A Skin-to-Skin Contact Facilitating Garment used by Mother-Infant Dyads: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.

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Abstract

Background and Setting

To date, no systematic investigation has considered the role of facilitating ongoing skin-to-skin contact (SSC) through babywearing for healthy, term babies to address early breastfeeding cessation and encourage relational development. Set in a large city in the West Midlands, England, this study recruited a diverse sample of healthy, term infants and their mothers to trial a skin-to-skin facilitating garment.

Aims

The study aimed to assess the safety and efficacy of the skin-to-skin facilitating garment, known as the Snuby, by examining its effects on neonatal thermoregulation, breastfeeding at six weeks post-birth, and its effect on engagement with SSC and dyadic relational bonding.

Methodology and Analyses

A multiphase mixed methods design was used, including a feasibility study (n=11) using participant observation and descriptive analyses, a randomised controlled trial (n=98) using purpose-made data collection tools and statistical inferential analyses, and a qualitative follow-up phase (n=44) using semi-structured interviews and the framework method of analysis.

Results

The Snuby was as efficacious at maintaining neonatal normothermia in SSC as conventional facilitation with a blanket or covering. The study did not identify a significant correlation between the Snuby and the frequency of SSC episodes, nor breastfeeding rates at six weeks post-birth. These findings are explained by the barriers and resources identified in the qualitative phase. The process of bonding was identified as a motivator and outcome of using the Snuby. Unexpectedly, the garment invoked reciprocal dyadic communication and was used as a means to safeguard the integrity of the mother-infant relationship in times of stress.

Implications

These findings suggest that the Snuby is a safe means of skin-to-skin facilitation. Contrary to expectations, the provision of the garment does not address early breastfeeding cessation; further research should seek to confirm this. The Snuby garment appears to mitigate against

the impact of breastfeeding stress on the development of the mother-infant relationship, and as such, has a potential application in the promotion of mother-infant bonding.

Acknowledgements and Declarations

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Firstly, I would like to acknowledge the continued support and guidance that I have received from my academic supervisors, Dr Helen McIntyre, Dr Merryl Harvey and Dr Kate Thomson, throughout my doctoral journey. I would like to thank Harry Reynolds, for patiently sharing his time and mathematical expertise with me, and Dr Robert Cook for introducing me to the dark art of SPSS. Finally, I would like to acknowledge the unwavering support and encouragement that I have received from my friends, family, and my partner, Dayna. You had no doubt that I could, and would, achieve my doctorate, and that belief has enabled me to see it through to the end.

Dedication

I would like to dedicate this thesis to the women who gave their time and energy to take part in this study throughout the highs and lows of new motherhood. I have learnt so much from you which could not be quantified in my thesis, and I am sincerely grateful.

Declarations

I declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person, except where due acknowledgement has been made in the text. I confirm that no part of the material presented in this thesis has previously been submitted by me or any other person for a degree in this or any other institution.

Statement of Copyright

Word count

The word count of this thesis is approximately 80,000 excluding references and appendices.

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Glossary of terms and abbreviations

ALTE	Apparent life-threatening events
BFI	Baby Friendly Initiative: an evidence based accreditation programme developed by the World Health Organisation and Unicef to enable public services to better support infant feeding and developing relationships.
CASP	Critical Appraisal Skills Programme: part of a small social enterprise that supports health systems achieve optimal outcomes for populations and individuals given the resources available. CASP provide checklists to aid the review of research literature.
CONSORT	Consolidated Standards of Reporting Trials: CONSORT checklist and statement aim to improve the reporting of randomised controlled trials.
DDH	Developmental dysplasia of the hips
GDPR	General Data Protection Regulation
GRD	Generalised resistance deficit: a concept developed by Aaron Antonovsky in his theory of salutogenesis, meaning the barriers to the generation of health.
GRR	Generalised resistance resource: a concept developed by Aaron Antonovsky in his theory of salutogenesis, meaning the resources used to generate health.
ICF	Informed consent form
KMC	Kangaroo mother care: a care bundle for premature or low birth weight infants consisting of constant or plentiful skin-to-skin contact, near or exclusive breastfeeding, and early discharge from inpatient care.
NHS	National Health Service
NMC	Nursing and Midwifery Council
ONS	Office of National Statistics
PIS	Participant information sheet
PPI	Patient and public involvement
RCT	Randomised controlled trial

REC	Research ethics committee
SAE	Serious adverse event
Salutogenesis	Meaning 'origins of health'. A theory of health promotion developed by Aaron Antonovsky, concerned with health, stress, and coping.
SIDS	Sudden infant death syndrome
SOC	Sense of coherence: a concept developed by Aaron Antonovsky in his theory of salutogenesis, a mechanism which explains how people deal with stressors in life.
SSC	Skin-to-skin contact, also termed skin-to-skin care: when a baby is placed prone against a caregiver's chest, with the infant's trunk in close contact with the caregiver's chest. Skin-to-skin contact usually refers to the mother and her infant, but may be performed by any caregiver.
SUPC	Sudden unexpected postnatal collapse
Snuby®	The registered skin-to-skin facilitating garment being trialled. The garment is designed to be worn by mothers as a vest style top with an inbuilt panel which contains the unclothed infant against its mother's chest in skin-to-skin contact.
UK	United Kingdom
UNICEF	Also termed 'unicef': The United Nations Children's Emergency Fund. International organisation working to improve the lives of children.
VIF	Variance inflation factor: statistical quantifier of multicollinearity.
WHO	World Health Organisation

1. Introduction

This chapter presents an overview of the thesis. The chapter describes the background and context of the study, the research aims and questions, the methodology, and the research findings. The contribution of the study to the research field is outlined with reference to the state of the literature on skin-to-skin contact. Finally, the structure of the thesis is presented.

This study examined the effects of providing a garment to mother-infant dyads shortly after birth. The garment is worn by the mother and contains the baby against the chest of its mother in skin-to-skin contact using a stretchy fabric panel. The unique features of the garment include adjustable shoulder straps to facilitate infant feeding whilst in skin-to-skin contact, ruched panelling with breast pad pockets to allow for variation in breast size and support, a reinforced front panel with tie straps to safely contain the infant, breathable and stretchy fabric to aid temperature regulation and comfort, and no complex fastenings (Figure 1.1). The garment is hereafter referred to as the Snuby (patent: P346539GB). The garment was developed prior to the commencement of this research study by a midwife academic, Dr Helen McIntyre, and textiles student Jade Ming. The garment was designed to facilitate skin-to-skin contact between mothers and their healthy, term infants in recognition of the positive outcomes associated with ongoing skin-to-skin contact with premature and low birth weight infants (Conde-Agudelo and Díaz-Rossello, 2014). At the time of development, skin-to-skin contact was predominantly facilitated in English maternity units by the mother holding her baby against her chest, covered by a blanket. This method of facilitation relies on the mother to place and sustain the infant in a safe position for the skin-to-skin contact episode, whilst maintaining her own position. This was considered to be a potential barrier to mothers and infants engaging in ongoing skin-to-skin contact in the hospital and following discharge home. The garment was developed to provide a safe and sustainable way of engaging in skin-to-skin contact which secured safe neonatal positioning, and optimised maternal comfort to make skin-to-skin contact more sustainable. It was identified that skin-to-skin facilitating garments were being used on neonatal units with unwell or premature infants, which had not been clinically trialled. These garments generally used a wrap design, or had been made from repurposed materials such as stretchy tube

bandage. A full critique of other available garments is provided in Chapter Two. The purpose-made Snuby garment was developed for use with full term infants, and manufactured for a clinical trial, as described in this thesis.

Figure 1.1 The Snuby garment: on mannequin and model

The study aimed to investigate the effect that the Snuby had on dyadic health-promoting behaviours, namely engagement in breastfeeding and skin-to-skin contact. The study also aimed to establish the safety of the garment in regards to its ability to maintain neonatal normothermia in skin-to-skin contact, and maintain a safe neonatal position. Finally, the study sought to explore the effects of providing the Snuby on dyadic relationship building and the process of bonding.

Introducing the background and context of the study

Breastfeeding is the physiological norm for all mammals, including humans. Breastfeeding provides nutrition and immunity transfer which is developmentally appropriate and adapted to the changing needs of the infant. Although much research has investigated the benefits or effects of breastfeeding (Chowdhury et al., 2015; World Health Organisation, 2013), responses and outcomes associated with breastfeeding are the physiological baselines to

which other interventions should be compared. Despite the ongoing research supported by the multi-billion dollar global formula milk industry, no evidence demonstrates that any breastmilk substitute can improve on, or even equate to, the nutritional and immunologic constituents found in breastmilk (Save The Children, 2018; Munblit et al., 2020). As such, the World Health Organisation (2003a, 2014) recommend exclusive breastfeeding for the first six months of the baby's life, followed by continued breastfeeding alongside solid foods for two years and beyond.

Despite unequivocal evidence on the value of breastfeeding, national statistics demonstrate that only 34% of mothers in the United Kingdom are still exclusively breastfeeding at six weeks post-birth, dropping to just 1% by six months post-birth (McAndrew et al., 2012). More poignantly, 8 out of 10 women surveyed had stopped breastfeeding before they wanted to (McAndrew et al., 2012), suggesting that the early cessation of breastfeeding is not largely attributable to women's informed decision making. The termination of the national Infant Feeding Survey (McAndrew et al., 2012), alongside widespread closures of SureStart centres which host community-based breastfeeding support (Smith et al., 2018), is telling of the poor prioritisation of breastfeeding as part of the political public health agenda.

Global and national standards have been developed by the World Health Organisation and UNICEF to address such low breastfeeding rates. The Baby Friendly Initiative (BFI) provides an evidence-based staged accreditation programme for providers such as maternity units, health visiting services, and higher education institutions (UNICEF UK, 2017). The Baby Friendly Initiative aims to enable public services to better support families with feeding and developing close and loving relationships to ensure that all babies get the best chance in life (UNICEF UK, 2017). A key component of the BFI standards is the promotion of skin-to-skin contact. The BFI standards require healthcare professionals to support immediate and ongoing skin-to-skin contact for all babies, irrespective of their feeding method (UNICEF UK, 2017).

These standards have national significance as BFI accreditation has been incorporated into the NHS Long Term Plan (NHS England, 2019). The facilitation of skin-to-skin contact also features in a national safety improvement programme which aims to reduce admissions of term babies to the neonatal unit (known as the ATAIN programme). The programme

identified early skin-to-skin contact as a modifiable factor for reducing admissions due to neonatal hypoglycaemia (Upton, 2018). The programme recognises the deleterious effects of mother-infant separation in the hours and days following birth, and the positive impact of skin-to-skin contact on early feeding and reducing the incidence of hypothermia (Upton, 2018).

Introducing the key concepts

Skin-to-skin contact refers to the placing of the naked baby prone on the mother's chest, typically with the baby's head covered by a dry cap, and its back covered with a warm blanket (Moore et al., 2016). Skin-to-skin contact is also termed skin-to-skin care (Johnston et al., 2017); both terms are frequently abbreviated to SSC or S2S. Skin-to-skin contact is generally categorised as *immediate*, commenced immediately after birth, or *early*, commenced within the first day (Moore et al., 2016). When skin-to-skin contact is continued after the first day of birth, it is frequently termed *kangaroo mother care* (World Health Organisation, 2003b) or *ongoing* skin-to-skin contact. However, skin-to-skin contact and kangaroo mother care are not synonymous terms; important distinctions exist between the two concepts.

A primary difference between the terms is the applicable population. Kangaroo mother care (KMC), also termed kangaroo care, is a care bundle aimed at low birth weight or premature babies (Conde-Agudelo and Díaz-Rossello, 2014), whereas skin-to-skin contact applies to all babies, irrespective of gestation and size. The KMC care bundle consists of early, continuous and prolonged skin-to-skin contact, frequent and exclusive or near-exclusive breastfeeding, and early discharge from hospital with adequate follow-up (Conde-Agudelo and Díaz-Rossello, 2014; World Health Organisation, 2003b). As this is a midwife-led research study, the scope of the research included healthy, term babies and their mothers. Premature or unwell babies fall outside the remit of midwife-led care. This study investigated the facilitation of *ongoing* skin-to-skin contact*,* pertaining to any skin-to-skin contact between the mother and her baby *after the first hour* post-birth, until the end of the midwife's professional remit: six weeks post-birth.

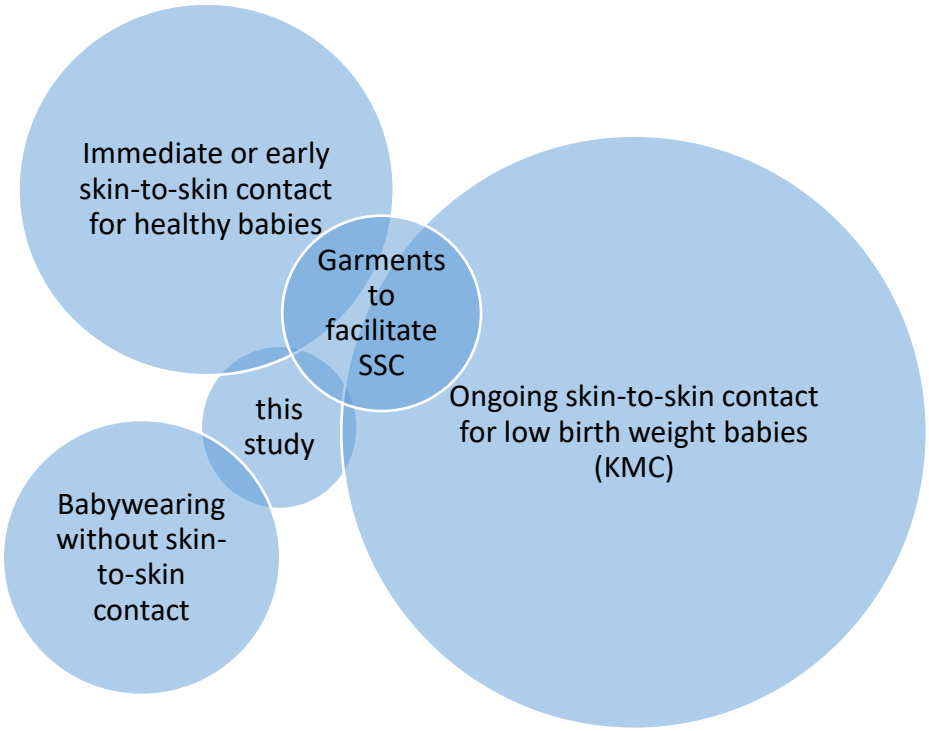
Although the term skin-to-skin contact usually refers to the mother and her baby, research has also been conducted on father-infant skin-to-skin contact (Shorey et al., 2016). Parent-infant skin-to-skin contact activates the release of oxytocin in both mothers and

fathers (Cong et al., 2015). Paternal-infant skin-to-skin contact has been recommended when the mother is not available for skin-to-skin contact (Erlandsson et al., 2007), although the significance of the skin-to-skin contact provider is not well documented. For the purpose of this study, skin-to-skin contact refers to the mother and her baby, unless stated otherwise.

Introducing the research fields

This research study bridges several research fields to provide a new conceptualisation of skin-to-skin contact. The following subsection serves as an introduction to these research fields, and positions the research study in the illustrated gap in the literature; a comprehensive and in-depth review of the literature is presented in the following chapter. Evident in the scope of the cited systematic reviews, the focus of research on skin-to-skin contact is generally on either early skin-to-skin contact for healthy, term babies (Moore et al., 2016) or ongoing skin-to-skin contact as part of the KMC bundle for premature or low birth weight babies (Conde-Agudelo and Díaz-Rossello, 2014).

Figure 1.2 Situating this study within the research fields (not to scale)



Research into the effects of early skin-to-skin contact for healthy term babies and their mothers has identified that babies demonstrate the innate neurobehaviours needed to locate the nipple and successfully feed when they are maintained against their mother's skin (Widstrom et al., 2011). The effects of early skin-to-skin contact are evident in increased rates of breastfeeding initiation (Lau et al., 2018), breastfeeding exclusivity at discharge to one month post-birth (Moore et al., 2016), and any breastfeeding at one to four months post-birth (Moore et al., 2016). Early skin-to-skin contact appears to maintain the baby's temperature 0.3°C higher than standard care, although this difference is not clinically significant as both standard and skin-to-skin care appear to support neonatal thermoregulation (Moore et al., 2016).

However, the quality of evidence for early skin-to-skin contact is impacted by generally small sample sizes in individual studies, significant heterogeneity in the study design of trials, and a lack of successful blinding (Moore et al., 2016). These limitations appear to result from heterogeneous definitions of standard care following birth, varying levels of breastfeeding support, and a lack of standardisation of the 'intervention' of skin-to-skin contact, particularly the timing of skin-to-skin initiation. Lack of blinding is a recurring barrier to methodological quality in trials of skin-to-skin contact as it is impossible to conceal the allocation from the participant, and unviable to conceal the allocation from the researcher collecting the data. Despite these limitations, a meta-analysis of outcomes has demonstrated no short- or long-term adverse effects of early skin-to-skin contact (Moore et al., 2016), conferring its safety for healthy babies.

Aside from early skin-to-skin contact with healthy babies, the research field is dominated by studies examining the effects of kangaroo mother care (KMC) on low birth weight babies. Conceptualised in Colombia in the 1980s, KMC was developed in response to a lack of incubators in resource-limited settings, and high rates of neonatal infections and maternal abandonment (Rey and Martinez, 1983). Meta-analyses have found that the care package has resulted in considerable reductions in neonatal infectious morbidity (RR 0.35, 95% CI 0.22 to 0.54), mortality (RR 0.60, 95% CI 0.39 to 0.92), and rates of neonatal hypothermia (RR 0.28, 95% CI 0.16-0.49) in comparison to incubator or cot care (Conde-Agudelo and Díaz-Rossello, 2014). A statistically significant increase in rates of partial and exclusive breastfeeding at discharge from hospital care, and at 1-3 months for babies

receiving kangaroo mother care has also been demonstrated (Conde-Agudelo and Díaz-Rossello, 2014).

Although meta-analyses suggest that KMC is efficacious in reducing morbidity and mortality, in a systematic review of 299 studies, Chan et al. (2016) identified significant heterogeneity in the definition of kangaroo mother care. Half of these studies included SSC as the only component of kangaroo mother care (Chan et al., 2016). Variations were reported in the timing of initiation, definition of neonatal stability before KMC, duration of SSC, equipment and supplies, discharge criteria, follow-up, and neonatal positioning, and clothing (Chan et al., 2016). A lack of standardisation and operationalisation has the potential to reduce the accuracy of estimated effect sizes and is a notable limitation of the research field. Despite this limitation, both national and international guidelines have been developed to implement Kangaroo Mother Care for premature and low birth weight babies across the world (Joint Neonatal Guidelines Group, 2019; Maternal and Child Health Integrated Programme, 2012; Newborn Services Clinical Practice Committee, 2015; World Health Organisation, 2003b). However, the success of Kangaroo Mother Care implementation has been highly variable (Cattaneo et al., 2018).

An international workshop on Kangaroo Mother Care reported that experiential, resource-related, and socio-cultural barriers exist which make it difficult for parents to practice KMC. These parent-perceived barriers are in addition to health worker and health systems barriers (Cattaneo et al., 2018). Experiential barriers for parents tended to be physical or psychological, including pain and fatigue during kangaroo mother care, difficulty maintaining the kangaroo care position, and fear of hurting the infant (Cattaneo et al., 2018). Resource-related barriers primarily related to low-resource settings, and included lack of rooming-in facilities, and difficulty accessing healthcare facilities.

However, Cattaneo et al. (2018) also identified a lack of knowledge of kangaroo mother care as a parent-perceived barrier to kangaroo mother care, which related to both high and low resource settings. Socio-cultural barriers affected implementation to a lesser extent, but concerns regarding gendered parenting roles prohibited fathers from participating in kangaroo mother care (Cattaneo et al., 2018). Key enablers were also identified, which included social support for parents, senior support for health workers, and the allocation of space, staff, and equipment from hospital directors (Cattaneo et al., 2018).

These findings suggest that further research is required to explore how ongoing skin-to-skin contact can be encouraged and facilitated, in response to the identified barriers and enablers (Cattaneo et al., 2018).

Between the areas of early skin-to-skin contact for healthy babies, and ongoing SSC as part of kangaroo mother care for low birth weight babies, the research field has yet to consider the potential impact of ongoing skin-to-skin contact for healthy, term babies. It is plausible that ongoing skin-to-skin contact confers the same benefits to breastfeeding rates as it appears to for low birth weight babies. Similarly, the thermoregulatory effects of KMC may also be replicated in a population of term babies. However, there is a considerable paucity of literature which explores the value of ongoing skin-to-skin contact for healthy babies, despite the high rates of early breastfeeding cessation (McAndrew et al., 2012), and the recommendation for ongoing skin-to-skin contact in national infant feeding support standards (UNICEF UK, 2017).

