New Zealand cot death study was set up to try and identify SIDS risk factors amenable to change in order to reduce the high rates of SIDS in New Zealand (Mitchell 2009). The cot death study was important in recognising three modifiable risk factors; prone sleeping positions, maternal smoking, and not breastfeeding (Mitchell et al. 1991) leading to behaviour change interventions and a dramatic fall in SIDS prevalence. Subsequent research had identified the association between SIDS and bed-sharing and consequent interventions have focused on providing parents with evidence based guidance on the risks of SIDS from bed-sharing (Mitchell and Blair 2012) through the provision of 'safe sleep enablers', the *wahakura* and the pēpi-pod.

The *wahakura* attempts to address the existing disparities in New Zealand between SIDS rates in Māori and non-Māori communities, by providing Māori parents with a culturally embedded portable safe-sleep space. Māori infants are 4-5 times more likely to die of unexplained death than non-Māori, non-Pacific infants with 62% of unexplained infant deaths occurring in Māori communities (Child and youth mortality review committee 2009). Māori have been shown to exhibit high levels of maternal smoking as well as bed-sharing and sleeping in unsafe environments (Tipene-Leach & Abel

2010). Bed-sharing has been shown to hold cultural significance for Māori populations and serves an important role in facilitating the transient and mobile nature of their population (Able et al. 2001). In a study of infant care practices among Māori mothers in Auckland, 53% reported maternal smoking in pregnancy with 21% of them regularly co-sleeping with their infant (Tipene-Leach et al. 2010).

The *wahakura* combines knowledge of culturally significant childcare and lifestyle practices with generalised safe sleep recommendations in order to generate a tailor-made and culturally specific public health intervention. The *wakahura* is woven from *harakeke* or native flax, incorporating traditional weaving techniques to create a bassinet like structure. *Harakeke* is perceived to have sacred and healing qualities that nurtures and warms the baby giving the *wahakura* spiritual and historical value (Abel et al. 2015). The *wakahura* aims to encourage close infant and maternal sleep by recognising the cultural value of bed-sharing. It provides parents with a sleeping space designed to mitigate the risk of SIDS by creating a separate sleeping surface that can be used in the parental bed. As well as providing families with a safe sleep device, the *wahakura* comes with a number of 'safe sleeping rules' which aim to educate parents about safe infant sleep behaviours such as, 'face up, face clear'; 'smoke free environment'; 'no intoxicated adults'; and 'no loose blankets' (Tipene-Leach and Abel 2010).

Current understandings of the efficacy of the *wahakura* as a safe sleep device are limited and studies are currently underway to understand the success of the *wahakura* and the implications of providing them to high risk families. Baddock et al. (2014) recently conducted a randomised controlled trial using overnight video in the home to compare a *wahakura* to a standard bassinet and found that families engaged in more mother-baby interactions when allocated a *wahakura*. There was no other significant difference in behaviours between the bassinet and *wahakura* groups, leading the authors to conclude that providing a *wahakura* as a safe sleep intervention was as reasonable as providing a bassinet in that population. Alongside the overnight sleep studies, Baddock and colleagues (2017) randomly allocated either a bassinet or a *wahakura* to 200 Māori families at birth, asking them to sleep their infants in the allocated device from birth. Participants were followed up with 1, 3 and 6 month questionnaires and a 6 month interview. At the 6 month interview the *wahakura* group reported twice the level of breastfeeding than the bassinet group. The research of Baddock and colleagues has indicated that *wahakura* are relatively safe and can be promoted as an alternative to bed-sharing.



Figure 3. The Wahakura (left) and ISSB (right)

Pēpi-Pod portable safe sleep spaces (PSS), described as ‘a sister’ to the *wahakura* (Cowan, Clark and Bennett 2012) and created as a cheaper, more readily available device to the *wahakura* were employed in the period following the Christchurch earthquake of February 2011 as a response to increases in same bed co-sleeping driven by the effects of the earthquake (Cowan et al. 2013). The project aimed to use the Pēpi-pod as a tool to facilitate discussions about safe sleep among parents, with recipients of the device and associated safety briefing acting as ‘educators’ who would spark conversations among peers about safe sleep. Responses from recipients of the Pēpi-pod during the period following the earthquake were shown to be positive, with 97% of participants reporting that they engaged in discussions about safe sleep to an average of 3.5 ‘others’ (Cowan et al. 2013).

Pēpi-Pod ‘portable sleep space plus safety education’ programmes have also been applied in some regions of New Zealand for infants who are at increased risk of suffocation (such as in or on an adult bed, co-sleeping on a sofa, when away from home, in provisional situations). During 2012, 2967 PSSs were supplied to 5 regions in NZ as described in a follow-up report by Cowan (2013). Feedback from the programme was positive, showing that portable sleep spaces encouraged close maternal and infant sleep without same-surface co-sleeping; 77% of babies always or usually slept in the PSS when same bed co-sleeping occurred. Three people reported incidents with the PSS, which included a sibling attempting to carry the PSS with the baby in and dropping it, PSS being leaned on and tipping, tipping slightly with the baby’s movement, a baby bumping their lip on the edge of the box and a family member sitting on the PSS without the baby in it. Frequency of SIDS in the regions providing the Pepi-pod programme have shown a more significant reduction than in regions where the programme was not provided (Cowan 2013). Infant mortality, in particular Māori infant mortality showed a significant decline for the year following the introduction of the pēpi-pod programme (Cowan 2013), falling from 7.4 deaths per 1000 live births in 2009 to 5.7 in 2012 (New Zealand Ministry of Health 2012). The programme is currently being trialled among Aboriginal and Torres Strait Islander families in Queensland, Australia who are three times more likely to die of SIDS that

non-Aboriginal and Torres Strait Islander infants. A preliminary feasibility study has indicated that the Pēpi-pod programme would be accepted among the cultural groups, allowing them to reap the benefits of co-sleeping whilst respecting culturally significant infant care practices (Watson et al. 2014).

Preliminary studies of safe sleep enablers have indicated that providing vulnerable populations with an enabler may prove effective in reducing SIDS rates by facilitating to the reduction of unsafe co-sleeping events, however research is still limited. Firstly, research has currently only been conducted within New Zealand with predominantly Māori populations. The failure of previous safe sleep interventions has emphasised the need to provide context specific interventions which sympathise with the cultural practices of specific populations (Salm-Ward & Balfour 2015; Ball & Volpe 2013). It is therefore important to generate data relating to the use of portable safe sleep spaces among a range of other populations before branding the devices as universally successful. Secondly there is a lack of empirical data relating to the use of portable sleep spaces. Associations between the devices and reduced rates of SIDS may be a by-product of engaging in more focused interventions rather than providing parents with an enabler.

### The present study

The present study attempted to build on current knowledge relating to safe sleep enablers by generating observational data of parent-infant dyads using Infant Safer Sleep Boxes (ISSB) in the Durham University parent-infant sleep lab. This study used videosomnography to evaluate the efficacy of providing an ISSB compared to a standalone cot in the same room to reduce the occurrence of modifiable risk factors associated with SIDS whilst bed-sharing. The ISSB aims to reduce the instances of same surface co-sleeping by providing an alternative sleeping space that can be used in the parental bed to provide the same benefits of close infant maternal sleep without the risks associated with same surface co-sleeping. Mother-infant dyads were recorded sleeping in the parent-infant sleep lab for two nights, one using a ISSB and one using a standalone cot.

It is hypothesized that on nights using an ISSB in comparison to using a standalone cot in the same room:

1. There will be less time spent same-surface co-sleeping
2. There will be increased breastfeeding episodes and greater breastfeeding duration
3. There will be more 'looking and touching' episodes

4. Mothers will sleep closer to their infants for the majority of the night
5. There will be fewer head covering events

Any specific box related risks were also recorded in order to understand if using an ISSB poses alternative or unknown risks to the mother or the infant.

# Methods

## Anthropology and experimental research methods

Anthropology as a historical discipline has traditionally been associated with ethnographic and participatory research methods, occupying an interpretivist position, which places the researcher within the research as an active participant and posits that reality is socially constructed and fluid, only to be understood by rigorous empirical study (Bernard 2011). However, the subfield of Biological Anthropology, which focuses on the adaptations, variability and evolution of human beings and their fossil relatives has readily utilised a positivistic approach, using experimental and multi-disciplinary research methods in order to examine the foundations of human life and culture. Bernard (2011) describes anthropologists as “prodigious inventors, consumers and adapters of research methods” (Pg. 2), ready to utilise a variety of research methods to answer questions of humanness.

Anthropological findings have previously been criticised by other disciplines, in particular biomedicine. Medicine and anthropology have long been perceived as having an asymmetrical power relationship, with medics seeming to hold considerably more power than anthropological observers (Ecks 2008). Medicine, which prioritises evidence based research informed by large randomised control trials have been known to “shrug off” (Ecks 2008: 82) anthropological findings which tend to be gathered through smaller, more case specific methods. In order to balance this relationship, Ecks (2008) proposes that medical anthropologists face two alternatives; either to “subscribe to biomedical notions of good evidence” (Pg. 83) or insist that their methods are just as robust as those employed in the medical sciences.

Anthropological studies of parent-infant co-sleeping has successfully incorporated both biomedical and anthropological methods with much of the data produced by laboratory and in-home field studies having considerable influence over medical discourse and public policy (Trevathan, Smith, McKenna 2008; pg. 226). Accepted by clinicians, parents and policy makers anthropological findings relating to the relationship between infant care and health outcomes have been widely accepted.

## Randomised Crossover Trials

The present study will use a randomised crossover trial design in order to assess the viability of portable sleep spaces as an alternative to sleeping in a cot in the same room. Crossover trials, used predominantly in clinical research to understand the difference between individual treatments serve as a useful means of determining the effectiveness of certain interventions. In crossover trials, the response of a subject to treatment A is contrasted with the same subject's response to treatment B (Sibbald 1998), allowing researchers to understand variation in the same subject's response to different treatments. Crossover trials are distinguished from parallel-group trials as all subjects are given a number of identical treatments, meaning that each subject serves as their own control (Wellek & Blettner 2012). Within-subject comparisons require smaller sample sizes than other parallel group trials; fewer subjects have to be recruited to obtain the same number of observations and the same precision in estimation (Senn 2002).

Although crossover trials can be advantageous for comparing the effects of a number of different treatments, using the same participants to test different conditions can be problematic. The likelihood of participant drop-out between first and second interventions can be greater than alternative parallel group trials (Senn 2002). Crossover trials require greater commitment over time from participants, increasing the chances that they may withdraw from the study. Incomplete data from participants who did not complete the full trial cannot be used in analysis and high dropout rates can mitigate the advantage of requiring smaller sample sizes than similar parallel group trials.

It is also important to consider the period by which treatments are given, as the order in which treatments are given can modify the effects of treatments. Known as period by treatment interaction (Senn 2002), this is an important consideration when planning and conducting crossover trials. The effects of carryover from one period to the next can also distort data collected from crossover trials. The results of the second treatment may be polluted by the effects of the first, by using the same subjects to trial subsequent treatments (Altman 2002). Carryover effects may lead to the observation of simultaneous outcomes of various treatments rather than the effect of a single treatment in relation to the effect of another treatment (Senn 2002). The effects of period by treatment interaction and carryover can be ameliorated to some extent by randomising the order of treatments.

A number of previous studies have used a successfully used a crossover design to assess the effects of different conditions on night-time parent-infant care. Young (1999) compared bed-sharing and

cot sleeping among mother infant pairs, the pairs were monitored over a two-night period, once a month for the first five months and alternated between bed-sharing and sleeping separately. The results indicated that bed-sharing mothers engaged in more frequent interactions, aroused more quickly and breastfed more frequently than separate surface sleeping mothers. In order to assess the influence of using a baby sleeping bag on infant core temperature and parental care strategies; White (2014) used a crossover design to monitor infants sleeping in a laboratory for one night with a traditional blanket and one night with an infant sleeping bag, concluding that the infants involved in the study were as able to maintain a safe recommended temperature when sleeping in a sleeping bag as a traditional blanket. Ball (2009) used a randomised crossover trial to compare airway covering during bed-sharing and cot sleeping, observing parents sleeping in the laboratory for three consecutive nights; a habituation night, a bed-sharing condition and a cot-by-the-bed condition randomised with a coin toss. Ball notes that by using each infant as their own control the effects of developmental differences between infants was minimised, as well as reducing the effects of within-infant developmental differences as the two conditions were monitored over two consecutive nights.

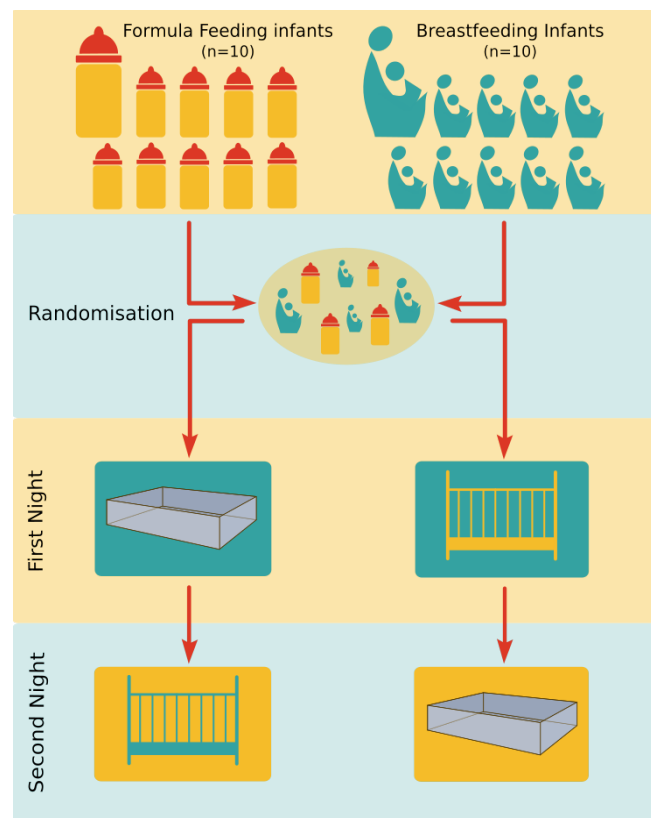


Figure 4. Illustration showing the randomized crossover study design; Participants were recruited and randomised to receive an ISSB on the first night and a standalone cot on the second night or vice-versa.

## Let's talk about sleep!

This project was embedded within a parent project; 'Let's talk about sleep', a feasibility study set in Sunderland, UK which aimed to change the way safe-sleep messages are given, allowing parents to make more informed decisions about night-time care. The three-component study involved the use of an Infant Sleep Safety Tool (ISST) to enhance health professional's confidence in discussing safe-sleep with parents and educate parents about safe sleep, the infant safer sleep box (ISSB) to support safe co-sleeping for parents whose infants might be at risk of SIDS from co-sleeping and a training framework for health professionals which embeds the ISST and ISSB to encourage open discussion with parents about a variety of sleep locations. The present study was intended to provide empirical evidence about the use of ISSBs to complement the data generated in the Let's talk about sleep! study.

## Ethical Considerations

Ethical approval for this project was obtained from the Durham University Anthropology department ethics committee, following the ASA (2011) guidelines and consideration of the literature about conducting ethical visual research (Wiles et al. 2008). In order to ensure that prior informed consent was gained, participants were required to read and sign a consent form (see Appendix I) acknowledging that they were aware of the aims of the study before any recording began which consented to themselves and their babies being recorded. The consent form also outlined that any published video data would remain anonymous. The participant's anonymity was treated with the highest regard; Bristol online surveys (Bristol Online Survey 2016) was used to electronically collect participants volunteer form data, chosen for its compliance with UK data protection laws. All communication with participants was done through a university e-mail account which ensured that data protection was upheld and any digital data relating to participants was kept in an encrypted file on the university system. Physical copies of the volunteer forms (see Appendix II) relating to participating individuals were printed and shown to the participants when they came into the lab to ensure that they were satisfied with the data they provided. Each printed volunteer form was allocated with a number which corresponded to the participant's video file and the forms were kept in a locked cabinet in the sleep lab office, separate from the video data. Video data was stored in the sleep lab at all times and was locked away when not in use. Video files were named with a participant number which corresponded to each volunteer form. Data from the videos could be cross referenced with background information provided in the volunteer form using the participants code but participants could not be personally identified through the videos alone.

