THE ESCCaPE TRIAL

RESEARCH PROTOCOL

Enabling **S**afe and **C**lose **Ca**re
In **P**ostnatal **E**nvironments:
A Pilot

HREC/17/QBW/162

Professor Jeanine Young, Dr Lauren Kearney, Cheryl Rutherford, Stephanie Cowan, Kendall George, Joanne Hoey

Table of contents

FULL STUDY TITLE

Enabling Safe and Close Care In Postnatal Environments: A Pilot

SHORT TITLE

The ESCCaPE Trial

DESCRIPTION

This pilot study aims to determine the acceptability and feasibility of two novel infant sleep spaces for newborns devised to promote closeness and consistency with safe sleeping recommendations within the Sunshine Coast Hospital and Health Service (SCHHS) maternity unit. Impact upon breastfeeding outcomes and maternal-infant attachment will also be monitored to inform the development of a larger trial.

COMPLIANCE

The researchers are committed to comply with the following nursing and midwifery practice standards, regulations and guidelines throughout the duration of the study:

Australian Nursing and Midwifery Council 2008, *Code of Ethics for Midwives*
Australian Nursing and Midwifery Council 2008, *Code of Ethics for Nurses in Australia*
Australian Nursing and Midwifery Council 2008, *Code of Professional Conduct for Midwives*
Australian Nursing and Midwifery Council 2008, *Code of Professional Conduct for Nurses*
Australian Nursing and Midwifery Council 2010, *Professional Boundaries for Midwives*
Australian Nursing and Midwifery Council 2010, *Professional Boundaries for Nurses*
Australian Nursing and Midwifery Council 2016, *Registered Nurse Standards for Practice*
Australian Nursing and Midwifery Council 2006, *Midwifery Competency Standards*
Australian Health Practitioner Regulation Agency
National Health and Medical Research Council, the Australian Research Council and Universities Australia 2007, *Australian Code for the Responsible Conduct of Research*
National Health and Medical Research Council 2007 (update 2015), *The National Statement on Ethical Conduct in Human Research*
Sunshine Coast Hospital and Health Service 9/11/2015, *Safe infant sleeping, co-sleeping and* bed sharing guideline QH-GDL-36 V3 (DOC ID 000431)
The Hospital and Health Boards Act 2011 (Qld)
The Information Privacy Act 2009 (Qld)
The Public Health Act 2005 (Qld)
The Therapeutic Goods Act 1989 (Cth)
Therapeutic Goods Administration 2000, *Note for guidance on good clinical practice* (CMP/ICH/135/95)
University of the Sunshine Coast 2010 (updated 12/7/2016), *Human Research Ethics – Governing Policy*
University of the Sunshine Coast 2007 (updated 18/12/2015), *Risk Management - Procedures*

STUDY INVESTIGATORS

Name	Phone	Email	Institution	Study Role
Professor Jeanine Young	07 5456 5895	jyoung4@usc.edu.au	University of the Sunshine Coast	Principal Investigator
Dr Lauren Kearney	07 5470 6603	lauren.kearney@health.qld.gov.au	University of the Sunshine Coast, Queensland Health	Associate Investigator
Ms Cheryl Rutherford	07 5470 6810	cheryl.rutherford@health.qld.gov.au	Queensland Health	Associate Investigator
Ms Stephanie Cowan	+64 3 379 6686	stephaniecowan@changeforourchildren.nz	Change for our Children Ltd	Associate Investigator
Mrs Kendall George	0439 994 475	kgeorge@usc.edu.au	University of the Sunshine Coast	Associate Investigator
Mrs Joanne Hoey	0428 748 946	jplaydo1@usc.edu.au	University of the Sunshine Coast	Associate Investigator

THE ESCCaPE TRIAL RESEARCH PROTOCOL

1. INTRODUCTION

Interventions that facilitate maternal-infant attachment and breastfeeding, whilst promoting safe sleep, reduce infant mortality which is a public health priority. Sharing a sleep surface with a baby is a common occurrence in Australia and internationally, especially for breastfeeding mothers and babies. However, this may increase risk of sudden unexpected death in infancy in certain circumstances (Blair et al., 2014; Carpenter et al., 2013).

In the immediate hours and days following birth, a challenge exists for mothers and hospital facilities in facilitating closeness to promote maternal attachment and successful breastfeeding, whilst keeping baby safe. Healthcare providers have an integral responsibility in role modelling safe practices that parents are able to utilise in home environments. A novel approach to address the need for close mother-baby contact, safety, parent education and awareness about safe sleeping, and to assist continuity of care from hospital to home, is the use of a co-sleeping device in the immediate postnatal environment. Limited evidence currently exists to support the co-sleeping device, however international trials have reported positive results in mother-baby interaction, infant safety and breastfeeding establishment. Queensland Indigenous community trials of a safe sleep enabler have reported acceptability, feasibility and increased safe sleeping awareness. This will be the first trial of a postnatal safe sleep enabler in an Australian hospital environment.

2. BACKGROUND

Breastfeeding and reducing infant mortality are national and international public health priorities (WHO, 2016). Shared parent-infant sleeping on the same sleep surface is a common practice in Australia, and a cultural norm for many families. Bed-sharing refers to bringing a baby onto a sleep surface when co-sleeping is possible, whether intended or not (ACM, 2014; Qld Health 2013) while co-sleeping is defined as a mother and/or her partner (or any other person) being asleep on the same sleep surface as the baby (ACM, 2014; UNICEF, 2004; Qld Health, 2013). Co-sleeping with an infant has been associated with an increased risk of sudden infant death, in certain circumstances (Blair et al., 2014; Carpenter et al., 2013).

Simple advice for parents never to co-sleep on a bed with their infants, a risk elimination approach, is argued to be impractical for new parents. Importantly, compared to sleeping on the parental bed, the risk of entrapment and suffocation is greatly increased if parents feed their infants on sofas or armchairs (to apparently avoid co-sleeping) and fall asleep with their baby (Blair et al., 2014; Carpenter et al., 2013). It is increasingly acknowledged that risk minimisation polices will be more effective in reducing preventable infant deaths, as risk minimisation acknowledges that babies will be placed to sleep, intentionally, or unintentionally, in their parents bed at some stage, particularly if they are breastfed. Parents can then be supported to ensure awareness of specific hazardous circumstances and make informed decisions about bed-sharing and co-sleeping (Young et al., 2012; Blair et al., 2014; ACM, 2014; SIDS and Kids, 2015).

It is recognised that co-sleeping and breastfeeding share a mutually supportive relationship (Blair et al., 2010). The Baby Friendly Hospital Initiative (BFHI) (of which SCHHS is an approved institution) advocates sustained skin-to-skin contact between mother and infant in the first 24-hours post birth as being critical to establishing optimal breastfeeding (McKenna

& Gettler, 2015; Nvquist et al., 2010; UNICEF, 2012). Skin-to-skin contact and breastfeeding makes co-sleeping and bed-sharing very common in maternity units (Drever-Smith et al, 2013), despite some units opting for a risk elimination approach. However, the dangers of taking a newborn into bed with an exhausted or sedated, poorly mobile new mother have been demonstrated (Herlenius & Kuhn 2013; NSW Child Death Review Team, 2010), including unexpected infant deaths in which accidental asphyxia has been associated with breastfeeding while cosleeping (Monson et al., 2008), and calls for mechanisms that improve safety within hospitals have been made (Herlenius & Kuhn, 2013; NSW Child Death Review Team, 2010). The most common in-hospital falls of babies are from the arms of a parent who fell asleep holding the infant, usually in the early morning hours, either from a bed or chair, with some morbidity associated with these falls (Matteson et al., 2013; Monson et al., 2008, Qld Health, 2011). During the past five years, there have been several infant falls within the Sunshine Coast Hospital and Health Service, and including three falls reported during 2016 (Rutherford C, NUM Postnatal Unit, personal communication).

Policy makers and care providers are caught between promotion of concepts that support the mother-infant need for closeness to support attachment and breastfeeding, and those that focus on reducing hazardous sleep environments known to increase infant mortality or adverse events. SCHHS supports risk minimisation for cosleeping in postnatal units based on UNICEF guidelines, however in order to minimise risk of further infant falls and other adverse events, interventions that support safer sleep environment alternatives for breastfeeding families have been identified as a priority area for investigation.

There are several sleep enablers available on the market for domestic use, such as the Finnish Baby Box (Lee, 2013) or Safe and Secure Sleeper, but there has been little formal research into the safety or acceptability of these devices. In addition, these devices may have sides too high to allow co-sleeping or physical contact while contained in the device (e.g. Finnish Baby Box) or have design features including a flexible sleep surface that is reliant on being placed on a firm, flat surface for safe use (e.g. Safe and Secure Sleeper). Similarly, within hospital environments, means of facilitating mother-infant closeness while providing a safe sleep environment for the infant have been called for, with several devices identified in the literature.

The few devices to enable 'safer' sleep in the context of close contact with a primary caregiver, which have been or are currently being evaluated, are discussed.

Side Car Cots: Several studies have reported on the use of side car cribs/ cots in postnatal care. These 3-sided bassinettes temporarily fix to the mother's hospital bed to facilitate a level, but separate, sleep surface for baby that is easily accessed by the mother (Ball et al., 2011). UK based trials of the NECOT, a side car crib, were positive in relation to frequency of mother-infant interaction, infant safety and establishment of breastfeeding (Ball, 2006). Further trials within institutions have demonstrated it to be a positive alternative to free standing cribs for participants, and a safer option for infant handling (Tully & Ball, 2012), but did not demonstrate improved breastfeeding outcomes, nor did it impact bed-sharing practice post discharge (Ball et al 2011).

Pēpi-Pod® Sleep Space and the Pēpi-Pod® Program: New Zealand: The Change for our Children Pēpi-Pod® Program was specifically developed to address high Māori infant

mortality rates. The Pēpi-Pod® is a rectangular polypropylene [food grade plastic] box with a fitted mattress and bed linen to be used on the parent bed, billed as the sister to the Māori Wahakura, a flax woven basket (Abel & Tipene Leach 2013, Abel et al., 2015). Additionally, the Pēpi-Pod® Program incorporates safe sleep education and a family undertaking to spread safe infant sleep message amongst their social network (Cowan et al., 2012; 2013). Findings to date have been positive in relation to a significant fall in infant mortality over the intervention period [2011-2014] from 2.4 to 1.9 per 1000 all population and 4.5 to 3.5 per 1000 Maori (Cowan, 2015). The community based Pēpi-Pod Program has been supported by New Zealand's Ministry of Health with over 15,000 pods distributed through the country (Cowan et al., 2013, Mitchell et al., 2016) together with approximately 1500 handwoven Wahakura, and was recently acknowledged as a major contributor to New Zealand's recently reported infant mortality reductions (Mitchell et al., 2016). Most recently, a smaller version of the Pepi-pod© (the First Days Pod) has been developed for use in birthing facilities and is currently being trialled in New Zealand (Cowan, 2016).