A second gap in the field is also recognised: a considerable lack of research addressing the parent-perceived barriers to maintaining a safe neonatal position whilst in skin-to-skin contact (Cattaneo et al., 2018); and confounding variation in neonatal positioning and clothing (Chan et al., 2016). A few studies have explored the use of garments to facilitate skin-to-skin contact, including during early skin-to-skin contact for term babies (de Alberquerque et al., 2016), for ongoing skin-to-skin contact for low birth weight babies following discharge home (Thapa et al., 2018), and for premature or vulnerable babies whilst in hospital (Gregson and Blacker, 2011). These studies are critiqued in depth in the following chapter. However, the cited studies fail to consider the use of baby-wearing to facilitate safe and ongoing skin-to-skin contact for healthy, term babies in the home environment.

In response to this gap in the literature, two concepts are bridged: ongoing skin-to-skin contact and baby-wearing. Baby-wearing refers to the practice of carrying a baby in a soft carrier close to the body (Blois, 2005). Although the practice of baby-wearing has been popularised by advocates of attachment parenting (Sears and Sears, 2014), baby-wearing predates modern parenting trends. Blaffer-Hrdy (2000) suggests that baby-wearing was a result of a technological leap approximately 50,000 years ago which enabled mothers to carry food as well as their babies, resulting in a new division of labour, better maternal nutrition, and reduced birth intervals resulting in an expanding and migrating population.

Despite its long history, the research field of baby-wearing remains small and underdeveloped. Methodological weaknesses of the research field include a poorly defined scope; key terms are frequently conflated, including skin-to-skin contact, kangaroo mother care, clothed baby-wearing, attachment parenting practices, and therapeutic touch. Secondly, studies of baby-wearing explore wide-ranging outcomes such as breastfeeding duration (Pisacane et al., 2012) and attachment security (Anisfeld et al., 1990). Without aligned research outcomes within the field, the actual effect on the study outcomes has not been rigorously explored. The emerging work of Miller (2018) has begun to explore the use of baby-wearing as a means to maintain close and safe neonatal positioning against the mother as an extension of kangaroo mother care. However, Miller's (2018) research on baby-wearing has not incorporated the concept of skin-to-skin contact and maintains a focus on low birth weight babies.

This research study addresses the weaknesses identified in the baby-wearing field by aligning the research outcomes with previous baby-wearing research (Pisacane et al., 2012). This research study also bridges the fields of KMC for low birth weight babies and early SSC for healthy babies to explore the impact of ongoing skin-to-skin contact for healthy babies in recognition of the theorised transferable benefits. The concept of baby-wearing is included as a response to the experiential barriers cited by Cattaneo et al. (2018), as it offers a means to facilitate sustainable, ongoing skin-to-skin contact. This study expands the small research field of garments to facilitate skin-to-skin contact in order to serve a population of healthy, term babies.

Overview of study aims and hypotheses

Based on previously cited research, and the identified gaps between the research fields, the following research questions are addressed. The research questions were used to develop a holistic assessment of the use of the Snuby to facilitate baby-wearing in skin-to-skin contact for healthy babies and their mothers:

- How is a skin-to-skin facilitating garment used by mothers and their babies in the postnatal period?

- Does a skin-to-skin contact facilitating garment maintain normal neonatal axillary temperatures as well as conventionally facilitated skin-to-skin contact?
- Does the provision of a skin-to-skin contact facilitating garment affect the uptake, continuation, or exclusivity of breastfeeding practices?
- What are the experiences of mothers partaking in skin-to-skin contact in the postnatal period?
- What is the meaning of the phenomenon of ongoing skin-to-skin contact to mothers of healthy babies?
- How does the experience of ongoing skin-to-skin contact between the mother-infant dyad explain skin-to-skin contact and infant feeding practices recorded in the postnatal period?

It was hypothesised that:

- The provision of the Snuby garment would increase rates of breastfeeding at six weeks postnatal.
- The provision of the Snuby garment would increase the frequency of skin-to-skin contact over the postnatal period.
- The Snuby garment would be as efficacious at maintaining neonatal normothermia as conventionally facilitated skin-to-skin contact using a blanket or covering.

The key variables and outcome measures were defined before commencing the study. To respond to the research questions, breastfeeding data were collected weekly until six weeks postnatal. At six weeks postnatal, breastfeeding status was recorded as total, partial, or none. Neonatal temperature was recorded before and during SSC by mothers using the Snuby and mothers engaging in conventionally facilitated skin-to-skin contact. Neonatal normothermia was defined as 36.5-37.5°C in line with WHO (2003b) and local Trust guidelines. Mothers recorded the frequency of SSC episodes throughout the six week study period.

Overview of study methodology and design

A multiphase mixed methods design was employed. This three-phase design included a feasibility study (n=11), a randomised controlled trial (n=98), and a qualitative aspect using interviews (n=44). A mixed methods approach gathered quantitative data pertaining to the

garment's safety and efficacy and qualitative data pertaining to relational bonding and experience. A pragmatist approach was taken as it supports the integration of quantitative and qualitative methods in response to the research questions. A theoretical framework of salutogenesis shaped the design and conduct of the research study, providing a theoretical underpinning of health promotion in line with the focus on the health-promoting behaviours of breastfeeding and skin-to-skin contact.

For the feasibility study, 11 mother-infant dyads trialled the Snuby garment during direct researcher observation. Mothers used the specially-designed study documentation to record the baby's temperature and behaviour before and after the skin-to-skin contact episode. The researcher completed a checklist to identify any issues with the use of the Snuby, thermometer, or the accompanying documentation. The findings of the feasibility study were presented using descriptive analyses.

For the randomised controlled trial, 98 mother-infant dyads were randomised to equally weighted intervention and control groups. All participating dyads received standard postnatal and neonatal care; the intervention group also received a Snuby garment. Data were collected on infant feeding and skin-to-skin contact practices weekly throughout the six week postnatal period to compare the engagement in health-promoting behaviours. Descriptive and inferential statistical analyses were used to present the quantitative findings of the RCT.

Finally, 44 mothers were interviewed following their completion of the randomised controlled trial. The semi-structured interviews were analysed using the Framework method, which enabled the generation of themes in line with the research questions. The data from each study phase were integrated following analysis in response to the research aims.

Overview of study findings

Collectively, the three study phases demonstrated that the Snuby was safe for mothers and their babies to use without professional supervision. There were no serious adverse incidences of neonatal slips or falls in the Snuby, or with conventional facilitation with a blanket or covering; no safety issues were identified in interviews with participants. There was no significant difference in incidences of neonatal hypothermia or neonatal hyperthermia in SSC when comparing Snuby facilitated skin-to-skin contact with

conventionally facilitated skin-to-skin contact, which provides evidence in support of the hypothesis that the garment would be as efficacious as conventional facilitation at promoting neonatal normothermia.

The following predictor variables were identified for inclusion in inferential analyses relating to skin-to-skin contact engagement: maternal age, body mass index, parity, and ethnicity. Descriptive analysis showed that a higher percentage of participants in the intervention group engaged in one or more episodes of SSC than those in the control group (87% vs 74%). However, this difference was not statistically significant either when unadjusted or adjusted for the predictor variables. Regarding the frequency of engagement in skin-to-skin contact, the descriptive analysis showed that the group with the Snuby garment had on average two more episodes of skin-to-skin contact than those without the garment (twelve vs ten episodes). Inferential analysis using negative binomial regression testing found no statistically significant difference in the frequency of skin-to-skin contact episodes between the intervention and control group when unadjusted or adjusted for the predictor variables. However, the exploratory stepwise analysis suggested that the frequency of SSC episodes was negatively correlated with Black, Asian, or minority ethnic (BAME) identity.

Binary logistic regression testing was used to test the hypotheses that the provision of the Snuby would increase exclusive and partial breastfeeding at six weeks postnatal. Provision of the Snuby garment did not significantly affect rates of partial (feeding of any breastmilk), exclusive breastmilk feeding (feeding of only breastmilk), or exclusive breastfeeding (exclusively from the breast). Breastfeeding initiation was similar between the intervention and control groups (90.4% vs 91.1%), but increasing maternal age and identifying as Black, Asian or from an ethnic minority (BAME) were significantly correlated with breastfeeding initiation. Increasing age and BAME identity also explained breastfeeding continuation. Women from an ethnic minority appeared to be over six times more likely to still be breastmilk feeding at six weeks postnatal, compared to white women (OR: 6.87, 95% CI 2.22-21.22). With each increasing year of maternal age, the odds of continuing to breastmilk feed at six weeks postnatal increased by 16%. Binary logistic regression testing found that neither the provision of the Snuby garment nor the predictor variables significantly explained rates of exclusive breastmilk feeding or exclusive breastfeeding.

In light of the comparative rates of breastfeeding and skin-to-skin contact between the intervention and control groups, in-depth qualitative data collection sought to explain dyadic engagement in health-promoting behaviours in the postnatal period. Extracting the core tenets from Antonovsky's (1979, 1987) theory of salutogenesis, thematic findings were produced on the barriers, resources, and motivators which informed women's engagement in breastfeeding and skin-to-skin contact as health-promoting behaviours. The usage, acceptability, and value of the Snuby were explored in relation to its impact on breastfeeding, skin-to-skin contact, and the development of the maternal-infant bond.

Theme one collated the barriers and enablers to both engagement in breastfeeding and in skin-to-skin contact, which were conceptualised as resource continuums. Women's position on the resource continuums explained their engagement in health-promoting behaviours. Resource continuums included cognitive, social, and psychological resources. These continuums were 'knowledge and understanding', 'professional support and referrals', 'problem-solving and seeking help', 'social support and role modelling', and 'agency and autonomy'.

Theme two identified the motivators for women's engagement in skin-to-skin contact and breastfeeding; social motivating factors fed into cognitive and experiential motivating factors. The primary motivating factors were 'beliefs, attitudes, and conceptualisations', 'reciprocity, attachment, and bonding', and 'social acceptability and expectation'.

Theme three addressed the Snuby garment specifically, and identified five subthemes that explained the role and value of the garment to participants: 'security and mobility', 'dyadic bonding and reciprocity', 'preservation of modesty and bodily exposure', 'prompting and validating quiet time', and 'facilitating breastfeeding and lactation'.

Collectively, these findings explained why the provision of the garment did not significantly change rates of breastfeeding and skin-to-skin contact. The provision of the Snuby did not comprehensively address issues which affected breastfeeding continuation, including a working understanding of how breastfeeding is established and maintained, and the social support required to continue with breastfeeding. Concerns about bodily exposure and modesty were not comprehensively mitigated with the provision of the Snuby garment when living in extended family units. When coupled with a lack of privacy and competing

social demands at home, women's abilities to engage in skin-to-skin contact and breastfeeding at home were diminished.

The process of bonding was identified as both a motivator and an outcome of using the Snuby garment. Using the garment invoked reciprocal dyadic communication, whereby mothers were able to interpret and respond to their baby's behaviour. Unexpectedly, the garment was found to be particularly valuable for mother-infant dyads experiencing breastfeeding-related difficulties. Although the garment did not rectify the barriers previously mentioned, it was used as a means of safeguarding the integrity of the mother-infant relationship in times of breastfeeding-associated stress or cessation.

These findings make several contributions to the research fields.

Firstly, the study conceptualises a new paradigm of skin-to-skin contact: continued and responsive skin-to-skin contact. This reconceptualisation has implications for the focus of midwife-led research on the subject of skin-to-skin contact and underpins the research field with a coherent theoretical framework of health promotion. Secondly, this study is the first to produce comparative findings on the safety of ongoing skin-to-skin contact facilitation methods, demonstrating that the use of a Snuby garment promotes neonatal thermoregulation as well as conventional facilitation.

This study also identified unanticipated and novel effects of baby-wearing in skin-to-skin contact for healthy babies and their mothers. Skin-to-skin contact in the Snuby garment facilitated the development of dyadic reciprocal communication, including the identification and interpretation of the infant's needs for closeness and love, and providing an environment which responded to the infant's needs. Additionally, the findings of this study contribute to a new interpretation of the relationship between skin-to-skin contact and breastfeeding. Before this research study, skin-to-skin contact was positioned as a breastfeeding aid to facilitate positioning, attachment, or lactation. This study identifies a new relationship between skin-to-skin contact and breastfeeding, whereby skin-to-skin contact is used to preserve, repair, and safeguard the mother-infant relationship usually developed through breastfeeding in the face of breastfeeding-associated problems.

Thesis structure

This thesis contains nine chapters:

Chapter 2 presents a review of the literature. A narrative style of review precedes an integrative literature review which uses systematic approaches to identify and critically appraise published research. The chapter investigates the effects of ongoing skin-to-skin contact on breastfeeding, bonding, and thermoregulation for healthy, term infants. The review quantifies and appraises the relevant literature, providing a summary of findings pertinent to the research areas of interest. It demonstrates the paucity of research on mother-infant skin-to-skin contact beyond the first hour, with particular reference to skin-to-skin contact facilitation garments.

Chapter 3 describes the research methodology. The research questions, aims, and objectives are described for the feasibility and main study. The chapter provides a rationale for the use of a mixed methods design with reference to the epistemological and ontological foundations of the study. The theoretical framework of salutogenesis is explored and critiqued, and its relevance and application to the research study is demonstrated.

Chapter 4 details the methods used in the feasibility and main study. The study setting, eligibility criteria, and outcome measures are reported, and the study procedure is described chronologically. The ethical considerations are explored with reference to both the participants and the researcher, including the concept of informed consent, research participation, and researcher practices.

Chapter 5 details the rationale and process of data analysis for the quantitative aspect of the study. The chapter is structured into three parts to respond to the three relevant research questions on the effect of the Snuby on breastfeeding rates, skin-to-skin contact frequency, and neonatal temperature stability. The results of the quantitative data analysis are presented.

Chapter 6 describes the process of qualitative data analysis using the framework method. The choice of analysis method is rationalised with reference to its epistemological and methodological congruence with the research design. The theoretical framework is

applied to the analysis process to situate the data. The process of familiarisation, indexing, charting, mapping, interpreting, and thematic refinement is detailed. The findings from the qualitative analysis are presented in three themes.

Chapter 7 explores the processes of reflection and reflexivity. A reflective cycle is used to structure a personal reflection about the research process, critically evaluating the strengths and weaknesses of the research study. The importance of researcher reflexivity is discussed, and positionality is explored from a personal and professional perspective.

Chapter 8 discusses the qualitative and quantitative findings in the context of the research field and the researcher's processes of reflection and reflexivity. The qualitative and quantitative findings are integrated in response to the research aims. A summary of findings for each research aim is produced, highlighting the contribution of the research to the research field.

Chapter 9 summarises the research study, reviewing the aims and objectives of the study and the contribution of the data in response to them. The findings of the study are reviewed with reference to their implications for healthcare policy and practice. The theoretical and empirical contributions to knowledge are summarised, and recommendations are made for further research.

A list of references and appendices are situated at the end of the thesis.

2. Literature review

Introduction

Firstly, this chapter explores the background and context of the study by reviewing the literature on skin-to-skin contact and its impact on breastfeeding, bonding, and thermoregulation. Next, a focussed integrative review using systematic methods is presented, in response to the research questions. The methodology used in the integrative review is described, and the findings of the review are presented. Finally, the contribution of the review is discussed, and the Snuby garment is situated within the research field.

Review of the background and context of the study

The following section reviews the literature which informed the conception of the research study. A brief narrative review of the literature is provided to illustrate the background and context of the study, building upon the key concepts introduced in Chapter One. The interwoven mechanisms and effects of skin-to-skin contact, breastfeeding, bonding, and neonatal thermoregulation are explored.

The concepts of skin-to-skin contact and maintaining close mother-infant proximity are underpinned by Anderson's (1977) model of Mutual Caregiving. The model identified that the ecological niche required for newborn infants to self-regulate and develop is skin-to-skin on the maternal chest. Many studies have since supported the theory that skin-to-skin contact supports neonatal self-regulation. Most notably, randomised controlled trials examining the effects of skin-to-skin contact on healthy babies have found significant positive effects on the regulation of blood glucose concentration (Christensson et al. 1992), behavioural states (Christensson et al. 1992; Hofer 2005; Ferber and Makhoul 2004), and temperature (Bystrova et al. 2003; Christensson et al. 1992) when compared to cot care.

Babies have a reduced ability to regulate their temperature due to their physiology; they lack subcutaneous fat and have a high surface area: volume ratio, which increases heat loss (Bailey and Rose, 2001). The World Health Organisation (1997) recommends a set of ten interlinked procedures, known as the warm chain, to reduce the incidence of hypothermia and hyperthermia. The warm chain features skin-to-skin contact commenced immediately

post-birth and includes further use of skin-to-skin contact if the environment is cool, or the baby requires rewarming from mild hypothermia (World Health Organisation and Maternal and Newborn Health, 1997). Several physiological mechanisms have been postulated to explain how the skin temperature of the mother's breasts modulates in response to the baby's skin temperature, but the exact mechanism remains unclear (Ludington-Hoe et al., 2006). Case study research by Ludington-Hoe et al. (2006) on twins receiving concurrent skin-to-skin contact suggests that maternal breasts work independently of each other, but do not work independently of the baby. Ludington-Hoe et al. (2006) reported highly significant correlation coefficients between the temperature of the baby and the breast; the breast temperature increased until the baby's temperature reached 36.9°C or higher, then quickly cooled to avoid hyperthermia.

Despite evidence that skin-to-skin contact supports normal physiological development and regulation, research on babies is unique in generally conceptualising close and uninterrupted contact, rather than maternal-infant separation, as the research intervention (Moore et al., 2016). The concept of the ecological niche is not unique to humans; in mammalian research using rat pups, Alberts (1994) identified the significance of habitat on infant learning. Alberts (1994) found that the learning of newborn behaviours required to survive ex-utero was habitat dependent; if the rat pups were removed from the evolutionary habitat of the mother's body, the rat pups did not exhibit the behaviours needed to instigate suckling and thus survive. Alberts (1994) concluded that exposure to evolutionarily unexpected contexts, such as via mother-infant separation, may inadvertently create pathology.

Exploring the effects of maintaining close and uninterrupted contact after birth, Widstrom et al. (2011) isolated and defined nine neonatal behaviours exhibited after birth when the human infant was maintained in the evolutionarily expected environment of the maternal chest (Figure 2.1). Congruent with the theories of Alberts (1994) and Anderson (1977), infants who exhibited these nine behaviours soon after birth during skin-to-skin contact were primed to establish a reciprocal feeding pattern with their mothers, and optimal self-regulation (Widstrom et al., 2011; Moore et al., 2016).

Figure 2.1 Adapted from Widstrom et al. (2011) Neonatal Behaviours

Although the behaviours cited by Widstrom et al. (2011) were identified from a small sample of babies (n=28), the positive effects of early skin-to-skin contact have been rigorously investigated, and subjected to meta-analyses. In their systematic review, Moore et al. (2016) found that early skin-to-skin contact significantly increased rates of a first successful breastfeed, and continued breastfeeding at one to four months. Collectively, these findings are in support of the positive effects of maternal skin-to-skin contact on the establishment and continuation of breastfeeding. However, the potential role of the mother in breastfeeding establishment and continuation is not explored.

Colson's (2008) observations of the behaviours of breastfeeding mother-infant dyads identified that a semi-recumbent position which maintained the infant against the mother's body elicited both maternal instinctive behaviours and primitive neonatal reflexes which were responsible for successful breastfeeding. Although Alberts (1994) theory of infant learning is apparently in contradiction of Colson's (2008) theory of innate, not learnt, breastfeeding behaviours, the findings of the studies are consistent. The ability of the mother-infant dyad to establish breastfeeding is supported by close mother-infant contact; the infant maintained in the habitat of the maternal chest is enabled to exhibit the neurobehaviours associated with successful feeding, which are supported by maternal instinctual behaviours.

Mother-infant skin-to-skin contact is a physiological stimulant of endogenous oxytocin (Cong et al., 2015). Maternal nurturing behaviours are elicited by endogenous oxytocin (Ross and Young, 2009; Galbally et al., 2011), the neuropeptide associated with birth, lactation, and mother-infant bonding (Galbally et al., 2011; Lee et al., 2009; Lim and Young, 2006). However, the concept of bonding remains poorly defined, and difficult to quantify; surrogate outcomes include maternal-infant interactive behaviours, maternal self-report, maternal sensitivity, and attachment behaviours in the infant (Galbally et al. 2011). Tessier et al. (1998,

17) hypothesised 'the bonding effect': that skin-to-skin contact, as part of KMC, invoked a bonding effect for mothers of preterm babies. Although KMC elicited the parenting skills needed to foster the infant's development, Tessier et al. (1998, 17) concluded that KMC resulted in a 'resilience effect', whereby mothers remained responsive to the needs of a preterm baby requiring hospital care, rather than a definitive bonding effect. These findings lack transferability to a population of healthy infants cared for at home, as the resilience effect is based upon the stress of caring for an at-risk infant in hospital. Additionally, as skin-to-skin contact is investigated as part of the KMC package, the resilience effect may have been elicited through an increase in mother-infant contact rather than the specific mechanism of skin-to-skin contact.