## Recruitment

Participants were recruited for the project between November 2015 and July 2016 from the North East of England. A convenience sampling method was used to recruit participants with a broad eligibility criteria and any volunteers with infants under the age of 5 months were eligible to participate. An information poster (see Appendix III) giving details about the project was shared to local mother and baby groups; such as the North East Sling Library, Durham Mums, Breast Buddies (Teesside), Teesside Slings and Mums in Teesside primarily through their Facebook and Twitter pages. Facebook groups, particularly breastfeeding support groups have been increasingly important in engaging isolated mothers, chosen for their ability to provide immediate feedback and support from a trusted community (Bridges 2016). Potential members requesting to join the groups had to be verified by group admins who ensured that posts conformed to a pre-agreed set of guidelines. Prior to joining these groups, a message was sent to the admins explaining the study and outlining why it would be useful to discuss the project with the group members. Upon confirmation by the group admin that it was appropriate to join the group and post the study information, a copy of the recruitment poster was posted on the group as well as a small explanation as to who I was, what the project involved and who was eligible to participate. Recruiting via these groups meant that group members could add comments to the post if they had any questions or concerns, they could verify my legitimacy by looking at my personal Facebook profile and could directly message me if they wanted to volunteer for the study. This method also proved useful as the study went on as previous participants endorsed the study to other group members through enthusiastic comments.

Alongside this, an information sheet was also posted on the Infant Sleep Information Source (ISIS) website, Facebook and Twitter pages; sent around in the Durham University 'Dialogue' staff newsletter, posted on relevant Mumsnet forums, sent through a number of internal Durham University mailing lists and physical copies were put up around Stockton and Durham (Stockton library, Costa coffee shops community notice boards, Splash Stockton). Local sling groups, the North East Sling Library and Teesside Slings were also attended to discuss the project with the present mums, build a rapport with the organisers and ultimately recruit participants however most of the attending families had infants who were too old to participate. Recruiting through local NHS trusts and maternity clinics was considered in the planning stages of the project but did not present itself as a viable option given the limited timeframe of the project and the time consuming process of gaining NHS research clearance, therefore all recruitment was done independently.

Although a number of different recruitment methods were pursued, many strategies were unsuccessful. Recruitment via Facebook networks, particularly posts on the ISIS Facebook page and periodic posts in Facebook groups associated with local mother and baby groups were the most fruitful and recruitment became focused on utilizing these outlets.

Interested parents were advised to contact the researcher, via e-mail or telephone and were subsequently sent a volunteer form where they could register their interest and contact details. For potential participants recruited online, a hyperlink was attached to the information poster which directed parents to an online copy of the volunteer form. Volunteer forms were used to determine eligibility to participate in the study by asking baby's date of birth and primary feeding method. Feeding method was determined by recording breastfeeding status as either 'Exclusively (My baby has only ever been breastfed)', 'Predominately (My baby is mostly breastfed but has been given water based drinks in the past)', 'Partially (My baby is receiving some breastfeeds but also has other foods such as formula milk or weaning foods)' and 'No breastfeeding (My baby is formula-fed/does not receive any breastmilk)'. Breastfeeding status definitions followed the Unicef UK breastfeeding category definitions (Unicef 2016). Parents who reported 'partially' breastfeeding their infants were eligible to participate but were requested to use only one preferred feeding method throughout the overnight sleep studies. Volunteer forms also recorded infant's sex, smoking status during pregnancy, current smoking status, infants date of birth, current at home sleeping arrangement ('In my bed', 'in a side-car crib/bed nest', 'in a moses basket', 'in a cot in the same room', 'in a cot in another room', 'other'), and frequency of bed-sharing ('How many nights in the past week, at any point has your baby slept in your bed?'). On arrival at the sleep lab, prior to the overnight study participants were asked to confirm and edit any changes to feeding method, home sleep arrangement or smoking status to ensure that all data was accurate and up to date. Pregnant women who were interested in participating after birth were requested to record their due date, and were contacted by their preferred contact method around 4 weeks after their expected due date and asked if they still wished to participate.

### Infant Safer Sleep Box

The infant safer sleeper box is a 38 x 75 cm Phthalate and BPA free clear plastic storage box, provided with a specially fitted 68 x 29.5 x 4cm foam mattress with a PVC protective cover, a cotton fitted sheet and a fleece blanket. Participants were permitted to bring their own blanket or baby sleeping bag and use that in the box if they preferred. The design of the box was based on the Pepi-Pod which has been associated with a reduction in SIDS (Cowan 2013), and refined in a consultation

with a focus group conducted by sleep lab staff in preparation for the Let's talk about sleep! project. The transparency of the box allows mothers to easily monitor their infants whilst lying down, the rigid sides protect the infant from crushing or overlaying hazards whilst still being discreet enough to fit in the bed.



*Figure 5. The ISSB allows parents to sleep with their infants in bed, but in their own sleep space*

### Standalone Cot

The standalone cot was positioned 60cm away from the bed, meaning that mothers could not touch infants without getting out of bed. When sleeping in the cot, infants were provided with the same blanket that was provided with the baby box but were also permitted to use their own blankets or sleeping bags. Participants were asked to attempt to settle their baby in the cot but were also encouraged to sleep as they usually would at home.



*Figure 6. The standalone cot, it was positioned away from the bed which meant that parents could not touch infants settled in the cot*

### Safe Sleep Instructions

Prior to coming into the lab, participants received a 'Where might my baby sleep?' leaflet (see Appendix IV) created by the Parent-Infant Sleep Lab in partnership with health professionals from NHS Blackpool and North Lancashire (Russell et al. 2015). The leaflet was designed to help safe sleep advisors discuss the various risks and benefits associated with different sleep locations with parents and was previously shown to be successful in increasing parents' knowledge of safe sleep practices.

The illustrated 8-page leaflet was provided to ensure that participants were briefed in safe sleeping practices as well as providing them with specific information about how to safely and appropriately use Infant safer sleep boxes. The safe sleep handbook outlined SIDS risk factors, what to consider when deciding where babies should sleep and information about using ISSBs safely. A copy of the leaflet was given to participants at the start of the overnight, and participants were permitted to refer to the leaflet if they had any concerns about infant sleep safety. Parents were also briefed about how and where to use the ISSB and were permitted to ask any questions related to the use of the ISSB.

### Overnight Sleep Studies

Overnight observational studies have been previously used to examine night-time infant sleep and parenting behaviours (Volpe, Ball and McKenna 2012; Volpe 2010, Baddock et al. 2006; Young 1999;

Richard et al. 1996) and the effects of sleep environment on SIDS risk (Gettler and McKenna 2011). The use of video data has proved useful in assessing non-physiological influences of sleep environment and behaviour on SIDS risk. Observational studies avoid issues relating to inaccurate recall of night-time behaviours that can impact the quality of data collected by other methods, for instance sleep diaries. Maternal recall of night-time behaviours, for example feeding have been shown to be inaccurate due to factors such as bed-sharing infants latching on and feeding whilst mothers continue to sleep (Gettler and McKenna 2011; McKenna et al. 1994). Surveys assessing sleep environment, position, location may only be interpreted as relating to the initial or anticipated sleep environment whilst overlooking changes throughout the night, video data allows for the analysis of the entire night taking into consideration behaviours which may diverge from the normal or expected. Self-reporting bias can also be present in self-reported data, participants may be reluctant to record behaviours which are inconsistent with safe sleep recommendations. Batra and colleagues (2016) conducted at home overnight video recordings at ages 1, 3 and 6 months in an attempt to assess frequency of environmental risk factors. Although they were aware of being recorded, most parents placed their infants to sleep in environments with established risk factors. By using observational data, the authors noted a higher proportion of sleep environment risk factors, such as bed-sharing and loose bedding in the infant sleep environment, than previously found in studies that relied on parental reports.

Although observational video studies allow for a more accurate and holistic data collection of certain behaviours, such as feeding latency and frequency they may show inaccuracies with recording some variables, in particular sleep time. Yoshida et al. (2015) compared the use of actigraphy and EEG for monitoring 3-4 month old infants sleep and found that at some points actigraphic recordings recorded infants as asleep whereas the EEG recorded them as awake, indicating that they were awake but showing no sign of behavioural arousals, particularly in formula fed infants. This could have implications for observational studies as they may overestimate or not be able to accurately record sleep time. Using EEG recordings to record sleep time was considered but it was deemed inappropriate as the project was attempting to stimulate an 'at home' sleep environment; EEG machines can be bulky and require attaching nodes to the participant's head. The use of EEG machines can limit the behaviour of the participants, potentially affecting feeds and maternal monitoring of infants as well as making infants less mobile and total sleep time was not considered a primary outcome of this study.

Overnight sleep studies were conducted at the Durham University Parent Infant Sleep Lab, Queens Campus between December 2015 and July 2016. Participants were advised to arrive at a similar time they would usually be settling their babies to sleep and remained in the lab overnight until they fully awoke the next morning and were permitted to leave at any time after awakening. Parents were asked to attend the sleep lab for two overnight sessions, one session using the ISSB, one session using a standalone cot in the same room. Habituation nights have been recommended for laboratory overnight sleep studies in order to ameliorate 'First night effects'; adults have been shown to have more disturbed sleep and delay in the onset of Stage IV and I-REM sleep on their first night in a laboratory setting (Agnew, Webb and Williams 1966) and young (two and eight week old) Infants have exhibited increased fussy-crying and decreased alertness within the first four hours of laboratory based observation (Sostek and Anders 1975). However, Richard and Mosko (2004) observed no such first night effects in their laboratory based observation study of mother-infant sleep proximity. A habituation night was excluded from this study in order to decrease the likelihood of participant drop out and to prioritise the logistical considerations of participants. In order to mitigate first night, first order and carry-over effects that have been shown to limit the strength of data collected through crossover studies (Altman 2002, Senn 2002), the order of sleep device used was determined randomly using an online random number generator (Haahr 2006). Randomisation was done whilst the participants were present, before the overnight began.

Durham University Parent Infant Sleep lab is designed to appear like a self-contained apartment, fully equipped with a small kitchenette, bathroom and bedroom. The bedroom comprised of a double bed, a drop side wooden slatted standalone cot, a rocking chair with v-shaped support pillow, leather sofa, changing table, television and chest of draws.

Three infra-red cameras were fitted around the lab to record the night-time behaviours of the parent-infant dyads, which included two fixed position cameras, one facing the double bed and the other over the standalone cot. A 360° rotating camera with zoom function, which could be remotely controlled from the observation room was positioned above the sofa and was utilised when participants moved around the room or moved out of sight of the fixed position cameras. Video data was transmitted to an adjacent observation room and recorded on Noldus Observer XT in preparation for offline coding.



*Figure 7. Durham University parent-infant sleep lab*

A researcher remained present in the monitoring room throughout the overnight sleep studies to ensure that there were no issues with the monitoring software and to guarantee the safety of the parent-infant dyads. There was minimal interaction between the researcher and the participants throughout the studies, but parents were permitted to approach the researcher if they had any questions or concerns. An intervention criterion was in place which allowed the researcher to intervene if any concerns about infant or parent safety arose (See Appendix V).

## Gratuity Budget

As a thank you for partaking in the study, participants were given £15 in Love2Shop high street vouchers for each night spent in the lab (£30 overall on completion of two overnight stays). Participants received the vouchers at the beginning of the overnight and were reminded that their participation was optional and they could leave at any time. Head (2009) notes that it is preferable to give payment at the beginning of the research encounter to ensure that participants understand that they are being rewarded for their participation, not their actions. The amount was negotiated after discussion with the sleep lab team and a review of the reimbursement amounts in previous sleep lab projects. Payment was given to compensate for time spent away from home and any travel costs.

Paying participants has previously been a controversial topic, with distinctions between 'fair return' and exploitation of more vulnerable research participants blurred. Paying participants can be seen as a method of balancing power relations between the researcher and informant (Thompson 1996, cited in Head 1999), ensuring that the research is mutually beneficial. However financial compensation challenges ideas of freely provided informed consent which is an integral foundation of ethical research (Head 1999). This was considered in the planning of the project alongside the ethical guidelines of the Association of Social Anthropologists of the UK and Commonwealth (ASA 2011) and the American Anthropological Association (AAA), which acknowledge that it is necessary to provide fair return to participants whilst being wary of exploitation. Payment was thus deemed appropriate given the strains on parents of raising young babies and the impact of spending two nights without the support of their partners. The cost of the vouchers was covered by the Parent-Infant Sleep Lab budget.

## Coding Procedure

The video data was collected and coded using Noldus Observer XT software package. The coding followed a taxonomy created for this project which measured sleep location, feeding method, head covering events, total sleep duration, non-feed related looking and touching, infant sleep position, mothers sleep position and specific box related risks (see Appendix VI for full taxonomy).

## Sleep Location

The sleep location of the infant, mother and father (if applicable) was recorded continuously throughout the night. The possible sleep locations were: ISSB, standalone cot, bed, parent's bed (specific bed location 1-5), sofa, chair, on parent, out of sight, 'other' location and location not

applicable. Locations in the bed were numbered 1-5, with one referring to the upper left third of the bed, two the upper central section, three the upper right third, four the lower left half and five the lower right half of the bed (See Figure 7). The specific bed locations referred to the level of falling or suffocation risk throughout the night for the infant, with section two as the optimal position for infants, and sections four and five the specific bed locations with the greatest risk to infants. By measuring sleep location for all participants throughout the night it was possible to determine, the amount of time the infant spent in each sleep location, maternal proximity to infant, number and length of same-surface co-sleeping events, location of ISSB and falling risk of infant and ISSB.

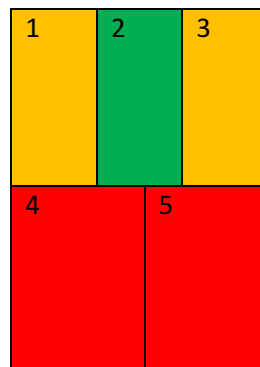


Figure 8. Bed locations for 'location of ISSB bed'

### Total Sleep Time and Sleep Orientation

Total sleep time was measured for both the mother and the infant. The infant was defined as 'asleep' if they had their eyes closed and had been settled for at least 2 minutes. Arousals or awakenings which lasted for under 2 minutes were included as sleep, but behavioural arousals which exceeded 2 minutes were defined as 'awake' (Baddock et al. 2006). Infant sleep position was coded as either 'prone', 'side', 'supine', 'on mother' or 'N/A' during sleep measurement. Parents were defined as 'appears asleep' if they were lying still, with their eyes closed and had not exhibited signs of wakefulness, if they appeared to be in a sleep like state for more than 10 minutes they were then defined as 'asleep'. Only 'asleep' states were analysed as 'total sleep time'. Mothers sleep orientation was coded as 'toward infant', 'away from infant', or 'neutral' for all recorded sleep time. All other participant's total sleep time and orientation (eg. Father) was not coded.

### Feeding

Number and length of feeding bouts was measured throughout night to understand how the various sleep locations affected feeding frequency and latency. The onset of breastfeeding was defined by breast attachment, and ended at breast detachment which could be verified through observation of

the recordings. Feeding bouts were defined as a single bout if the infant came off the breast for no more than 10 minutes, in instances where the infant was off the breast for more than 10 minutes but continued to feed it was recorded as a separate feeding bout. Classifications of feeding bouts are variable; McKenna, Mosko and Richard (1997) defined a breastfeeding bout as when the infant had not been off the breast for more than 5 minutes, Klingaman (2009) also used this definition. Ball et al. (2006) classed breastfeeding bouts as single bouts if intervals did not exceed ten minutes (Ball, personal communication, October 2015). Feeding was measured continuously throughout the night and was coded as either 'no feeding', 'breastfeeding', 'bottle feeding' or 'out of sight'. It was also possible to specify who was feeding the infant (Mother or father) and what was being administered ("breastmilk", "formula", "water", "other").