A randomised controlled trial with 200 mainly Māori women and their families comparing the Wahakura with a standard bassinet was conducted to evaluate safety and potential effects upon infant sleep position, head covering, breastfeeding, bed-sharing and maternal sleep and fatigue. No significant differences were found in infant risk behaviours in wahakura compared with bassinets however there was a significant benefit relating to breastfeeding with the wahakura group reporting twice the level of full breastfeeding at 6 months (22.5% vs 10.7%, p=0.04). (Baddock et al., 2017). The authors concluded that wahakura were relatively safe and can be promoted as an alternative to infant-adult bed-sharing (Baddock et al., 2017).

Pēpi-Pod® Sleep Space and the Pēpi-Pod® Program in Australia: Many Aboriginal and Torres Strait Islander families co-sleep as a cultural norm and experience social determinants of health which increases risk of sudden unexpected deaths in infancy (SUDI) four-fold, compared to non-Indigenous babies. In collaboration with the NZ Pēpi-Pod® Program, the pilot Pēpi-Pod® Program was launched in Queensland in 2013 in collaboration with participating health services working with Aboriginal and Torres Strait Islander families (Young et al., 2015). Responses relating to use, acceptability, convenience and safety of the infant sleep space have been positive. A larger trial of this program (n=250) is underway in rural/remote, regional and urban Aboriginal communities in Queensland (Young et al., 2015) with completed recruitment anticipated by mid 2017. Nil adverse events have been reported with use of the Pēpi-Pod® in the Queensland study, to date (Young et al., 2016; Young, 2016). Preliminary data suggests that the use of the Pepi-Pod reduces same surface co-sleeping with caregivers who are smokers; a known risk factor that increases risk of mortality ten-fold (Young et al., 2016).

Devices that have been designed to promote safer sleep in close proximity to a parent have been termed side-car cots, co-sleepers, safe sleep enablers and infant safe sleep devices (ISSDs) in the literature (Mitchell et al., 2016). The researchers acknowledge that evidence is required to establish safety and that context, environment and guidelines for use impact upon the safety of any device. The use of infant sleep devices are a novel approach in Australian postnatal environments despite integration of these devices into postnatal unit care models in some hospitals in the United Kingdom (Tully and Ball 2012, Infant Sleep Information Source 2016), New Zealand (Cowan 2011), and Italy (personal communication Mitzi Bollani, MaBim Leura, 2016). There is currently no evidence that side car cots, Pēpi-Pods® or

wahakuras pose any risk to babies when used as intended (Tully and Ball, 2012, ISIS website 2016, Mitchell et al 2016, Cowan 2015 report, Young et al., 2015, Baddock et al., 2017). One study has suggested that following caesarean section the height and angle of a standard cot posed several potential risks to the infant whose mother's movements were limited as a result of her surgical procedure (Tully and Ball 2012) and these observed risks are supported by evidence relating to baby falls reported in postnatal environments (Herlenius & Kuhn 2013, Matteson et al., 2013).

For the purpose of this pilot and proposed trial, the terms 'infant safe sleep device' and/or 'safe sleep enabler' will be used to describe the two devices that will be piloted in this study. These terms are preferred as they consistent with the terms used currently in the literature (Cowan et al 2012, Mitchell et al 2016), and reflect the intention of this study which was to identify and pilot a portable neonatal sleep space for babies, which promotes closeness and safety, at a time that is critical for both.

Health professionals play an integral role in promoting public health messages through role modelling, parent education and supporting evidence-based guidelines and hospital policies and procedures. Safe sleep enablers, apart from standard hospital cots, are currently not utilised in Australian maternity hospitals. There is an urgent need to pilot and test the acceptability of alternatives to unsafe co-sleeping hospital environments. This study proposes to test two safe sleep enablers within the Maternity Unit of the Sunshine Coast University Hospital, SCHHS to evaluate the acceptability of the enabler to families and midwifery staff, and examine potential indicators which may demonstrate an improvement in health outcomes.

3. AIM

The aim of this study is to pilot two neonatal infant sleep spaces designed to promote closeness and safe sleeping environments in the postnatal environment, within the SCHHS. The Safe Sleep Devices (SSD) to be used include 'The First Days Pēpi-Pod®' and 'The MaBim Side-Car Crib'.

4. OBJECTIVES

4.1 Primary Objectives

This pilot study aims to determine

1. Acceptability and maternal satisfaction with a safe sleep enabler.
2. Acceptability of safe sleep enablers (intervention) by staff working within a busy postnatal maternity unit.
3. Feasibility of a large randomised controlled trial using the proposed protocol

   and
4. Describe clinical outcomes of the safe sleep enabler group and control (including maternal satisfaction with care options, breastfeeding initiation and duration, maternal-infant attachment, awareness of safe sleeping recommendations, incidence of shared sleeping, length of stay) to inform protocol revisions for the larger randomised controlled trial.

5. HYPOTHESES

5.1 Primary Hypotheses

The priority of the pilot is to test the novel concept of safe sleep enablers for the first time in an Australian setting. Two primary hypotheses will focus on maternal acceptability of the safe sleep enablers as alternative infant sleep spaces and the feasibility of the proposed protocol in a busy maternity setting.

The primary hypotheses are:

1. Acceptability with infant safe sleep enablers will be demonstrated by mothers in the maternity unit setting.
2. Feasibility of a pilot protocol to evaluate safe sleep enablers in the maternity unit setting will be demonstrated (as measured by staff support, appropriate application of the protocol: consent, randomisation, documentation processes).

5.2 Secondary Hypotheses

This study has several secondary hypotheses, due to the need to pilot a protocol and identify key outcomes for a larger, randomised controlled trial. Secondary hypotheses include:

1. Maternal satisfaction with infant safe sleep enablers will be demonstrated by mothers in the maternity unit setting.
2. Staff who use the infant safe sleep enablers will find infant safe sleep enablers acceptable to use in practice in the maternity unit setting.
3. Mothers who use a safe sleep enabler for their infant in the postnatal unit will report higher levels of satisfaction with care, maternal-infant attachment outcomes, breastfeeding rates, and safe sleeping awareness during the postnatal period (≥3 days and 6-8 weeks) compared to mothers who use the current standard cot and separate maternal bed.
4. Mothers who use a safe sleep enabler for their infant in the postnatal unit will report higher breastfeeding rates and safe sleeping awareness at 4 months postnatal age compared to mothers who use the current standard cot and separate maternal bed.
5. Mothers who use a safe sleep enabler for their infant in the postnatal unit will report the same or reduced length of hospital stay, and the same or lower rate of adverse events including baby falls during hospitalisation.
6. Compared to pretest knowledge, attitudes and self reported practices, staff will demonstrate an improvement in knowledge, attitudes and self reported practices consistent with current safe sleeping recommendations and known risk factors at the conclusion of the pilot period.
7. Compared to pretest audits of infant sleep position, environment and documentation of parent education, there will be an improvement in practices and documentation processes consistent with current safe sleeping recommendations and known risk factors at the conclusion of the pilot period.

6. STUDY DESIGN

This will be a pilot observational descriptive study in the first instance, intended to support the design of a non-blinded, randomised controlled trial in the future. The study will use a concurrent mixed methods design conducted in three phases: 1) trial of the pilot protocol with mothers and babies (Phase 1 and 2); 2) evaluation of staff perceptions relating to impact of

the safe sleep enablers on provision of care and awareness of safe sleeping recommendations (Phase 3).

7. STUDY SETTING/LOCATION

Sunshine Coast University Hospital, Innovation Parkway, Birtinya, Queensland, Australia.

8. STUDY DURATION

(06/2017 –06/2020)

Date (m/y)	1/ 17	2/ 17	3/ 17	4/ 17	5/ 17	6/ 17	7/ 17	8/ 17	9/ 17	10/ 17	11/ 17	12/ 17
SCUH opening												
Ethics & Governance												
Data Collection												
Phase 1												
Phase 2												
Phase 3												

Date (m/y)	1/ 18	2/ 18	3/ 18	4/ 18	5/ 18	6/ 18	7/ 18	8/ 18	9/ 18	10/ 18	11/ 18	12/ 18
Data Collection												
Phase 2												
Phase 3												
Reporting												
Data Analysis												
Write up												

Date (m/y)	1/ 19	2/ 19	3/ 19	4/ 19	5/ 19	6/ 19	7/ 19	8/ 19	9/ 19	10/ 19	11/ 19	12/ 19
Reporting												
Write up												
Publication												
Dissemination												

Date (m/y)	1/ 20	2/ 20	3/ 20	4/ 20	5/ 20	6/ 20
Archiving						
Close out						
Dissemination						

9. STUDY POPULATION

The study population will comprise of a) eligible women who birth at the Sunshine Coast University Hospital during the period of recruitment (estimated June – November 2017) and their babies, and b) nursing staff who provide care to mothers and their babies in the postnatal setting (inclusive of registered midwives, registered nurses and enrolled nurses).

Sunshine Coast Hospital and Health Service currently provides services for approximately 2800 birthing women per year. The Maternity Unit in the Sunshine Coast University Hospital will have approximately 50 maternity beds. Using calculations based on eligible births per week, conservative participation rates, attrition post enrolment, in addition to average length of hospital stay, it is anticipated that a target sample of 90 eligible mothers and their babies with complete datasets will be achieved in 4- 6 months.

The total population of staff members for the study sample is approximately 80 nurses and midwives; it is anticipated that a target sample size of approximately 65-70 staff will participate based on previous study participation with this cohort.

All patients and staff members who meet inclusion criteria will be approached to participate. Specific inclusion and exclusion criteria will be applied.

9.1 Mother and baby inclusion criteria

- ≥ 36 weeks of gestation at time of consent
- Attending the SCUH for antenatal care
- Intending to be admitted to the postnatal ward at the SCUH after the birth
- English speaking
- Intending to breastfeed
- Singleton pregnancy
- BMI < 40
- ≥ 15 years of age
- Ability to read and understand English

9.2 Mother and baby exclusion criteria

- < 36 weeks of gestation at time of consent
- Maternal condition which significantly interferes with breastfeeding
- Intending to feed infant with artificial formula
- Maternal BMI ≥ 40
- < 15 years of age
- Multiple pregnancy
- Newborn admitted to SCN / NICU immediately after birth
- Neonate requiring phototherapy +/- CPAP
- Inability to read and understand English

9.3 Maternity staff inclusion criteria

- Registered midwives, registered nurses or enrolled nurses holding current registration with Australian Health Practitioner Regulation Agency (AHPRA)
- Have permanent full-time or part-time positions or present for a regular casual position attending ≥ one shift/week
- Currently working in the postnatal environment
- Providing care to mothers and babies during the recruitment period
- 18-75 years of age
- Male or female

- Conversant in English

9.4 Maternity staff exclusion criteria

- Midwives or nurses not registered with APHRA i.e. assistants in nursing
- Not currently employed in permanent full-time or part-time positions in the clinical and community sites, i.e. bank, pool and agency staff
- Not working in postnatal environment during recruitment period (i.e. recreational, long-service, maternity or long term sick leave).