Examining the specific effects of oxytocin on bonding, Galbally et al. (2011) identified unique methodologies, populations, and outcome measures in the studies included in a systematic review of oxytocin and mother-infant relations. Although there was considerable heterogeneity in the study methodology, seven of the eight included studies found significant and strong associations between oxytocin and various measures of mother-infant relations. Vittner et al. (2017) corroborated the theorised mechanism between episodes of skin-to-skin contact, oxytocin release, and parental responsiveness; parental salivary oxytocin levels increased significantly during skin-to-skin contact with their premature infant and were associated with increased parental synchrony and responsiveness in their interactions with their babies.

The specific effects of skin-to-skin contact on the process of bonding with healthy babies remain contentious. Early studies by Château and Wiberg (1977) found that early skin-to-skin contact resulted in a significant increase in positive maternal interactions such as looking at the infant's face and kissing, and infant smiling and laughing. However, the quality of the findings is limited by a small sample size (n=40) and short observation periods (10 minutes). Eyer (1992) and Redshaw and Martin (2013) suggest that the relationship between early skin-to-skin contact and bonding is poorly substantiated by evidence, and its implementation in maternity care was used to bridge the gap between medicalised hospital care and the ideologies of the natural childbirth movement, rather than based on its efficacy. However, their assertion is in contrast to studies using a qualitative methodology to explore the effects of skin-to-skin contact. Mothers have experienced immediate and visceral feelings

of bonding associated with skin-to-skin contact following birth (Finigan and Davies 2004). A paucity of quantitative evidence on the effects of skin-to-skin contact on bonding is not a rationale for implementing maternal-infant separation, based upon the theory that the habitat of the maternal chest is the physiological norm for newborn infants.

Summarising the importance of close and constant mother-infant contact for neonatal physiological regulation and feeding, Bergman (2000; 2014) presents the case for zero separation of mother and infant, arguing that nature, nurture, and niche – the environment – are all fundamental to neonatal development. Given the significance of close contact between mothers and their babies for breastfeeding, bonding, and physiological regulation, an integrative review was conducted to examine the specific effects of ongoing skin-to-skin contact for healthy babies and their mothers.

Integrative review: rationale and approach

The rationale for the integrative review was twofold: firstly, to identify and critique research which is specific to the population and intervention of interest, and secondly to explore the position of the phenomenon of mother-infant skin-to-skin contact across disciplines and methodologies. Scoping the research field through reviewing the literature is fundamental to gaining a comprehensive understanding of the phenomenon of interest (Booth et al., 2016) before conducting primary research. An integrative review of a topic facilitates the review and critique of extant literature like many forms of review, yet also allows the research topic to be reconceptualised (Torraco, 2005).

The notion of reconceptualisation is particularly pertinent to the area of mother-infant skin-to-skin contact, where research spans the fields of medicine, social sciences, and psychology, as illustrated in the review. Integrative reviews have been effectively used to summarise research evidence from a diverse range of research fields and methodologies, on paternal-infant skin-to-skin contact (Shorey et al., 2016), breastfeeding interventions (Cartwright et al., 2017), and Kangaroo Care for preterm infants (Evereklian and Posmontier, 2017). The integrative review facilitates the inclusion of primary studies with diverse methodologies, often including qualitative and quantitative research (Whittemore and Knafl, 2005), and as such, lends itself to the pragmatist approach of focussing on addressing the research questions.

Integrative reviews still require a systematic and rigorous approach (Booth et al., 2016). Whittemore and Knafl's (2005) modified framework has been used to inform the conduct of the review and to structure the chapter into the following sections: problem identification, literature searching, data evaluation, data analysis, and presentation. Use of reporting guidelines, such as PRISMA, aims to improve the reporting of systematic reviews to increase the clarity and transparency of the review method (Moher et al., 2015) and has been used as an adjunct guide to inform the review of applicable quantitative studies. Critical appraisal tools from the Joanna Briggs Institute (2017a; 2017b; 2017c) have been used to provide a rigorous and reproducible method of critical appraisal.

Problem identification

This review focusses specifically on *ongoing* skin-to-skin contact, as opposed to initial or immediate skin-to-skin contact. Such a distinction is made to reflect the different physiological processes taking place immediately following birth: of neonatal neuro-programming, the first breastfeed, and the adaption to extra-uterine life. For ongoing skin-to-skin contact, the physiological processes may occur over a longer period of time, such as the maintenance of lactation and breastfeeding and the stabilisation of neonatal temperature. Immediate skin-to-skin contact dominates the research field for healthy, term babies with little reference to ongoing skin-to-skin contact, despite both immediate and ongoing skin-to-skin contact featuring in healthcare policy and standards. The rationale for reviewing the literature on ongoing skin-to-skin contact with healthy, term babies is to appraise whether similar benefits have been found for healthy, term infants as those reported in a population of premature or low birth weight infants receiving kangaroo mother care. Further details of terms and inclusion criteria can be found later in the chapter.

Creating research questions

A systematic search and review is integral to a well-conducted integrative review and is preceded by a well-focussed research question or questions (Booth et al., 2016). Four specific research questions were identified during the development of the research proposal and were used to shape the focus of the review and identify the areas of interest. The four research questions were:

In healthy, term babies…

1. What effect does ongoing skin-to-skin contact have on breastfeeding initiation, continuation, and exclusivity?
2. What effect does ongoing skin-to-skin contact have on mother-infant relational bonding?
3. What effect does ongoing skin-to-skin contact have on neonatal thermoregulation?
4. What methods of skin-to-skin contact facilitation have been used?

Review objectives

The development of objectives before conducting the review helps to shape the process of the review and avoids scope creep when the aims and direction of the review expand and change over time (Saunders, 2009). The objectives of the review were to:

- Evaluate the quantity and quality of research on ongoing skin-to-skin contact specific to a population of healthy, term mother-infant dyads.
- Evaluate the use of garments or devices to facilitate mother-infant skin-to-skin contact.
- Summarise research evidence on the outcomes of neonatal thermoregulation, breastfeeding, and relational bonding in relation to mother-infant skin-to-skin contact specific to a population of healthy, term mother-infant dyads.
- Assess the contribution of various research disciplines and fields to the phenomenon of mother-infant skin-to-skin contact.

Scoping exercise

Scoping is an exploratory process to assess the likely quantity and quality of the literature, identify search terms, synonyms, and relevant sources of information (Booth et al., 2016). This process is used to define and refine the variables of interest, including the healthcare issue, and the target population (Whittemore and Knafl, 2005). Scoping exercises adopt a less exhaustive approach than a full review, as they provide a preliminary assessment of the scope of the field of research (Booth et al., 2016). A scoping exercise was performed to

collate search terms and synonyms (Table 2.1). Booth et al. (2016) recommend the use of one or two databases for familiarisation with the topic and the volume of literature. CINAHL database was used for the scoping exercise, without filters or restrictions, and produced 676 results. A search strategy was developed to provide a systematic, explicit method of refining the large body of literature.

Table 2.1 Search terms and generated synonyms

Number assigned to search term	Original search term	Synonyms
1.	Skin-to-skin contact	Kangaroo mother care, Kangaroo care, skin-to-skin contact, STS, SSC, S2S
2.	Breastfeeding	Breast feeding
3.	Bonding	parent-infant bonding mother-infant relations mother infant bonding parent infant attachment
4.	Neonatal temperature	newborn temperature rectal body temperature axillary body temperature thermoregulation
5.	Garment	Device, wrap, innovation, binder, top

Literature search

Search strategy

Well-defined literature search strategies are crucial in conducting rigorous reviews, as incomplete or biased searches result in erroneous results and an inaccurate conclusion (Whittemore and Knafl, 2005). Many frameworks have been developed to define the scope of a review (Booth, 2004; Cooke et al., 2012; Denyer and Tranfield, 2009; Pettricrew and Roberts, 2006) and have been utilised depending upon the type of research question that the review seeks to address (Booth et al., 2016). Following the development of search terms, the PICOS acronym (population, intervention, control, outcome, study design) (O'Connor et al., 2008) was used to define the scope of the review, as it is well suited to refining the scope of reviews which predominantly feature experimental research (Table 2.2). The use of the PICOS acronym is recommended when conducting a systematic review of interventional research (Moher et al., 2015; O'Connor et al., 2008) in order to collate and exclude studies based upon

specific criteria. Although this does not directly apply to non-interventional studies featured in an integrative review, the PICOS framework best lent itself to the development of criteria which refined the population and outcome of studies on skin-to-skin contact.

Backwards and forwards chaining was used to identify pertinent publications related to those already identified. ResearchGate profiles of authors of pertinent studies were also explored to identify other publications within the same field. Publications which were not written or available in English were excluded due to a lack of reliable translation resources. The publication date range was set from the year 2000 to the present date to collate the most contemporary literature. Grey literature is information produced, which is not controlled by commercial publishing (Greynet, 1999). As such, it is typically challenging to identify and obtain (Booth et al., 2016). However, searching for grey literature reduces the risk of publication bias, demonstrated in the work of McAuley et al. (2000), who found that studies excluding grey literature reported significantly larger effect sizes than those including grey literature. Upon this rationale, literature was sought in ongoing clinical trial registers, conference proceedings, and EThOS theses database, in addition to health science databases. Searches were performed in CINAHL, Medline, MIDIRS Maternity and Infant Care, PubMed, PsychInfo, Cochrane Library, ScienceDirect, and TRIP, and repeated throughout the duration of the study to identify recently published literature. Conventional search engines were also used to identify commercially marketed devices or garments for skin-to-skin contact, and links to any supporting research were sought from the websites.

Table 2.2 PICOS criteria

P: Population	Included: mother-infant dyads – healthy, term Excluded: premature, low birth weight, receiving care on a NICU
I: Intervention	Included: Kangaroo care, Ongoing skin-to-skin contact past the first hour of birth Use of a facilitating device or garment for skin-to-skin contact * Excluded: immediate skin-to-skin contact only, early skin-to-skin contact only (the first episode of skin-to-skin contact post-birth, usually commenced in the first hour)
C: Comparisons	If applicable: conventional care, cot care
O: Outcomes	Neonatal thermoregulation OR Breastfeeding continuation and exclusivity OR Mother-infant relational bonding OR Experience OR Acceptability
S: Study design	Primary research only Quantitative or qualitative

*Given the lack of research on facilitation methods of skin-to-skin contact, any study trialling a novel method of skin to skin facilitation was included, irrespective of the study's population.

Search results

The literature search produced 1938 results which broadly covered kangaroo care or skin-to-skin contact, and featured one or more of the outcomes. By using multiple databases, many results were duplicates. Two methods of refinement were used simultaneously: duplicates were removed, and the publication titles were screened using the PICOS criteria (Table 2.2). The primary reason for not meeting PICOS criteria when screening both the publication titles and the abstract contents was the study population; the vast majority of studies pertained to

low birth weight or premature infants. The remaining references that appeared to meet PICOS criteria following title screening were filed into an electronic folder, and citations were exported and filed using Endnote software (Version X8.2). The abstracts of the remaining references were screened next, following the PICOS criteria. Finally, the full-text articles of the remaining publications were reviewed for inclusion. Of these publications, thirteen met the review criteria, and were therefore included. A flowchart detailing the screening and review process was created to demonstrate transparency when selecting the literature, including the primary reasons for exclusion of studies (Figure 2.2). The characteristics of the included studies are detailed in Table 2.3, with a full reference list of included studies in the appendix (appendix A).

Although they did not meet the PICOS review criteria, expert opinion, commentary pieces, and seminal texts on the development and evolution of kangaroo mother care and skin-to-skin contact were collated to inform the development of the introduction chapter and the narrative review. The rationale for this approach was to build context and situate the study focus more broadly within the wider research field, followed by a focussed integrative review which addressed the specific population and intervention of interest.

Figure 2.2: literature screening flowchart

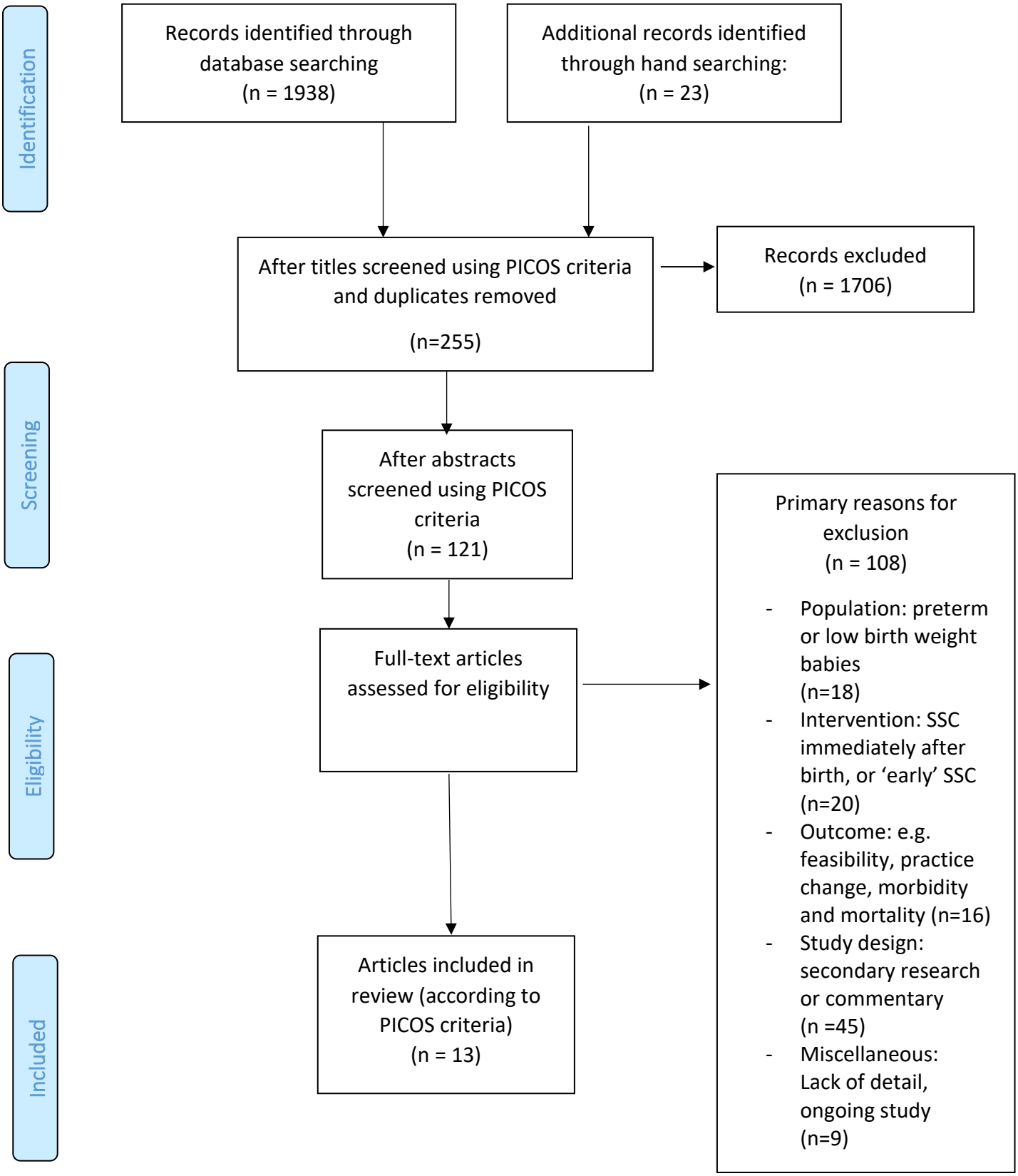


Table 2.3 Characteristics of included studies

Studies regarding mother-infant interaction and bonding					
Study	Citation	Location	Design	n=	Outcomes
A	Dalbye, R. et al. (2011)	Sweden and Norway	Qualitative lifeworld phenomenology	20	Mother-infant interaction and bonding: maternal experience of ongoing SSC
B	Bigelow, A. E. and Power, M. (2012)	Canada	Quasi-randomised longitudinal trial: high vs low SSC	80	Infant-mother interaction: response to Still Face Task at 1 week, and 1, 2, and 3 months of age.
C	Owusu-Ansah, F., et al. (2019)	Ghana (+ archival data from Canada)	Retrospective comparison design: high vs low SSC	26	Infant-mother interaction: response to Still Face Task at six weeks postnatal
Studies regarding breastfeeding					
Study	Citation	Location	Design	n=	Outcomes
D	Ruxer, D. J., et al. (2013)	USA	Descriptive correlational study: SSC duration and breastfeeding	35	Breastfeeding: exclusive breastfeeding at 4 and 8 weeks postnatal.
E	Svensson, K. E., et al. (2013)	Sweden	Randomised controlled trial: breastfeeding support +/- SSC	103	Breastfeeding: proportion achieving regular latching, time to establish regular latching, breastfeeding at 4 months

F	Bigelow, A. E., et al. (2014)	Canada	Quasi-randomised longitudinal trial: high vs low SSC	77	Breastfeeding: exclusive and partial breastfeeding at 1 week, and 1, 2, and 3 months of age.
G	Horst, J. (2017)	USA	Case study: retrospective comparison design	75	Breastfeeding: rates of exclusive breastfeeding at discharge
Studies regarding neonatal temperature					
Study	Citation	Location	Design	n=	Outcomes
H	Chiu, S.-H. et al. (2005)	USA	One group pretest-test-posttest, repeated over 4 breastfeeding support interventions	48	Neonatal temporal artery temperature: before, during, and following breastfeeding attempt in SSC
I	Ramani, M. et al. (2018)	Zambia	Randomised controlled trial: KMC vs standard care	203/ 165	Neonatal temperature: incidence of moderate or severe hypothermia at 1 hour postnatal, and discharge
Studies regarding facilitation devices or garments					
Study	Citation	Location	Design	n=	Outcomes
J	de Albuquerque, R. S., et al. (2016)	Brazil	Case-control study: SSC in facilitating garment vs radiant heater care	60	Neonatal axillary temperature: at 5, 10, and 30 minutes postnatal
K	Amaliya, S., et al. (2017)	Indonesia	Pilot study using crossover design: comparing 3 KMC carriers via questionnaire	20	Maternal comfort

L	Thapa, K. et al. (2018)	Nepal	Mixed methods feasibility study: randomised crossover design traditional vs ergonomic KMC carrier	96	Quant: Preference of carrier, duration and frequency of SSC episodes Qual: Acceptability, experience and value of KMC carrier
M	Gregson, S. and Blacker, J. (2013)	UK	Cohort study on transitional care ward: Use of wrap garment to facilitate KMC vs conventional care	214	Quant: Length of hospital stay, BF at discharge and 6 weeks Qual: Experience of feeding, bonding, and evaluation of the garment.

Data evaluation

Critical appraisal tools

Critical appraisal of the quality of the included studies is necessary to determine the strength and validity of the review findings (Booth et al., 2016). As integrative reviews may feature a diverse range of research methodologies, a standardised approach to evaluating the quality of the sources cannot necessarily be undertaken (Whittemore and Knafl, 2005). By selecting a suitable critical appraisal tool, quality assessment is structured and systematic, as all primary research articles are subject to an established assessment procedure dependent upon their study design. The Critical Appraisal Skills Programme (CASP) developed checklists to enable researchers to assess the trustworthiness, relevance and results of published research (CASP, 2018). These checklists have been utilised in this review as they are orientated at healthcare research, have been piloted and validated, and have method-specific checklists to evaluate different types of research (CASP, 2018). Although simple to use and useful in conducting a preliminary review of the research quality, the CASP checklists did not elicit the necessary level of critical appraisal to evaluate the studies rigorously. Following initial evaluation using the CASP checklists, JBI Critical Appraisal Checklists (Joanna Briggs Institute, 2017a; 2017b; 2017c) were used to appraise the included studies in further depth. Although in integrative reviews, studies are not necessarily excluded on the basis of quality (Booth et al. 2016), the quality of the study determines the weighting of the data in the presentation of the review findings (Whittemore and Knafl, 2005). The weighting of the study contribution is conveyed in the summarised findings of the review with reference to the methodological strength of the study design.

Structure of the data evaluation

The thirteen included studies were divided according to the research intervention or outcome into the following categories: mother-infant bonding, neonatal temperature, breastfeeding, and use of a device or garment (Table 2.3). In the following sections, the included studies are critically appraised with the use of the critical appraisal tools discussed in the previous section, and the key findings are discussed in detail.