### Non-feed related Looking and Touching

Non-feed related looking and touching events referred to any parental looking and touching which occurred throughout the night, and did not coincide with feeding sessions. Looking and touching events were coded as: 'no looking or touching', 'looking', 'touching', 'looking and touching'. This measured number of looking events, number of touching events, length of looking events and length of touching events. Recording of non-feed related looking and touching events began from the onset of parental sleep throughout the night, until the parent-infant dyads had finally awoken the next morning. Events which met the following criteria were coded as looking and touching events; Parent visually inspecting the infant, parent relocating the infant (lifting entirely and replacing), repositioning the infant (moving/pushing infant's whole body of limbs), re-blanketing the infant, undressing/dressing the infant and affectionate behaviour (hugs, kisses, pats, caresses, whispers, holds hands, strokes, touches, winds) as well as any time the mother and infant were in physical contact.

### Head Covering Events

Head covering events were defined as any instances where infants had their face, nose and mouth or head covered by bedding, clothes or soft toys. Head covering events were coded as 'Airways covered', 'Head (not airways) covered', 'head and airways covered', 'head not covered' or 'Other head covering'. Head covering was measured as the time from when the infant's airways or head was covered until it was removed. Outcome measures were the number of head covering events and the duration of head covering.

## Specific ISSB Related Risks

Specific ISSB related risks were recorded throughout the night to understand the nature and extent of risks involved in using ISSBs as opposed to other sleep devices. Risks were coded as either 'tipping risk', 'falling risk', 'carrying ISSB with baby in' or 'unspecified risk'. 'Tipping risk' refers to any time in the night where the ISSB tipped or was left on an uneven surface and displayed a risk of tipping with the infant inside. 'Falling risk' was defined as any instances the ISSB was placed close to the edge of an elevated surface, such as the edge of the bed and had the potential to fall whilst the baby was inside. 'Unspecified risk' was used to code for risk events which had not been previously anticipated, and stood for novel risk not associated with the ISSBs prior to the observation studies. 'Unspecified risks' were coded appropriately and consequently qualitatively analysed.

## Data Analysis

Data was exported from Noldus Observer XT, edited in Microsoft Excel and analysed using IBM SPSS statistics version 24. Before exporting 'looking' and 'touching' behaviours were merged into a new group ('Looking and touching') which meant that any overlaps in time or frequency were only counted as one event and durations were merged where they overlapped. The data was then selected in pairs corresponding to each participant (eg. 001a and 001b) and run through a 'behavioural analysis' in Observer before being exported. The behavioural analysis produced the data for the number of times each behaviour occurred, the overall duration of the behaviour, the total duration of the observation, the subject engaging in the behaviour and details of any behaviour modifiers associated with that behaviour. The data was then exported into an Excel spreadsheet, amalgamated, unnecessary data was removed and the 'IF' function was used to code the data into a numeric format ready to be imported into SPSS for data analysis. The split data for observation 003 was also merged into one observation in Excel. This provided the data for looking and touching, head covering and breastfeeding.

The 'select intervals' function in Observer was used to select the data for the infant's location whilst the mother was asleep, maternal proximity and any instances of bed-sharing. This function allows the user to define behaviours and produces data for all other behaviours that were occurring simultaneously. For example, to generate data for bed-sharing the behaviour 'asleep' and subject 'mother' were selected, then any instances when the baby was in Parent's bed (1, 2, 3, 4 or 5) or on mother were selected and exported. As all mothers only slept in the bed it was not necessary to define mothers sleep location. The same filters were applied to generate data for the location of the infant whilst the mother was asleep but all locations were considered, not just when the infant was

in the parent's bed or on mother. Maternal proximity was defined as any instance that the infant was within arm's reach of the mother whilst the mother was asleep so that included when the infant was in the parent's bed, ISSB or on mother. Behavioural analysis was run with the select intervals function, only the infant was selected and all observations were exported into an excel spreadsheet to be coded, edited and imported into SPSS.

In order to determine normality Kolmogorov-Smirnov tests were run on the two sets of data and their within-subject differences, which compared the scores in the sample to a normally distributed set of scores with the same mean and standard deviation in order to detect divergence from normal. The results of the tests all produced a non-significant result, indicating that the data was normally distributed. However, Q-Q plots showed that the data did not follow a normal distribution and the results from the Kolmogorov-Smirnov test were attributed to the small sample size and large range in results, therefore non-parametric tests were used.

Wilcoxon signed-rank tests were used to determine if there was a statistically significant difference in the results for the two conditions. Because of the small sample size statistical tests were used to understand the direction of the results and have been considered with caution.

# Results

## Study population

Of fifty-four people who responded to the call for volunteers and filled out an online volunteer form, ten were recruited for the study (19%). One participant was recruited through the sleep lab database of interested volunteers who had contacted the sleep lab directly. Six of the respondents were excluded from further contact about participating because their baby's due date was after the end of data collection. Figure 8 demonstrates the flow of volunteers and participants throughout the project.

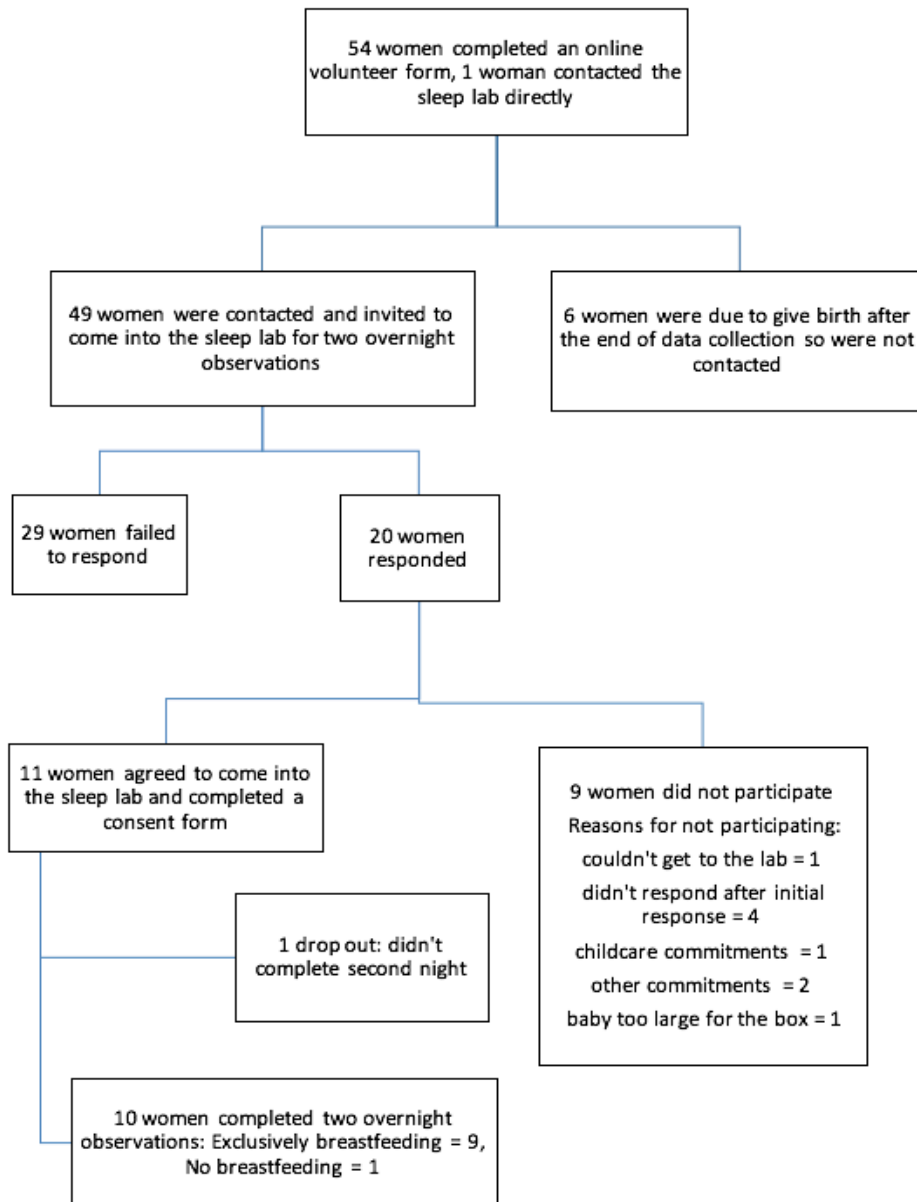


Figure 9. Recruitment and exclusion of participants for the project

The study aimed to recruit equal numbers of breastfeeding and formula feeding parent-infant dyads (mother-infant pairs) or triads (consisting of mother, infant and another individual, usually the father). The final number of participating parent-infant dyads was 11, consisting of 10 exclusively breastfeeding and one formula feeding infant. A majority of the study sample was recruited through the Facebook groups of local mother and baby groups or the ISIS Facebook page however one participant was recruited through the sleep lab database of interested parents.

One infant was considered 'high-risk' because she was born before 37 weeks' gestation. None of the participants reported smoking currently or smoking in pregnancy and all infants usually slept in the same room as their mothers. One participant dropped out after their first night (005), only completing the box condition. Although it is standard practice to include all participants who have been randomised to a condition, the small sample size resulted in this participant being excluded from analysis because of the large effect that their missing data would have on the outcome of the results. The sample consisted of mother and infant dyads, although fathers and partners were invited to attend. One participant brought her other child who slept in the bed alongside her, data for that child has been omitted from analysis, but the mother-infant data is included and henceforth referred to as the 'triad'. Table 1 summarises the background information provided in the volunteer forms.



*Figure 10. A mother and her son sleeping in bed with the infant in the ISSB*

Table 1. Background participant information

Born after 37 weeks gestation?	Currently smoking?	Smoked in pregnancy?	Feeding status	Usual sleep location	Frequency of bed-sharing (per week)	Median age of infant at first overnight (range)
Yes (10)	Yes (0)	Yes (0)	Exclusively breastfeeding (10)	Side car crib (6)	0 (2)	15 weeks (4 – 19)
No (1)	No (11)	No (11)	No breastfeeding (1)	Moses basket (2)	1-4 (5)	
				Cot in the same room (3)	5-7 (4)	

Table 2. Order of condition, age of infant, feeding method, at home sleep location, use of sleeping bag on overnight observations and dyad or triad information for each participant

	First night	Second Night	Age of infant	Feeding Method	Sleep location at home	Sleeping bag	Dyad/Triad
<b>1</b>	ISSB	Cot	9 weeks and 6 days	Exclusively breastfeeding	Side-car crib/parent's bed	N	Dyad
<b>2</b>	ISSB	Cot	15 weeks and 2 days	Exclusively breastfeeding	Side-car crib/parent's bed	Y	Dyad
<b>3</b>	Cot	ISSB	17 weeks and 5 days	Exclusively breastfeeding	Side-car crib/bed nest	Y	Dyad
<b>4</b>	ISSB	Cot	13 weeks	Exclusively breastfeeding	Side-car crib/bed nest	Y	Dyad
<b>5</b>	ISSB	-	4 weeks	Exclusively breastfeeding	Side car crib/bed nest/Parent's bed	N	Dyad
<b>6</b>	ISSB	Cot	15 weeks	Exclusively breastfeeding	Side-car crib/bed nest	Y	Dyad
<b>7</b>	ISSB	Cot	19 weeks 5 days	Exclusively breastfeeding	Cot in the same room	Y	Dyad
<b>8</b>	ISSB	Cot	18 weeks	Exclusively breastfeeding	Cot in the same room	Y	Dyad
<b>9</b>	Cot	ISSB	15 weeks 5 days	No breastfeeding	Cot in the same room	Y	Dyad
<b>10</b>	ISSB	Cot	6 weeks 3 days	Exclusively breastfeeding	Moses basket/parent's bed	N	Triad
<b>11</b>	ISSB	Cot	8 weeks 1 day	Exclusively breastfeeding	Moses basket/parent's bed	N	Dyad

## Video complications

Two observations had complications which may have affected the quality of data collected. When recording the first cot condition (001) the fixed camera was not positioned over the cot resulting in difficulties viewing the infant in detail. This became an issue when attempting to code the sleep/wake states of the infant when in the standalone cot, potentially resulting in inaccurate coding of infant's behaviour. Because the infants total sleep time is not relevant in this study it should not significantly affect the outcomes of the study.

Due to issues with the computer, the recording for participant 003 in the box condition was split into two observations with a gap of 53 minutes. The data was accumulated into one observation but there was missing data for the time in between the two recordings. Researchers notes indicate that the mother and infant were asleep during the missed period and there was no change in behaviour. The data for observation 003 in the box condition has been used in the analysis as it did not seem to deviate significantly from the other results.

## Adherence to allocated condition

Location of the infant was recorded throughout the night, the mean and median times spent in the ISSB were higher than all other locations, closely followed by the standalone cot. This includes all locations the infant was in regardless of sleep state of the mother or infant. Figure 10 shows the mean time spent in each location for each condition, infants spent a greater average amount of time in the parent's bed when allocated to the cot condition than the box condition. Pie charts indicating the proportion of time each infant spent in each condition can be found in Appendix VII.

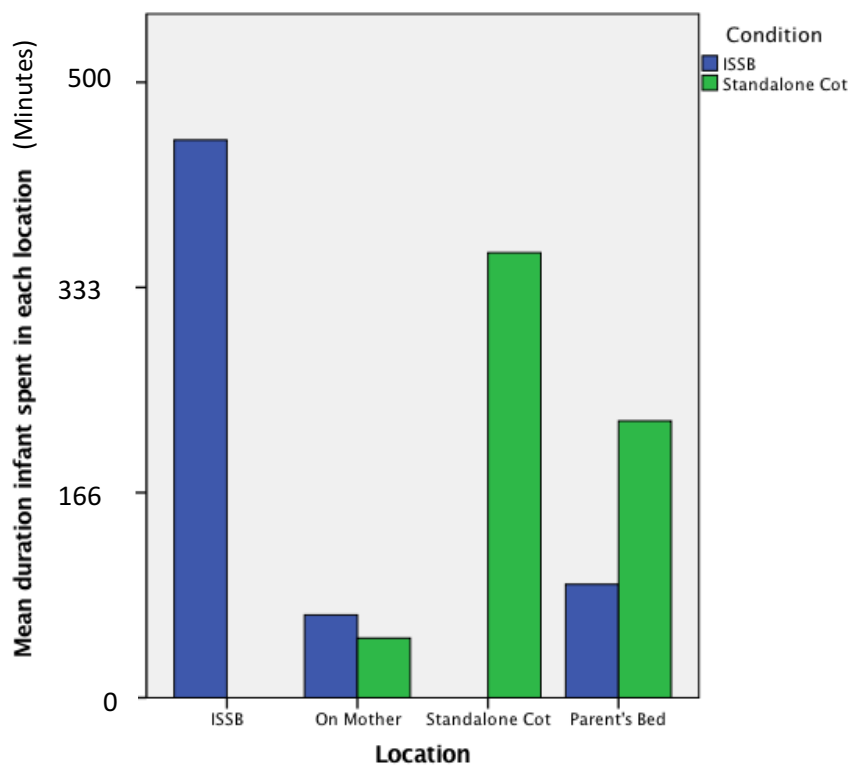


Figure 11. The mean duration that infants spent in each location for each condition

Following the principles of the intention-to-treat concept, which postulates that when conditions are randomised all participants have to be included in analysis regardless of their adherence to the allocated condition (Gupta 2011), analysis was done with all participants who had two overnight observations. Given the small data set, analysis was also done with only participants who spent >50% of the night in the allocated condition to understand how adherence to allocated condition effected the outcomes, this was defined as per-protocol analysis (Shah 2011). The infants' location when the mother was asleep was analysed to understand adherence to the allocated condition. Infants' location when the mother was asleep was much less varied than infants' location throughout the whole night, showing that mothers were careful to put their infants back to sleep in the allocated sleeping space before returning to sleep themselves. All infants spent >50% of the night in the ISSB, showing complete adherence to the box condition, however on nights using the cot one participant (10%) spent <50% of the night in the cot condition, choosing to bed share instead. Although this participant spent less than half the night in the cot condition they did show substantial adherence to the box condition, with the infant spending most of the night (95%) in the ISSB. This participant reported usually sleeping in close proximity to their infant, in a side-car crib and described bed-sharing frequently (5-7 nights a week) therefore it can be considered that this behaviour was commonplace and did not deviate considerably from their usual sleeping practices. Figure 11 illustrates the mean time spent in each location whilst the mother was asleep, for each

condition. The average time infants' spent in the parent's bed on the cot night is reduced but still remains greater than on the ISSB night. Pie charts illustrating the proportion of the night each infant spent in each location when the mother was asleep can be found in Appendix VIII.