9.5 Potential risks

The Pēpi-Pod® safe sleep device has been broadly distributed in New Zealand (Cowan, 2015). During the Change for Our Children program, Pēpi-Pods® were allocated to 3961 infants identified to be at an increased risk of sudden infant death (Cowan, 2015). The program's final report 'Their First 500 Sleeps' acknowledges that there were a 'few babies exposed to unsafe practices despite a personalised safety briefing and enabling device, although in all cases there is evidence of risks being mitigated to some extent' (Cowan, 2015). By 2016, 15,000 Pēpi-Pods® and 1500 Wahakuras had been distributed through twenty New Zealand District Health Board services with safety advice reflected in snapshots of care (Mitchell et al, 2016). The Pēpi-Pod® safe sleep device, including the First Days Pēpi-Pod®, has not been directly attributed to any serious adverse event in Australia or New Zealand to date (Cowan, 2015; Cowan, 2016); Young, 2016). Safety of the Wahakura (the handwoven equivalent to Pēpi-Pod®), has been supported by a recent randomised controlled trial which examined key outcomes associated with SUDI risk (Baddock et al., 2017).

The ESCCaPE Trail is supported by The Australian Department of Product Safety, Office of Fair Trading. The Department have an interest in preparing guidelines for Australian domestic side-car co-sleepers, and have offered to support the examination of sleep spaces for this study, as part of that guideline development. Both devices used in this study meet safety standards in other countries (Change for our Children NZ Pēpi-Pod First Days Pod, New Zealand; MaBim neonatal cot for co-sleeping, Italy). To date, Australian-based commercial co-sleeping cots for post-natal hospital environments are not available.

The MaBim Neonatal Cot has CE marking. This reflects that the product meets European high standards of health and safety. The MaBim Neonatal Cot has operating instructions for use produced by Leura (Bollani, 2016). Personal communication with Leura Helpful Design indicate that the MaBim is in use in several hospitals in Italy (Milan, Melegano, La Spezia, Modena) and France (personal communication, M Bollami Director Leura Helpful Design, dated 30th November 2016).

Safe sleeping recommendations are relevant to all sleeping environments that an infant is placed in. Not following Safe Sleeping recommendations creates risk for infants in any sleep environment that they are placed to sleep in (Mitchell et al 2012, SIDS and Kids 2016).

The Quick Guide will be laminated and attached to each safe sleep device to enable staff and parents immediate reference to safety instructions.

<u>First Days Pēpi-Pod®</u>
If the protocol is not followed, the potential for physical harm to infants who are allocated the First Days Pēpi-Pod® group include: a) falling off the mother's bed if the bed rails are left

down, b) suffocation if additional blankets or toys are placed in the cot, c) increased risk of sudden infant death if placed in the prone or lateral position, and c) slipping between the Pēpi-Pod and mother.

The potential risk for mothers allocated the Pēpi-Pod® cot is physical discomfort after a caesarean section due to rotating the trunk to pick up and place the baby in the cot.

MaBim
The MaBim Neonatal Cot has CE marking. This reflects that the product meets European high standards of health and safety. There is however, the potential for risk of physical harm in utilising the MaBim Side-Car Crib if the protocol is not adhered to.

Potential physical harm to the baby includes; a) jamming fingers or toes in the side door on opening and closing, b) falling from the crib if the wheels are left unlocked and the side access is not closed, c) falling from the crib if rotated away from the mothers bed (while the side access is open), d) suffocation if additional blankets or toys are placed in the cot, and d) increased risk of sudden infant death if placed in the prone or lateral position.

Mothers have the potential of physical harm from jamming fingers in the side door of the crib.

Standard cot
Risk of physical harm for mothers allocated to the standard cot after a caesarean section include physical discomfort due to rotating or extending the upper body to pick up and place the baby in the cot.

Risks for the baby include a) falling during transfer between being held in bed and the cot, b) suffocation if additional blankets or toys are placed in the cot, c) increased risk of sudden infant death if the baby is placed in the prone or lateral position to sleep.

There are minimal risks anticipated for maternity staff participating in the survey and in the audit of unit practices. Staff survey data will be collected securely and in a re-identifiable format to allow matching, where possible, of pre and post-test responses using a unique identifier code. The unique identifier code and list of participants will be kept separately and destroyed following completion of data collection and cleaning. Audit data is not linked to individual staff members. Monitoring of staff awareness and practice relating to safe sleeping recommendations is recommended by the current Queensland Health Guideline for Safe Infant Sleeping, Co-sleeping and Bed-sharing (Queensland Health 2013). Participation in this study therefore provides monitoring data to assist the organisation in meeting this recommendation.

9.6 Potential burdens

The potential burdens to mothers include a) decreased space to move freely in the bed if allocated to the First Days Pēpi-Pod, and b) time taken to consent to participate in the study and complete the questionnaires. This is supported by the New Zealand trial of The First Days Pēpi-Pod, in which two mothers reported that the ‘hospital bed is small’, ‘difficult to use (FDP) for large women’ and that there is ‘not enough room in the hospital bed to get comfortable overnight’ (Cowan 2016).

There is no anticipated burden for infants who participate in this study. Staff who participate will have the burden of completing a survey before and after the pilot that will take approximately 15-20 minutes to complete. All staff on the unit who care for women and babies in the study will participate in the safety briefings associated with use of the safe sleep enablers, similar to staff briefings that are undertaken with the introduction of new hospital equipment.

9.7 Benefits to mother and baby participants

A mother's ease of access to her baby may increase oxytocin levels by promoting maternal-infant gaze and skin-to-skin contact (SSC) (Kim et al, 2014; Moore et al, 2012). In a Cochrane Review conducted by Moore et al (2012), it was found that infants separated from the mother's bedside were 10 times more likely to distress cry than those infants who had SSC with their mother. Babies who are in close contact with their mother have better rates of breastfeeding and thermoregulation than those separated from their mother (Moore et al, 2012). Maternal increase in oxytocin levels, from SSC with the infant, decreases maternal anxiety and risk of post-partum haemorrhage, and increases rates of maternal-infant responsiveness (Moore et al, 2012).

Shared sleeping with an infant by a parent who smokes, or who has taken medications or other drugs which may affect their level of consciousness, significantly increase the risk of sudden unexpected infant death if they sleep with a baby. Shared sleeping in the immediate postnatal environment may occur intentionally as part of the parent's preferred infant care approach or cultural practice in keeping their newborn in close contact; or unintentionally when the mother may fall asleep holding or feeding baby, or during skin to skin contact, particularly in the first 24 hours as advocated in the BFHI guidelines to support successful breastfeeding. Use of a portable safe sleep enabler that is easily accessible to an often less mobile postnatal mother, which facilitates close contact while on a separate sleep surface, has the potential to reduce the risk of a fatal sleeping accident for babies associated with some bed-sharing environments, particularly for mothers who have identified risks (UNICEF, 2012).

Cowan (2016) reported that 86% of mothers would recommend the First Days Pēpi-Pod. The neonatal safe sleep device facilitates more choice with postnatal care, facilitates rooming in (Mitchell et al, 2016), and can be beneficial for mothers who have had a caesarean section (Tully & Ball, 2012). In a mixed-methods study, mothers have variously described the First Days Pēpi-Pod as useful with unsettled babies, beneficial in facilitating ease of access and valuable in promoting independence to care for their baby (Cowan, 2016).

To date, there are no published studies available relating to use and outcomes associated with the MaBim Neonatal Cot.

There are no anticipated direct benefits for staff who choose to participate in this study. If mothers find that ISSD cots keep their baby more accessible to them, this may reduce staff time in responding to call bells to assist mothers to access their babies, particularly for women who have experienced a caesarean section. The impact of new processes and service delivery strategies upon staff work practices is often a factor which influences the success of models of care. Understanding staff perceptions and experiences with the new cots, and how these may influence care and workload, if at all, will provide important information to inform the translation of new models of care into practice to ensure safe and effective outcomes for families.

10. STUDY OUTCOMES

10.1 Primary Outcomes

- Data relating to acceptability of the safe sleep enabler/ISSD by mothers
- Feasibility data - for providing cots; educating staff; ease of implementation for protocol processes: consent, randomisation, safety briefing of parents in context of busy ward environment; documentation.

10.2 Secondary Outcomes

- Maternal satisfaction with care
- Provision of culturally appropriate care
- Accessibility of personal options and choice in care
- Improving breastfeeding rates
- Improving opportunities for maternal-infant attachment
- Improving uptake of safe sleeping recommendations as parents' transition to home environments
- Length of stay
- Safety Data – PRIMES, baby falls, any adverse events that are reported
- Reducing adverse events associated with baby falls from maternal beds or chairs
- Improving staff awareness of safe sleeping recommendations
- Implementation of safe sleep recommendations in the postnatal unit
- Staff satisfaction with postnatal safe sleep enablers
- Data relating to staff perceptions of intervention's impact on workload, e.g. time spent responding to mothers' needs

11. STUDY PROCEDURES

11.1 Recruitment and consent of maternal participants

During the routine 36 week gestation midwife visit, all eligible women will be informed about the study by the midwife by viewing the Information Video and written Participant Information.

After the woman has had time to review the Participant Information Sheet and Consent Form (PISCF), the midwife will obtain written informed consent for her to participate in the study.

A copy of the signed consent is to be given to the participant and Research Assistant, and the original is to be filed in the client health record.

The Study Label is to be placed in the client health record and participant details will be written in the study log book for the Research Assistant to monitor and await the birth.

The total period of recruitment is expected to be four to six months.

11.2 Withdrawal of participants from a study

Participants are free to withdraw from the trial at any time by notifying the treating midwife or research team verbally or in writing. The contact details for the research team will be located on the PISCF. The decision to withdraw from the study will be documented by the

clinician or researcher in the client health record and the Study Log Book which is to be located in clinical areas (Antenatal Clinic and the Postnatal Ward).

11.2.1 Participant withdrawal from study procedures

A participant who withdraws from the study procedure after the birth, though has consented to the study will still have their data collected and analysed up to the point of withdrawal. This is detailed in the PISCF.

11.3 Randomisation

The aim of this pilot study is to test the concept of a novel cot/safe sleep enabler in the maternity unit in the first instance. The availability of the MaBim Neonatal Cot will be limited to 4 cots (due to costs) and the First Days Pēpi-Pod® will be limited to 15 cots for this pilot. All beds will have a standard cot available.