Studies on ongoing skin-to-skin contact and mother-infant relational bonding

Three studies are included in the review which pertain to mother-infant relational bonding. Dalbye et al. (2011) report the findings of a study which interviewed 20 mothers about their experiences of engaging with skin-to-skin contact with their baby across two hospitals, one in Norway and one in Sweden. Although the authors suggest that the sites share a similar institutional culture regarding skin-to-skin contact, they concede that practices for co-sleeping differ between the two hospitals. These variations on maintaining side-lying closeness with the baby throughout the night may change the experiences of the participants according to the hospital that they resided in. Although the authors identify the essential meaning of the phenomenon, they do not identify the nature of the phenomenon. There is no description of the frequency or duration of skin-to-skin contact episodes that the participants had in the one to two weeks before the interview. This omission makes it difficult to compare and contextualise the study findings with other research, as the practising of skin-to-skin contact may have differed considerably.

The researchers identify three themes of meaning that were developed from meaningful clusters. The three themes of meaning are: “produces feelings of naturalness and wellbeing”, “the surrounding’s influence” and “the child signifies satisfaction” (Dalbye et al., 2011, 109). The authors relate the former theme to bonding. Skin-to-skin contact created an “increased mother-infant affinity”, whereby skin-to-skin contact was an expression of maternal feelings of “nearness and love” (Dalbye et al., 2011, 109). However, it is unclear how the authors developed the theme of “produces feelings of naturalness and wellbeing” from the meaningful cluster “the mother finds it increases the bonding between herself and her baby”. The nuance of terminology and language may be lost in the process of analysis as only one of the authors is bilingual in the two languages spoken by the participants, and as such, it appears that only one author had been able to engage with the data in the form it was provided. Coupled by the authors’ admission that they had “insufficient experience… in carrying out open interviews” (Dalbye et al., 2011, 110), the descriptive richness and nuance, which is integral to phenomenological analysis may have been somewhat compromised. However, the study has sufficient methodological rigour to be included in the review.

Rather than using inductive methods to explore dyadic experiences of engaging with skin-to-skin contact, the following two studies use quantitative methods to test the bonding

hypothesis. Bigelow and Power (2012) recruited a low-risk community sample of Canadian infants to test the hypothesis that ongoing plentiful skin-to-skin contact in the first month of life hastens infants' developing social expectations of their mothers, and increases the infants' awareness of themselves in these dyadic interactions. The authors used the Still Face Task (Tronick et al., 1975), whereby the mother or other social partner engages with the infant (phase 1) then "become suddenly still and expressionless (phase 2), then resumes normal interaction" (phase 3) (Bigelow and Power, 2012, 241) at one week, one month, two months, and three months post-birth, to assess the behavioural changes in the infant in response to the mother. The assessed infant behaviours in the Still Face Task and their relevance to infant development are explained with the study findings later in this section.

Bigelow and Power (2012) conducted a longitudinal quasi-experiment, randomising the two recruitment sites and switching the allocation halfway through the recruitment period. It appears that mothers knew the group allocation of their hospital at the time of consenting for the study, given the recruitment disparity between the control group (n=52) and the intervention group (n=28), resulting in possible selection bias. As the individual dyads were not randomised after consenting, the mothers who consented to participate in the intervention group may have been more motivated to engage with their infants in close contact than those in the control group, not just using skin-to-skin contact, but perhaps other mothering behaviours which may affect infant socio-emotional development. Although the authors report the percentage of mothers initially choosing to breastfeed (79%) in the sample, without follow-up data on breastfeeding status at the data collection points, breastfeeding is a potentially confounding variable which has not been accounted for in the analysis.

The study design required that participating dyads engaged in either a high quantity or low quantity of SSC dependent upon the allocation result. This method relied on weekly participant self-reporting of skin-to-skin contact duration, which was assessed by the researchers to determine whether the participating dyad had met the prescribed quantity of skin-to-skin contact or had deviated from the study protocol. Seventeen dyads were excluded from the trial based on their deviation from the study criteria; fourteen dyads in the intervention group had less than 4000 minutes of SSC in the first month, and three dyads in the control group had more than 4000 minutes of SSC in the same period. This exclusion is

contrary to the Consolidated Standards of Reporting Trials (CONSORT) guidelines, which state that participants in each group should be analysed according to an intention-to-treat (ITT) principle (Moher et al., 2001). Intention to treat preserves the sample size, thus avoiding reduced statistical power (Gupta, 2011) and minimises the risk of type 1 error (Fergusson et al., 2002), whereby the null hypothesis is rejected despite being true. Additionally, it is not explicit within the methodology that the '4000 minute' exclusion criteria was conceived a priori, and may have been applied following initial analysis.

Engagement in skin-to-skin contact was recorded as a continuous variable, measured by how many minutes the dyads spent skin to skin. However, as the seventeen dyads were excluded on non-adherence to the study protocol on skin-to-skin engagement, the continuous variable has been converted into a dichotomous variable to create two groups: the intervention group who engaged with plentiful SSC (>4000 minutes in the first month) and the control group (<4000 minutes in the first month). The analysis does not allow the investigation of a dose-response relationship between time spent SSC and infants' scoring on the Still Face Task. However, the mean hours per day of SSC vary considerably between the two groups, (5.03 vs 0.47 in week one, 2.77 vs 0.20 in weeks 2-4), increasing the likelihood that main effects found in the analysis were attributable to the intervention.

Single blinding was used appropriately to conceal the allocation of the dyad from the coder when assessing the infant's responses to the Still Face Task, reducing the chance of observer bias. A second coder, who was also blinded, independently scored a subset of the participating infants, demonstrating significant reliability by analysing intraclass correlations for all three types of assessed infant behaviour: visual attention (0.99), smiles (0.96), and vocalisations (0.97) (all $p<0.001$). Non-distress vocalisations are the primary social signals to elicit maternal reciprocity and communication and may be an "index of positivity" in face-to-face interactions between mother-infant dyads (Hsu et al., 2001, 107).

At one week of age, infants used visual attention to respond to the Still Face Task, irrespective of group allocation. At one month of age, the infants in the intervention group used non-distress vocalisations in response to the Still Face Task, and the infants in the control group did not. The difference between the intervention and control groups was significant for vocalisations ($p=0.015$). No differences between the groups were found at two months when the infants in both groups had changed their behaviour as a result of the task.

At three months, Chi-Square analysis demonstrated a significantly higher proportion of intervention group infants vocalised more during the still face phase than in the other two phases ($X^2(1) = 4.059, p = 0.044$).

The key study finding was that infants in the intervention group receiving skin-to-skin contact responded to the Still Face Task with non-distress vocalisations one month before infants in the control group did so. However, as the task was repeated at intervals one month apart, it is possible that the actual time difference in developing this behaviour was less than one month. The differences in non-distress vocalisations at three months suggests that the infants in the intervention group were actively trying to re-engage their mothers when they were in the still face phase, eliciting social bidding behaviours which were considered to be unusual for infants under six months of age (Moore et al., 2001). Overall, the results support the hypothesis that skin-to-skin contact hastens socio-emotional development and dyadic interaction. Although, the authors acknowledge that as the intervention of skin-to-skin contact involves both the mother and infant, the causal direction of the intervention is not known, and there may be "bidirectional influences" (Bigelow and Power, 2012, 249). The findings apply only to a similarly homogenous population, as the sample was 99% non-Hispanic White women; the authors note the significance of socio-cultural context for the method of maternal-infant interaction.

Owusu-Ansah, Bigelow and Power (2019) conducted a similar study to evaluate the response of Ghanaian mother-infant dyads to the Still Face Task (Tronick et al., 1975), comparing them to archival evidence of Canadian dyads in previous research (Bigelow and Power, 2012). The study aim was to investigate whether the findings from the previous research (Bigelow and Power, 2012) apply to cultural contexts using proximal parenting practices. Proximal practices focus on tactile contact and body stimulation, where babies may be worn on the mother's back, rather than distal parenting practices, which focus on face-to-face interaction, and are more prevalent in Western societies (Owusu-Ansah et al., 2019). The recruited Ghanaian dyads (n=26) were retrospectively divided into two groups based on a median split of their time spent in skin-to-skin contact, resulting in a group of high skin-to-skin contact experience, and a group of low skin-to-skin contact experience. Comparing the mean times spent skin to skin between the Ghanaian and Canadian cohorts demonstrated significant differences in the times spent skin to skin between weeks 2-4. For the high SSC

experience groups, Ghanaian dyads spent 5.2hours in SSC vs 2.8 hours for Canadian dyads (p= 0.001).

The different methods of group allocation, as well as a varying 'dose' of the intervention, limits the internal validity of the study when drawing comparisons between the two cohorts. This issue is further impacted by the difference in data collection points, as the Still Face Task was performed at six weeks of infant age with the Ghanaian dyads, and at one and two months of infant age with the Canadian dyads. Although the authors hypothesise that the results from the Ghanaian dyads at six weeks will be between the data collection points at 1 and 2 months in the Canadian study, the methodology lacks standardisation needed to draw robust conclusions from comparing the two cohorts.

Owusu-Ansah et al. (2019) found that Ghanaian infants with high experience of SSC showed similar behavioural changes to the task at six weeks post-birth to Canadian infants with high experience of SSC at one month post-birth. These behavioural changes suggest that high experience of SSC accelerates the infant's understanding of dyadic communication and their ability to respond to their mother's social behaviour. However, the behaviour of the Ghanaian and Canadian infants differed; Ghanaian infants used smiling, and Canadian infants used non-distress vocalisations during the task. The authors postulate that body contact or stimulation prevalent in Ghanaian proximal parenting methods may elicit smiling, whereas face-to-face interactions more prevalent in Canadian dyads may elicit vocal turn-taking, and result in infant non-distress vocalisations. However, the study did not assess or quantify these parenting behaviours outside of the Still Face Task. Therefore, the role of parenting behaviours on the study outcome is unclear. Given the different socio-cultural practices of distal and proximal parenting, the results of the initial Canadian study (Bigelow and Power, 2012) and the Ghanaian study (Owusu-Ansah et al., 2019) provide a contextually bound investigation of the effects of ongoing skin-to-skin contact on the development of mother-infant interaction.

All three included studies report advantages to ongoing skin-to-skin contact for healthy mother-infant dyads, such as accelerated development of the infant's social expectations (Owusu-Ansah et al., 2019), active participation of the infant in mother-infant communication (Bigelow and Power, 2012) and increased "mother-infant affinity" (Dalbye et al., 2011, 109). The recruitment of small samples across demographically heterogeneous

populations limit the generalisability of the findings to a U.K. context, particularly given the wide variation in methodology. These studies illustrate the complexity of operationalising mother-infant relational bonding as a research outcome, demonstrating various psychological, anthropological, and sociological perspectives on the phenomenon of attachment and bonding. Although the practice of breastfeeding also features in these academic disciplines, there is still considerable variation in research methodology and the operationalisation of outcomes, as demonstrated in the following section.

Studies on ongoing skin-to-skin contact and its effect on breastfeeding

Extending upon the previously discussed findings of Bigelow et al.'s (2012) study on the Still Face Task, Bigelow et al. (2014) sought to investigate the effects of ongoing skin-to-skin contact on the maintenance of mothers' decisions to breastfeed. Using data from apparently the same research sample (minus two participants presumed lost to follow up), the authors used Cochran Q tests to examine breastfeeding rates between 1 week, one month, two month and three month visits between the SSC group and the control group. Limitations of the study design in regards to lack of participant randomisation and ITT analyses are detailed in the previous section. In the same publication, Bigelow et al. (2014) assess the impact of SSC on maternal depressive symptoms, which is outside the scope of this review.

The key findings reported by Bigelow et al. (2014) were that dyads in the SSC group were more likely to sustain exclusive breastfeeding, and were more likely to sustain any breastfeeding, than dyads in the control group. Chi-square tests at the initial one week visit showed no significant difference in rates of exclusive or partial breastfeeding between the groups. Using Cochran Q tests, the longitudinal study design demonstrated a significant decline in the provision of any breastfeeding and exclusive breastfeeding at one month ($p=0.031$), two month ($p=0.031$), and three month ($p=0.016$) visits for dyads in the control group. Contrastingly, there was no significant decline in breastfeeding rates for dyads in the SSC group ($p=1.00$); all dyads in the SSC were still partially or exclusively breastfeeding at three months. These findings support the authors' hypothesis that ongoing SSC maintains the mothers' decision to breastfeed, but do not account for external motivating factors which may influence both the continuation of SSC and the continuation of breastfeeding. By excluding participants who did not meet the study requirements of >/< 4000 minutes of SSC

in the first month dependent upon group allocation, motivation to practice health-promoting behaviours is not accounted for as a potential confounder.

Adopting a more rigorous method of randomisation, Svensson et al. (2013) conducted a trial to examine the effects of combining skin-to-skin contact with breastfeeding support for mother-infant dyads experiencing severe latch-on problems. The authors hypothesised that when an older infant with latch-on problems is put skin-to-skin, it will restore the innate biological behaviour to attach to the breast and feed. The 103 mother-infant pairs experiencing latch-on issues after a standardised session of initial breastfeeding support were randomised to either receive SSC during breastfeeding support or to receive breastfeeding support without SSC. The study outcomes were the establishment of regular latching-on, time taken to achieve regular latching-on, breastfeeding pain score, and breastfeeding experience score.

The study intervention used a laid-back position in skin-to-skin contact, with the infant placed prone between the mother's breasts, whereas the control group generally received breastfeeding support with the mother in an upright, sitting position. Colson's (2008) theory of biological nurturing suggests neonatal position may be a potentially confounding variable in Svensson et al. (2013) study design, as placing the baby in a prone position facilitates the exhibition of primitive neonatal reflexes used to locate and latch to the breast, both when clothed and when skin-to-skin.

By using a randomised block design and opaque sealed envelopes, Svensson et al. (2013) effectively demonstrate allocation concealment. However, the study was unblinded and used subjective rather than standardised outcome assessments, both of which introduce a significant risk of bias in the assessment of outcomes (Karanicolas et al., 2010). The authors robustly screened the dyads for severe latch-on problems to determine their eligibility for the study but asked mothers to self-report on whether they achieved "regular latching-on", and if so, when this was achieved. Of the 83 dyads which achieved regular latching-on, 19 could not recall when this had happened; almost one quarter of the data on this outcome is missing. Although the authors found no significant differences in demographic data for the dyads with missing data, there may be an unidentified factor which affected both the ability to determine when regular latching-on was achieved and the time that latching-on was

achieved. This missing data further reduces the power of a small sample and introduces the prospect of another potentially unidentified variable confounding the analysis.

Svensson et al. (2013) found that the proportion of infants achieving regular latching-on and suckling was not significantly different between the two groups (p=0.217). However, the study did not recruit its anticipated sample size, and as such, the study may have been underpowered to detect a small effect size (Banerjee et al., 2009). Svensson et al. (2013) also found that infants receiving SSC began latching-on in a significantly shorter median time than the control group (2.0 weeks vs 4.7 weeks, p=0.020) and that mothers in the SSC group reported significantly lower breastfeeding pain scores (p=0.044), and significantly higher breastfeeding experience scores (p=0.022), suggesting increased positivity towards breastfeeding. However, the results should be interpreted with caution, as neither breastfeeding scale had been formally validated in previous research, and particularly small sample sizes for the time to latching outcome (n=64) increase the likelihood of a type I error when the null hypothesis has been rejected despite being true.

In their doctoral research, Horst (2017) used a retrospective data review and practice change implementation to evaluate whether an additional episode of skin-to-skin contact increases exclusive breastfeeding rates at discharge from hospital. Horst (2017) used a historical dataset of breastfeeding intention and exclusivity of the 695 mothers attending the hospital for birth in the three months before the practice implementation (July- September 2016). Following the practice change, 75 mothers who expressed a desire to breastfeed exclusively were offered the second episode of skin-to-skin contact. The rationale for the sample size and the method of selecting the 75 dyads is unclear, which introduces a risk of selection bias, and the possibility of an underpowered study producing erroneous results.

Horst (2017) found a 27% increase in exclusive breastfeeding rates at discharge in women that had two SSC episodes compared to historical control data in which women had one SSC episode, which was statistically significant (p=0.003). Analysis of the demographics of the sample of 75 women showed significant associations between marital status, educational level, ethnicity and breastfeeding exclusivity. However, a similar analysis is not available for the historical control data. As the groups may not be comparable in demographics which are significant to the study outcome, outcome comparisons should be interpreted with caution.

As the study was conducted in the United States of America (U.S.A.) under a different healthcare provision model, the results of this study may not be replicable in hospitals in the National Health Service. Horst (2017) describes a nursing practice change implementation which does not directly translate to a U.K. context where midwives are the lead professionals in maternity care. Given the significance of demographic factors in breastfeeding exclusivity, the results lack generalisability to a demographically disparate population.

Using a nurse-midwife-led study design in the U.S.A., Ruxer et al. (2013) performed a descriptive correlational study to determine if the dose of skin-to-skin contact affected the duration and exclusivity of breastfeeding after discharge. A convenience sample was recruited, comprised of 65 women who were planning to have a vaginal birth and instigate breastfeeding. Convenience sampling can reduce the generalisability of the results, as the sample may not be representative of the general population. Ruxer et al. (2013) reported that the sample had a disproportionate number of married and formally educated women, both characteristics which have been identified as significant predictor variables for breastfeeding exclusivity (Horst, 2017).

Ruxer et al. (2013) found no correlation between the amounts of time that dyads spent in SSC during the hospital stay and breastfeeding exclusivity at four weeks (rho=0.027, p=0.44) or eight weeks postnatal (rho=0.126, p=0.24). However, participant attrition through exclusion after birth based on study criteria (n=13), lost to follow-up (n=10), and other reasons (n=7) resulted in a small sample size (n=35), and as such, reduces the degree of confidence in detecting correlations between the variables. Sample size calculations based upon anticipated effect size and confidence intervals for effect sizes are recommended to aid the interpretation of results (A.P.A., 2015; Moinester and Gottfried, 2014). A sample size calculation is not evident in the study methodology, and as confidence intervals for the correlation coefficients have been provided, the accuracy of parameter estimations is unclear.

The study methodology featured follow-up phone calls at 4 and 8 weeks postnatal to collect data on breastfeeding exclusivity. However, these were made by a lactation consultant who provided lactation support as needed. The involvement of a lactation consultant may affect the external validity of the study, as lactation advice may have influenced the duration and exclusivity of breastfeeding amongst the sample which would

not be replicated in the wider population. A larger, more representative sample with standardised breastfeeding support provision would be needed to determine if SSC duration correlates with breastfeeding practices in the general population.

Regarding the effect of ongoing skin-to-skin contact in the hospital setting on breastfeeding exclusivity, the findings from Horst (2017) and Ruxer et al. (2013) appear to be contradictory. Ruxer et al. (2013) identified no significant correlation between time spent skin-to-skin and exclusive breastfeeding rates at 4 and 8 weeks, whereas Horst (2017) found a significant increase in breastfeeding rates at discharge. However, as the study outcomes were measured at different time points, ongoing SSC in the hospital may confer advantages to breastfeeding exclusivity over a short term of hospital stay which is not maintained in the weeks following discharge. When ongoing skin-to-skin is practised in the home setting throughout the postnatal period, it appears to have a maintenance effect on decisions to exclusively breastfeed (Bigelow et al., 2014), but not when severe latch-on difficulties are experienced (Svensson et al., 2013). Methodological and population heterogeneity, small sample sizes, and varying definitions of ongoing skin-to-skin contact limit the collective interpretation of these findings in relation to the outcome of breastfeeding. Further research is required to identify and understand the potential effects of ongoing skin-to-skin contact on breastfeeding continuation and exclusivity.

Studies on ongoing skin-to-skin contact and neonatal thermoregulation

In this review, studies were identified to examine the effect of ongoing skin-to-skin contact on the prevalence of hypothermia in the term neonate. Only two studies have been identified which investigate the effects of ongoing skin-to-skin contact compared to conventional care on the thermoregulation of healthy, term neonates. The paucity of research in this area may be due to the positioning of skin-to-skin contact for healthy term infants mainly in the context of immediate post-birth care, evident in the WHO (1997, 4) guidance which vaguely defines the scope of the guidance “from birth until the first few hours and days”.

Ramani and colleagues (2018) conducted a two phase randomised controlled trial in a tertiary delivery centre in Zambia. Healthy, term neonates were randomised either to receive KMC or standard care from birth to 1 hour (phase 1) and from 1 hour to discharge (phase 2), assessing the incidence of moderate or severe hypothermia (axillary temperature <36.0).

Phase 2 of the study is the focus of this review following the inclusion and exclusion criteria (Table 2.2). Regarding the study design, the randomisation method is detailed and appropriate, using variable block sizes and equally weighted groups to reduce the risk of selection bias (Karanicolas et al., 2010). Given the participatory nature of the intervention, neither participants nor researchers were blinded to the group allocation, as both were required to facilitate KMC. However, a lack of researcher blinding risks a biased assessment of study outcomes (Karanicolas et al., 2010), especially when the researcher can adjust the intervention whilst collecting the data.