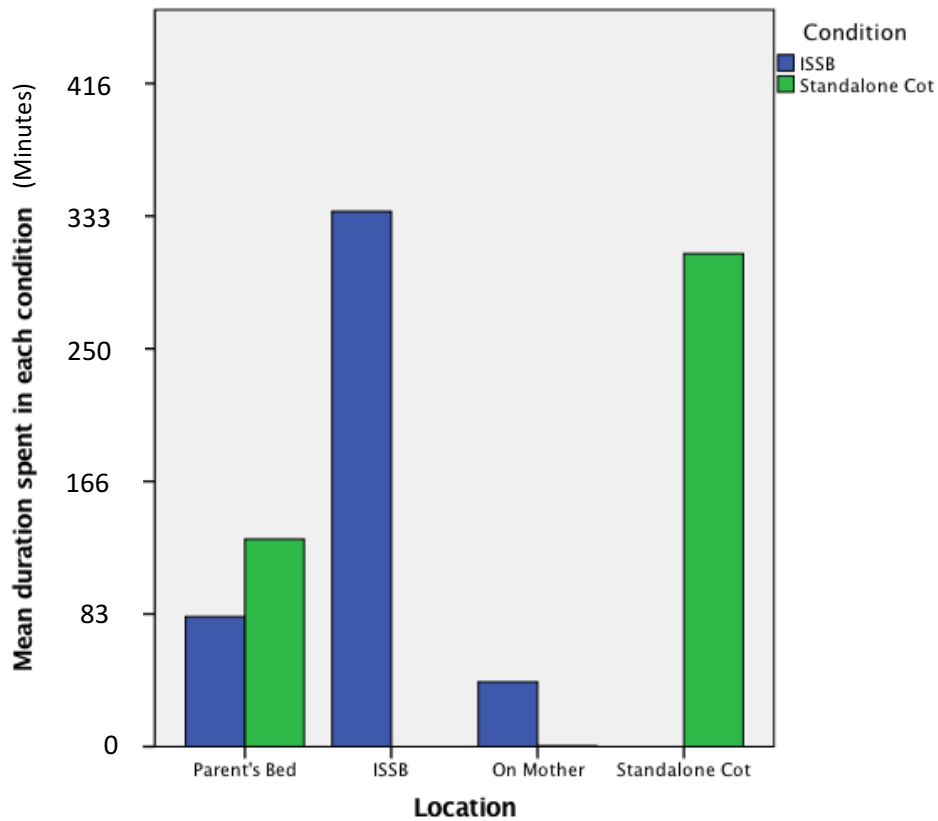


Figure 12. The mean duration that the infants spent in each condition whilst the mother was asleep

Percentage of the night that mother spent asleep was calculated to ensure that the 'mother asleep' data gave an accurate account of night-time behaviour. Percentage of the night spent asleep was used instead of actual sleep time to control for differences in observation length. The mean and median values were calculated to understand if there was any relationship between allocated condition and percentage of the night that the mother spent asleep. There was no difference between the median values for percentage of the night mothers spent asleep in the two conditions. Table 4 illustrates those averages and Table 5 demonstrates the percentage of the night mothers spent asleep for each participant, in each condition.

Table 3. Frequencies for percentage of the night that mothers spent asleep for each condition (%)

Condition	Mean	Median	Range
ISSB	61.50	62.00	34

			(46 - 80)
<b>Standalone Cot</b>	66.20	62.00	37 (47 - 84)

Table 4. Percentage of night mothers spent asleep for each participant (%)

	1	2	3	4	6	7	8	9	10	11
<b>ISSB Condition</b>	46	54	61	51	63	70	64	80	57	69
<b>Cot Condition</b>	60	62	80	58	84	61	62	72	47	76

### Maternal Proximity

Maternal proximity included any time that an infant was within arm's reach of their mother whilst the mother was asleep (either in ISSB in bed, on mother or in parents bed). All participants were included in the analysis for maternal proximity (n = 10). As expected, Wilcoxon signed rank tests indicated there was a significant difference in maternal proximity on nights using an ISSB than nights using a standalone cot, mothers slept within arm's reach of their infants for a significantly greater amount of time when using and ISSB (*Mdn* = 9.0 hrs) than a standalone cot (*Mdn* = 3.9 hrs),  $T=.00$ ,  $p=.005$ ,  $r=-.63$ . For per-protocol analysis there was still a significant difference between the duration of maternal proximity between the two conditions, ISSB (*Mdn* = 9.5 hrs) and standalone cot (*Mdn* = 3.7 hrs)  $T=.00$ ,  $p=.008$ ,  $r=-.63$ . The average values for maternal proximity are summarised in Table 6. Figure 12 illustrates the duration of maternal proximity for each participant in the per protocol group.

Table 5. Average values for the effect of allocated condition on the amount of time infants spent within arm's reach of their mothers (hours)

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	10	9.3	9.0	4.4 (8.1 – 12.5)
	Standalone Cot	10	3.2	3.9	7.3 (0.1 - 7.4)
<b>Per protocol</b>	ISSB	9	9.4	9.5	4.4 (8.1 - 12.5)
	Standalone Cot	9	2.7	3.7	4.9

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

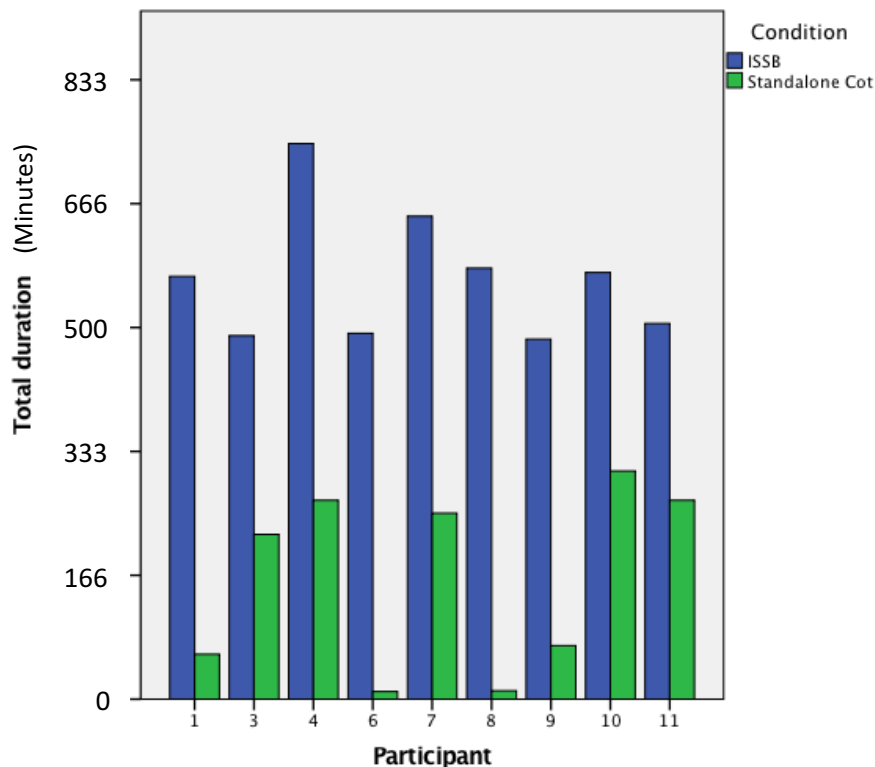


Figure 13. Duration of maternal proximity for each participant in per protocol group

### Same surface bed-sharing

Same surface bed-sharing, which included any time that the infant was in the parental bed or on mother whilst the mother was asleep in the bed, was employed by five breastfeeding dyads at least once throughout their two overnight stays. The formula feeding dyad did not engage in any bed-sharing and their results have consequently been omitted from this analysis. One participant (7) didn't engage in any bed-sharing for the box condition, but did in the cot condition so was included in the analysis.

The greatest difference in bed-sharing behaviour was seen for the participant who spent less than half the night in the allocated condition, showing a very small amount of bed-sharing on the box night and bed-sharing for almost the whole night in the cot condition. Three participants showed very little difference in the duration of bed-sharing between the two conditions, however there was a large difference in mean and median time spend bed-sharing when all results were considered, with mean duration of bed-sharing less on nights allocated an ISSB (1.2 h) than nights allocated a standalone cot (2.6 h). These results are reflected in a small, but not significant result ( $T=12$ ,  $p=.225$ ,  $r=.38$ ) which may have been due to the large range in results. As expected, when the per protocol

group was analysed the results became even less significant ( $T=7$ ,  $p=.465$ ,  $r=.26$ ) and there was a much smaller difference in the averages for duration of bed-sharing for each condition (see Table 7). Figure 13 illustrates the duration in same surface bed-sharing for each participant in the per protocol group for each condition.

Table 6. Average values for the duration of same surface bed-sharing (hours)

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	5	1.2	1.2	2.5 (0 – 2.5)
	Standalone Cot	5	2.6	2.2	4.6 (1.1 – 5.7)
<b>Per protocol</b>	ISSB	4	1.5	1.7	2.5 (0 – 2.5)
	Standalone Cot	4	1.8	1.6	1.8 (1.1 – 2.9)

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

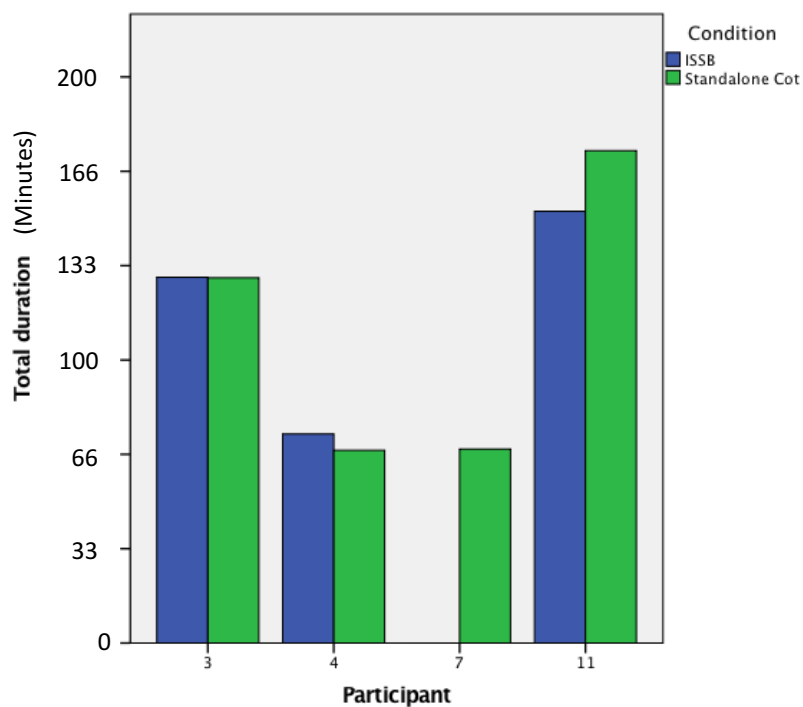


Figure 14. Duration of same-surface bed-sharing for each participant in per protocol group

## Breastfeeding

The number of breastfeeding bouts and the total duration of breastfeeding was analysed; all the exclusively breastfeeding dyads were included in the analysis ( $n = 9$ ), one participant did not engage in any breastfeeding for the entirety of the observation, that data was included as '0'. There was a greater mean and median duration of breastfeeding on nights using an ISSB than a standalone cot but the difference was not great enough to be significant ( $T=6, p=.093, r=-.69$ ), after per-protocol analysis the significance further decreased ( $T=6, p=.176, r=-.36$ ). The average values for each condition in the intention to treat and per protocol group are presented in table 8. Figure 14 illustrates the duration of breastfeeding for each participant in the per protocol group, showing that although the differences did not manifest as significant, six participants engaged in a greater duration of breastfeeding on nights allocated to an ISSB than nights allocated to a standalone cot and two participants breastfed for longer on nights allocated to a standalone cot.

Table 7. Average values for the total duration of breastfeeding (hours)

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	9	2.1	1.4	4.3 (0.2 - 4.6)
	Standalone Cot	9	1.2	0.9	2.9 (0 - 2.9)
<b>Per protocol</b>	ISSB	8	1.8	1.4	3.0 (0.3 - 3.3)
	Standalone Cot	8	1.2	1.1	2.9 (0 - 2.9)

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

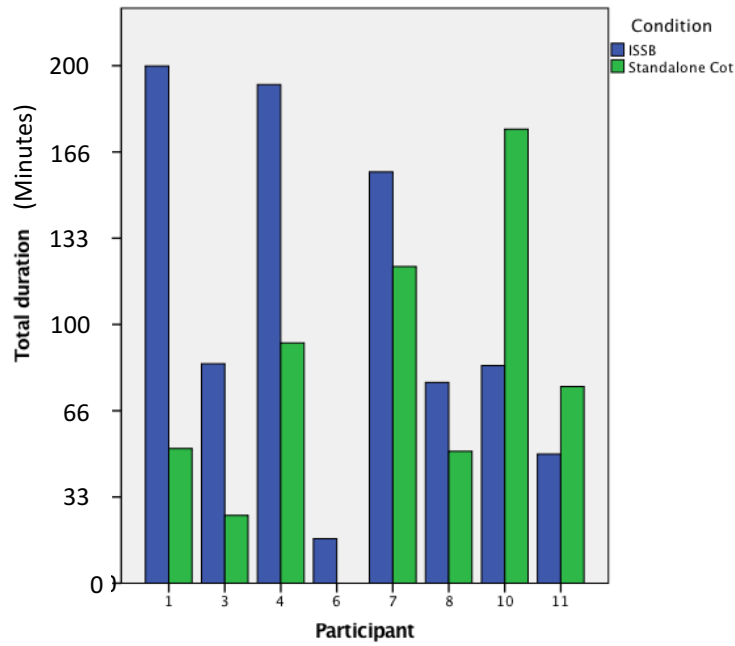


Figure 15. Duration of breastfeeding for each participant in per protocol group

The mean number of breastfeeding bouts was slightly higher for the cot condition than the box condition and no difference in the median, which was surprising considering that breastfeeding duration was higher on box nights than cot nights (shown in Table 9). However, the differences were so small that analysis resulted in a non-significant result,  $T=17.5$ ,  $p=.944$ ,  $r=-.02$ . After per-protocol analysis the median became slightly greater for the box condition (4.50) and the significance increased but not enough to become significant  $T=12$ ,  $p=.734$ ,  $r=-.90$ . Figure 15 illustrates the number of breastfeeding bouts for each participant, indicating that five participants engaged in a greater number of breastfeeding bouts on nights allocated an ISSB and three participants engaged in more breastfeeding bouts on nights allocated to a standalone cot.