This study intends to provide information to inform the development of a protocol for a randomised controlled trial. The pilot protocol will include a trial of the randomisation process to be used in the larger trial as staff education relating to processes used in the pilot have been considered. Introducing differences in the randomisation process to accommodate the unequal number of intervention cots was considered problematic; particularly as feasibility of the protocol was a key outcome of the pilot. The following methodology for randomisation has been adopted based on the intentions of the pilot within the resource limitations of limited numbers of First Day the pilot study, and is believed to be workable given the average length of stay of mothers in this maternity unit.

On arrival to the postnatal unit, participants will be randomised to one of three options; 'The First Days Pēpi-Pod®', 'The MaBim Neonatal Cot' or a standard bedside cot. The midwife will take the next sealed, opaque envelope located on a box of envelopes, in a locked cabinet, in the midwives' work station. The midwife in charge of the shift will hold the key for the cabinet. Inside the envelope will either be a label stating, 'The First Days Pēpi-Pod®', 'The MaBim Neonatal Cot' or standard bedside cot. This randomisation label will then be placed on the postnatal pathway. The midwife in charge will make an entry in the Project Register (held in locked cabinet with sealed envelopes) of participant name, envelope number and cot allocation.

If the allocated cot is not available (i.e. the First Days Pepi-Pod® or MaBim are already in use) the participant will be allocated to a standard cot. These allocations will be managed as a fourth group in the analysis in which demographic information should theoretically be similar to the standard cot allocated group. This method also serves as an internal checking procedure for the randomisation process used in the clinical environment. In this instance, the midwife in charge will make an entry in the Project Register for participant name, envelope number, first cot allocation, non-availability and reallocation to standard cot and will place the envelope into the discard box (to allow checking of integrity of the randomisation process).

A total of 300 envelopes will be prepared representing each of the three options equally (100/100/100) and which will also allow for the envelope discard process. A mock run of the randomisation process indicated that based on an estimated 7 deliveries per day and an average stay of 3 days, the four MaBim cots would be in almost constant use and approximately half of those mother-baby pairs randomised to the MaBim would be allocated

to use them. This process will allow integrity of the randomisation of process while still maintaining recruitment for each target sample within a feasible timeframe.

An allocation to a cot is intended for the duration of hospitalisation. The usual length of hospital stay for a woman having a vaginal delivery is 1-3 days; for a woman delivering by caesarean section 3-5 days. Analyses will be by Intention to Treat according to actual allocation and Actual Use, consistent with a recent randomised controlled study of safe sleep enabler use (Baddock et al., 2017).

The study will continue until there is a minimum of 60 participants in each group (total n=180) and will allow an attrition rate of up to 50% during the 4 month follow-up period following discharge from the post-natal unit. The final target sample for this pilot is 30 participants in each group with a complete data set.

11.4 Measurement tools used

Data collection tools developed for this study have been based on previously used tools, including those recommended in the literature, including:

- ICHOM Pregnancy and Childbirth standard set (ICHOM, 2016) which includes questions relating to breastfeeding outcomes, maternal-infant attachment and maternal satisfaction (Dennis, 2003, Taylor et al., 2005);
- New Zealand First Days Pod evaluation tool (Cowan, 2016);
- Queensland Indigenous Pēpi-Pod® Program evaluations (Young, 2016; Young et al., 2016);
- Published breastfeeding evaluation tools, Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (Dennis, 2003) and the Breastfeeding success variable (ICHOM, 2016);
- Queensland Nursing and Midwifery Knowledge, Attitudes and Practices relating to risk for SUDI (Young and Schluter, 2002; Young and O'Rourke, 2003; Young et al., 2008);
- Safe Sleep Education Project Survey and Practice Audit Tools (Young et al., 2010);
- Queensland Infant Care Practice Study (Schluter and Young, 2002; Young et al 2008).

Additional questions have been developed to address specific outcomes of this pilot where no pre-existing tool was available. Please see Table 1 for the outcomes that will be measured.

Table 1: Proposed outcome, measurement tool and time point of data collection

Outcome	Measurement tool	Time point	Person responsible
Maternal and neonatal demographic data	Client Health Record	≥ 36 weeks of gestation AND after birth	Research Assistant, Registered Midwife
Breastfeeding Method	Breastfeeding success variable (ICHOM, 2016)	≤ 3 days / prior to discharge (immediate rate) AND 6-8 weeks (medium rate) AND	Research Assistant, Registered Midwife

		4 months (long term rate)	
Breastfeeding self-efficacy	Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (Dennis, 2003)	≤ 3 days / prior to discharge (immediate rate) AND 6-8 weeks (medium rate) AND 4 months (long term rate)	Research Assistant, Registered Midwife
Maternal acceptability of the SSD or control	Questionnaire (author developed)	≤ 3 days / prior to discharge	Research Assistant, Registered Midwife
Staff acceptability of the SSD or control	Questionnaire (author developed)	Approx. 16-20 weeks after study commencement	Research Assistant, Registered Midwife
Maternal-infant attachment	Mother-to-Infant Bonding Scale (MIBS) (Taylor et al., 2005, ICHOM, 2016)	≤ 3 days / prior to discharge AND 6-8 weeks AND 4 months	Research Assistant, Registered Midwife
Maternal satisfaction with the care received, elements of intervention (comfort, access to baby, impact upon sleep, settling, feeding)	Maternal Satisfaction Questionnaire (adapted ICHOM, 2016)	≤ 3 days / prior to discharge	Research Assistant, Registered Midwife
Delivery of culturally appropriate care	Demographic Questionnaire (author developed)	≤ 3 days / prior to discharge	Research Assistant, Registered Midwife
Accessibility of personal options and choice in care	Care Options Questionnaire (author developed)	≤ 3 days / prior to discharge	Research Assistant, Registered Midwife
Adverse events (e.g. baby falls from maternal beds or chairs)	PRIME, Client Health Record	≤ 3 days / prior to discharge	Research Assistant, Registered Midwife, Midwifery Unit Manager
Maternal consistency of practice with safe sleeping recommendations	Maternal Safe Sleep Awareness Questionnaire (Schluter & Young	≤ 3 days / prior to discharge AND 6-8 weeks AND	Research Assistant, Registered Midwife

	2002) AND Audit / compliance of Safe Sleep recommendations (Young et al., 2010)	4 months (sleep position, sleep location) Pre-Audit: 4 weeks prior to study commencing Post-test: ≤ 3 days / prior to discharge	
Staff consistency of practice with safe sleeping recommendations	Staff Safe Sleep Awareness Questionnaire and Chart Audit Tool (Young and Schluter 2002, Young et al., 2008)	Pre-test: 4 weeks prior to Phase One recruitment Post-test: Approx. 16-20 weeks after Phase One commencement	Research Assistant, Registered Midwife

11.5.1 Study involvement by mothers and infant participants

Phase 1: Pretest Infant Sleep Observation and Maternal Chart Audit
In liaison with maternity unit manager and shift coordinators for the postnatal unit, the research assistant will identify eligible mother-baby pairs for a) the maternal medical charts/nursing notes audit (n=100) and b) infant sleep period observations (n=100). Consent from mothers will be obtained prior to observed sleep periods and chart documentation. Chart and observational audits will be conducted with audit tools used in a previous study, which included safe sleeping outcomes in postnatal settings (Young et al., 2010). Audits will be conducted during a 4-6 week period prior to Phase 2, which involves recruitment with a second maternal sample.

An observational assessment (infant sleep observation) of participating infants nursed in the Postnatal unit (target n=100) will be conducted during which infant sleep position and infant sleep environment will be observed and documented using an audit tool that addresses infant sleep position and sleeping environment consistent with current safe sleeping messages e.g. baby placement in cot, bedding used and placement, presence of objects in cot. Based on the estimated number of births per month at this tertiary facility (approx 230/month with 10-15% admitted to special care nurseries) the target sample of audits is achievable during this 4 week period.

Audit inclusion criteria for infants will include all newborns admitted with their mothers to the postnatal unit, including those term and preterm infants who have recovered from acute respiratory distress; infants with reflux; and infants for whom sepsis for investigation has been ruled out. Infants with upper airway malformations such as Pierre Robin Syndrome will be excluded given their individualised positional needs that influence safe sleeping recommendations for the supine sleep position, depending on severity of the condition. The observational period will be conducted during an intended rest or sleep period for the infant, to ensure that allocated 'tummy play time' is excluded.

Maternal charts will be audited to determine staff documentation of care and discharge information provided to parents/caregivers about safe sleeping messages. An entry in the

maternal chart relating to parent education about safe sleeping messages will be coded as a positive entry.

Phase 2: Safe Sleep Devices
Once the mother has birthed, she will be randomly allocated on admission to the postnatal unit to the MaBim side-car crib, First Days Pēpi-Pod® or control (usual care with baby sleep space being independent hospital Perspex cot on wheels) during the postnatal stay.

All participants will be shown the Video Clip titled 'Safe, Sleep, Little One' (CFOC Ltd, 2016) by the midwife once orientated to the ward. If allocated to the First Days Pēpi-Pod, participants will also be asked to view the Picture Demonstration (CFOC Ltd, 2016). Participants allocated to the MaBim neonatal crib will be shown the MaBim Product Brochure. Those randomised to the control group (usual cot care) will receive standard care instructions.

Participants will be followed up by the Research Assistant during the hospital admission to assess breastfeeding rates, acceptability of the ISSD or control, maternal-infant attachment, maternal satisfaction with the care received, culturally appropriate care, accessibility of personal options and choice in care, adverse events (baby falls from maternal beds or chairs) and awareness of, and compliance with, safe sleeping recommendations. Participants will be asked to complete the questionnaires, expected to take thirty minutes of the participants' time. The participant will be given the choice to complete the questionnaires independently or have the Research Assistant read the questions. The questionnaire will be available online (Opinio Survey Software 7.1) and in paper format.

If participants discharge prior to contact with the Research Assistant, she will be contacted within seventy-two hours of discharge, or at the next time of convenience.

Prior to discharge, participants will be asked to view the 'Red Nose Safe Sleeping' information (SIDS and Kids Australia, 2016) available via the mobile phone application. This information video promotes safe sleeping practices in the home environment.

Infant sleep observation and maternal chart audits for participating mothers and babies will be conducted (using the audit tools described in Phase 1) prior to discharge.

Six to eight weeks after the birth, the participants will be contacted either by phone or email depending on individual preference. During this point of contact, breastfeeding rates, maternal-infant attachment, and safe sleeping practices, will again be assessed. Participants will be asked to complete the Questionnaires, which is expected to take ten to twenty minutes of their time. The questionnaire will be available online (Opinio Survey Software 7.1) and in paper format.