The intervention and control group characteristics were mostly comparable, but both featured heterogeneous samples, including twins and low birth weight babies. As the gestational age of the infants was estimated via various methods, there is a risk that the study sample was not representative of the population of term infants, thus undermining the generalisability of the study. Although a rigorous approach was used to estimate sample sizes based on previously estimated effect sizes, heterogeneity in a large sample risks the actual treatment effect of the intervention not being detected (Garg, 2016). Heterogeneity also impacts on the external validity of the study, as the result may not be clinically applicable to a definable group of the population (Rothwell, 2006).

Quality control aims to standardise the procedures of the study, including measuring outcomes and administering the intervention in order to avoid inaccurate results (Kendall, 2003). In the study by Ramani et al. (2018), the administration of the intervention was not standardised; the duration of SSC in the intervention group ranged from 0-22 hours, (mean 7 hours +/- 4 hours), and the technique used to facilitate SSC varied with the inclusion of clothed and naked infants. Such variation in the administration of SSC, as well as the discharge data collection points varying from 4 – 24 hours post-birth reduces the internal validity of the study and increases the chance of inaccurate results.

Additionally, the authors did not quantify the duration of SSC that the control group were exposed to, detailed as “only during breastfeeding” (Ramani et al., 2018, 494). The duration of SSC may vary considerably between infants in the control group, and may well have exceeded the quantity of skin-to-skin contact that some infants in the intervention group received. As such, Ramani et al.’s (2018) findings that there was no difference in the incidence of hypothermia between the infants receiving KMC compared to the infants

receiving standard thermal care (RR: 0.96, 95% CI 0.49-1.89) should be interpreted with caution. The authors conclude that the study demonstrated that KMC was effective in preventing hypothermia only if it is practised more than 80% of the time, or for at least 9 hours during the day of birth ($r2=0.24$, $p<0.03$). However, this conclusion appears to have been reached using exploratory analysis, without an a priori hypothesis. Exploratory analysis is valuable in hypothesis generation and guiding further research, but is not a sound basis for efficacy claims (Ciulla, 2017).

Using a contrasting methodology to evaluate the effects of skin-to-skin contact on neonatal hypothermia, Chiu et al. (2005) used a pretest-test-posttest design to investigate the effects of skin-to-skin contact on term infants experiencing breastfeeding difficulties. One group pretest-posttest designs are situated low on the hierarchy of quasi-experimental studies, as they lack a comparison group, and therefore do not use group switching or a time-series design (Harris et al., 2006). The rationale for focussing on infants experiencing breastfeeding difficulties stemmed from concerns from healthcare professionals that infants may become hypothermic during breastfeeding in skin-to-skin contact due to frequent position changes and unintentional uncovering (Chiu et al., 2005).

Temporal artery temperatures were recorded before SSC, 30 minutes into the SSC episode, and just before the end of the SSC episode. These SSC interventions were repeated during four breastfeeding sessions per dyad before discharge; three episodes were to occur between 12-24 hours post-birth, and the final fourth episode to occur as close as possible to 24 hours post-birth. The study design sought to use the participants as their own controls (Chiu et al., 2005) by comparing temperatures in SSC with the baseline temperature. Shadish et al. (2002) identify maturation as a threat to internal validity, whereby naturally occurring changes of time confound the treatment effect. Chiu et al. (2005) acknowledge that this may apply to the stabilisation of neonatal temperature over the first 24 hours, as the neonate rapidly adapts to extra-uterine life and its environment.

Difficulty implementing the study protocol due to staffing issues and discharge times appears to have negatively affected the completeness of the dataset. Most notably, from the 48 participating dyads, there were only 12 completed temperature datasets for the third episode of SSC. Attrition in study participants in quasi-experimental studies may produce artifactual events if the attrition is correlated with the intervention (Shadish et al., 2002).

Although Chiu et al. (2005, 119) found “no systematic error” in the missing data, without comparable presentation of demographic and clinical variables of the included and excluded participants, missing data may lead to invalid conclusions (Kang, 2013).

Descriptive data analysis involved the calculation of mean, standard deviation, and range of neonatal temperatures. Chiu et al. (2005, 117) found that “most” infants maintained thermoneutral temperatures during skin-to-skin contact. Mild hypothermia in SSC occurred, evident in temperatures ranging from 36.3°C, but the exact incidence of hypothermia is not recorded. Descriptive analysis may illustrate a specific dataset, and is a prerequisite for further statistical evaluation (Spriestersbach et al., 2009), but should not be used to extrapolate study-specific findings to a broader population.

The studies by Ramani et al. (2018) and Chiu et al. (2005) share few generalizable findings on the effect of ongoing skin-to-skin contact on the thermoregulation of term neonates as the studies sample heterogeneous populations of infants: a mixed-risk sample of infants in a developing country (Ramani et al. 2018) and an apparently low-risk sample of infants with breastfeeding issues in a developed country (Chiu et al. 2005). As the study by Ramani et al. (2018) uses a comparative design and inferential analysis, the study suggests that ongoing skin-to-skin contact may not have a significant effect on the prevalence of hypothermia compared with standard care unless the engagement in skin-to-skin contact is very high. However, more rigorous research with a controlled dose of SSC or explicit recording of SSC frequency and duration between both groups is required to confirm this. Contrastingly, the study by Chiu et al. (2005) uses a one group design, providing no comparison between SSC and conventional care. High participant attrition and descriptive analysis suggest that the findings of this study should be interpreted and extrapolated with caution. Considering the results of both studies, it appears that ongoing skin-to-skin contact does not have a deleterious effect on neonatal thermoregulation with term infants. However, the exact effect of the practice of SSC on the incidence of neonatal hypothermia remains uncertain.

Studies on skin-to-skin contact facilitating garments or devices

Mother-infant skin-to-skin contact may be facilitated using various garments, devices, or techniques, dependent upon region, country, and availability of resources. Primarily aimed at addressing the needs of low birth weight babies receiving kangaroo mother care, the World

Health Organisation (2003b) recommend initially using a soft piece of fabric folded in two and secured in a knot to hold the baby closely against the maternal chest, later followed by a carrying pouch of the mother's choice. For healthy, term babies immediately after birth, the maintenance of clear airways, and a thermoneutral temperature is crucial in safely facilitating skin-to-skin contact, usually with a warm towel or blanket over the mother and baby (UNICEF UK, 2017).

Blomqvist et al. (2013) identified that one of the reasons that mothers discontinue skin-to-skin contact was a lack of KMC carriers. For the facilitation of ongoing skin-to-skin contact between healthy term babies and their mothers, commercial garments are available to facilitate skin-to-skin baby-wearing (NuRoo, 2016; Seraphine, 2019; VIJA, 2019). However, no supporting clinical research has been identified which evaluates the safety of the referenced commercially available garments. One commercially available product, the Hugsy blanket, has been subject to a clinical trial (Kommers et al., 2019). The Hugsy blanket aims to recreate the sensory experience of Kangaroo Mother Care once the baby is settled down to sleep independently by replaying a recording of the parental heartbeat and transferring the parental scent absorbed from the parent whilst containing the skin-to-skin contact (Kommers et al., 2019). As the Hugsy blanket does not aim to secure or facilitate skin-to-skin contact, its inclusion is outside the scope of this review.

Four studies were identified which investigated a method of facilitating skin-to-skin contact. Amaliya et al. (2017) conducted a pilot study to compare the effect of various kangaroo mother care carriers on maternal comfort. The study compared a kangaroo pouch (Figure 2.2), thari wrap (Figure 2.3), and a traditional Indonesian wrap (Figure 2.4). The study used a crossover design with a three hour wash-out period to trial the different carriers with a sample of 20 mother-infant dyads. Counterbalancing was used to produce six different sequences of KMC facilitation which were randomly allocated to the dyads, comprised of 2 episodes of KMC with each carrier. By counterbalancing, the study addressed the risk of maturation affecting the internal validity of the study, when the passage of time may affect the outcome of interest (Shadish et al., 2002). In this case, counterbalancing ensured that familiarity with KMC over time did not inadvertently influence the mothers' perceptions of comfort during SSC.

Figure 2.3 Amaliya et al. (2017) facilitating device – 'kangaroo pouch'

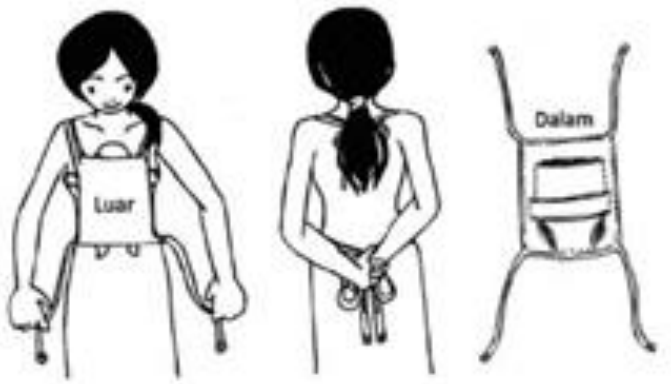


Figure 2.4 Amaliya et al. (2017) facilitating device – 'thari wrap'

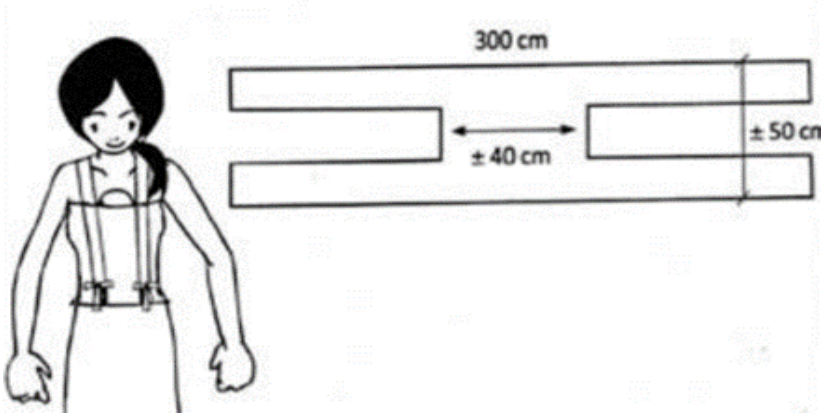
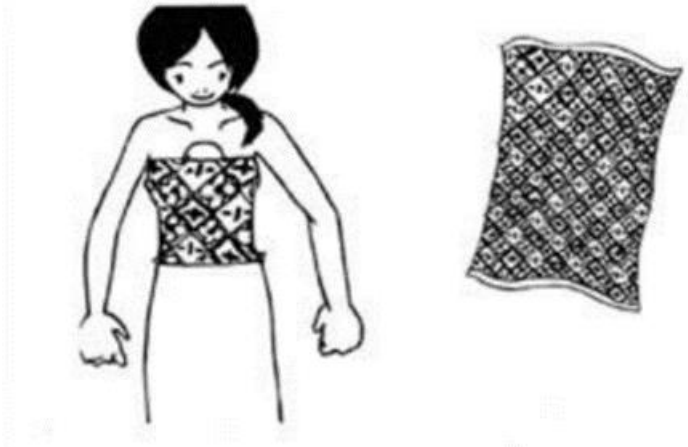


Figure 2.5 Amaliya et al. (2017) facilitating device – 'traditional Indonesian wrap'



The study used The Maternal Comfort Questionnaire (Amaliya et al., 2017) to determine maternal comfort levels in KMC, and the 'Am I Blue?' questionnaire to assess maternal anxiety as a secondary outcome. The Maternal Comfort Questionnaire (Amaliya et al., 2017) was tested for validity and reliability prior to the study (r=0.755), suggesting that the results obtained are an accurate representation of the study outcome. Contrarily, the anxiety questionnaire was not tested for its validity and reliability prior to the study, and it is not evident whether the questionnaire has been used in a similar population before. Therefore, the resulting findings should be interpreted with a degree of caution.

Using repeated and one-way analyses of variance and Pearson's Chi-Squared tests, no significant difference was found in maternal comfort levels between the three KMC carriers (p=0.366). A significant inverse relationship between maternal anxiety and maternal comfort was identified (r=-0.324, p=0.012). As the study featured a population of low birth weight (mean weight: 1771g) and preterm infants (mean gestation: 33 weeks), the findings on maternal comfort are not necessarily generalizable to a population of healthy, term dyads using KMC carriers as increasing neonatal weight and mobility may affect maternal comfort levels. The findings also lack generalisability to a U.K. setting as the KMC carriers are not universal, and acceptability and choice of a KMC carrier may be culturally or location-specific.

One study of a skin-to-skin facilitating garment was conducted in a U.K. setting. Gregson and Blacker (2011) investigated the effects of KMC using a wraparound garment compared to conventional care in a population of infants receiving transitional care in hospital. Specific details of the wraparound garment are not provided in the publication. The study used a cohort design to recruit 107 babies who were born premature (34 – 36+6 weeks), low birth weight, or to diabetic mothers to receive KMC in hospital and at home for the first six weeks post-birth. This study group was matched to a control group of 107 babies who were born in the preceding year, who received standard transitional care without KMC. The methodological strength of a cohort design is limited by a lack of randomisation. As the control group was formed through retrospective records, there may have been an unaccounted difference between the intervention and control groups. Participating mothers who actively consented to take part in the cohort study (intervention group) may have been more orientated to engage in health-promotion behaviours such as breastfeeding, compared

to the control group formed of mothers and their babies who received standard care who did not have to participate actively.

The study found that babies receiving KMC had a reduced median length of hospital stay (4 days vs 5 days, p= 0.04), higher rates of exclusive breastfeeding at discharge (OR 2.09, 95% CI 1.18 – 3.69), but no difference in breastfeeding rates at six weeks. However, these results pertain to babies requiring transitional care and are, therefore, outside the focus of this review. Specifically regarding the facilitating garment, data on the parental experience of KMC was collected using a Likert scale survey and a kangaroo care diary. However, the authors recognised that the experience of KMC and the experience of using the garment were conflated in participants' responses, as participants gave a low score on the Likert scale regarding their experience of KMC, but provided positive comments about their experience having skin-to-skin contact.

Thematic analysis of diaries identified four themes: positive effects of KMC for bonding, positive effects of KMC for feeding, how settled the baby was in KMC, and comments about the garment. Comments about the garment were mixed, with 20 negative comments and 23 positive comments. The analysis of the diary comments is mostly descriptive, with little exploration of the meaning and content of the themes. However, participants identified that the garment was fiddly to use, too bulky to wear in bed, and too hot to wear in the summer. This study has identified that although KMC using a garment may result in decreased length of hospital stay and increased rates of breastfeeding at discharge, the specific garment trialled is not widely acceptable for mothers. Further research is required to trial alternative garments which may be more acceptable and preferential for mothers and their babies.

Thapa et al. (2018) conducted a feasibility assessment to explore the preference and acceptability of a new ergonomic wrap designed by Laerdal Global Health (Figure 2.6, left), compared with a traditional wrap (Figure 2.6, right). Addressing the perception that KMC is not widely practised in Nepal, the feasibility assessment used a sequential explanatory design, with interviews and focus groups conducted to explain quantitative data on SSC engagement and duration between the two facilitation method groups. By using a mixed-method design, research questions may be addressed more comprehensively than through a

quantitative or qualitative approach alone, particularly when concerning complex health interventions (Tariq and Woodman, 2013).

Figure 2.6 Thapa et al. (2018) facilitating device: ergonomic baby carrier (Left), traditional wrap (Right)

Although the 96 participating dyads were randomised to which wrap they would receive first, a lack of allocation concealment may have resulted in selection bias, as the researchers were aware of the allocation result before enrolling the participants in the study. The sample size of the study was based upon the feasibility of recruitment rather than a sample size calculation. A post-hoc power calculation demonstrated that the sample of 96 women would only be sufficiently powered to reject the null hypothesis if there was at least 56% difference in the odds of choosing one wrap over the other. Given this large difference, the quantitative arm of the study is underpowered to detect smaller but still clinically meaningful effects.

Thapa et al. (2018) found that the majority of mothers preferred the new wrap to the traditional wrap: 81.3% in the group that received the new wrap first, and 89.6% in the group that had the traditional wrap first, with preference not significantly affected by the order of trialling the wraps (p=0.24). Whilst using the new wrap, mothers had, on average, an additional 77.4 hours of skin-to-skin contact over the 28 day postnatal period, but this difference was not statistically significant. The duration of SSC data is subject to recall bias, as

mothers were asked weekly to recall how much SSC they had over the previous week, without provision of written data collection tool. The authors also note that the study was underpowered to examine this outcome.

In the qualitative arm of the study, Thapa et al. (2018) found the new wrap to be regarded as preferential by healthcare workers and mothers alike, for the preservation of decency, and ability to have KMC with little assistance. Healthcare workers found the traditional wrap to be cumbersome and uncomfortable for mothers, especially in the summer season. In interviews with healthcare workers, Thapa et al. (2018) identified that the new wrap was more acceptable to fathers and male family members, based upon a perceived increase in interest and engagement between healthcare workers and male relatives. The reason provided for increased acceptability was that the new wrap was not considered to be women's clothing like the traditional wrap was. In interviews with mothers, Thapa et al. (2018) found that irrespective of which wrap was chosen by the mother for use at home, mothers recommended the new wrap over the traditional one. Although this seems to reflect positively on the new wrap, this finding does not explain why a minority of mothers (approximately 15%) chose the traditional wrap for themselves but would recommend the new one. Wholly positive recommendations for the new intervention may be a result of social desirability bias, whereby the participants recommend the new intervention to be favourably viewed by the research team or healthcare staff (Lavrakas, 2008). Outcome measures such as neonatal temperature stability, morbidity, and mortality, were not evaluated in the feasibility study and could be considered in a follow-up study.

One study evaluated the effect of a skin-to-skin facilitation method on neonatal temperature. De Albuquerque et al. (2016) conducted a case-control study to compare the temperatures of babies put under a radiant warmer at birth, to those put in skin-to-skin contact using a Top Maternal. The Top Maternal is developed by the Maternity Hospital Leonor Mendes de Barros and is described as "made of cotton tissue in a circular shape, 90 cm wide and 90 cm height" (de Albuquerque et al., 2016, 2742). The device has been designed as a way of "reducing the embarrassment related to bodily exposure" and to avoid potential slipping and falling of the baby in skin-to-skin contact (de Albuquerque et al. 2016, 2742).

Several methodological factors threaten the internal validity of the study. Firstly, the dyads were not randomised to group allocation. Instead, the neonatologist attending the birth decided on group allocation with little rationale provided. The lack of randomisation is reflected in the group demographics: baby born vaginally were typically allocated to the SSC with Top Maternal group (exact numbers not published), and all babies born via caesarean section were allocated to the radiant heater group. The study was conducted over two sites, a normal delivery centre (NDC) with an average ambient temperature of 23°C which varied, and an obstetric unit (OU) with an average ambient temperature of 24°C, controlled by air-conditioning. Each site also had skewed group allocation: 93.3% of babies born at the NDC were allocated to the SSC group, and only 16.6% of babies born at the OU were allocated to the SSC group. As the ambient temperature, place of birth, and mode of birth are not controlled for in the study design, these factors may confound the actual effect of the interventions.

De Albuquerque et al. (2016) found that there was no significant difference in temperatures taken at 5, 10, and 30 minutes post-birth between the skin-to-skin contact with Top Maternal device and radiant warmer care ($p>0.05$). However, the incidence of mild hypothermia, between 36.0°C and 36.4°C, varied considerably between the groups: 38.9% in the SSC with Top Maternal group, and 61.9% in the radiant warmer group. As the study compares facilitated SSC and a radiant warmer, it is not possible to determine the thermoregulatory effects of the Top Maternal in comparison to otherwise facilitated SSC, thus understanding to what degree the incidence of hypothermia is attributable to the device or the SSC. Given the significance of the extra-uterine transition in the first hour of life on the establishment of neonatal thermoregulation (de Albuquerque et al. 2016), these findings should not be extrapolated to later infancy.

Although six skin-to-skin facilitation devices are included in these four studies, the varying study outcomes, sample demographic, and timing of the trials prohibit the seven devices from being compared to each other. The findings from Amaliya et al. (2017) on similar levels of maternal comfort with various carriers is not supported by the findings from Thapa et al. (2018) who reported a preference for carriers without a knot tied at the back due to comfort and ease of use. The findings of both of these studies suggest that mothers find purpose-made skin-to-skin facilitating devices to be acceptable, although their rationale for

choosing a particular design was not comprehensively explored. The acceptability of the Top Maternal (de Albuquerque et al. 2016) is not assessed, although the rationale for its usage suggests that healthcare workers find it more acceptable than the mother remaining unclothed on the basis of preserving modesty. Of the devices used across the four studies, none are rigorously evaluated for safety and efficacy as none of the studies compare the thermal properties of the devices to each other. Similarly, none of the studies evaluate the maintenance of neonatal position, nor the occurrence of slips or falls. Further research is required which operationalises safety outcomes such as neonatal temperature and position to compare skin-to-skin facilitation methods.