Table 8. Average values for the number of breastfeeding bouts

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	9	4.67	4	7 (2 - 9)
	Standalone Cot	9	5.13	4	6 (3 - 9)
<b>Per protocol</b>	ISSB	8	5.00	4.50	7 (2 - 9)
	Standalone Cot	8	5.29	4	6 (3 - 9)

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

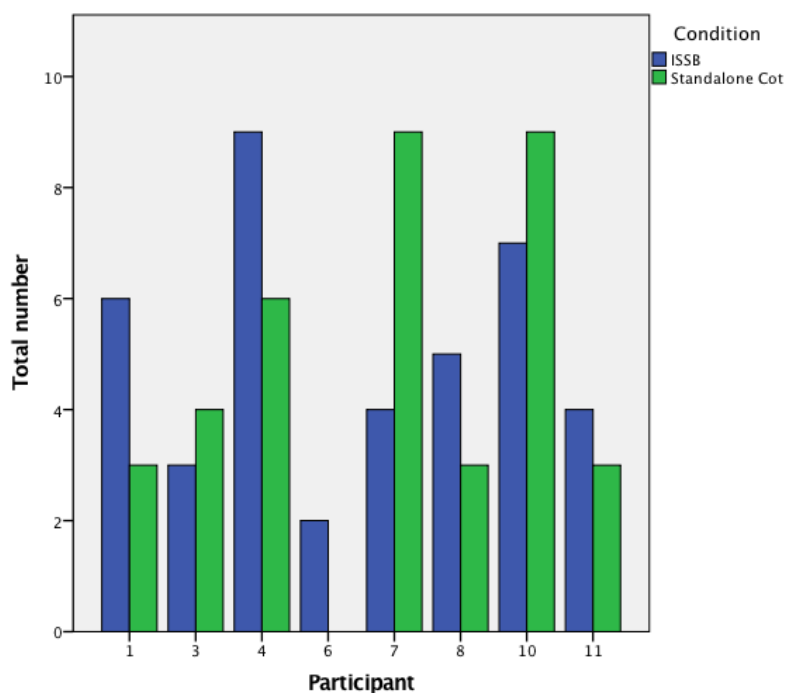


Figure 16. Number of breastfeeding bouts for each participant in per protocol group

### Looking and touching

The frequency and duration of looking and touching was recorded, which included all instances of non-feed related maternal looking and/or touching events. All participants were included in the intention to treat analysis for number of looking and touching events and the mean and median values showed a higher average number of looking and touching events in the box condition, as shown in Table 10. Wilcoxon signed-rank tests demonstrated that the number of looking and touching events were significantly greater on nights using and ISSB ( $Mdn = 16.50$ ) than a standalone cot ( $Mdn = 13$ ),  $T=6.5$ ,  $p=.032$ ,  $r=-.48$ . When analysed as per-protocol significance increased slightly (ISSB ( $Mdn = 18$ ), cot ( $Mdn = 13$ ),  $T=3.5$ ,  $p=.024$ ,  $r=-.53$ ). Figure 16. demonstrates the frequency of looking and touching events for each participant, the formula feeding dyad (ppt 9) did not engage in any looking and/or touching on the night allocated to a standalone cot.

Table 9. Average values for the number of looking and touching events

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	10	21.10	16.50	45 (6 – 51)
	Standalone Cot	10	12	13	21 (0 – 21)

<b>Per protocol</b>	ISSB	8	22.22	18	45 (6 – 51)
	Standalone Cot	8	11.89	13	21 (0 – 21)

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

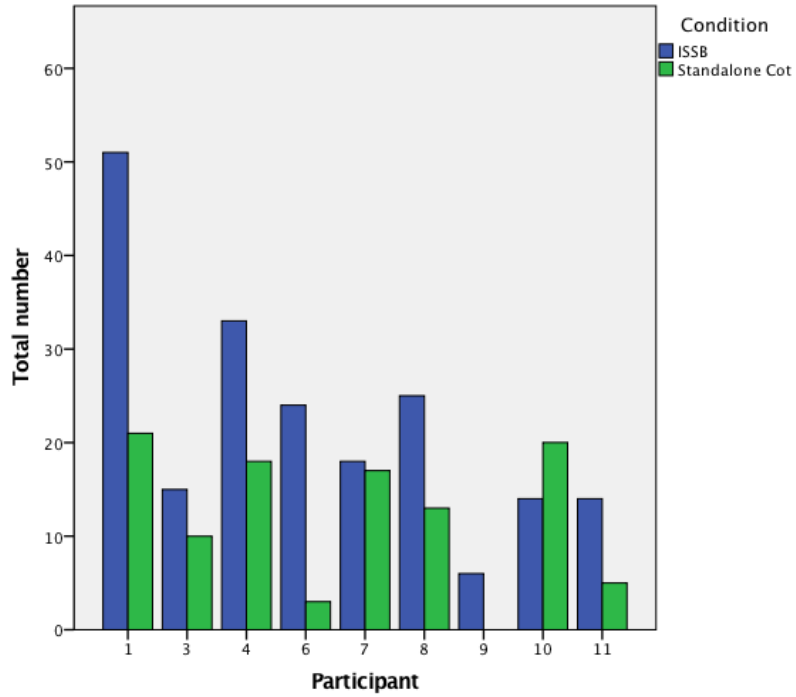


Figure 17. Number of looking and touching events for each participant in per protocol group



Figure 18. A mother touching her infant whilst he sleeps in the ISSB

Looking and touching duration was also analysed, the average values, as shown in table 11, demonstrate that there was an increase in looking and touching duration on nights allocated an ISSB however Wilcoxon signed-rank tests indicated the difference was not significant  $T=14$ ,  $p=.169$ ,  $r=-.03$ . When the per protocol group was analysed the significance increased slightly but not enough to become significant  $T=8$ ,  $p=.086$ ,  $r=-.40$ . Figure 18. illustrates the individual duration of looking and touching for the per protocol group, six participants engaged in a greater duration of looking and touching on nights allocated an ISSB, compared to two participants who had a longer duration of looking and touching on nights allocated a standalone cot.

Table 10. Average values for duration of looking and touching (hours)

	Condition	N	Mean	Median	Range
<b>Intention to treat</b>	ISSB	10	2.4	2.2	5.1 (0 - 5.1)
	Standalone Cot	10	1.4	1.2	3.0 (0 - 3.0)
<b>Per protocol</b>	ISSB	9	2.5	2.4	5.1 (0 - 5.1)
	Standalone Cot	9	1.4	0.9	3.0 (0 - 3.0)

Intention to treat = as randomised, regardless of compliance and Per Protocol = only those who complied with randomised allocation

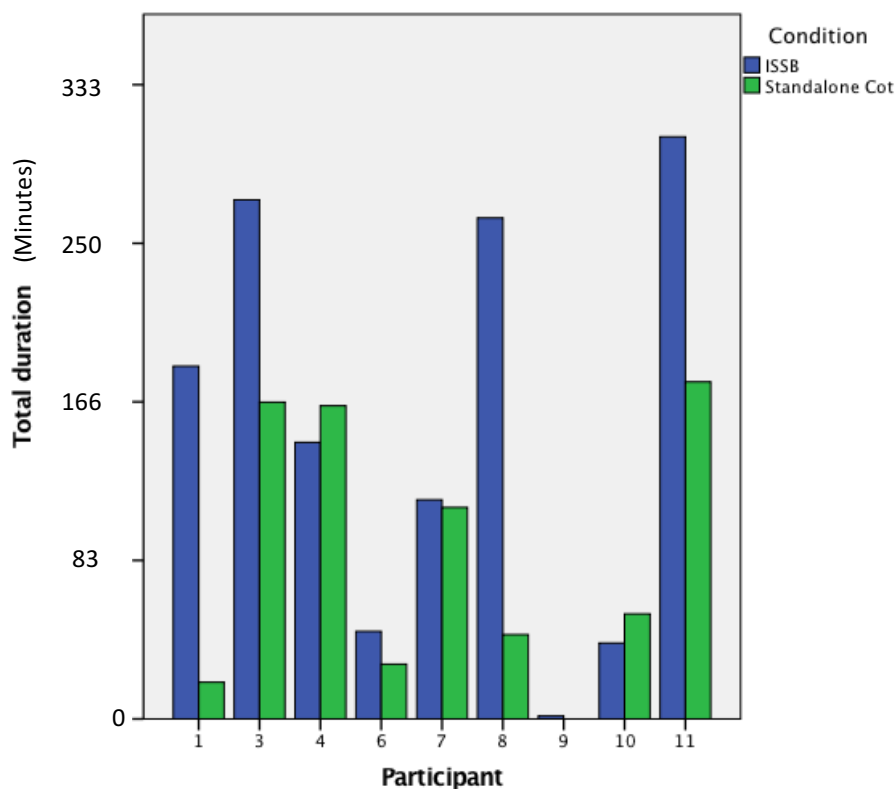


Figure 19. Duration of looking and touching for each participant in per protocol group

### Head Covering

Three observations included head covering events, one event lasted for 14s and therefore was not considered significant enough to be considered a risk. Two observations noted instances of head covering; both occurring on the night when the standalone cot was used, both happened when the infant was brought into the parental bed and both with breastfed infants. Table 12. summarises the head covering events.

Table 11. Head covering events

Participant	Extent of head covering	Material	Total Number	Total Duration	Condition	Feeding
<b>3</b>	Head and airways covered	Duvet	1	21 mins	Standalone Cot	Breast fed
<b>10</b>	Head and airways covered	Duvet	4	19 mins	Standalone Cot	Breast fed

Two noteworthy incidents of head covering occurred which lasted more than 10 minutes which will be described. In the first head covering was caused by the mother pulling the duvet up over her shoulders whilst she was lying in bed next to her infant (figure 19). The infant had initially been

positioned higher in the bed but had moved down the bed slightly. The head was covered by the duvet but was not enclosed and the infant's face could be seen facing up out of the duvet as can be seen in figure 19. The head covering event was ended by the infant wriggling and pushing covers off his head which prompted the mother to wake and further remove the covers off the infant's head. This infant was wearing a baby sleeping bag in the cot but was removed from the sleeping bag when he was moved into the bed with the mother.

In the second, the baby would not settle in the standalone cot so the mother brought her into bed. Again, the infant's head and airways were covered by not enclosed in the duvet. The infant seemed to be attempting to remove the covers and was observed wriggling around under the duvet, eventually the head covering event was ended by intervention of the researcher as the mother did not appear to be responding to the infant's cues. This instance of head covering can be seen in figure 20.



*Figure 20. An instance of head covering; the baby's head is covered by the duvet*



*Figure 21. Another instance of head covering; the baby's head is covered by the duvet*

Three participants used the blanket provided with the ISSB and seven (64%) brought their own baby sleeping bags which may have mitigated head covering events.

## Risks

There were no recorded specific box-related risks, tipping risks, or falling risks. All mothers placed the box in the suggested position according to the recommendations in the 'Where might my baby sleep?' booklet and as advised by the researcher. It is important to note that no harm occurred to any of the participants throughout the overnight observations.

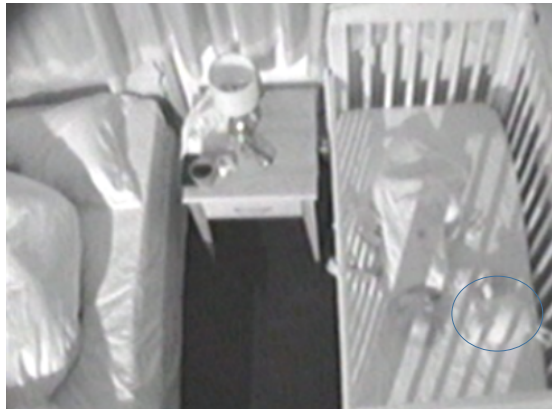
There was however a number of incidents of infants sleeping with soft toys in their immediate sleep environment, which has been defined as a risk factor for SIDS (The Lullaby Trust 2016). One participant bought a soft toy which was placed in the standalone cot close to the infant's head, shown in figure 21. This soft toy was not present on the night using an ISSB. Figure 22. shows two participants who brought a plush infant sleep aid<sup>1</sup> to the lab which was placed next to the ISSB and in the cot next to the infant.

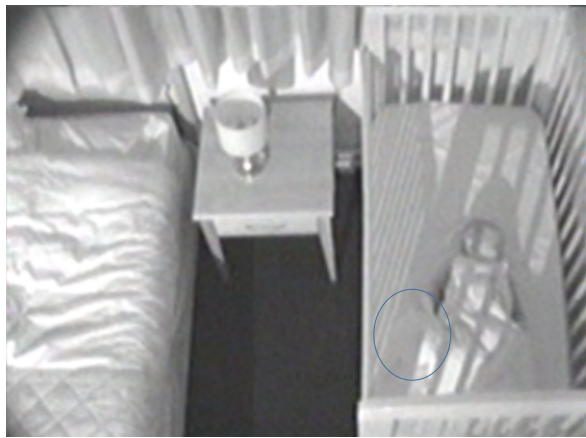
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<sup>1</sup> Plush infant sleep aids are stuffed toys which emit soothing sounds of a similar frequency to those heard in the womb and a soft glow supposed to simulate an in utero experience (Sweet Dreamers 2016)



Figure 22. A soft toy in the standalone cot





*Figure 23. Two participants bought a plush audio infant sleep aid, it was next to the box on box nights and in the standalone cot on cot nights*

## Discussion

This study set out to compare maternal-infant night-time interactions when infants were allocated to sleep in an 'infant safer sleep box' and a standalone cot in the same room, with the aim of assessing the efficacy of ISSBs as safe sleep devices for infants at high risk of SIDS from bed-sharing.

### The effect of allocated condition on maternal caregiving

Infant sleep location has been shown to significantly affect the frequency and quality of maternal caregiving throughout the night (Baddock et al. 2014; Baddock et al. 2006). The present study used looking and touching events, breastfeeding and maternal proximity to assess how using an ISSB compared to a standalone cot in the same room influences maternal caregiving throughout the night.

The results from this study indicate that using an ISSB facilitates significantly more looking and touching episodes than a standalone cot, consistent with the findings of Baddock et al. (2014) who also reported a significant increase in mother-baby interactions for participants allocated a *wahakura* compared to a standalone bassinet. The relationship between maternal checking and SIDS is unknown, however increased looking and touching episodes may protect against SIDS by stimulating arousals in infants and reducing the occurrence of dangerous sleep apneas (McKenna 2014). Mosko and colleagues (1997) found a decrease in stage 3-4 sleep and an increase in stage 1-2 sleep for breastfeeding bed-sharing women, which could indicate that lighter sleep episodes facilitated by close proximity may increase the mother's ability to respond to their infant's cues. It is probable that the increased risk of SIDS in separate room sleeping infants (Blair et al. 1999) is related to separate room sleeping infants receiving fewer parental checks than room sharing infants. Baddock et al. (2006) reported a significant increase in parental checks when bed-sharing compared to cot sleeping, this suggests that using an ISSB in the parental bed may provide the same benefits for maternal monitoring as bed-sharing, allowing parents to touch or visually inspect infants without substantial disruption to their sleep. Because of the strains on parental sleep in the postnatal period parents are likely to prioritise caregiving practices that minimize sleep disruption, therefore bed-sharing may be adopted as an effective method to enable increased parental checks whilst limiting levels of sleep deprivation. If the ISSB is to effectively provide a safe alternative to bed-sharing it must provide the benefits of bed-sharing whilst mitigating the risks, these results have shown that an ISSB can support increased maternal checking associated with bed-sharing.

Formula feeding is a risk factor for SIDS and is strongly influenced by deprivation score and maternal education (Wright et al. 2005). Maternal smoking is also associated with low levels of maternal education, more prevalent in lower income populations (Ward, Lewis & Coleman 2007; Dyson et al. 2010) and mothers who smoke are more likely to formula feed their infants (Dorea 2007). Using an ISSB increased number of looking events for the formula feeding dyad, who did not engage in any looking or touching when allocated to the cot condition. Although there was only a small increase in maternal monitoring when allocated an ISSB and these differences may have been isolated to this dyad, it is important to consider that the ISSB could have greater benefits to formula feeding dyads. Formula feeding has been associated with reduced infant crying at 6 weeks (Lucas & St James-Roberts 1998) which may reduce the frequency of maternal waking and monitoring over the course of the night. Formula feeding infants have also been shown to arouse less easily from sleep (Horne et al. 2004) increasing their risk of SIDS and emphasizing the value of maternally induced arousals facilitated by frequent checking. Considering the increased risk of SIDS in formula feeding infants it is important to provide interventions that can encourage maternal monitoring and keep the infant close to the mother.

The number of breastfeeding bouts for both nights were broadly similar to those noted in other observational studies; Gettler and McKenna (2011) noted a mean of 4.5 feeds per night for routinely bed-sharing infants whilst bed-sharing over three nights; Richard, Mosko et al. (1996) also recorded a mean of 4.7 breastfeeding bouts for routinely bed-sharing mother-infant dyads. Ball (2006) reported a median of 3 feeds per night for routinely bed-sharing infants recorded in the home. Sellen (2001) recorded infants breastfeeding an average of 4.2 times per night among Datoga pastoralists in Tanzania. A Swedish study that relied on mothers completing sleep diaries in order to measure the number of feeds per night reported significantly less night feeds than recorded in observational studies, a median of 2.2 feeds per night at 2 weeks and 1.3 feeds at 12 weeks (Hörnell et al. 1999). The difference in self-reported and observational data shows the necessity of observational studies to accurately record night-time breastfeeding behaviour.