Four months after the birth, participants will be contacted to assess the way that they are feeding their baby at that time (to determine breastmilk feeds and breastfeeding rates), maternal-infant attachment and safe sleeping practices. The questionnaire will be available online (Opinio Survey Software 7.1) and in paper format. This questionnaire is expected to take expected to take ten to twenty minutes of their time.

Participants will not receive any financial compensation for participation in this study.

The safe sleep enabler study protocol will be implemented and mother and baby recruitment is expected to take approximately 4-6 months.

11.5.2 Study involvement by staff

Nurses and midwives, the primary health professionals in contact with parents of young infants, have a key role in reducing the incidence of SUDI. This part of the study aims to determine postnatal nursing and midwifery staff perceptions of the acceptability of the safe sleep intervention and its impact on clinical practice and staff awareness of safe sleep recommendations.

The Staff Study (Phase 3) will use a pre-test post-test intervention design conducted in two parts. The sample of nurses and midwives involved in the care of infants and their families will include all eligible staff in the postnatal unit (approx. target n=80).

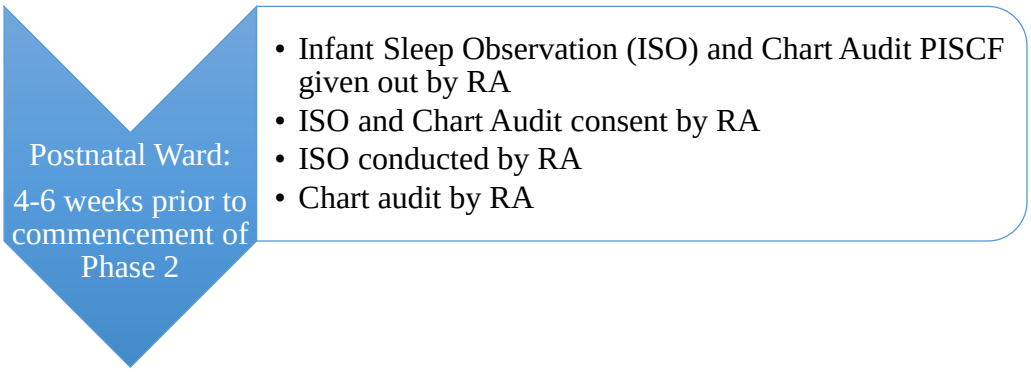
Staff Orientation to Protocol (Phase 2)
Phase 2: Staff Orientation to Safe Sleep Enablers and RCT Protocol
In collaboration with ward managers in the participating clinical areas, the Investigators and Research Assistant will negotiate appropriate days and times to conduct the orientation to the new safe sleep enablers, including safety briefing and set-up with postnatal ward staff. The study protocol will be explained in detail with written information provided and reminder sheets provided in mutually agreed sites in the participating sites. The protocol briefing willl include consent process, randomisation process, documentation, and research team contact information. All team leaders will be briefed in order to ensure they are able to support staff.

Phase 3: Staff Knowledge, Attitudes and Practices
Part 1: Pre-test Knowledge, Attitudes and Practices Staff Questionnaire
The Research Assistant will identify participants meeting the inclusion criteria from the unit roster in liaison with the Maternity Unit Manager of the postnatal unit (target n=80). All identified enrolled, registered nurses and midwives practicing in this unit will be approached to participate in the pretest survey. The survey and participant information sheet will be delivered to participants at their mail point in the postnatal unit in Phase 1. The Staff safe sleeping survey will take approx. 15-20 minutes of the participant's own time to complete. Participants will return the form by sealed collection box available on the unit or by Opinio Survey Software (Opinio 7.1, ObjectPlanet, Inc.) using a specific code. Surveys will be numerically coded to allow one reminder notice to be sent for failures to return, two weeks after the original distribution. This numerical code will also facilitate matching of pretest (prior to trial) and post-test 1 (4-5 months' post commencement) staff surveys. Initial distribution will occur approximately 6 weeks prior to Phase 2 commencing.

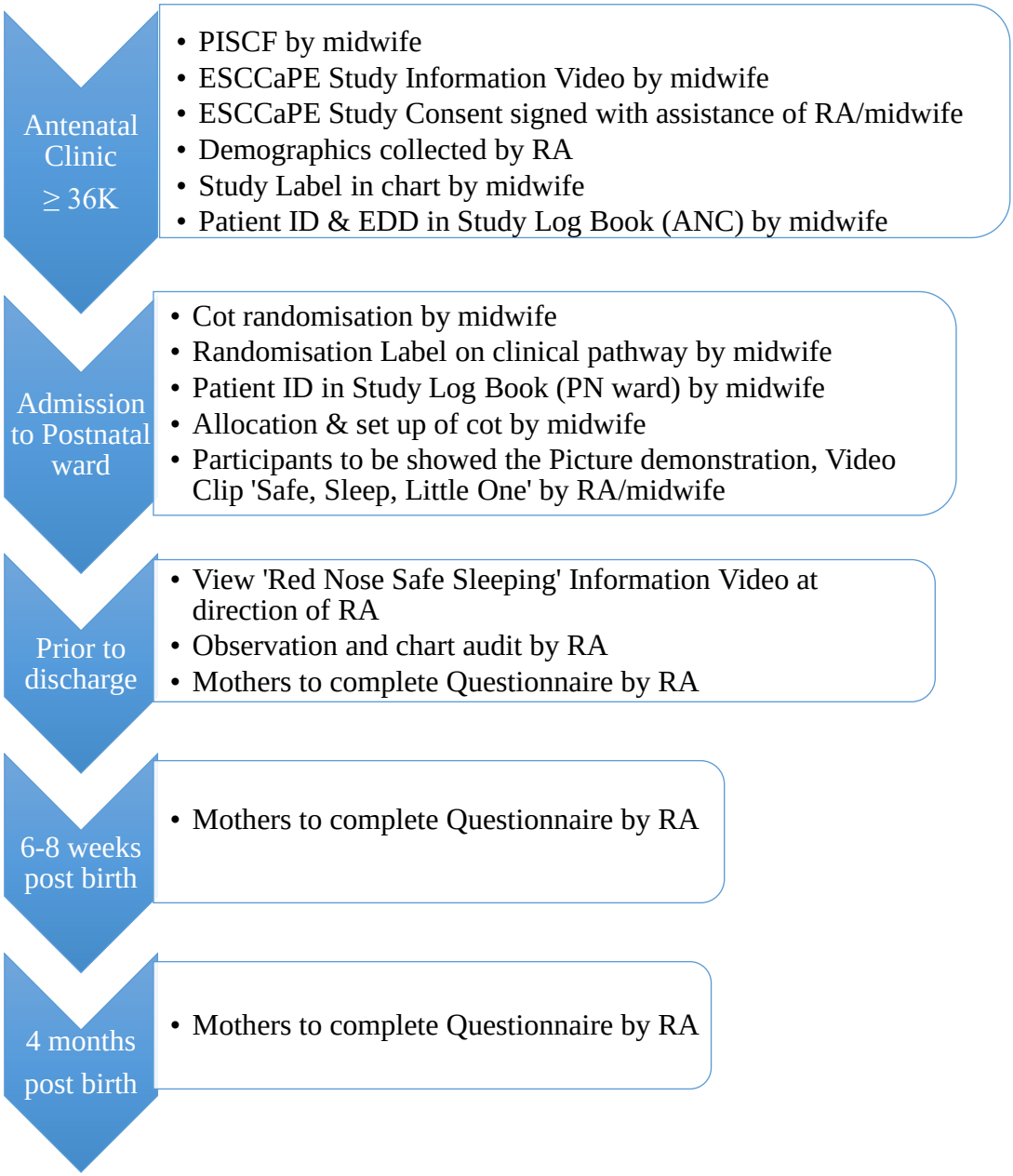
Part 2: Post-test Knowledge, Attitudes and Practices Staff Questionnaire
The post-test survey is identical in content to the pretest with the addition of questions relating to staff perceptions of the infant sleep spaces available for parents on the ward to use. This survey is anticipated to take 20 minutes to complete. This questionnaire will be conducted at the commencement of the 4-5th month after the trial has begun to allow familiarity with procedures. A four week return period with reminders at staff handovers will be provided.

Reminders to complete questionnaires will be given in staff meetings and shift handover periods through liaison of the researchers with departmental managers. One reminder notice and survey will be sent to each participant who does not return the survey form within 2 weeks of receiving it. It is anticipated that a minimum of 65-70 nurses and midwives will be recruited based on previous participant response rates.

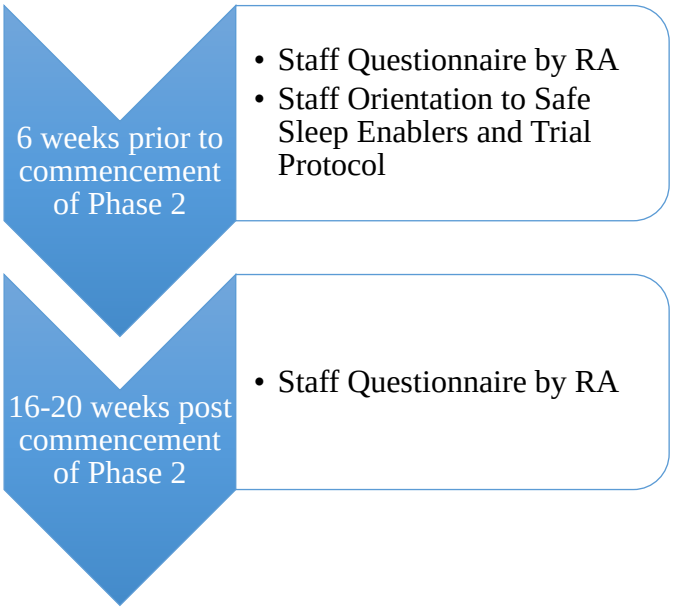
The below flow chart demonstrates the study involvement of participants Phase 1:



The below flow chart demonstrates the study involvement of mother and infant participants Phase 2:



The below flow chart demonstrates the study involvement of staff participants Phase 3:



11.6 Data management and storage

The Research Assistant will be responsible for collecting the study data. The data will be collected from the Client Health record, Study Log Books (located in the antenatal clinic and postnatal ward) and questionnaires which will be conducted face-to-face and on-line options (using Opinio Survey Software) and over the phone.

The Opinio Survey Software (Opinio 7.1, ObjectPlanet, Inc.) will be the system used to contain, distribute and administer the quantitative survey questionnaire as the on-line option and is available via a free electronic platform through USC. Opinio 7.1 is easily accessible via an email or on-line web link.

The time period for the data collection taken prior to discharge is expected to be over a four to six month period between 06/2017-12/2017. The 6-8 week and 4 month data collection is expected to be from 6/2017-2/2018.