Data analysis

Introduction

Data analysis in an integrative review aims to provide an unbiased and thorough interpretation and synthesis of primary sources (Whittemore and Knafl, 2005). Cooper (1998) suggests that research reviews require the data from primary sources to be ordered, categorised, and summarised into an integrated conclusion about the research focus. However, strategies for data analysis are one of the least well-developed methods in the integrative review process (Whittemore and Knafl 2005). As detailed in their framework, Whittemore and Knafl (2005) suggest the adoption of methods used for iterative comparisons between data sources which are prevalent in mixed methods research, such as those described by Miles and Huberman (1994). The stages of data analysis comprise data reduction, data display, data comparison and integration, and conclusion drawing (Whittemore and Knafl 2005, Miles and Huberman 1994). These methods do not require data to be comparable in the same way that techniques such as meta-analysis require study homogeneity, as the data are compared and analysed thematically, rather than pooled and analysed statistically. In this review, data have been compared and integrated where possible. Where data are not comparable due to various outcome variables, a narrative presentation of findings has been used (Shorey et al., 2016).

Data reduction and display

Data reduction is the process of classifying the data into subgroups, then extracting the data from the primary sources and creating a framework or matrix (Miles and Huberman 1994,

Whittemore and Knafl 2005). Data were primarily classified according to the research outcome: mother-infant bonding, breastfeeding, thermoregulation, and use of a garment of device. Data for each research outcome were reduced to a single page through simplification and refinement from the primary source. This process of data reduction enables a systematic comparison of primary data on specific issues, such as the outcome of interest (Whittemore and Knafl 2005). A data framework was created for each outcome of interest to collate the data, and begin the process of interpretation (appendix B).

Data comparison and integration

Data comparison is an iterative process of comparing the data displays to identify patterns, themes and relationships (Whittemore and Knafl 2005). Notes were made to record emerging links between the data sources, beginning with similarities and differences between the data and the study methodology, moving towards more generalised findings related to the research outcome. Mapping diagrams served to explore and illustrate these connections between the studies and their findings; an example of a mapping diagram is provided (appendix C).

Conclusion drawing and verification

The final stage of data analysis in the integrative review is drawing conclusions (Whittemore and Knafl 2005) and verifying the results. All discernment of themes and concepts requires verification with primary source data to confirm that findings are accurate (Miles and Huberman 1994). Notes and diagrams were developed into draft summaries to present the findings of the review. These were then refined by revisiting the original sources and making amendments and clarifications as necessary.

Presentation of review findings

The findings from this integrative review are presented in two ways; the overarching findings pertaining to the research outcome are presented first, followed by a narrative presentation of study-specific findings. Where possible, overarching themes and findings are presented from the integration of outcome-specific data, illustrating what is known generally in regards to the research outcome. The narrative presentation of findings presents more specific findings to reflect the included studies with heterogeneous methodologies or populations

where data are not comparable (Shorey et al. 2016). In the narrative presentation, the findings are attributed to the supporting studies as they are alphabetised in Table 2.3.

Ongoing skin-to-skin contact and relational bonding

Ongoing skin-to-skin contact and relational bonding: overarching findings

The effects of ongoing SSC on mother-infant relational bonding appear to be unequivocally positive, both from a maternal and neonatal perspective. Research on the effect of skin-to-skin contact on dyadic relational bonding has been conducted in various research fields, including infant psychology and midwifery. The studies were conducted in both developing and developed countries which consistently demonstrated that ongoing mother-infant skin-to-skin contact has benefits for dyadic relational bonding in various contexts. However, the exhibited neonatal behaviours which evidence this positive effect appear to be culturally-bound and dependent upon parenting practices.

Ongoing skin-to-skin contact and relational bonding: narrative summary

Infants receiving skin-to-skin contact have typically accelerated social development, including an awareness of their agency in the mother-infant dyad, demonstrated through their ability to employ social bidding to engage their mothers in communication (Study B; Study C). Skin-to-skin contact also seems to enable reciprocal mother-infant communication as the mother interprets the behaviour of her baby whilst in skin-to-skin, creating a positive spiral effect (Study A). How the effects of SSC are evaluated appears to depend upon whether SSC is conceptualised as an intervention (Study B; Study C) or as a norm (Study A). Depending upon this conceptualisation, SSC may be interpreted as accelerating the development of neonatal behaviours involved in reciprocal dyadic communication (Study B; Study C), or as enabling normal mother-infant reciprocity and communication (Study A).

Ongoing skin-to-skin contact and breastfeeding

Ongoing skin-to-skin contact and breastfeeding: overarching findings

The effect of skin-to-skin contact after the immediate postnatal period on breastfeeding has been investigated from various perspectives, including the use of SSC in the hospital, SSC at home, and SSC during breastfeeding support, in a general population of healthy babies, and a subset of those experiencing breastfeeding issues. The primary finding of this review is that ongoing skin-to-skin contact supports the continuation of a mother's decision to breastfeed.

This finding is considered to be credible, as it is logically inferred but subject to challenge (Shorey et al. 2016), given the methodological issues detailed in the data evaluation section. Skin-to-skin contact appears to have a positive effect on the longevity and exclusivity of breastfeeding for healthy, term babies and their mothers. A dose-response mechanism has not been established, and the direction of a possible causal relationship between SSC and breastfeeding is unclear and may be bidirectional, or subject to external factors, such as maternal motivation, engagement, and experience of breastfeeding. To understand the nature of the relationship between SSC and breastfeeding, interventional studies should be adequately powered to detect a meaningful change in breastfeeding rates.

Ongoing skin-to-skin contact and breastfeeding: a narrative summary

The effect of SSC on breastfeeding is presented in a narrative summary following a chronological order from 1+ hours post-birth. Engagement in SSC may be the physiological norm for exclusively breastfeeding infants, or may be an intervention which aims to enable breastfeeding exclusivity (Study F; Study G). For women intending to breastfeed, high uptake of SSC in the postnatal period appears to sustain their decision to breastfeed (Study F). For women already likely to breastfeed, skin-to-skin contact initiated in the hospital setting after the first post-birth episode appears to increase rates of exclusive breastfeeding at discharge from the hospital (Study G). There is a possibility of a dose-response effect between SSC and breastfeeding exclusivity, as women with an additional SSC episode have a significantly higher rate of exclusive breastfeeding at discharge (Study G). However, this effect is not demonstrated in the analysis of SSC duration and breastfeeding rates at four and eight weeks postnatal (Study D).

For dyads with breastfeeding issues, skin-to-skin contact appears to reduce breastfeeding pain, and create a more positive experience of breastfeeding for the mother (Study E). Reduced pain and maternal feelings of positivity may be attributed to SSC stimulating the release of maternal endogenous oxytocin, rather than solely attributed to a change in the baby's latching ability (Study E). For a subset of babies with a strong, negative reaction to hands-on breastfeeding support, SSC appears to result in significantly higher rates of latching-on than breastfeeding support without SSC (Study E). However, for babies in general, SSC does not appear to affect rates of latching-on but does reduce the time it takes to achieve regular latching-on (Study E). A reduction in the time taken to establish regular

latching-on may in itself contribute to higher rates of exclusive breastfeeding; breastmilk supply may be preserved through effective latching-on providing stimulation and milk removal using a cyclical supply-demand mechanism (Study E).

Ongoing skin-to-skin contact and neonatal thermoregulation

Ongoing skin-to-skin contact and neonatal thermoregulation: overarching findings

Research was lacking on the effects of skin-to-skin contact after the first hour post-birth on neonatal temperature; as such, the findings presented are descriptive and tentative. Ongoing skin-to-skin contact appears to be at least as good as conventional care for supporting neonatal thermoregulation. Typically, SSC seems to have a regulatory effect on neonatal temperature, from either a relatively high or relatively low baseline temperature.

Ongoing skin-to-skin contact and neonatal thermoregulation: a narrative summary

In the first days of life, engagement in SSC as part of kangaroo mother care appears not to significantly affect the incidence of moderate or severe neonatal hypothermia in a heterogeneous cohort of infants, unless the duration of SSC exceeds 80% of the total duration of the hospital stay (Study I). For babies experiencing breastfeeding issues, it appears that thermoneutral temperatures are generally maintained during intermittent SSC episodes during breastfeeding support sessions (Study H). The true effects of SSC on neonatal temperature may not be apparent due to a lack of standardisation in neonatal positioning for SSC, both during KMC and breastfeeding support (Study H; Study I).

Use of a facilitating garment or device for mother-infant skin-to-skin contact

Use of a facilitating garment or device for mother-infant skin-to-skin contact: overarching findings

Various formal and informal methods of skin-to-skin contact facilitation exist, including use of a wrap or carrier designed specifically for the purpose, or traditional methods of baby-wearing used whilst skin-to-skin. Across the reviewed research studies, seven facilitating garments or devices have been evaluated to determine their acceptability, comfort, or thermoregulatory properties. The acceptability and usefulness of the garments is variable; mothers frequently identify issues with ease of use, particularly securing the garment independently. Generally, purpose-made garments appear to be preferable to traditional adaptive methods.

Use of a facilitating garment or device appears to be an enabler for both healthcare professionals and mothers when considering skin-to-skin contact, with no evidence of harm. The safety and efficacy of the facilitation devices have not been rigorously evaluated; further research is required to inform the usage of facilitating devices. Of the seven garments or devices included in this review, only one was found to have accommodated term babies for ongoing skin-to-skin contact (babies born to diabetic mothers). However, this garment was poorly evaluated by the mothers trialling it. There is a notable lack of garments or devices which are both designed to accommodate term babies and are user-friendly and acceptable to mothers.

Use of a facilitating garment or device for mother-infant skin-to-skin contact: narrative summary

Reviewing the minimal data on this outcome, it is tentatively suggested that neonatal temperature appears to be predominantly maintained within the normal physiological range when a device is used to facilitate skin-to-skin contact (Study J). Skin-to-skin contact using a facilitating device appears to reduce the incidence of neonatal hypothermia by approximately one third when compared to non-skin-to-skin care under a radiant warmer (Study J). However, this is not suggestive of the thermoregulatory properties of the device, but those of skin-to-skin contact whilst using a facilitating device (Study J). The true effect of facilitating garments or devices on neonatal thermoregulation is unknown, as no research has been identified that compares neonatal temperature ranges between two facilitation methods. A significant paucity of research exists which compares the effects of different methods of skin-to-skin facilitation on neonatal thermoregulation.

Addressing the data on maternal comfort, it is unclear whether traditional, adapted methods of facilitation and purpose-made carriers provide similar levels of comfort (Study K) or purpose-made carriers without knot ties at the back are more comfortable (Study L). The traditional, adapted methods are specific to, and embedded in, the location of the research (Study J; Study K; Study L); use in a different geographical context may be unfamiliar, and this reduces levels of maternal confidence and comfort. Maternal anxiety appears to be inversely correlated with maternal comfort (Study K), which is likely to affect the mothers of unwell or premature babies disproportionately (Study K; Study M). As such, levels of maternal comfort may be dependent upon the setting and population in which the devices are used.

Purpose-made devices conferred some advantage for independent use as an alternative to traditional devices that fastened around the back (Study L). However, fastenings on purpose-made devices such as wraparound garments were fiddly, which impacted on the mother's experience of skin-to-skin contact (Study M). Purpose-made devices offered more security for neonatal positioning, which in turn enabled increased maternal mobility (Study L), and were felt to preserve the dignity of the woman by avoiding bodily exposure (Study J; Study L).

Discussion

The contribution of the review to the field of research

This integrative review is the first of its kind to review the field of mother-infant skin-to-skin contact with reference to the outcomes of neonatal thermoregulation, breastfeeding, and relational bonding for healthy, term infants and their mothers. This integrative review included studies conducted in various settings, using diverse methodologies, in a plethora of research fields. By reviewing these studies, it is apparent that the phenomenon of mother-infant skin-to-skin contact sits outside of a single research paradigm, and is ripe to be reconceptualised beyond the field of kangaroo mother care for preterm and low birth weight infants.

Ongoing skin-to-skin contact appears to have a positive effect on breastfeeding exclusivity (Bigelow et al. 2014, Horst 2017), whether through the acceleration of efficient latching-on (Svennson et al. 2013), stimulation of milk supply, or another unidentified mechanism. A systematic review by Moore et al. (2016) on the effects of early skin-to-skin contact on healthy babies showed similar beneficial effects of skin-to-skin contact on breastfeeding duration and continuation. Also in keeping with the findings of this review, Conde-Agudelo and Díaz-Rossello (2014) found higher rates of breastfeeding exclusivity at discharge in their systematic review of the effects of ongoing skin-to-skin contact on low birth weight babies. These findings suggest that extending skin-to-skin contact beyond the first hour of birth may increase rates of breastfeeding exclusivity in a population of healthy terms infants, much like the effects seen in low birth weight infants. However, rigorous and population-specific research is needed to test this hypothesis.

The effect of ongoing skin-to-skin contact on the thermoregulation of healthy, term infants is unclear, as a paucity of research exists which addresses this research outcome. A review of the two studies on neonatal temperature in healthy, term babies showed no adverse effects of ongoing skin-to-skin contact on neonatal thermoregulation when compared to routine care (Ramani et al. 2018, Chiu et al. 2005). It provided tentative evidence that ongoing skin-to-skin contact may be beneficial in temperature regulation if used almost continuously in the first days of life (Ramani et al. 2018). Contrarily, Conde-Agudelo and Díaz-Rossello (2014) found that continuous skin-to-skin was not needed to significantly reduce the incidence of hypothermia, as intermittent skin-to-skin contact significantly reduced this risk in low birth weight infants. Further research is needed to determine if the effects found by Conde-Agudelo and Díaz-Rossello (2014) on a population of low birth weight infants receiving intermittent skin-to-skin contact may be replicated in a population of healthy, term infants receiving intermittent skin-to-skin contact.

Mother-infant relational bonding appears to be positively affected by the instigation of skin-to-skin contact, notably when the dyad participates in a high duration of skin-to-skin contact (Owusu-Ansah et al. 2019; Bigelow and Power 2012). Benefits of skin-to-skin contact to relational bonding are evident in both objective interpretations via the Still Face Task (Owusu-Ansah et al. 2019; Bigelow and Power 2012) and subjective interpretations through phenomenological analysis (Dalbye et al. 2011). Combining various outcome measurements related to mother-infant interaction and bonding, Conde-Agudelo and Díaz-Rossello (2014) also found ongoing skin-to-skin contact to have a significantly positive effect on dyadic attachment between low birth weight infants and their mothers. In similar research assessing responses to the Still Face Task (Tronick et al. 1975), Neu and Robinson (2010) found that ongoing skin-to-skin contact for preterm infants resulted in enhanced maternal-infant co-regulation at six months of age. Longitudinal research is needed to determine if ongoing skin-to-skin contact in heathy term dyads confers the same advantages at six months of age.

This systematic literature search revealed a considerable lack of evidence on the effects of skin-to-skin contact facilitation methods on important health outcomes such as thermoregulation, breastfeeding, and relational bonding. Various outcomes were examined in the retrieved literature, which compared facilitation devices, such as maternal comfort (Amaliya et al. 2017) and maternal and healthcare worker acceptability (Thapa et al. 2018).

However, these comparison studies did not evaluate the effects of facilitation devices on health outcomes. From the research of de Albuquerque et al. (2016), it appears that a facilitation device has no adverse effects on neonatal thermoregulation, but without a comparison group also receiving skin-to-skin contact, the true effects remain unknown. Experimental research is needed to explore the effects of skin-to-skin contact facilitation devices in comparison with conventionally facilitated skin-to-skin contact, with a rigorous methodology and a well-defined description of the intervention and its comparison.

The only device which was identified in accommodating term infants was not positively evaluated by the mothers (Gregson and Blacker, 2011). Several issues were identified, including fiddly fastenings, maternal overheating, and discomfort (Gregson and Blacker, 2011). Few details were published about the facilitating garment, possibly due to the negative evaluation, which limits the comparison of the trialled garment and the Snuby garment. However, the Snuby garment has specific characteristics designed to avoid the issues identified. Firstly, the Snuby garment is made of breathable bamboo fabric to prevent overheating. Simple tie-up, front-facing straps are simple to use without assistance and avoid the discomfort of fastenings against the mother's back when reclining in skin-to-skin contact, as found with traditional garments in the study conducted by Thapa et al. (2018). Finally, as the Snuby garment serves as an undergarment, and is worn like a vest top, mothers can adapt their other clothing according to the climate, do not need to secure wrap-around designs to accommodate their baby as described by Gregson and Blacker (2011), nor do they need to wear additional garments as depicted by Thapa et al. (2018). This review has identified the requirement for rigorous research to trial a facilitating garment designed to accommodate term babies, which addresses the issues mentioned earlier with existing facilitating garments.

Limitations of this review

Although this review featured a diverse range of studies, only those published in English were included; after refining the search strategy according to language, one additional publication was excluded as no translation could be found. Having such exclusion criteria may limit the generalisability of these findings to populations which generally publish in another language, as the populations may not be comparable. As the review featured varied methodologies and research outcomes, the data were not consistently comparable, and as such, the

development of the findings from the thematic analysis includes a narrative presentation of results. Finally, due to the paucity of research on the outcomes of interest, the review findings are presented with an appropriate degree of caution, and may not be generalizable beyond the populations referenced. Despite these limitations, the review provides an evaluation of the quality and quantity of relevant research in the field of ongoing skin-to-skin contact for healthy term dyads. It presents essential findings to consider in the development and the positioning of the research topic.

Conclusion

This review found that ongoing mother-infant skin-to-skin contact has a multitude of positive effects for healthy term dyads. These effects include the infant's acceleration of social expectations and communication within the dyad, feelings of mother-infant affinity, and positive breastfeeding experiences, without any adverse effects. Although a small volume of research exists which evaluates skin-to-skin facilitation strategies, there is little consideration of the effects of skin-to-skin facilitation on the relevant and measurable health outcomes, such as thermoregulation, breastfeeding, and relational bonding. Similarly, there is a paucity of literature informing the safety and acceptability of facilitating garments for a population of term babies and their mothers. This review demonstrates the need for experimental research to evaluate methods of facilitation, considering their safety, and their effects on the health and wellbeing of the mother-infant dyad. Various methodological and theoretical perspectives were identified in the studies included in this review, including the conceptualisation of skin-to-skin contact as an intervention to both promote health and avoid pathology, and as an intrinsic aspect of motherhood and infancy. The following chapter describes the methodology used to underpin this study, including the application of a theoretical framework of health promotion.

3. Methodology

Introduction

This chapter presents the purpose of this research study, followed by the overall aims and objectives, the hypotheses, and outcome measures. The chapter explores the philosophical and paradigmatic aspects of the study and describes the methodological and theoretical considerations that shaped the study design, including a rationale for the use of mixed methods and the theoretical framework of salutogenesis. The following chapter describes the resulting study method in practical detail.

Aim and purpose of the overall research project

The purpose of this multi-phase study was to evaluate the effects of implementing a novel skin-to-skin contact facilitation strategy for healthy, term babies and their mothers. The purpose of the feasibility study, referred to as Phase I, was to conduct a preliminary assessment of the garment's safety and assess the feasibility of participant-led data collection in the home setting. The purpose of the randomised controlled trial, referred to as Phase II, was to investigate the effects of the Snuby garment on health outcomes such as breastfeeding, thermoregulation, and engagement in skin-to-skin contact. The qualitative follow-up phase, referred to as Phase III, aimed to explore the role of the Snuby garment and skin-to-skin contact on the maternal experience of feeding and nurturing the newborn baby, including the development of the mother-infant bond.

The overall aim of the research was to explore the safety, acceptability and value of a skin-to-skin facilitating garment for healthy term babies and their mothers, in response to a paucity of research exploring the combination of baby-wearing and skin-to-skin contact as a health promotion mechanism, as identified in the integrative review. The research study aimed to investigate the effect of skin-to-skin baby-wearing on the dyadic postnatal experience, including infant feeding practices, neonatal thermoregulation, and maternal-infant relationship building and bonding. In addition, the research aimed to understand a potential link between resources available to facilitate skin-to-skin contact, and the duration and frequency of time spent in skin-to-skin contact. The specific objectives of the research are split between the study phases as follows.

Study Objectives

Objectives of the feasibility study (Phase I)

The objectives of the feasibility study were:

- To assess the comprehensibility of the study documentation and the feasibility of participant self-conducted data collection.
- To identify any problems in the design of the main study or the design of the facilitating garment.
- To assess the maintenance of neonatal positioning and normal neonatal temperatures whilst in the garment.
- To explore the views of mothers on the garment's acceptability, style, and design.