Frequent suckling is associated with increased milk output (Prentice et al. 1986) and an extended duration of lactational amenorrhoea (Gnish et al. 2006). Short, sporadic and frequent breastfeeding sessions have been shown to be more effective in continuing lactational amenorrhoea than longer, more scheduled breastfeeding bouts (Taylor et al. 1999; Konner and Worthman 1980). The production of prolactin, the hormone responsible for regulating milk supply, is stimulated by the

frequency, intensity and duration of infant suckling; prolactin secretion has been shown to increase at night, emphasizing the importance of night feeding on supply regulation (Jellife & Jellife 1978). Increased milk output, facilitated by frequent suckling can ensure that infants are getting sufficient milk, potentially delaying the introduction of formula or complementary foods. An increased duration of breastfeeding has significant protective effects for both the mother and the infant including a reduced risk of SIDS (Venneman et al. 2012), therefore any intervention that encourages an increase in frequency and duration of breastfeeding has the potential to improve health and wellbeing outcomes for both mothers and infants. However, when allocated an ISSB infants showed no significant difference in the number of breastfeeding bouts per night than when allocated to the standalone cot condition. Given that all the breastfeeding mother-infant dyads were exclusively breastfeeding, the consistency of breastfeeding bouts in the two conditions may have been due to the already established routines and milk synthesis of the dyads, unaffected by a night of separation. Previous research of *Wahakura* use from birth to 6 months showed that infants allocated a *Wahakura* reported twice the level of full breastfeeding at 6 months compared to infants allocated a bassinet (Baddock et al. 2017). This may indicate that the effect of increased mother-infant proximity through allocating a safe sleep enabler that can be used in the parental bed may be similar to that reported from regularly bed-sharing mother-infant dyads.

The total duration of breastfeeding recorded in this study, for both conditions was much higher than recorded in other studies; Ball (2006) recorded a median of 36 mins breastfeeding for ten bed-sharing mother-infant pairs recorded sleeping at home. In a similar finding, Young et al. (1999) reported a median of 34 mins total breastfeeding duration for five mother-infant pairs recorded sleeping a hospital laboratory. Richard, Mosko et al. (1996) recorded six bed-sharing breastfeeding Latino mother-infant pairs and reported a mean of 56 mins total breastfeeding, a result more consistent with the results reported in this study.

Mothers were observed to sleep closer to their infants on nights using an ISSB than a standalone cot. This result was expected as sleep locations were limited in the lab to the ISSB, standalone cot or same-surface co-sleeping. No mothers put their infant to sleep in the standalone cot on nights using an ISSB, either complying with the allocated condition or bringing their baby into bed. This may indicate that the ISSB was preferred over the standalone cot as a sleep location. Alternatively, it may imply that parents were diligent in adhering to the allocated condition. Research has shown that close infant and maternal sleep encourages breastfeeding (McKenna, Mosko and Richard 1997; Ball 2003; Hooker et al. 2001; Ball et al. 2006). Maternal proximity has been positively correlated with

the number of attempted and successful feeds in the immediate postnatal period (Ball et al. 2006), as well as stimulating the onset of lactogenesis II, shown to consequently increase milk output (Robinson 2009). Unhindered access to infants throughout the night, most frequently associated with bed-sharing has been correlated with a greater number of months breastfeeding. Santos and colleagues (2009) found that bed-sharing at 3 months protected against weaning up to 12 months after birth consistent with Ball's (2003) finding that parents who began bed-sharing in the first month of life were twice as likely to be breastfeeding when their infants were 4 months old. The provision of unimpeded access to infants throughout the night may act to mitigate the costs of night waking and could be used as a tactic by tired parents to manage the pressures of frequent breastfeeding. Perceptions that formula use promotes infant sleep have been acknowledged as an important component contributing to the introduction of formula milk to ease the burdens of night-time care (Ball 2002; Pinilla & Birch 1993; Marchland & Morrow 1994) therefore it is important to provide interventions that promote breastfeeding by limiting the burden of night-time feeding.

Previous literature has thus established that maternal proximity influences two phases of breastfeeding: (1) establishing milk synthesis in the immediate postpartum period and (2) continuation of breastfeeding over a number of months. Given that this study was only conducted over two nights, after participants had developed milk synthesis, the influence of allocated condition on breastfeeding was difficult to establish. Alternatively, the results could indicate that the ISSB represents a physical barrier to breastfeeding similar to the standalone cot, which requires mothers to wake and physically move their infants to facilitate feeding; providing no benefit to breastfeeding frequency over a standalone cot in the same room. This could have implications for reducing the occurrence of same-surface co-sleeping as parents may still revert to bed-sharing as a behaviour to better facilitate the costs of night-time feeding. Although the differences did not manifest as statistically significant, there was a preponderance of participants with an increased frequency of breastfeeding in the box condition, five participants (63%) had a mean of two more breastfeeding bouts when allocated to an ISSB. Of the three participants who showed a greater number of breastfeeding bouts when allocated to the cot condition; one participant bed-shared for a proportion of the night in the cot condition but did not when allocated to the ISSB, another spent less than 50% of the night asleep. This may explain why the number of breastfeeding bouts increased in the cot condition for these participants and could provide evidence to support the suggestion that using an ISSB does not provide the same benefits to breastfeeding as same-surface co-sleeping. It is also important to consider that a greater proportion of participants did engage in

more breastfeeding bouts on the box night so there is some evidence of a positive effect on feeding frequency when allocated an ISSB.

Night feeding has been shown to contribute considerably to overall milk intake, with 20% of daily milk consumed at night (Kent et al. 2006). The composition of breastmilk changes throughout feeding with fat content increasing as the feed progresses (Hall 1979). Fat content is associated with emptiness of the breast; an emptier breast has a higher fat content and a faster rate of milk production than a full breast (Daly et al. 1993). High fat hind milk can increase satiety and is reported to be effective in improving weight gain in low birth weight infants (Valentine, Hurst & Schnaler 1994). Longer feeding bouts result in emptier breasts, contributing to supply regulation and ensuring that sufficient milk is produced for the next feed. The total duration of breastfeeding in the two conditions was shown not to be statistically significant, however six participants (75%) breastfed for a mean of 64 mins longer on nights using an ISSB compared to a standalone cot, indicating that for some individuals using an ISSB did increase the total duration of breastfeeding. Consistent with the results reported in this study, Baddock et al. (2014) reported a small, but non-significant increase in breastfeeding duration for participants allocated to use a *wahakura* compared to a standalone basinet. Although the results indicate that for a preponderance of the study population feeding duration was longer on nights using a ISSB, the results may be confounded by the use of observational data to assess length of feeding bout. The data collected signifies how long the infant spent at the breast but does not indicate the amount of breastmilk ingested or the time the infant was engaged in nutritive suckling, therefore these results may not indicate that infants were actually gaining the benefits of increased milk ingestion.

### Infant safer sleep boxes as 'safe sleep spaces'

Safe sleep interventions have focused on reducing the occurrence of modifiable risk factors for vulnerable infants. This study endeavoured to understand the safety implications of using an ISSB in comparison to a standalone cot in the same room and the effectiveness of using an ISSB to reduce the occurrence of risky co-sleeping events such as head covering, same-surface co-sleeping, falling and tipping. It also intended to understand if the ISSB posed specific risks to infant and maternal safety that had previously been overlooked due to an absence of direct observational data relating to the use of safe sleep enablers.

The rate of bed-sharing in this sample was consistent with Blair and Ball's (2004) findings; 47% (10/21) of the overnight observations featured same-surface co-sleeping at some point. Although

the duration of same-surface co-sleeping was greater on the cot night, there was no significant difference between duration of same-surface co-sleeping in the two conditions. All but one of the participants who engaged in same-surface co-sleeping did so for similar amounts of time on both nights and all reported bringing the baby to sleep in the bed at home, therefore bed-sharing incidence is likely to have been related to the participant's predisposition for bed-sharing. This is an important consideration when implementing the ISSB as an intervention to reduce the occurrence of same-surface co-sleeping, it may be less successful with multiparous parents who have already established a bed-sharing routine with previous infants, or if provided after parents have had time to establish their own habits. Within the context of this study, bed-sharing was considered an 'unsafe' practice given that the intervention is intended for families who are contraindicated for bed-sharing. However, for most of the participating families bed-sharing could be considered a potentially beneficial practice. Many of the participants were aware of safe sleep practices and could be defined as intentional co-sleepers. The distinction between intentional and reactive co-sleeping (Ramos 2003) is meaningful within the context of this intervention as the ISSB may be more beneficial in providing an alternative to reactive co-sleeping situations than intentional co-sleeping.

Consistent with the proposed hypothesis, there were fewer head covering events on nights using an ISSB than a standalone cot. There were no head covering events whilst infants were in the ISSB or on the nights using an ISSB. There was also no head covering whilst infants were in the standalone cot, but head covering did occur on nights using a standalone cot, however these occurred in the parental bed. This suggests that there is no difference in head covering risk between using an ISSB and Standalone cot, however given the nature of the study sample there may have been an increased propensity for bed-sharing when infants were allocated to a standalone cot which resulted in a greater chance of head covering events on those nights. Previous studies have found that a quarter of SIDS infants were found with their head under the bedclothes (Blair et al. 2008), with head covering considered a major risk factor for SIDS. Infants who were found with their head covered tended to be older, with more developed motor skills (Mitchell et al. 2008). A number of head covered infants have also been found sweating indicating that thermal stress induced by restriction of heat loss through the head may play a part in SIDS (Mitchell et al. 2008). Studies have indicated that healthy infants are able to regulate body temperature in cases of head covering (Baddock et al. 2004), however infants with predisposed vulnerabilities, such as brainstem abnormalities may struggle to maintain homeostasis during sleep (Kinney et al. 2009) increasing the risk of SIDS from head covering.

Bed-sharing has previously been associated with an increased number of head covering events, Baddock and colleagues (2006) found that 55% of bed-sharing infants had blankets above their eyes compared to only one cot sleeping infant (3%), Ball (2009) also found a significant increase in head covering for bed-sharing infants compared to cot sleeping infants. Within this study there was a high proportion of dyads using their own infant sleeping bags which may have mitigated the risk of head covering. One infant who experienced head covering was sleeping in a baby sleeping bag in the standalone cot but was removed from the sleeping bag when he was brought into bed, so although the sleeping bag may have been useful in mitigating head covering risk in the infant's own sleep environment when the infant was moved to sleep with the mother, the potential risk returned. The rising popularity of infant sleeping bags have been attributed to decreases in SIDS prevalence (Blair et al. 2009) alongside the adoption of the feet to foot campaign. L'Hoir and colleagues (1998) found that use of an infant sleeping sack was associated with a lower risk of SIDS however another study found no association between sleeping bag use and SIDS risk (Blair et al. 2009). The limited size of the box may have stopped infants from wriggling down and becoming covered by the blanket when sleeping in the ISSB which may also have contributed to the absence of head covering events on nights allocated an ISSB.

The position of the duvet on the triadic night may suggest the duvet is more likely to cover the ISSB in triadic sleeping situations, potentially increasing the likelihood of infant head covering. Due to a lack of data for parent-infant triads sleeping with the ISSB it is difficult to draw any accurate conclusions about how another adult may influence the frequency of risky events occurring. However, it seems reasonable to hypothesize that in triadic sleeping arrangements the duvet would spend more time covering the ISSB, but not necessarily the infant's head. Ball (2006) studied the effects of father presence on the height of bed covers during bed-sharing and found that that bedding was lower on the infant's body when sleeping with just the mother however there was no significant increase in head covering events when the father was present, suggesting that father presence increases duvet height but not enough to pose a risk to infants.

Safe sleep guidelines advise against putting soft toys in the infant's immediate sleep environment in order to mitigate the chances of head and airway covering (The Lullaby Trust 2016). Soft bedding, including soft toys can pose a suffocation risk through facial obstruction or rebreathing (Guntheroth & Spiers 1996) and contribute to the risk of SIDS. The results of this study indicate that mothers were more likely to put soft toys in the infant's immediate sleep environment when allocated to the standalone cot; there were three instances of mothers placing a soft toy in the standalone cot with

their sleeping infants. The size of the ISSB, with limited extra space surrounding the infant appeared to deter mothers from placing additional soft bedding or toys inside it, however they did place them near to the box in the adjacent area. The standalone cot offered substantial space around the infant and the mothers inclination to place soft toys in the infant's sleeping environment when sleeping in the cot may have been due to the extra space afforded by the cot. The function of a soft toy or security blanket in comforting infants is thought to be benign for infants under six months as they are developmentally too young to explore objects in their sleeping environment or form attachments to inanimate objects (Busch 1973; Passman & Halonen 1979). For mothers who were used to sleeping close to their infants, placing a soft toy in the cot may have provided them with the comfort that their infants were not 'alone' in the cot. Although the box seemed to be successful in creating an environment with reduced suffocation risks it should be noted that in instances where excess soft bedding was to be introduced to the box the risk of suffocation may considerably increase because of the limited space around the infant. This observation is merely hypothetical and the results of this study did not indicate that the ISSB increased suffocation risk, but was shown to deter parents from creating an unsafe sleep environment.

Two of the participants bought a plush infant sleep aid and placed that in the cot with their infants on the cot night and just outside of the box on nights allocated an ISSB. Plush infant sleep aids are stuffed toys which emit soothing sounds of a similar frequency to those heard in the womb and a soft glow supposed to simulate an in utero experience. They are claimed to improve infant's sleep; however, no formal research has been conducted to support this (Sweet Dreamers 2016). The guidelines provided with the plush infant sleep aid reiterate the importance of not placing soft toys in the infant's sleep environment and suggest that the aid should be attached to the upper rails of a cot; however, promotional images defy these guidelines and the product lends itself to being placed within the infant sleep environment as noted in this study. It is important that safe sleep guidelines and product manufacturers consider these devices and provide parents with targeted and appropriate advice about creating a safe sleep environment, free from risks.

### Adverse Events

It is important to note that throughout the overnight sleep studies the participants encountered no actual harm and discussions about 'risk' are specifically relating to the potential to cause harm. However, throughout the overnight observations there was one instance of an adverse event occurring which involved intervention by the researcher in order to alleviate a potentially risky (dangerous?) event. An intervention protocol was established before data collection which outlined

key situations for intervention; nonetheless when conducting the overnight observations, it became apparent that the intervention criteria were difficult to generalize across the study population given the multifaceted and variable nature of parental caregiving and SIDS risk. It was important that the lab simulated an 'at home' environment and participants felt free to engage in their usual caregiving practices without fear of judgment or discipline. Data collected at recruitment indicated if the infants were contraindicated to bed-sharing and the usual sleep locations of infants. It was important to understand if infant sleep location in the lab was considerably divergent from usual sleep location in order to assess potential risks.

The intervention occurred when a participant who had had very little sleep and was showing signs of extreme tiredness fell asleep with her infant in the bed and the infant's head was covered by the duvet. The head covering exceeded ten minutes and the infant appeared to be wriggling around under the duvet in an attempt to wake the mother and/or remove the duvet. An attempt was made to wake the mother by gently knocking on the door which was unsuccessful. It was decided that because the mother appeared difficult to arouse that intervention was required to wake the mother and emphasise the importance of keeping the infants face in view of the cameras. Because the project only involved recording observational data and not physiological recordings it was difficult to ascertain the infant's physiological responses to the situation and it was decided that a conservative approach to this potential risk was appropriate.

### Ecological Validity

Although this study attempted to simulate a 'normal' night-time environment for participants, observational data produced in the parent-infant sleep lab falls short of achieving full ecological validity. The study population included ten mother-infant dyads and one mother-child-infant triad, failing to fully capture the breadth of possible co-resident family members who may interact with the infant throughout the night and be influenced by a change in infant sleep location or the addition of an ISSB. Having a second adult in the bed may affect the practicality of the box as it could limit sleeping space, particularly with large or overweight parents. From observing the mother-child-infant triad it became apparent that the box may influence caregiving behaviour differently when used within a family context. For parents who had additional children, participation in laboratory based overnight studies becomes difficult. Although volunteers were told they that were free to bring along additional children, many justified not participating due to childcare strains. Childcare constraints also contributed to the absence of many partners in the study as they tended to stay at home looking after other children whilst the mother participated in the study.