The Midwifery Unit Manager of the Postnatal Ward will be responsible for notifying the research team of adverse events documented in the Client Health Record and PRIME. It is anticipated that this data will be collected between 6/2017-12/2017.

The Midwifery Unit Manager (MUM), Research Fellow, Research Assistant and local Principal Investigator (PI) will have access to the study files in a Qld Health computer, located at the Sunshine Coast University Hospital. All identifiable files will be password protected. This file will contain the list of participants against the allocated study ID.

The Research Assistant will liaise with the Research Team members to upload the collected data into a de-identified Excel Spreadsheet which is also password protected, and located in a separate Queensland Health secure folder. This information will be re-identifiable; a link between Maternal UR and the study code will be kept in a separate and secure password protected file, which will make re-identification of data possible. The re-identifiable data will only be re-identified by the Research Team in exceptional circumstances (i.e. Serious Adverse Event).

The re-identifiable data will be securely stored within Qld Health. De-identified data may be transferred to the University of the Sunshine Coast (USC) for statistical analysis.

Data will remain re-identifiable for the course of the study. Data will then be made non-identifiable for data dissemination processes and storage of final datasets after data collection is complete.

On completion of the study, the data located on files in Qld Health and the USC, as well as data collected in paper form, will be archived in a secure folder and storage company (i.e. GRACE) for no less than fifteen years. Destruction of data will not occur prior to fifteen years after the study has been completed and will be authorised by the Principal Investigator.

11.7 Safety considerations/Patient safety

Midwives will need to attend at least one in-service on the ISSDs prior to setting up and safety briefing associated with the cots. This in-service, will include all aspects associated with the introduction of new hospital equipment as advised by the relevant local hospital committee (EDMS SCACT committee and Infection Management Services), and will inform the clinicians of the manufacturers set up instructions as follows:

a) MABIM – MaBim Product Brochure.
b) First Days Pēpi-Pod® - 'Picture demonstration' of 'how to make up and use the Pēpi-Pod, and the 'Video Clip' titled 'Safe, Sleep, Little One' (CFOC Ltd, 2016).

During Phase 2, monitoring of the newborns by the clinical staff (midwives, doctors) will occur during the usual care of the infant. No additional observations will be made whilst the infant is in the safe sleep device. During the Infant Sleep Observation (ISO), the research assistant / research midwife undertaking the ISO will have a duty of care to notify the clinical midwife caring for the participant, if the mother or baby are found to be sleeping in an unsafe position.

The SSDs are to be cleaned according to the SCHHS cleaning Work Instruction 'Clean and healthy environments for patients, staff and visitors' (2016). Clinicians will care for participants in accordance with the SCHHS 'Safe infant sleeping, co-sleeping and bed sharing guideline' (2015).

The definition of an **Adverse Event** for the purposes of this study include:
Superficial injury to any part of the body from closing the cot door
Mechanical failure of the MaBim cot.

The definition of a **Serious Adverse Event** for the purposes of this study include:
Neonatal death resulting from suffocation whilst in the SSD
Newborn fall from the SSD to the ground
Newborn treated with antibiotics for a nosocomial infection attributed to SSD use
Newborn admission to the NICU for >72 hours following time spent in the SSD.

The Research Assistant will notify the Principal Investigator of any Adverse or Serious Adverse Event (SAE) immediately to decide causality. The Human Research Ethics Committee and Research Governance Office will be notified of the SAE as soon as possible.

12. SAMPLE SIZE AND DATA ANALYSIS

12.1 Sample size and statistical power

A total of 90 maternal participants and their babies will be recruited (approximately 30 in each group) in this pilot. The primary aim of this pilot is to gather observational data relating to the feasibility and acceptability of the Safe Sleep Enabler options and to test the non-blinded, randomised control trial protocol intended for a larger study.

The Sunshine Coast Hospital and Health Service currently provide services for approximately 2800 birthing women per year. The maternity unit in the Sunshine Coast University Hospital will have approximately 50 maternity beds. Based on an estimated 30-40 eligible births per week, and taking into account conservative participation rates of 40% and attrition post enrolment (50%), in addition to average length of hospital stay (approx. 1-3 days for vaginal deliveries, 3-5 days for delivery by caesarean section), it is anticipated that a maximum recruitment period of 5-6 months will be required to achieve the target sample of 90 eligible mothers and their babies with complete datasets.

The estimated staff population is approximately 80 nurses and midwives; it is anticipated that a target sample size of approximately 65-70 staff (approx. 80% response rate) will be achieved based on previous study participation with this cohort. Power calculations have not been conducted as the population is fixed by the maternity unit setting, and the primary aim of the pilot was to determine feasibility of the protocol and staff acceptance and use of a novel safe sleep enabler in this environment.

Audits of maternal charts and infant sleep observations prior to pilot RCT have been included to provide important baseline relating to current safe sleep practices in this setting. The sample size of 90-100 infant sleep observations and matched maternal chart audits will be adequate to provide a snapshot of current practice; to compare with data collected in previous studies in similar settings (Young et al., 2010); is feasible to collect within a relatively short period of time using in-kind time and resources available to the investigating research team; and provides the SCUH with valuable data to meet state guideline recommendations relating to current monitoring of safe sleep practices (Queensland Health, 2013).

Sample size calculations for the larger study have been conducted. Current exclusive breastfeeding rates in Australia are estimated at approximately 38% at infant age 3 months. An improvement of 5-10% associated with an intervention would be considered clinically significant given the health outcomes afforded by breastfeeding. Breastfeeding rates at 3 months were used to determine sample size. With a 90% power at an alpha level of 0.05, anticipating a small to moderate effect of delta=0.1, it was determined that we will require n=454 in each group. A total of 1,362 postnatal mothers and their babies will be recruited in the larger RCT. To allow for 50% attrition, due to ineligibility after delivery, 2,040 families will be approached which is determined to be achievable within a 12-14 month recruitment period at this site.

12.2 Data analysis

Data collection and analyses will include maternal and infant demographics; breastfeeding outcomes (at discharge, 6-8 weeks and 4 months); length of stay; maternal-infant attachment; maternal satisfaction and perceptions relating to enabler use; staff time to recruit and educate families, perceptions relating to intervention impact and adverse events; and maternal and

staff awareness of safe sleep recommendations (self reported and observed). Data from this pilot, the first Australian trial of a hospital postnatal safe sleep enabler, will be used to inform a randomised controlled trial of safe sleep enablers in postnatal environments.

Maternal Data: Analysis of maternal data will be conducted using the principles of intention to treat. All participants who were enrolled and randomly allocated to treatment are included in the analysis and will be analysed in the groups to which they were randomised. A further analysis will be based on actual use, consistent with a recent published study on Wahakura use, a Maori safe sleep enabler, intended for domestic use after discharge home to the community (Baddock et al., 2017) which performed analyses based on intention to treat and actual use.

Statistical analyses will be performed to report the prevalence and proportions of variables surveyed. Questionnaire results will be entered into a purpose-built Microsoft Excel database for data cleaning and preparation for statistical analysis. A 10% random selection (approximately 9-10 questionnaires from each of the maternal records, staff survey and audits) will be double entered to assess data-entry accuracy and intra-rater reliability. Consistency checks will be performed on all variables to ensure that only valid responses will form the basis of the ensuing analysis.

Quantitative data will be analysed using descriptive techniques such as frequency and percentage and measures of central tendency and distribution (for example, mean and standard deviation or median and IQR). Normality of data will be assessed. Group comparisons to comparing equivalency of control and interventions will be conducted with Chi-squared test for categorical measures and analysis of variance or Kruskal-Wallis test for continuous measures as appropriate assessing for normality and equality of variances.

Staff Survey Data: Should continuous data be distributed symmetrically, then means and standard deviation (SD) will be reported. Medians, inter-quartile ranges (IQR), frequencies and percentages will be used to report the central tendency, spread and empirical distributions of categorical and non-symmetric continuous variables elicited at each survey. All bivariate comparisons of categorical frequencies will be undertaken using Fisher's exact test, log-linear and logistic models, while McNemar’s test and Agresti's test of symmetry will be used to detect differences between participants' responses at any two survey points (pretest vs post-test). Continuous data will be analysed using Student's t-test, Student's paired t-test, ANOVA or using their nonparametric equivalents (should the data exhibit non-normality).

Audit data: All qualitative data will be coded prior to data entry. Frequency data will be reported and analysed using standard categorical techniques (accounting for the matched nature of the data between mother and baby). Univariate linear modelling will be conducted for dependent variables that will include infant sleep position, infant placement in the cot, placement and securement of bedding; and presence of particular objects in the cot, e.g. Infant quilts, toys, cot bumpers.

All statistical comparisons will be analysed using the SAS or SPSS statistical software package (IBM Corp 2013). A value of p=0.05 will be used to define statistical significance for primary outcomes as they are independent of each other. We recognize that there are a large number of secondary outcomes and will report uncorrected p values with a nominal level of significance of 0.05.

13. ETHICAL CONSIDERATIONS

The ESCCaPE trial is a collaboration between the Sunshine Coast Hospital and Health Service, the University of the Sunshine Coast and Change for Our Children Ltd.

Ethical approval has been acquired from the Royal Brisbane and Women's Hospital Human Research Ethics Committee. For ethical concerns regarding the conduct of this study please contact: Human Research Ethics Office, Royal Brisbane and Women's Hospital, Level 7, Block 7, Butterfield Street, Herston, Qld, 4029. Phone: (07) 3646 6132. Email: RBWH-Ethics@health.qld.gov.au .

This trial requires voluntary participation. Informed consent will be gained from all participants. Participants are free to withdraw at any time.

In the case of injury to participants during the course of the study, participants will be insured as patients of the Sunshine Coast Hospital and Health Service. Liability of participants is stipulated in the collaborative research agreement, signed by all parties prior to gaining governance approval.

The researchers are guided by The National Statement on Ethical Conduct in Human Research (NHMRC 2007 updated 2015). Ethical principles of research merit and integrity, justice, beneficence and respect will be upheld at all times by the researchers (NHMRC 2007 updated 2015).

14. DISSEMINATION OF RESULTS AND PUBLICATIONS

Members of this research team have led the first trial of the Queensland Pēpi-Pod® Program in collaboration with NZ Change for our Children so are ideally positioned to build on this work in an Australian context and to disseminate findings to key stakeholders through existing networks.

Relevant findings will be shared with key stakeholders and collaborators, including:

- SCUH Hospitals and Health Services
- Queensland Paediatric Quality Council and the QPQC Infant Mortality Subcommittee
- QH Statewide Maternal and Neonatal Network
- State Coroner, Terry Ryan and Brisbane Coroner, John Lock
- Commissioner Queensland Family and Children's Commission
- Department of Product Safety, Office of Fair Trading
- Patient Safety and Quality Improvement Service, Queensland Health
- Red Nose Foundation
- Change for our Children Ltd, New Zealand
- And, all who have been briefed and indicated support for the Pēpi-Pod Program concept.