Objectives of the randomised controlled trial (Phase II)

The objectives of the randomised controlled trial were:

- To determine the relationship between resources available to support skin-to-skin contact and the uptake, duration, and frequency of skin-to-skin contact.
- To determine the relationship between resources available to support skin-to-skin contact, and the initiation, continuation, and exclusivity of breastfeeding at six weeks postnatal.
- To assess the effect of skin-to-skin contact facilitation on the incidence of abnormal neonatal temperature.

Objectives of the qualitative follow-up (Phase III)

- To describe how a skin-to-skin facilitating garment may be used by women and their babies in the home setting.
- To explore women's experiences of skin-to-skin contact, skin-to-skin contact facilitation, and infant feeding decisions and practices with their healthy, term babies.
- To understand the value attributed to skin-to-skin contact and breastfeeding by women, and their motivation to engage in skin-to-skin contact and breastfeeding.

Research questions and hypotheses

Research questions aim to shape and accurately focus the purpose of the research study (Creswell and Creswell, 2018) and may be descriptive, exploratory, or inferential (Robson, 2011; Creswell and Creswell, 2018). A combination of these research question types was used, with the addition of an integrative question.

Inferential questions address quantitative outcomes and serve to test a hypothesis, as detailed in the next section of this chapter (Creswell and Creswell 2018). Inferential questions were used to determine the relationship between the provision of a facilitating garment and the frequency of skin-to-skin contact episodes, infant feeding practices, and neonatal thermoregulation.

Exploratory questions address qualitative outcomes and tend to focus on one concept or phenomenon (Creswell and Creswell 2018). Exploratory questions sought to understand the experiences of the participants over the postnatal period and what meaning they attributed to the phenomenon of skin-to-skin contact. Creswell and Creswell (2018) suggest the use of a mixed methods research question which integrates the qualitative and quantitative strands of the research.

Phase I research questions

The following research questions were developed for the feasibility study:

Exploratory question:

1) How do mothers of healthy, term babies perceive the provision of a skin-to-skin baby-wearing garment?

Descriptive questions:

2) Is it feasible to conduct a randomised controlled trial with participant-led data collection to investigate a skin-to-skin contact facilitating garment?
3) Is the skin-to-skin contact facilitating garment safe for unsupervised trialling in the main study?

Phase II research questions

Descriptive question -

- Does a skin-to-skin contact facilitating garment maintain normal neonatal axillary temperatures as well as conventionally facilitated skin-to-skin contact?

Inferential questions -

- Does the provision of a skin-to-skin contact facilitating garment affect the uptake, continuation, or exclusivity of breastfeeding practices?
- Does the provision of a skin-to-skin contact facilitating garment affect the frequency of skin-to-skin contact episodes in the postnatal period?

Phase III research questions

Exploratory questions -

- What are the experiences of mothers partaking in skin-to-skin contact in the postnatal period?
- What is the meaning of the phenomenon of ongoing skin-to-skin contact to mothers of healthy babies?
- How is a skin-to-skin facilitating garment used by mothers and their babies in the postnatal period?

Integrated question –

- How does the experience of ongoing skin-to-skin contact between the mother-infant dyad explain skin-to-skin contact and infant feeding practices recorded in the postnatal period?

Hypotheses

Hypotheses were generated in line with the quantitative research questions and in response to the findings of the integrative review. The hypotheses were reframed into null hypotheses for statistical inference (Sim and Wright, 2000), which is addressed later in Chapter Five.

Hypotheses:

H: Provision of a skin-to-skin contact facilitating garment increases the frequency of skin-to-skin contact over the first six postnatal weeks.

H: Provision of a skin-to-skin contact facilitating garment increases the rate of any breastmilk feeding at six weeks postnatal.

H: Provision of a skin-to-skin contact facilitating garment increases the rate of exclusive breastmilk feeding at six weeks postnatal.

H: Skin-to-skin contact within a facilitating garment maintains neonatal temperature within the normal range as well as conventionally facilitated skin-to-skin contact.

Null hypotheses:

H_0: The provision of a skin-to-skin contact facilitating garment does not affect the frequency of skin-to-skin contact in the postnatal period.

H_0: The provision of a skin-to-skin contact facilitating garment does not affect the rate of any breastmilk feeding at six weeks postnatal.

H_0: The provision of a skin-to-skin contact facilitating garment does not affect the rate of exclusive breastmilk feeding at six weeks postnatal.

H_0: Skin-to-skin contact within a facilitating garment is not as effective at maintaining neonatal axillary temperature within the normal range when compared to conventionally facilitated skin-to-skin contact.

Research approach and paradigms

Introduction to research paradigms

Research paradigms provide a philosophical underpinning that shapes the way research is conducted (Harvey and Land, 2017), incorporating a set of generalizations, beliefs and values of a community of specialists (Kuhn, 1970). Research paradigms are formed of ontological, epistemological and methodological beliefs which vary between paradigms (Harvey and Land 2017). Such paradigms situate the researcher and their work within a school of thought which reflects their own notions of the nature of truth and knowledge, and how knowledge can be generated (Harvey and Land 2017). Examination of the research paradigm underpinning a study is essential to develop and demonstrate coherence between study design, methodology, and generated knowledge (Creswell and Creswell, 2018; Easterby-Smith et al., 2002). This section describes the ontological, epistemological, theoretical, and

methodological positions adopted by the researcher, providing a coherent rationale for the use of pragmatism and mixed methods in this research study, and the application of the theoretical framework of salutogenesis.

Ontology and epistemology in dominant research paradigms

Positivism has been the dominant paradigm in health care research in the last century (Harvey and Land 2017), and as such, the ontological and epistemological foundations of the paradigm are briefly described for context. Ontological beliefs underpin research aims and objectives, as they influence how the researcher conceptualises the nature of reality, and what it is that they are attempting to understand (Crossan, 2003). Positivism features ontological beliefs that there is a single reality which is governed by universal laws (Harvey and Land 2017). Within the paradigm of positivism, researchers believe in, and aim to uncover, a single reality, which is applicable throughout space and time, and independent of human behaviour (Crossan, 2003; Polit and Beck, 2014).

Epistemology refers to the study of the nature of knowledge (Cluett and Bluff, 2006). An individual's epistemological position underpins the paradigms in which they subscribe to; one's own belief on the nature of knowledge directly affects how they generate knowledge in research. The epistemological position of positivists rests on the tenet that the generation of knowledge is independent of the researcher (Polit and Beck 2014). The researcher sits outside of the generation of knowledge and can be both value-neutral and unbiased (Crossan 2003). The paradigm of positivism understands human behaviour to be a phenomenon that reacts to external stimuli which can be observed and measured, much like the natural sciences (Crossan 2003). The methodological premise of the positivist paradigm is a quantitative approach which produces measurable and generalizable data in controlled conditions with manipulated variables (Cluett and Bluff 2006). Progressing the positivist worldview, post-positivism assumes that knowledge is conjectural and that the absolute truth can never be found (Phillips et al., 2000). Upon this basis, theories are tested, and research aims to reject the null hypotheses rather than prove the hypotheses (Phillips et al., 2000), endeavouring to obtain probabilistic knowledge through the falsification of theories (Easterby-Smith et al. 2002) rather than make claims to an absolute truth (Harvey and Land 2017; Crossan 2003).

Despite the positivist and following post-positivist paradigms underpinning the foundations of medical research, such an objectivist approach to study no longer solely dominates healthcare research, as it fails to value what cannot be easily quantified, such as human experience and behaviours (Crossan 2003). Integral to the philosophy of midwifery is woman-centred care, whereby the woman defines the needs of herself, her baby, and her family (Leap, 2009). The positivist and post-positivist positions are rejected from this research study as they do not align with the subjective experience of motherhood, or address the social, emotional, and psychological experiences of the mother-infant dyad.

Interpretivist approaches that understand knowledge to be derived through social construction have made a significant contribution to the generation of qualitative knowledge (Creswell and Creswell 2018). Such approaches have been used to evaluate care according to the subjective perception of the individual (Harvey and Land, 2017). The interpretivist paradigm supports the contextualisation of human experience, rather than viewing observations of a person's experience in isolation, lending itself to the exploration of the individual journey of motherhood. Although interpretivism is in keeping with a qualitative exploration of women's experience of skin-to-skin contact, the relativist ontology and inductive nature of interpretivism is incongruent with the hypothesis testing method necessary to explore causal relationships between variables such as skin-to-skin contact, breastfeeding, and neonatal temperature. For this reason, a solely interpretivist stance is deemed inappropriate in supporting the exploration of both the qualitative and quantitative research outcomes.

Research paradigms used in mixed methods research

A carefully considered approach to the epistemological and ontological stance of the researcher is particularly important in mixed methods research, as qualitative and quantitative methods are traditionally located in antithetical paradigms (Hall, 2013), based on incongruent perceptions of the nature of truth and knowledge. The paradigm wars have resulted in differing conclusions as to whether ontological and epistemological congruence can be, and has been, achieved through mixed method design (Creswell and Plano Clark, 2018; Hall, 2013; Lincoln et al., 2017). Mixed methods involves the combining or integrating of qualitative and quantitative data in a research study (Creswell and Creswell 2018),

establishing a third methodological tradition which complements the quantitative and qualitative movements (Hall, 2013; Tashakkori and Teddlie, 2010). Given the necessity for quantitative data such as neonatal temperature recordings and qualitative data reflecting the experience and meaning of skin-to-skin contact, a mixed methods approach was warranted in this study. Mixed method research is generally underpinned by one of several paradigms: pragmatist, critical realist, or transformative approach. The rationale for adopting a pragmatist approach is provided, with a brief justification for the rejection of other approaches.

A transformative worldview can underpin a mixed methods methodology by requiring collaborative working between researchers to demarginalize disadvantaged communities and address issues of power and social justice (Creswell and Creswell 2018). Such a worldview applies to the population of interest, which is mostly comprised of women from a diverse range of ethnic groups, in an area of considerable economic deprivation. The emancipatory orientation of transformative research (Watkins and Gioia, 2015) lends itself to the underpinning research concepts of maternal autonomy and valuing of the maternal-infant dyad. Transformative research assumes multiple forms of reality which are constructed through intersections such as gender, ethnicity, and socio-economic position (Watkins and Gioia 2015). Although this echoes the concept of feminist intersectionality, which is inherent within the researcher's own worldview, such ontological relativism is not consistent with empirical data collection and analysis necessary to test hypotheses relating to neonatal temperature. In transformative research, participants tend to play a participatory role, rather than one which is controlled through the design method in a top-down approach (Watkins and Gioia 2015). Although participants in this study self-collected data, their role in the research was pre-determined through a randomisation process in order to assess the skin-to-skin facilitating garment. For these reasons, the application of a transformative worldview was rejected for this research study.

Critical realism provides another paradigm congruent with mixed methods research. Critical realism seeks to provide a coherent ontological and epistemological rationale for the use of multiple or mixed method research. Bhaskar (2008) synthesised a stratified ontology with a constructivist epistemology, forming critical realism as an ontological and epistemological stance. Critical realism is underpinned by the notion of enhancing human

freedom; it seeks to understand the social structures which may oppress individual autonomy and choice (Bhaskar 2008). Bhaskar (2008) describes a stratified concept of ontology where there are three levels of the truth: the empirical, actual, and real. Critical realist research requires multiple questions and methods in order to examine each layer of knowledge.

Despite its complexity, Bhaskar's stratified ontology supports the application of many midwifery research areas. Walsh and Evans (2014) used labour dystocia as an example of a relevant midwifery research topic. Skin-to-skin contact also presents a research area which is congruent with Bhaskar's (2008) theory of critical realism. Upon the empirical level, skin-to-skin contact is experienced by mothers and their babies and observed or facilitated by the attending midwife. The resulting neonatal reflexes, instigation of suckling, and change in the neonate's temperature can all be measured. On the actual level, the skin-to-skin contact is eliciting the release of oxytocin into the maternal bloodstream, encouraging maternal nurturing behaviours, and the instigation of the milk let-down reflex. The maternal breasts also increase their surface temperature in correspondence to the neonate's own skin temperature. This level is understood through professional analysis of the systems which affect what is happening, such as through maternal blood tests, temperature monitoring, and investigation of physiology through ultrasound. The real level underpins and affects the actual and empirical truth (Bhaskar 2008), in this case, the mechanisms which affect the instigation of skin-to-skin contact. This features diverse and wide-ranging agents such as the working culture of maternity units. These environments suppress the natural release of oxytocin, the technocratic paradigm in which maternal bodies are viewed as second best to technological interventions (Davis-Floyd, 2001), and sociocultural influences on the mother's decision making. Although the research topic of skin-to-skin contact can be coherently understood through Bhaskar's (2008) theory of critical realism, its application within this research study was rejected. The study aims to explore a wide range of outcomes resulting from skin-to-skin contact, rather than to solely examine the underpinning mechanisms responsible for the practice of skin-to-skin contact.

In their work on the use of pragmatism to support the integration of quantitative and qualitative methods, Tashakkori and Teddlie (2003) situated the research question as of primary importance, and above the concern of either the research method or the researcher's worldview. Pragmatism is primarily concerned with the application of knowledge

to real world problems, asking 'what works' (Creswell and Creswell 2018). Tashakkori and Teddlie (2003) called for an abandonment of metaphysical concepts such as truth and reality and instead argued for an applied research philosophy to guide methodological choices. Pragmatism was applied to mixed methods research in order to address the traditional quantitative-qualitative dichotomy, which positioned the differing methods in antithetical paradigms. This problem-based approach aligns well with health research where complex issues such as health service infrastructure, treatments, and interventions require exploration from multiple perspectives, including qualitative experiences of those concerned, and quantitative data on outcomes. The adoption of the pragmatist paradigm is particularly suited to research of a problem or issue that is under-researched, as it permits an eclectic approach to data collection and analysis methods in order to meet the research aims (Creswell and Creswell 2018). Upon this basis, a pragmatist approach was adopted.

Mixed methods in midwifery research

Mixed methods offer a means to collect both quantitative and qualitative data to inform evidence-based practice in a healthcare system which is continuously evolving (Donovan, 2006). Hekman (1990) proposed that natural and social sciences required different methodologies to reflect their differing goals: natural sciences seek to explain, and social sciences seek to understand. However, midwifery is a combination of the natural and social sciences, as it meets the holistic childbearing needs of women and their families socially, psychologically, and physiologically (Donovan 2006). The polarization of biomedical and social models of care is rejected (Donovan 2006) in keeping with the pragmatist emphasis on a 'continua rather than a set of dichotomies' (Tashakkori and Teddlie 2010, 10). By partaking in mixed methods research, the midwife can sidestep the false dichotomy expressed in obstetrics between safety and maternal experience (Davis-Floyd 2001). Instead, a mixing of quantitative and qualitative data collection and analysis can ensure methods are utilized based on their usefulness to the mother-infant dyad, in keeping with the underpinning concept of holistic care. This mixing provides a methodological approach which permits the holistic exploration of a phenomenon through multiple methods of research.

Mixed method design

A mixed methods design was developed in order to meet the varied research questions generated by the researcher. A typology-based approach to mixed methods design was employed, as it lends a guiding framework to plan for data collection, analysis, and the point of interface, where the mixing of the methods occurs, which is particularly valuable for less experienced researchers (Creswell and Plano Clark 2018). With a wide-ranging and ever-evolving choice of typologies, considerations to determine the most appropriate typology included the purpose of the study, the research questions, researcher ability, practicality, feasibility, and discipline alignment. From such considerations, a multi-phase mixed methods intervention design was adopted.

Mixed methods intervention designs involve the researcher collecting and analysing both quantitative and qualitative data, and integrating the information within an experiment or intervention trial (Creswell and Creswell 2018). This design has become popular in health sciences, as it facilitates the inclusion of qualitative data in randomised controlled trials (Creswell and Creswell, 2018). In mixed methods intervention designs, the qualitative aspect may precede or follow the experimental intervention, or the mixed methods may be conducted concurrently (Creswell and Creswell, 2018). In this study, the qualitative aspect of the design followed the intervention trial, so participants could reflect upon the intervention and explain how the mechanisms of the intervention may have worked.

Generally, when the qualitative aspect follows the quantitative aspect, the design is described as explanatory sequential (Creswell and Creswell, 2018). An explanatory sequential design intends to use a qualitative strand of data collection to explain initial quantitative results (Creswell and Plano Clark 2018, Watkins and Gioia 2015). Explanatory sequential designs can be used to explain significant or non-significant results, outliers, or particular exemplars of interest (Creswell and Plano Clark 2018; Creswell and Creswell 2018). However, this required the analysis of quantitative data to inform the collection of qualitative data; it was considered unfeasible to wait for all participants to complete the six week quantitative data collection period in Phase II in order to proceed to the qualitative follow-up in Phase III given the varying gestations of the participants' pregnancies. Upon this basis, the study used a modified explanatory sequential core design: for individual participants, a qualitative

follow-up was used to explain their infant feeding and skin-to-skin contact practices recorded in the randomised controlled trial. The quantitative-qualitative sequence order was most appropriate as it facilitated contemporaneous quantitative data collection through questionnaires and data collection tables, deemed necessary for safety and accuracy, then retrospective qualitative data collection so the participant could reflect upon the entire postnatal episode. However, for the researcher, quantitative and qualitative data collection occurred concurrently, as participants moved through the three study phases individually, depending on when they had given birth.

Potential disadvantages of the modification were considered, such as the inability to analyse all quantitative data to inform the focus of qualitative data collection. This issue was mitigated through recurrent interim quantitative data analysis. Quantitative data were reviewed at regular intervals in order to identify outcomes of particular interest, upon which to base purposive sampling for qualitative follow-up. Interim quantitative analysis was used to identify infant feeding practices and uptake and engagement in skin-to-skin contact to ensure qualitative sampling was representative of a range of experiences and to guide the interview questions used for each participant.

A range of data collection methods may be included in a mixed method study depending upon the research outcomes, and the characteristics and volume of the data (Creswell and Creswell 2018). A combination of data collection methods was used within the study, adopting methods which were most useful to answer the research questions. These methods are displayed in the diagrams below (Figures 3.1 and 3.2) to depict the explanatory sequential study design. These methods are described and justified in more depth in the following chapter.

Figure 3.1 Phase I: feasibility study methods

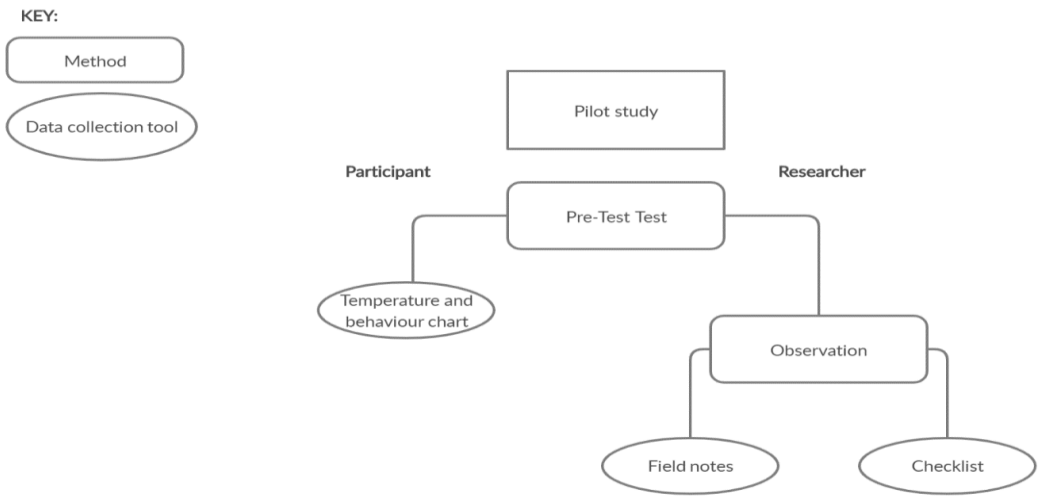
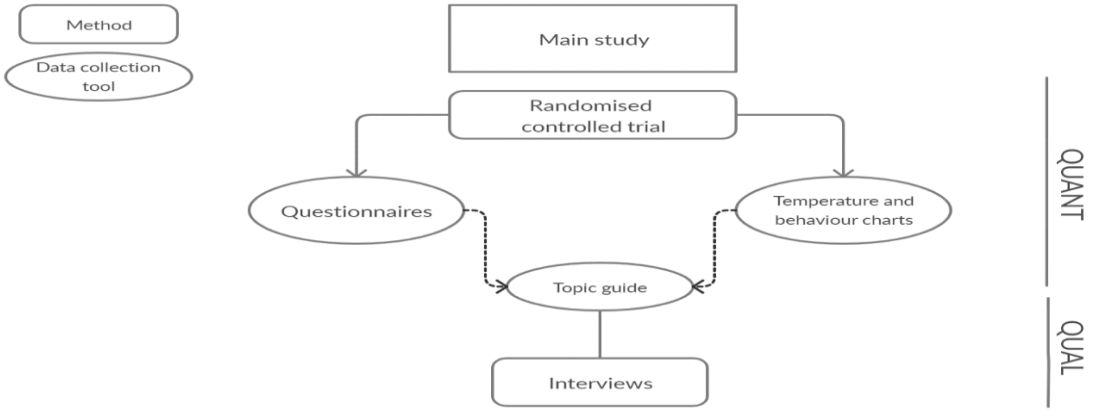


Figure 3.2 Phases II and III: randomised controlled trial with qualitative follow-up methods



Application of a theoretical framework in midwifery research

Grant and Osanloo (2015) cite the theoretical framework as one of the most important aspects of the research process. The theoretical framework is used to apply an established theory to the research process and design, both informing the development of the research project, and positioning the research within an existing school of thought (Grant and Osanloo 2015). Given the complexities of positioning midwifery research between the natural and

social sciences, a theoretical framework provides a consistent approach to inform the research concept, design, and conduct (Grant and Osanloo, 2015). This section includes a description of the process of identifying and adopting a theoretical framework and an explanation and critique of the theory of salutogenesis (Antonovsky, 1979; 1987) with reference to its epistemological and ontological foundations. The section builds a strong rationale for the adoption of salutogenesis as the theoretical framework for this research study and demonstrates its application to the research design.