A detailed account of 'at home' sleep behaviours was not recorded for participants which made it difficult to assess ecological validity. If participants had filled in sleep diaries prior to participation it would have been easier to understand how similar or different the observed behaviours were in relation to usual night-time caregiving. Additionally, it would have been useful to have collected more specific demographic data recording education level, socioeconomic status and income level in order to contextualize the study population. As an exploratory study it was not deemed necessary to collect the demographic information of the participants, however for further studies demographic characteristics may be useful in assessing the breadth of the study population and the applicability of study results within the general population.

Because participants were asked to settle their infants in the allocated location, mothers may have been more inclined to put the baby back to sleep in the allocated condition in order to comply with the study protocol. Six participants noted that their infants usually slept in a side-car crib attached to the parental bed; allocating infants to a standalone cot positioned away from the bed may have challenged their usual sleeping arrangements and forced infants who may have never slept out of arms reach of their mothers to settle and sleep away from their mothers. Adherence to the condition may have been increased because the effect of using an ISSB only had to be endured for one night. Use over a longer period may result in the manifestation of unsafe habits or inappropriate use of the ISSB, which this study was unable to assess.

Mothers were briefed on how to use the ISSB at the beginning of the night and encouraged to look in the 'Where might my baby sleep?' leaflet. This may have increased awareness of safe sleeping practices and resulted in fewer sleep related risks. When employing the intervention in a health-care setting, the briefing may occur days or weeks before the box is used and knowledge of safe and appropriate use may have diminished. The layout of the lab which did not provide many alternative sleeping spaces may also have contributed to increasing compliance with the condition.

Given that the study aimed to assess a novel sleep space and understand the risks it posed, it was deemed necessary to observe ISSB use in a controlled environment, the laboratory provided the opportunity to monitor overnight behaviour in real time and intervene if potential risks turned into actual threats to infant safety. The set-up of the cameras in the lab allowed for 360° observation of behaviours occurring throughout the night, something which would not have been achieved with fixed cameras set up in the home.

## Limitations

The present study was limited by its small sample size and failure to recruit an equal number of breastfeeding and formula feeding infants, this resulted in the loss of a main comparison group. This project aimed to recruit equal numbers of breastfeeding and formula feeding infants in order to understand the effects of feeding method on use of the ISSB, however only one formula feeding parent-infant dyad was recruited so this aspect of the analysis was dropped. Formula feeding infants were difficult to recruit, primarily because many of the baby groups were intended specifically for supporting breastfeeding families, based around an ethos of attachment or natural parenting which focused on encouraging breastfeeding and discouraging use of artificial formula. The absence of any specific support groups for formula feeding families meant that it was difficult to recruit them directly. Laws that regulate provision of information and educational material regarding infant formula (The Infant Formula and Follow-on Formula Regulations 2007) may alienate formula feeding mothers from engaging with parenting groups that actively encourage breastfeeding, or limit the creation of specific groups that aim to support formula feeding parents. Within published literature it is difficult to find examples of other studies which found it challenging to recruit formula feeding participants, this may be due to publication bias; only studies that report a high participation or response rate make it to publication or comparison groups with small sample sizes are dropped when data is published (Newcombe 1987).

Failure to recruit formula feeding infants may have also been because co-sleeping was seen as a behaviour irrelevant to formula feeding parents, or something that was more relevant to breastfeeding families. McKenna and Gettler (2015) proposed the term 'breastsleeping' to describe the deeply entwined relationship between breastfeeding and co-sleeping, emphasizing that breastfeeding and co-sleeping should be considered in its own context and distinguished from other types of same-surface co-sleeping. At the start of recruitment parents were rejecting their own eligibility because they did not co-sleep, which resulted in a strong emphasis during recruitment that all parents were eligible if their infants were under 5 months, irrespective of current sleep behaviour. However, beliefs about co-sleeping still seemed to influence the likelihood of volunteering for the study, with over half the sample using a co-sleeper (side-car crib/bed nest) and 80% of participants reporting bed-sharing with their infants at least once in the past week.

Young mothers, mothers who smoke and mothers of infants who are at high risk of SIDS during bed-sharing (for example premature or low birthweight infants) are the most likely to benefit from this

intervention therefore it would be beneficial to generate data about how the box interacts with common caregiving behaviours associated with those groups, such as bottle feeding (Dyson et al. 2010). Unfortunately, these participants appear to be difficult to reach. Recruitment through a healthcare trust may be more successful in engaging with and recruiting hard to reach participants than independent recruitment. Leech (2006) recruited exclusively breastfeeding parents through health visitors for a laboratory based, observational study and reported a final study population of 21 families, almost twice as many as this study.

There was a substantial range in the developmental stage of infants, with their ages ranging from 4 weeks to almost 20 weeks which may have limited the data produced. The effect of the box may be considerably different if used consistently from early life compared to its introduction as a novel condition for a baby who is already several months old. Although the use of a cross-over study design controlled for this to some extent, it would be useful to generate data relating to the effect of providing infants with an ISSB over a sustained period of time, through a number of developmental stages.

The sample size was smaller than expected which resulted in a number of difficulties when conducting the statistical analysis. The results required vast differences between the two conditions to be considered significant and a number of statistical tests were invalid due to such a small sample size. The statistical analysis had to be considered as a suggestion of potential statistical significance rather than a definitive indication that the results were significant (and could thus be applied to a general population). The small sample size did allow for an in depth and detailed analysis of behaviours that may not have been possible in a larger sample. The study aimed to create empirical data that could be used to inform future research relating to the feasibility of providing families with ISSBs and provide a framework for further observational studies. Although the study was successful in doing that with the limited sample size, it would have been additionally beneficial to have collected 'follow-up' data to understand how the ISSB was perceived by parents and any suggestions of how it could be improved.

### Directions for future research

The results of this study have indicated that maternal caregiving behaviour was influenced by allocation to an ISSB, however the data presented here was extremely limited by the small sample size and is in no way conclusive. The project was intended to provide preliminary data to inform

current knowledge about the use of ISSBs and the results of the study has highlighted a number of areas in which future research would be beneficial.

This study has shown that ISSBs can provide infants with a safe sleep space when used in the laboratory. Future research focused on collecting in-home observational data of ISSB use in the home setting and evaluating the safety and practicality of using an ISSB in the home would be valuable in assessing the feasibility of providing ISSBs as alternative sleep spaces. Home settings are considerably more diverse than the environment offered in the lab, with huge variation in critical aspects such as bed size which could considerably affect the practicality of using an ISSB. Home settings are constantly in a state of flux with other family members and pets who could also affect the suitability of using an ISSB.

Alongside observing families using ISSBs in the home setting, it would also be useful to generate data about the use of ISSBs over a sustained period of time. Understanding how ISSBs affect parental-caregiving over time is valuable and would be integral in understanding the true influence of ISSB use on caregiving behaviour. The ISSB may present as a physical barrier to behaviours such as breastfeeding and may not be influential in reducing the occurrence of same-surface co-sleeping over time. On the other hand, the ISSB may prove beneficial to infants who are contraindicated to bed-sharing by allowing close contact with caregivers throughout the night as well as providing a safe sleep space, certainly the results of this study have indicated that this could be the case.

Due to a failure to recruit formula feeding infants, there is still a need for research to understand how feeding method influences using an ISSB.



## Conclusion

This study is important because it provides empirical evidence to suggest that infant safer sleep boxes can provide an alternative sleep space for infants. Safe sleep guidelines advise putting infants who are contraindicated to bed-sharing in a standalone cot in the same room (The Lullaby Trust 2016), which is considered the safest sleep environment. The results found here have indicated that using an ISSB does not pose any additional risks to infants than sleeping in a standalone cot in the same room and may provide benefits such as closer infant and maternal sleep, increased maternal monitoring and a safer sleep environment than a standalone cot in the same room, potentially improving health and wellbeing outcomes for mothers and infants.

Reviews of previous safe sleep interventions have emphasized the need to tailor interventions to meet the needs of individuals and target populations in order to increase adherence and efficacy (Salm-Ward & Balfour 2015; Ball & Volpe 2013). The results of this study have shown that across the study population infant safer sleep boxes significantly increase the ease of infant monitoring by mothers and encourage maternal proximity. However, when considering individuals and isolated groups there were juxtaposing patterns which show that providing an ISSB has varying benefits for particular individuals. Given the small sample size involved in this study it is difficult to generalize the results across any population as statistical tests hold little power. The results of this study indicate that providing an ISSB may increase breastfeeding frequency and duration, reduce the frequency of head covering events and discourage parents from placing soft toys or additional soft bedding in the infant's sleep environment. The provision of ISSBs are intended as a targeted intervention for infants who are contraindicated to bed-sharing and further studies are needed to understand how the box may be accepted by high risk populations.

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# Appendix I

## Participant consent form

### Consent Form

'Can Infant Safe Sleeper boxes facilitate safe co-sleeping for both breast and formula feeding mothers?'

Consent form to participate in Alice-Amber Keegan's postgraduate research project at Durham University

- |   |          |
|---|----------|
| 1. I have been informed about and understand the purpose of this study  | Yes / No |
| 2. I have been given the opportunity to ask questions about the research  | Yes / No |
| 3. I understand that I can withdraw from the study at any time  | Yes / No |
| 4. Any information that may potentially identify me will not be used in published material  | Yes / No |
| 5. I give my permission for audio and visual recording equipment to be used in the project as a research aid in overnight sleep studies   | Yes / No |
| 6. I understand that the information collected will be used to support further research in the future, and may be shared anonymously with other researchers or health professionals for research and education. | Yes / No |
| 7. I agree to participate in the study and for my baby to participate in the study  | Yes / No |

\_\_\_\_\_

Name of Participant

\_\_\_\_\_

Signature of Participant

\_\_\_\_\_

Date

\_\_\_\_\_

Name of Researcher

\_\_\_\_\_

Signature of Researcher

\_\_\_\_\_

Date

# Appendix II

## Participant volunteer form

Study ID No: \_\_\_\_\_



### Volunteer Form for parents interested in the Baby Box study

Researcher: Alice-Amber Keegan (Durham University)

Please complete this form if you are interested in participating in the Baby-Box study at Durham University Parent Infant Sleep Lab, Queens Campus. Someone will get in touch with you shortly about taking part in the study.

If you are currently pregnant but would like to register your interest in taking part in the study when you baby is born, please fill in the contact information and then refer to the end of the form to register your baby's due date. We will be in touch to ask if you are still interested in taking part after your baby is born.

All contact information will be kept on a secure database and will be destroyed at the end of the study or at your request at any point throughout the study.

Full Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Phone (Home): \_\_\_\_\_

Phone (Mobile): \_\_\_\_\_

Email: \_\_\_\_\_

Preferred method of communication:

- Phone Call
- Email
- Text
- Post
- Other: \_\_\_\_\_

Is your baby? Male / female      Is your baby under 5 months of age? Yes / No

Baby's date of birth: \_\_\_\_\_

Was your baby born after 37 weeks of pregnancy?      Yes / No

Do you smoke?      Yes / No / Occasionally

Did you smoke during pregnancy?      Yes / No / Occasionally

Study ID No: \_\_\_\_\_

Do you breastfeed...

- Exclusively (My baby has only ever been breastfed)
- Predominately (My baby is mostly breastfed but has been given water based drinks in the past)
- Partially (My baby is receiving some breastfeeds but also has other foods such as formula milk or weaning foods)
- No breastfeeding (My baby is formula-fed/does not receive any breast milk)

I am currently pregnant and my baby's due date is: \_\_\_\_\_

(You will be contacted a month after your due date to ask if you are still interested in taking part in the study)

**Thank you!**

## Appendix III

### Study information sheet

My name is Alice-Amber Keegan and I am a postgraduate research student from Durham University. I am conducting a research project under the supervision of Professor Helen Ball about Baby-bed boxes.

### What are baby-bed boxes?

'Baby boxes' also known as 'Infant safer-sleep box' are boxes intended to provide safe co-sleeping environments for all babies, even those at increased risk of Sudden Infant Death Syndrome (SIDS). The aim of the box is to raise awareness and education about safe sleeping practices as well as helping parents to avoid hazardous co-sleeping. The boxes are 38 x 75cm Phthalate and BPA free clear plastic boxes which come with specially fitted mattresses and sheets. Babies can sleep in the box in the parents' bed or they can be used when travelling overnight if there is no safe sleep space. They allow mothers to sleep close to their babies, even share the same bed without increasing the risk of SIDS.

### How can you help?

This project is looking for women with young babies under 5 months of age to visit the Parent Infant Sleep Lab at Durham University, Queens Campus, Stockton and participate in an overnight sleep study using night-time video to record how mothers and babies use the baby-bed boxes. We are looking for mothers to spend two nights in the lab, one night using the baby box and another night using a standalone cot so we can compare the two. You do not have to be in a SIDS risk group to take part.

### Are they safe?

There are over 3000 baby boxes in circulation in New Zealand, and rates of infant death are at an all-time low, particularly in areas where the boxes have been provided. Along with a safe sleep programme the boxes were shown to provide high-risk babies with safe sleeping spaces\*. There will be a researcher present observing the study at all times who will stop the study if you or your baby are at any risk.

### What if I don't want to do it anymore?

You are welcome to leave the study whenever you want to; you are under no obligation to complete the study.



Photograph by Rob Mark Photography

### Thank you!

As a thank you for taking part you will receive a £30 voucher in Love2Shop gift vouchers, half after the first night completed in the lab and half after the second night.

You are welcome to come and visit the lab and we would be happy to answer any questions you have.

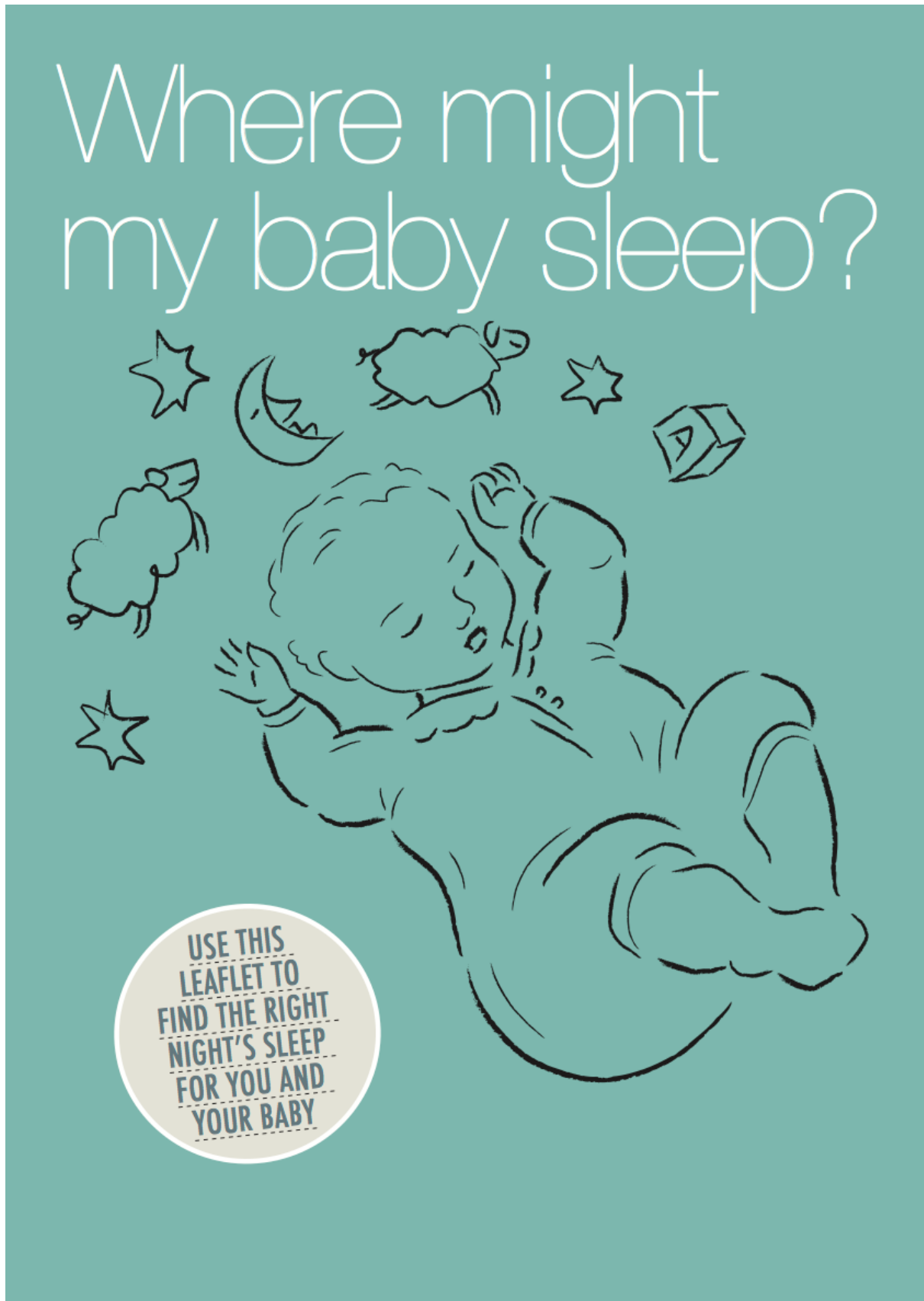
Contact: [alice-amber.keegan@durham.ac.uk](mailto:alice-amber.keegan@durham.ac.uk) Tel: 07828743146



\*Change for our Children (2014) Introducing the Pepi-pod sleep space programme: Notes to assist with beginning conversations about providing the programme. [http://www.changeforourchildren.co.nz/files/docs/pepi-pod%20programme/introducing%20the%20pepi-pod\\_qa\\_%202014.pdf](http://www.changeforourchildren.co.nz/files/docs/pepi-pod%20programme/introducing%20the%20pepi-pod_qa_%202014.pdf)

## Appendix IV

Where might my baby sleep? leaflet



# Introduction

## WHAT IS SIDS?

SIDS stands for Sudden Infant Death Syndrome. It happens when a baby dies in a sudden and unexplained way even after investigation and autopsy. It is also commonly known as “cot death.”