15. OUTCOMES AND SIGNIFICANCE

The significance of this study is that it addresses two internationally identified health priorities of relevance to Queenslanders, is timely, is innovative in this practice context, and addresses current clinical practice and safety issues experienced by the local SCHHS. It will also provide new knowledge that has the real potential to influence practice and care delivery to families with newborns at a state and national level.

The aims of this study address two public health priorities, recognised nationally and internationally (WHO, 2016): 1) the support of breastfeeding which is vital to reducing the burden of disease and mortality experienced by Australians; and 2) reducing infant mortality and morbidity.

This study will constitute the first trial of a safe sleep enabler in an Australian postnatal setting. Evaluations of innovative interventions which are designed to support breastfeeding and enhance safety of sleeping environments is an area which has been identified as a priority for investigation by organisations, clinicians and parent groups. These groups are committed to supporting safe, practical, and culturally appropriate safe infant care practices and role modelling safe sleep behaviours for parents in an effort to reduce infant mortality and morbidity (Dodd 2012; SIDS and Kids, 2015; Young et., 2012).

Health services have a responsibility to follow through from simply informing about safe infant sleep practice to enabling safe infant sleep action (Cowan et al., 2012). Safe sleep enablers such as the NZ Pēpi-Pod® First Days Pod and the MaBim Side-car Crib (Italy, Directive 93/42/CEE) draw attention away from problems for vulnerable babies in unsafe sleeping situations and instead focuses on a solution; support for parents and protection for the baby. Local SCHHS data also support the need to address safety issues relating to infant falls from adult postnatal beds in ways that support breastfeeding and safe infant sleeping.

The Australian Department of Product Safety, Office of Fair Trading have offered in principle support and collaboration to this investigation. The Department are currently reviewing and developing safety guidelines for side-car co-sleepers for domestic use, and have offered their support in reviewing the proposed sleep spaces for this study, given both devices meet safety standards in other countries (Change for our Children NZ Pēpi-Pod First Days Pod, New Zealand; MaBim neonatal cot for co-sleeping, Italy) as there are currently no Australian-based commercial co-sleeping cots for post-natal hospital environments. This study therefore offers a timely opportunity for clinicians and researchers to contribute directly to guidelines for product safety development. This study provides an opportunity for SCHHS to lead the way in Australian maternity services in the introduction of innovative practices in health service delivery to mothers and their newborns; which is timely given the opening of the new maternity facility at the Sunshine Coast University Hospital in 2017.

It is anticipated that the findings of this pilot will provide the platform for a randomised controlled trial. The RCT would aim to provide high quality evidence for the effectiveness of postnatal safe sleep enablers in improving optimal breastfeeding outcomes and parental uptake of safe sleep behaviours to reduce the risk of SIDS.

This pilot study will have a local and national impact. Health professionals play an integral role in promoting public health messages through role modelling, parent education and

supporting evidence-based guidelines, hospital policies and procedures. Local impact for SCHHS clients includes improving breastfeeding outcomes and maternal satisfaction with care received; increasing culturally appropriate and personal options and choice in care accessed; reduced adverse events associated with baby falls from maternal beds, or in chairs; improved uptake of safe sleeping recommendations as parents' transition to home environments; and development of evidence-based policies, procedures and associated parent education that support breastfeeding and safe infant sleeping. Key impact also, is the support of SCCHS staff to address current clinical safety issues in providing safe infant sleep environments that promote breastfeeding in the immediate postnatal environment and developing research capacity through participation in clinical research.

Feasibility of increasing reach of these study findings at state and national levels is optimised through the existing collaborations between the research team and organisations and government departments with an interest in reducing infant deaths and promoting optimal infant care. These include the current Queensland Pēpi-Pod Program®, Red Nose; Australian College of Midwives; the State Coroner; Office of Fair Trading, Department of Product Safety; Queensland Family and Child Commission; Queensland Maternity and Neonatal Network; Qld Paediatric Quality Council, and the Qld Child Death Review Panel.

Originality: There is a paucity of evidence on the use of postnatal safe sleep enablers and no published literature on use in an Australian setting; this will be the first study evaluating a safe sleep enabler in an Australian postnatal setting.

Feasibility: Members of this research team have led the first trial of the Queensland Pēpi-Pod® Program in collaboration with NZ Change for our Children so are ideally positioned to build on this work in an Australian context and to disseminate findings to key stakeholders through existing networks.

16. BUDGET

The ESCCaPE Trial has been awarded a Wishlist Grant from the Sunshine Coast Health Foundation for amount of $19,993.05. The remaining $6,174.46 will be covered through discretionary funding available to the research team through national nursing award prize monies awarded to the Principal Investigator for the purpose of research.

Task Allocation

Task	Clinician	Task *(mins)*	$ task	$ from sponsor	$ in kind SCHHS
Screen eligibility	RM	5	$4.89		
Collect baseline data	RA	5	$4.89		
Contact patient to discuss study and review PISCF / show Information Video	RM	5	$4.89		
Consent (n=90)	RM	30	$29.33		
Randomise	RM	10	$9.78		
Set up cot	RM	15	$14.67		
Data entry	RA	30	$29.33		
Questionnaire 1	RA	30	$29.33		
Telephone follow up Questionnaires 2&3	RA	30	$29.33		
*Infant sleep observation & consent (n=100)	RA	15	$14.67		
Total hours per participant:		**2hr 40m *15mins**	**$156.45 *$14.67**		
Total hours for study:		**240hrs *25hrs**			
Total labour related costs:			**$14, 080.50 *$1,466.75**	**$15,547.25**	**$0**

Non Labour Costs - Other

Type of cost	No. of events	$ per event *includes 30% on costs*	$ non-labour	$ from sponsor	$ in kind SCHHS
MaBim Pepi-Pod Standard cot	X4 X15 X30	$1,313.31 $75 $0	$5,253.25 $1,125 $0	$6,378.25	$0
Start up (NEAF / SSA)	(30hrs NEAF. 30hrs SSA)	USC RA: $51/hr CN: $58.67/hr	NEAF $1,530 SSA $1,530	$3,060	$0
Governance	1	$0 investigator initiated	$0	$0	$0
HREC / RGO reporting	per hr	CN: $58.67	$58.67	$58.67	$0
SAE reporting	per hr	CN: $58.67	$58.67	$58.67	$0
Close out	per hr	CN: $58.67	$58.67	$58.67	$0
Printing / stationery	per page	$0.01	$10	$0	$10
Computer	per month	$56	$336	$0	$336
Chart recall	1 chart	$4	$360	$0	$360

Archiving	15 years	$300 per box	$300	$0	$300
Total non-labour related costs:			**$10,620.26**	**$4,445.80**	**$996.00**
			$ all items	**$ from sponsor**	**$ in kind SCHHS**
Grand total:			**$26,167.51**	**$ $19,993.05**	**$996.00**
			-$6,174.46		

17. GLOSSARY OF ABBREVIATIONS

Bed-sharing (BS)
Co-sleeping (CoS)
Infant Safe Sleeping Device (ISSD)
Postnatal (PN)
Room-sharing (RS)
Safe Sleep Enabler (SSE)
Safe Sleeping Device (SSD)
Skin-to-skin contact (SSC)
Sudden infant death syndrome (SIDS)
Sudden unexplained death in infancy (SUDI)

18. REFERENCES

Abel S, Stockdale-Frost A, Rolls R, Tipene-Leach D. (2015). The wahakura: a qualitative study of the flax bassinet as a sleep location for New Zealand Māori infants. New Zealand Medical Journal, 128(1413): 12-19.

Abel S & Tipene-Leach D. (2013). SUDI Prevention: A review of Māori Safe Sleep Innovations for infants. The New Zealand Medical Journal, 126 (1379): 86-94.

Australian College of Midwives [ACM]. (2014). Position Statement on Bed-sharing and Co-sleeping, Australian College of Midwives. Viewed 11 February 2016 at https://www.midwives.org.au/resources/acm-position-statement-co-sleeping-and-bed-sharing.

Baddock SA, Tipene-Leach D, Williams SM, Tangiora A, Jones R, Iousa E, MacLeod EC, Taylor BJ. (2017) Wahakura Versus Bassinet for Safe Infant Sleep: A Randomized Trial. (January) Pediatrics 13(2):e 20160162.

Ball HL, Platt-Ward MP, Howel D, Russell C. (2011). Randomised trial of sidecar crib use on breastfeeding duration (NECOT). Archives of Disease in Childhood 96: 630-634. DOI:10.1136/adc.2010.205344

Ball HL, Ward-Platt MP, Heslop E, Leech SJ, Brown KA. (2006). Randomised trial of infant sleep location on the postnatal ward. Archives of Disease in Childhood, 91(12): 1005-1010.

Blair P, Heron J & Fleming P. (2010). Relationship between bed sharing and breastfeeding: Longitudinal, population based analysis. Pediatrics, 126(5), e1119-1126.

Blair PS, Sidebottom P, Pease A & Fleming PJ. (2014). Bed-Sharing in the Absence of Hazardous Circumstances: Is There a Risk of Sudden Infant Death Syndrome? An Analysis from Two Case-Control Studies Conducted in the UK. PLoS ONE, 9(9), e107799. DOI: 10.1371/journal.pone.0107799

Bollani M (2016) MaBim Neonatal Cot: Operating Instructions. Leura s.r.l Helpful Design. Italy. Available at http://www.mimmama.it

Carpenter R, McGarvey C, Mitchell, EA, Tapping DM, Vennemann MM, Smuk S, Carpenter JR. (2013) Bedsharing when parents do not smoke: is there a risk of SIDS? An individual level analysis of five major case-control studies. British Medical Journal Open 3(5):e002299. doi:10.1136/bmjopen-002299.

Change For Our Children Ltd (CFOC) 2016. Picture Demonstration, Short Video Clip. Available at http://www.changeforourchildren.co.nz/pepi_pod_programme/distributors

Condon, J. (2015). Maternal Postnatal Attachment Scale [Measurement instrument] Retrieved from: http:// hdl.handle.net/2328/35291

Cowan S. (2011) Baby Bed Innovations. Christchurch: Change for our Children Ltd. Available at http://www.changeforourchildren.co.nz/files/docs/babybedinnovations.pdf

Cowan S. (2012). Using Pēpi-Pods. Report on feedback from families who used protected sleeping spaces for babies following the Christchurch earthquake of February 2011. Christchurch: Change for our Children Ltd. [ISBN 978-1-877512-05-6 (Print)]

Cowan S, Bennett S, Clarke J, Pease A. (2013). An evaluation of portable sleeping spaces for babies following the Christchurch earthquake of February 2011. Journal of Paediatrics and Child Health, 49(5):364-8. doi: 10.1111/jpc.12196. Epub 2013 Apr 11.

Cowan S. (2015). Their first 500 sleeps. Pēpi-pod© Program Report 2012-2014. Change for our Children.

Cowan S. (2015) First Days Pēpi-pod® Sleep Space. Information Brochure. Christchurch: Change for our Children, New Zealand. Available from: http://www.changeforourchildren.co.nz/files/docs/pepipod%20programme/firstdays_trial_dle.pdf

Cowan S. (2016) First Days: Report on a trial run of a small-sized infant sleep space for safer co-sleeping in postnatal facilities. Christchurch: Change for our Children Ltd. January 2016. Available from www.changeforourchildren.nz.

Dennis, C-L. (2003) The Breastfeeding Self-Efficacy Scale: Psychometric assessment of the short form. Journal of Obstetric, Gynecologic, and Neonatal Nursing, 32, 734-744.

Dodd J. (2012) Evaluation of the Department of Health Western Australian Operational Directive Statewide Co-sleeping / Bed-sharing Policy for WA Health Hospitals and Health Services. Collaboration for Applied Research and Evaluation: Telethon Institute for Child Health Research under contract with the Department of Health, Western Australia.

Drever-Smith C, Bogossian F, New K. (2013) Co-sleeping and Bed sharing in Postnatal Maternity Units: A review of the literature and critique of clinical practice guidelines. International Journal of Childbirth 3(1): 13-27. http://dx.doi.org/10.1891/2156-5287.3.1.13

Dumville JC, Hahn S, Miles JNV, Torgerson DJ. (2006) The use of unequal randomisation ratios in clinical trials: A review. Contemporary Clinical Trials 27(1): 1-12. doi:10.1016/j.cct.2005.08.003

Herlenius E, Kuhn P. (2013) Sudden Unexpected Postnatal Collapse of Newborn Infants: A review of Cases, Definitions, Risks and Preventive Measures. Translational Stroke Research. 4(2): 236-247. DOI: 10.1007/s12975-013-0255-4.

International Consortium for Health Outcomes Measurement (2016) ICHOM Pregnancy and Childbirth Data Collection Reference Guide, Version 1.1, Revised 17 November, 2016. http://www.ichom.org/medical-conditions/pregnancy-and-childbirth/

Hey SP, Kimmelman J. The questionable use of unequal allocation in confirmatory trials. Neurology. 82(1): 77-79. doi: 10.1212/01.wnl.0000438226.10353.1c. Epub 2013 Dec 4.

Infant Sleep Information Source (ISIS) (2016) Available from https://www.isisonline.org.uk/

Kim, S., Fonagy, P., Koos, O., Dorsett, K., & Strathearn, L. (2014). Maternal Oxytocin Response Predicts Mother-to-Infant Gaze. Brain Research, 1580, 133–142. http://doi.org/10.1016/j.brainres.2013.10.050

Lee H. (2013). Why Finnish babies sleep in cardboard boxes. BBC News. Available online: http://www.bbc.com/news/magazine-22751415

Matteson T, Henderson-Williams A, Nelson J. (2013) Preventing in-hospital newborn falls: a literature review. MCN American Journal of Maternal Child Nursing 38(6): 359-66. DOI: 10.1097/NMC.0b013e3182a1fb91

McKenna JJ & Gettler LT. (2016). There is no such thing as infant sleep, there is no such thing as breastfeeding, there is only breastsleeping. Acta Paediatrica 105(1): 17-21. DOI: 10.1111/apa.13161

Mitchell EA, Freemantle J, Young J, Byard RW. (2012) Scientific consensus forum to review the evidence underpinning the recommendations of the Australian SIDS and Kids Safe Sleeping Health Promotion Programme – October 2010. Journal of Paediatrics and Child Health 48(8): 626-633. DOI: DOI: 10.1111/j.1440-1754.2011.02215.x

Mitchell EA, Cowan S, Tipene-Leach D. (2016) The recent fall in post-perinatal mortality in New Zealand and the Safe Sleep Programme. Acta Paediatrica Accepted 31 May 2016, DOI: 10.1111/apa.13494.

Monson SA, Henry E, Lambert DK, Schmutz N, Christensen RD. (2008) In-hospital falls of newborn infants: Data from a multihospital health care system. Pediatrics 122(2): e277. DOI: 10.1542/peds.2007-3811

Moore, E. R., Anderson, G. C., Bergman, N., & Dowswell, T. (2012). Early skin-to-skin contact for mothers and their healthy newborn infants. The Cochrane Database of Systematic Reviews, 5, CD003519. http://doi.org/10.1002/14651858.CD003519.pub3

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra

New South Wales Child Death Review Team (2010) A preliminary investigation of neonatal SUDI in NSW 1996-2008: opportunities for prevention, NSW Commission for Children and Young People. Heather E. Jeffery, Lucia Wang & Angela Carberry: Sydney. ISBN 978-0-7313-3452-0.

Noel-Weiss, J., Taljaard, M. & Kujawa-Myles, S. (2014). Breastfeeding and lactation research: exploring a tool to measure infant feeding patterns. *International Breastfeeding Journal*, 9(5). DOI: 10.1186/1746-4358-9-5.

Nyqvist KH, Anderson GC, Bergman N, Cattaneo A, Charpak N, Davanzo R, Ewald U, Ibe O, Ludington-Hoe S, Mendoza S, Pallás-Allonso C, Ruiz Peláez JG, Sizun J, Widström A-M. (2010) Towards universal Kangaroo Mother Care: recommendations and report from the First European conference and Seventh International Workshop on Kangaroo Mother Care. Acta Paediatrica 99(6): 820-826.

Queensland Health (2013) Safe Infant Sleeping, Co-sleeping and Bed-sharing: Guideline for Safe Infant Sleeping, Co-sleeping and Bed-sharing. Version 1.0 Effective 1 July 2013. QH-GDL-362: 2013

Queensland Health (2011) How to prevent baby falls in hospital. A guide for maternity staff. Published by the Central Maternity and Neonatal Clinical Network Quality and Safety Sub-Committee 2011.

Schluter PJ, Young J. (2002) Reducing the risk of Sudden Infant Death Syndrome: What infant care practices are being used by primary care-givers in Queensland? Neonatal, Paediatric and Child Health Nursing 5(2): 27-35.

SIDS and Kids (2015) Information Statement: Sharing a sleep surface with a baby. Melbourne, National SIDS Council of Australia. This information statement was first posted in February 2006. Available at http://www.sidsandkids.org

IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.

Sunshine Coast Hospital and Health Service (9/11/2015). Safe infant sleeping, co-sleeping and bed sharing guideline QH-GDL-36 V3 (DOC ID 000431)

Sunshine Coast Hospital and Health Service (2016). Clean and healthy environments for patients, staff and visitors (Work Instruction). Nambour: Sunshine Coast Hospital and Health Service.

SIDS and Kids (2016) SIDS and Kids Safe Sleeping app. Available at http://www.sidsandkids.org/safe-sleeping/

Taylor A, Atkins R, Kumar R, Adams D, Glover V. (2005) A new Mother-to-Infant Bonding Scale: links with early maternal mood. Archives of Women's Mental Health. 8(1): 45-51. DOI: 10.1007/s00737-005-0074-z

Tully K, Ball H. (2012). Postnatal unit bassinet types when rooming-in after caesarean birth: implications for breastfeeding and infant safety. Journal of Human Lactation 28(4): 495-505.

UNICEF. UK Baby Friendly Initiative. (2004). Babies sharing their mothers' bed while in hospital: A Sample Policy, London, UNICEF UK Baby Friendly Initiative.

UNICEF UK Baby Friendly Initiative 2012, Caring for Your Baby at Night: A guide for parents, In UNICEF UK Baby Friendly Initiative (Ed.), London, UNICEF.

World Health Organisation (2016). Children: reducing mortality (Factsheet) Available from http://www.who.int/mediacentre/factsheets/fs178/en/

Young J. (2016) Children's Health Queenland Hospital and Health Service Annual Report for Research Protocols: Reducing risk for Aboriginal and Torres Strait Islander babies: trial of a safe sleep enabler to reduce the risk of sudden unexpected deaths in infancy in high risk environments [HREC/13/QRCH/103 & Amendment No: HREC/13/QRCH/103/AM04], Submitted 27th September 2016, Sippy Downs: University of the Sunshine Coast.

Young J, Battistutta D, O'Rourke P, Thompson JMD. (2008) Infant care practices related to sudden infant death syndrome in Queensland 2002 [Final Report Executive Summary]: Royal Children's Hospital & Health Service District, Queensland Health: Brisbane. http://dx.doi.org/10.4227/39/578849b56aeac

Young J, Craigie L, Watson K, Kearney L, Cowan S, Barnes M. (2015) Safe Sleep, Every Sleep: Reducing Infant Deaths in Indigenous Communities. Women and Birth 28(Supplement 1): S31-32.

Young J, New K, Colditz P, Williams A, Higgins N, Raven L. (2010) Impacting nursing and midwifery knowledge, attitudes and practices relating to Sudden Unexpected Deaths in Infancy: effectiveness of a peer intervention program. Final Report. Royal Children's Hospital & Health Service District, Queensland Health, Brisbane.

Young J, O'Rourke P. (2003) Improving attitudes and practice relating to Sudden Infant Death Syndrome and the Reduce the Risk messages: The effectiveness of an educational intervention in a group of nurses and midwives. Neonatal, Paediatric And Child Health Nursing 6(2): 4-14.

Young J, Schluter PJ. (2002) Sudden Infant Death Syndrome: What do nurses and midwives know about reducing the risk? Neonatal, Paediatric And Child Health Nursing 5(2): 19-26.

Young J, Schluter P, Francis D. (2002) Final Report: reducing the Risk of Sudden Infant Death Syndrome: Nurses' Knowledge, Attitudes and Practices. Royal Children's Hospital & Health Service District, Queensland Health: Brisbane.
http://dx.doi.org/10.4227/39/578849186aeab

Young J, Watson K, Ellis L, Raven L. (2012) Responding to evidence: Breastfeed baby if you can: the sixth public health recommendation to reduce the risk of sudden and unexpected death in infancy. Breastfeeding Review 20(1): 7-15.

Young J, Watson K, Craigie L, Cowan S, Kearney L. (2016) Advice to Action: uniting cultural practices and safe sleep environments for vulnerable Indigenous Australian infants. Oral Presentation, ISA-ISPID Congress: The 2016 International Conference on Stillbirth, SIDS and Baby Survival. Radisson Victoria Plaza Hotel, Montevideo, Uruguay, 7-10th September, 2016.