## WHAT IS THE HISTORY OF SIDS IN THE UK?

In 1989, over 1,500 babies died from SIDS in the UK. This led to public health campaigns to lower the rate of SIDS. This included “Reduce the Risk,” which encouraged parents to place their babies to sleep on their backs.

Since the 1990s, the SIDS rate in the UK has been dropping from over 1, 500 deaths per year to about 300 deaths a year.

## WHAT IS NEXT?

We still don’t know why some babies die, but we do know how to keep babies safer during their sleep.

This leaflet has been developed to encourage families to carefully consider where their babies might sleep. It aims to help families make informed choices depending on their personal family circumstances, and to be aware that these may change from night to night.

# Some babies sleep in a room on their own



## WHY MIGHT I DO THAT?

**P**arents put babies in their own room because they have made a nursery or special room and think this is where their babies should sleep.

Some parents want to encourage their babies to sleep alone from a young age. Other parents don’t want to be disturbed at night.

**ALERT!**

1. *Studies have shown that when babies sleep in a room on their own before they are 6 months old, they have a greater chance of Sudden Infant Death Syndrome (SIDS), so it is safer to have your baby in the same room as you during this time.*
2. *Although monitors may allow you to see or hear when your baby wakes up, they don't prevent SIDS and they don't make your baby feel safe that you are nearby.*

Some babies sleep in a cot or crib beside their parents' bed



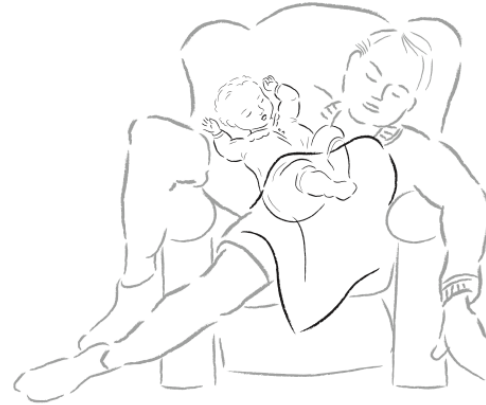
WHY MIGHT I DO THAT?

**S**leeping in a parent's room reduces the chance of SIDS and makes feeding easier. You can hear when your baby wakes up and he or she can also hear you at night and knows you are not far away.

CHECKLIST

- 1. Babies should be on their backs, feet to foot of the cot with no pillows or toys in the cot.
- 2. The room should be a comfortable temperature. Do not let anyone ever smoke around your baby.
- 3. Use sheets and lightweight blankets or a baby sleep bag, but not duvets, quilts, baby nests, wedges, bedding rolls or pillows. Because these are squashy, they can block babies' airways or make them too warm.

Parents and babies should NEVER fall asleep together on sofas or in armchairs



WHY MIGHT I DO THAT?

**T**aking your baby out of the bedroom to feed, settle, or avoid disturbing other family members could lead to you falling asleep on a sofa or armchair with your baby in your arms or on your chest.

Sofas, armchairs and makeshift beds, such as bean bags or airbeds, are dangerous places to sleep with babies who can easily get trapped, squashed or dropped. Sleeping with your baby on a sofa increases the chances of both accidents and SIDS.

ALERT!

*Don't be in a position where this could happen.*

Some babies sleep in bed with their parents for some or all of the night



WHY MIGHT I DO THAT?

**B**reastfeeding lying down in bed can be quick and easy. Breastfed babies feed frequently, so having your baby sleep next you in bed can help with frequent feeds. Breastfeeding also reduces the risk of SIDS.

**BED-SHARING AND BREASTFEEDING**

- 1. Parents also sleep with their babies under special circumstances, such as when they are unwell, unsettled, or have had an injection. Sometimes, parents take their babies into bed to feed or cuddle and fall asleep without meaning to.
- 2. Breastfeeding mothers often find bed-sharing a very positive experience when done carefully, but you must decide whether or not you are able to do it as safely as possible.
- 3. If you do not breastfeed your baby or do not intend to bed-share, it may happen by accident, or because it is the only option in an unusual situation. This is why it's important to think about bed-sharing safety and decide whether you should use a **Baby Bed Box** instead.

**Q&A** Before bed-sharing ask yourself these questions

**T**he following five questions will help you quickly assess whether your baby has an increased chance of SIDS as your circumstances or sleep arrangements change.

**ANSWER YES OR NO**

- 1. Did you smoke in pregnancy?  
 Yes  No
- 2. Do you smoke now?  
 Yes  No
- 3. Have you recently drunk alcohol?  
 Yes  No
- 4. Have you taken any illegal or legal drugs?  
 Yes  No
- 5. Was your baby born before 37 weeks or weighing less than 2 ½ kilograms or 5 ½ pounds at birth?  
 Yes  No

**MORE INFO:**



You can also use the **Infant Sleep Info** app at anytime, anyplace. The app, which was developed by the Infant Sleep Information Source and partners, is free to download from the Apple App Store.

# If you answer **YES** to **ANY** of these questions...

If you answer YES to ANY of these questions, then your baby will have a greater chance of SIDS when you bed-share.

The following have been shown to be associated with SIDS occurrence.

## RESEARCH SHOWS

1. Smoking during pregnancy increases the chances of SIDS among babies who bed-share.
2. Smoking after pregnancy increases the chances of SIDS among babies who bed-share.
3. SIDS and accidental infant death while bed sharing are increased if you drink alcohol.
4. Taking drugs or medications that impair your awareness or cause deeper sleep increases the risk of accidental death whilst bed-sharing.
5. Small at birth babies have an increased chance of SIDS when bed-sharing with non-smoking parents. There is a big increase in the chance of SIDS for babies born early who bed-share with parents who smoke.

## SOLUTIONS:



1. Instead of having your baby directly in bed, use the **Baby Bed Box** to keep your baby safe and close.
2. If you do not have a **Baby Bed Box**, keep your baby in a cot next to your bed or consider using a 3-sided cot that attaches to your bed.

# If you answer **NO** to **ALL** of these questions...

If you answer NO to ALL of these questions and you decide to bed-share or think you may bed-share accidentally, you should make sure the bed is as safe as possible for your baby.

## BEDSHARING BASICS

1. Remember your baby may lie on her back or side to breastfeed, but always put her on her back to sleep.
2. Your baby must not be left alone in or on the bed as even very young babies can wriggle into dangerous positions.
3. Make sure that your baby can't fall out of bed or get stuck between the mattress and the wall.
4. Make sure your mattress is clean, firm and flat and the room temperature is comfortable. Your baby should not wear any more clothes than you would wear in bed yourself.
5. Make sure your partner knows when your baby is in bed.
6. It's important to make sure your baby's head does not go under the covers or the pillow.
7. Do not have another child in bed with you and your baby. If this can't be avoided, then you or your partner should sleep between the child and baby.
8. Do not have pets or cuddly toys in or on the bed.

# Sleep position and feeding



## WHY MIGHT I DO THAT?

Most breastfeeding mothers naturally sleep facing their baby with knees bent up under their baby's feet and arm above his or her head. This C position protects the baby from moving down under the covers or up under the pillow.

### FYI

*If you have never breastfed and you do not naturally sleep in this position with your baby, but want to have your baby in your bed, then use the **Baby Bed Box**. Otherwise place your baby in a cot by your bed for nighttime sleep.*

# What is a Baby Bed Box?



The **Baby Bed Box** is a bed for babies under 4 months old. When used properly, the box provides a safer sleep space for your baby when you want to have him or her close to you in bed. Use your **Baby Bed Box** at night if you wish to bed-share or may do so accidentally if your baby has an increased chance of SIDS.

### FYI

*The **Baby Bed Box** can also be used when as a bed for your baby when you are away from home and you are unsure of the sleeping surface safety. The box must not be used to transport a baby in a car or bus.*

# How to use your Baby Bed Box

## BABY BED BOX BASICS

1. Be sure to place it on the bed between you and your partner or you and the wall. The box should be placed at the top of you bed and no bed covers should go over it.
2. Do not let ANYONE carry the box when the baby is in it.
3. ALWAYS keep your Baby Bed Box on or near your bed.
4. Do not use your box on a table, kitchen counter or other surface where a serious fall could happen.
5. The Baby Bed Box should only have the mattress, sheet and blanket provided inside when your baby uses it. No pillows, cuddly toys or quilts should be in the box.
6. Keep the bed box away from open flames and heat sources.
7. Your room temperature should be comfortable and your baby should not be overdressed.
8. Do not let anyone smoke around your baby.

## QUESTIONS:



If you have any questions about the safety guidelines for using the **Baby Bed Box**, please read the instructions included, speak with you health care provide, or visit (link with video and downloadable safety instructions).

# Where can I get more information?

If you have any further questions, please talk to your health care professional.

## YOU CAN ALSO VISIT:

- Infant Sleep Information Source
- UNICEF UK Baby Friendly Initiative
- The Lullaby Trust
- Best Beginnings



# Appendix V

## Safety Intervention Criteria

A researcher should intervene under the following conditions:

- If the ISSB is located near to the edge of the bed (or any raised surface) and appears to pose a risk of falling off
- If the ISSB becomes fully covered with the infant inside and/or has moved under the covers and does not occupy the top half of the bed
- If a baby is put to sleep in the prone position
- The researcher believes that the infant is in a vulnerable situation

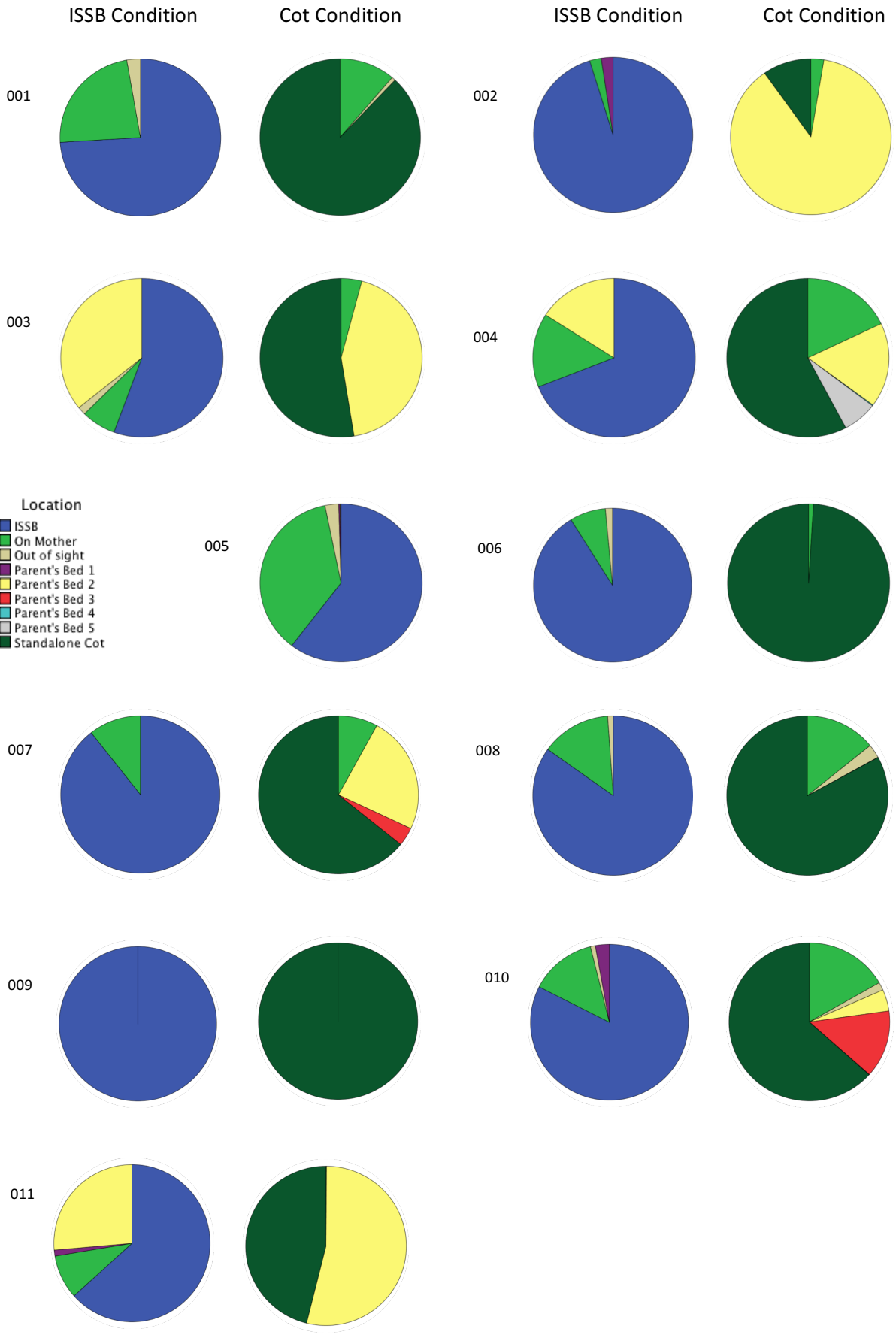
# Appendix VI

## Noldus Observer Coding Scheme

Subject	Behaviour		Modifier	
Baby, Mother, Father, Other	Sleep	Awake	Prone Side Supine Neutral	Facing mother Facing away from mother Facing infant Facing away from infant
		Appears Asleep		
Asleep				
Out of sight				
	Location	ISSB Standalone cot Parents bed – 1 Parents bed – 2 Parents bed – 3 Parents bed – 4 Parents bed – 5 Sofa Chair On mother Standing/walking Out of sight Other Location Location N/A		
Baby	Feeding	No feeding	Breast milk Formula Water Other	
		Breastfeeding		
		Bottle feeding		
		Out of sight		
	Head covering	Airways covered	Duvet Hat Blanket Other	
		Head (not airways covered)		
		Head and airways covered		
		No head covering		
Mother	Looking No Looking Looking N/A Touching No Touching Touching N/A			
ISSB	Risk	Unspecified risk Tipping Risk Falling risk Carrying ISSB with baby in Other risk		

# Appendix VII

Pie charts showing infants' location throughout the night for each infant, in each condition



# Appendix VII

Pie charts showing infants' location when mother was asleep for each participant, in each condition