The theoretical framework is aligned with the ontological, epistemological, and axiological stance of the researcher; its application may be based upon the worldviews of the researcher before the conception of the research study (Grant and Osanloo, 2015). However, such a linear journey may not be typical of the researcher's endeavours to apply a theoretical framework to their research study. Researchers may only establish the theoretical framework of the study once embarking upon the research project, following a systematic appraisal of the relevant literature, or following the collection or analysis of data (Furniss et al., 2011).

The identification of the theoretical framework may precede the research question, or result from it. Antonovsky (1987) cites the importance of theory informing the outcomes of the research, and the research question itself, and offers many examples of the adaptation of a research question based upon the utilized theory of salutogenesis. Conversely, McKenna (2018) regards the determination of the right research questions as the driver which informs the methods and theories. For example, McKenna (2018) notes the transcendence of the research topic of breastfeeding beyond individual schools of thought which both integrates new knowledge and maximises research impact. Following McKenna's (2018) rationale, a health promotion theoretical framework was sought, which positioned the phenomenon of skin-to-skin contact within the scope of the midwife as a health promoter, and best addressed the working research questions concerned with the adoption of health-promoting behaviours.

The identification and adoption of the theoretical framework began during the concurrent stages of preliminary research planning and wider reading of skin-to-skin contact research studies. Several theories which apply to health promotion were explored, including the bio-psycho-social model of health (Engel, 1977) and the hierarchy of needs (Maslow, 1943). The theory of salutogenesis (Antonovsky 1979, 1987) was adopted based on its

congruence with the philosophy of midwifery care, the research topic, and the researcher's own professional practice and underpinning worldviews. However, both Engel's (1977) and Maslow's (1943) models re-emerged during the process of qualitative data analysis and were used to explore and explain some of the research findings. The application of these supporting theories is described in the qualitative data analysis chapter.

Theory of salutogenesis

Salutogenesis (Antonovsky, 1979; 1987) is a theory of health promotion, which Antonovsky recognised was not limited to disciplinary borders, but connecting of disciplines through theory. Salutogenesis, meaning the origins of health, is a health orientation that views health as a continuum between total ill health and total health (Antonovsky, 1979; 1987). In contrast to the pathogenic model, in which the absence of disease is the marker of health, Antonovsky (1979) viewed salutary – or health-promoting – factors as the drivers that move people towards health. Antonovsky (1979) refuted the health-disease dichotomy and instead recognised people as complex organisms, all of which were capable of moving across the continuum. Antonovsky (1979) identified general resistance resources (GRRs) and general resistance deficits (GRDs) as the factors which affected whether a person had a positive and healthy response, a neutral response, or a negative and pathological response to stressors. Antonovsky (1976; 1979) identified myriad GRRs, which facilitated people, groups, or organisations to successfully manage tension.

The concept of tension management is fundamental to Antonovsky's theory, described as the process in which people respond to life's frequent challenges (Antonovsky, 1987). Antonovsky positioned tension as an unavoidable and routine part of life. He challenged prior assertions that tension was inherently pathogenic, citing the phenomenon of a notable minority of concentration camp survivors who remained in reasonably good mental and physical health, despite horrific life experiences (Antonovsky, 1979). Interest in how these tension-management resources were utilized led to the conceptualisation of a 'sense of coherence' (SOC), described as one's ability to view life as structured, manageable, and meaningful (Antonovsky, 1987). The SOC was thought to underpin people's ability to cope with and respond to life challenges with the resources that they had available to them (Antonovsky, 1979). Antonovsky (1987) hypothesised that the sense of coherence was

developed by early adulthood through exposure to challenges, and was responsible for how people respond to stressors in life. Antonovsky (1979) theorised that those with a strong sense of coherence experienced better mental and physical health throughout their lives, and were more likely to gain positive outcomes from stressors which moved them towards better health, than pathological outcomes which did the opposite.

The Orientation to Life questionnaire (Antonovsky, 1987) was designed to measure one's sense of coherence and test the hypothesis that a high SOC correlated with good overall health. Since its conception, the validity and reliability of the SOC questionnaire have been widely assessed. Lindström and Erikksen (2005) report acceptable face validity and cross-cultural applicability, with its usage recorded in 48 languages and 49 countries (Eriksson and Mittelmark, 2017). A positive correlation between a high SOC and self-esteem and quality of life has been demonstrated, with a strong negative correlation with anxiety and depression (Eriksson and Lindström, 2005). Antonovsky's hypothesis of a high SOC corresponding with good physical health has not been as well established, with some variation in correlation strength dependent upon the health instrument it was assessed against (Eriksson and Lindström, 2005).

Epistemology and ontology of salutogenesis

In respect to the epistemological underpinnings of salutogenesis, Eriksson (2017) found little insight in Antonovsky's (1979; 1987; 1996) writings. Although Antonovsky was not explicit about the epistemology of the theory, Antonovsky (1996) called for empirical testing of the theory, the identification of independent variables related to the sense of coherence, and the determination of linear relationships between concepts in the theory. Antonovsky's (1996) focus on causality and the testing of hypotheses using a scientific method suggest that the theory was constructed from a post-positivist perspective. Despite Antonovsky publishing little on the epistemology of salutogenesis, more is known about the ontological foundations of the theory. Antonovsky (1987) perceived reality to be in a heterostatic state, recognising chaos and change as normal states of life. He subscribed to the ontological notion of complexity and recognised that such complexity might cause conflict, which in turn may either generate chaos or coherence (Antonovsky, 1993a).

Antonovsky's theory of salutogenesis (1979; 1987) is ontologically congruent with Downe and McCourt's (2008) conceptualisation of childbirth. Downe and McCourt (2008) share Antonovsky's perception that complexity and uncertainty are normal states in pregnancy and childbirth. In keeping with Antonovsky's (1993a) view that change and chaos are fundamental to life's reality, Downe and McCourt (2008) assert that systems which are unpredictable and complex, such as labour and childbirth, are those most likely to be healthy and to innovate. As a medical sociologist, Antonovsky's writings also expressed systems theory underpinnings (Eriksson, 2017), as he positioned humans as part of a broader context. Similarly, Downe and McCourt (2008) locate systems theory in childbirth, finding that to answer questions about labour and birth, one must consider the contextual influences which arise within complex adaptive systems. This shared ontological conceptualisation of the nature of reality provides a strong rationale for the application of the theory of salutogenesis (Antonovsky 1979; 1987) to theoretically underpin research on health, pregnancy, and childbirth.

A critique of the theory of salutogenesis

Antonovsky's theory of salutogenesis is not without its critics. Suominen and Lindstrom (2008) argued that the 'sense of coherence' (SOC) concept is inextricable from health itself, thus not contributing new knowledge on how health is generated and maintained. However, the SOC's close alignment with the concept of health may instead demonstrate its validity as a theoretical concept, arising at a time of otherwise atheoretical public health policy and research (Antonovsky, 1996). Strümpfer (1995) argued that Antonovsky's concept of salutogenesis should be broadened to 'fortigenesis', meaning the origins of psychological strength, rather than health. Strümpfer (2006) redefines the continuum from ease/dis-ease (Antonovsky, 1979) to mental health/mental illness. This adaption is well supported by strong negative correlations demonstrated between strong SOC and anxiety and depression, and a less well-defined relationship between a strong SOC and good physical health (Eriksson and Lindström, 2005). Eriksson and Mittelmark (2017) regard Strumpfer's (1995, 2006) work on fortigenesis as an expansion of the SOC concept, rather than a revision, and complementary rather than contradictory to Antonovsky's ease/dis-ease continuum.

Antonovsky (1987; 1993b) conceptualised the SOC as a unidimensional construct with three inextricable tenets. However, subsequent research has suggested that the SOC is a multidimensional concept rather than a single factor (Eriksson and Mittelmark, 2017). Through confirmatory and exploratory factor analyses with a sample of 915 participants, Sandell et al. (1998) identified the dimensions of tolerance-intolerance, trust-distrust, and zest-depression as opposed to Antonovsky's tenets of comprehensibility, manageability, and meaningfulness. Sakano and Yajima (2005) offer an alternative construction of the SOC concept, identifying two dimensions: comprehensibility-manageability and meaningfulness. These convergent findings demonstrate weak construct validity and identifies the need for further theoretical deconstruction and exploration of the SOC concept. The consensual validity of the SOC instrument can also be regarded as weak (Eriksson and Mittelmark, 2017), with the SOC questionnaires being subject to considerable modification and contextual adaption. Between 1992-2003, Erikkson and Lindstrom (2005) identified 15 modified versions of the SOC questionnaire, with considerable variation in the scale used, and the number of questions. With the quantity and range of research on salutogenesis growing (Lindström and Eriksson, 2005), there is a danger that its various modified applications will precede thorough testing of the validity and reliability of the theory and its instruments.

Despite evidence of wide-ranging application, Antonovsky's theory of salutogenesis remains under-utilized in midwifery practice and research. Through systematic scoping of available literature, Perez-Botella et al. (2015) found salutogenesis to be rarely used in empirical maternity research, with only two examples found of research utilizing both a positive health orientation and explicit use of salutogenic theory. With a similar focus, Smith et al. (2017; 2014) appraised the research outcomes selected in systematic reviews of maternity research and identified the dominant risk-centric discourse which could be balanced with salutogenic outcomes of relevance to healthy women and babies. To counteract the risk rhetoric which has thrived in the medical model of maternity care, salutogenic theory is needed to create and carry out midwifery research which promotes health, recognises individual autonomy, and reconceptualises maternity care as a healthy event.

Rationale for choosing salutogenesis

As well as considering the ontological and epistemological underpinnings of the theory, the choice of a theoretical framework requires consideration of the researcher's own positionality, inherent beliefs, and research alignment in order to embed a coherent theoretical underpinning throughout the research project. Essential beliefs were identified by the researcher, which were analysed to identify convergent concepts with various theories. Fundamental beliefs, such as the principles of intersectional feminism, valuing of one's own perception of health, right to personal autonomy, and social justice, suggested feminist standpoint or critical social theory as most congruent with researcher positionality. However, these theories failed to encapsulate personal/professional values, such as the understanding of birth being a normal event, and valuing health-promoting behaviours outside of the technocratic paradigm (Davis-Floyd, 2008).

Antonovsky's theory of salutogenesis shares many underpinning concepts with the midwifery profession, such as personal autonomy to determine one's own health, personalised care based upon individual strengths and resources, and a critique of the pathological model which fails to value health as more than the absence of disease. Antonovsky (1996) overtly recognised maternal and child health as an area where a health-promoting philosophy is evident, providing a direct rationale for the theory's application in this subject area. Antonovsky (1996) focussed on structures which support health to decrease the incidences of diseases in the long term. Enablement of breastfeeding embodies this focus, having been identified by the World Health Organisation (2017) as a critical measure in reducing non-communicable diseases and childhood obesity. The theory of salutogenesis also facilitates midwives to remain experts in health and normality (International Confederation of Midwives, 2017), as the theory applies to the entire population, rather than a subsection based upon the prevalence of morbidity or a shared risk factor (Antonovsky, 1979; 1987). The metaphor of the river of life (Antonovsky, 1987) echoes the concept of childbirth as part of life's journey, which can move people across the health continuum.

By offering an alternative to risk-centric outcomes, salutogenesis instead considers salutary factors which promote health (Perez-Botella et al., 2015; Smith et al., 2017; Smith et

al., 2014). Both skin-to-skin contact and breastfeeding are health-promoting behaviours which can positively affect the health of the mother and infant but require consideration of Antonovsky's GRRs and GRDs, which affect how the mother-infant dyad engage with them. Salutogenesis offers a framework to promote positive wellbeing as a primary outcome, using the identification of pathology as a component, rather than a driver (Downe and McCourt 2008). Downe (2005) calls for midwives to adopt salutogenic theory in order to consider the anecdotal evidence base midwives share, which can reconceptualise pregnancy and childbirth as complex, dynamic, and health-orientated events. This reconceptualisation is particularly in keeping with a recent focus on universal and additional care, rather than high and low-risk status, in the Nursing and Midwifery Council (2019) midwife proficiency standards. Sinclair and Stockdale (2011) echo this notion, asserting that it is midwives' responsibility to design theoretically sound salutogenic interventions in antenatal education to empower women to move towards health.

Application of salutogenesis to the research design

The theory of salutogenesis was used to inform each aspect of the research design in order to develop theoretical coherence throughout the research project (Green, 2014). The researcher has published a guide to using the theory in midwifery research, which is attached as an appendix (appendix D). In addition to the adoption of a health-orientated topic, the theory of salutogenesis has informed the research population, outcomes, data collection, and analysis, which are described in detail in the following chapter. Suominen and Lindstrom (2008) identified that most studies using the theory of salutogenesis were of a quantitative design, many using the SOC questionnaires in a longitudinal design. Further research in qualitative and interventional research designs was necessary to test the theory in these fields (Suominen and Lindstrom, 2008).

Within the field of midwifery, qualitative researchers have used Antonovsky's themes of manageability, comprehensibility, and meaningfulness to structure thematic content analysis in order to understand how women conceptualise and fear childbirth (Greer et al., 2014), experience breastfeeding support (Thomson and Dykes, 2011), and breastfeed in a non-native setting (Kolanen et al., 2016). This style of analysis has yielded rich results, which illuminate women's experiences of the childbearing continuum from the perspective of a

health-orientated practitioner. A similar style of thematic analysis was adopted for the qualitative aspect of this study in sight of the similar subject topics and researcher positionality, providing thematic structure and a theoretical congruence.

Downe and McCourt (2008) also discuss using health-orientated outcomes, rather than pathology-based outcomes, which may be more subtle or long term, such as parenting capacity, or wellbeing. In this case, study outcomes such as the continuation of breastfeeding and participation in skin-to-skin contact were identified as the primary outcomes of interest, which could move mother-infant dyads towards 'ease' on the ease dis-ease continuum (Antonovsky, 1979). Similarly, study criteria focussed on recruiting participants based on health, rather than a risk factor or disease incidence. Inclusion criteria sought to define a study sample which had experienced a birth without undergoing a pathologising event resulting in ongoing medical intervention, such as a Caesarean section, or high dependency medical care. Antonovsky (1980; 1996) recognised the contribution one's socio-demographics might have on their ability to process life's stressors, regarding social support and financial stability as key general resistance resources. Considering this, demographic information was sought from the participants, in order to contextualise women's experiences of health-promoting behaviours in the postnatal period. The following chapter illustrates the application of the health-orientated theory in practical detail, describing the eligibility criteria, outcome measures, and plan for data collection and analysis.

Conclusion

Ontological, epistemological, and theoretical considerations informed the research design, outcomes, population, and analysis. The topics of skin-to-skin contact and breastfeeding are effectively positioned within the scope of the midwife and the field of health promotion through the application of the theoretical framework of salutogenesis (Antonovksy 1979, 1987). The application of this theoretical framework provides a valuable theoretical structure for the research study, which reflects the researcher's personal beliefs and professional values.

This research study is underpinned by a pragmatist philosophy, as pragmatism supports the integration of qualitative and quantitative research in order to respond to the research questions, and is therefore well suited to mixed methods research (Creswell and Creswell

2018). The collection and integration of quantitative and qualitative data is in keeping with the midwifery philosophy of woman-centred care (Leap 2009), whereby subjective experience and measurable health outcomes are considered to be both inextricable and fundamental to generating wellbeing (David-Floyd 2001). The following chapter describes the methods employed in the research study in practical detail.

4. Methods

Introduction

Following the pictorial outline of the mixed method research design in the previous chapter (Figures 3.1 and 3.2), this chapter describes the setting of the research and the research design in detail, including practical and ethical considerations and necessary changes made during the research process. The inclusion and exclusion criteria and outcome measures of the study are reported in line with the research protocol (appendix E), and the data collection and analysis methods are reported.

Setting

The setting of the research was the homes of participating women and an NHS trust in the West Midlands. The extent of local deprivation is considerable; the local authorities of the acute hospital and community settings both rank in the top ten most deprived in England (Office for National Statistics, 2015). After London, the West Midlands is the most diverse area in England and Wales, with a considerable increase in the variety of ethnic and national identities seen between the 2001 and 2011 censuses (Office for National Statistics, 2012). High levels of social deprivation and ethnically varied populations are both positively correlated with high infant mortality rates. The West Midlands has the highest infant mortality rate nationally, over 50% higher than the national average (Office for National Statistics, 2018). In recognition of the multidimensional disparities between those living within the study setting, and the white, middle-class population primarily associated with research participation (Weber Cannon et al., 1988), the study sought to recruit participants that were representative of the research setting, and place their experiences of breastfeeding and nurturing within the context of their identities.

Obtaining access to open settings such as hospitals generally requires less negotiation (Sim and Wright, 2000). However, in line with NHS requirements, research passports and ethical clearance were obtained in order to access maternity clinics and waiting areas within the NHS trust. Gatekeepers, such as the Head of Midwifery for the NHS trust, were navigated in order to obtain permission to conduct the research recruitment within the clinical setting; the issue of gatekeepers is explored further in the following chapter. Although time-consuming, such

navigation did not present any practical issues, as the research outcomes aligned with clinical performance measures of interest to the gatekeepers. Grady and Wallston (1988) suggest that a clinically orientated strand of the research is sufficient to gain the cooperation of the physician. However, the research outcomes exceeded this requirement by providing immediate practical relevance to the hosting organisation. Breastfeeding uptake and duration, and establishment of skin-to-skin contact remain key performance indicators in national healthcare guidance (National Institute for Health and Care Excellence (NICE), 2015).

The majority of study participation took place within the closed setting of the participants' homes. The home setting was selected for data collection, as the intervention is designed to be used in the home and hospital setting, and given its eligibility period from birth to six weeks postnatal, much of this time would be in the home setting. The home setting also enabled the maternal participants to remain as the expert in their baby's care, rather than under the care and guidance of hospital staff. Navigating access to the participants' homes for the feasibility study was without issue, possibly due to the culturally established pattern of midwives visiting the home within the postnatal period. Based upon this ease of access and high acceptability, data collection visits for the second phase of the study at six weeks postnatal for the main study were also conducted at the participants' home.

Eligibility Criteria

Inclusion and exclusion criteria for the feasibility and main study focussed on selecting a healthy sample of mother-infant dyads, rather than selection by disease characteristic or morbidity, in keeping with Antonovsky's (1996) health-orientated application of salutogenesis to the general population. Extending Antonovsky's (1987) concept of the ease dis-ease continuum, the low-risk/ high-risk categorisation of pregnancy was dismantled to avoid arbitrary and limiting definitions of health and disease which served no purpose in selecting eligible participants. Instead, criteria were developed in order to eliminate potential confounders which may affect the outcomes of interest, in this case, uptake and continuation of skin-to-skin contact and breastfeeding.

The inclusion criteria were definitively assessed following the birth of the baby. However, some of the criteria were applicable during pregnancy for a preliminary assessment of whether a pregnant woman may be eligible to participate postnatally. The inclusion and

exclusion criteria have been divided into maternal and neonatal criteria, recognising the dual participation within each recruited dyad. Due to the dyad sharing the pregnancy and birth, there is some duplication between the maternal and neonatal criteria. A list of the inclusion and exclusion criteria can be found below with a brief rationale.

Table 4.1 Maternal inclusion and exclusion criteria at enrolment

Inclusion	Exclusion	Rationale
Aged 16 years or older	Aged 15 years old or less	Capacity to consent: safeguard maternal autonomy
Less than one week postnatal	>1 week postnatal at enrolment	Able to administer intervention before the first data collection point
Receiving maternity care at hosting NHS trust	Within community catchment but booked for maternity care outside of the hosting trust	Capacity only for single centre study
Body mass index of 30m² or below at the beginning of their pregnancy	Body mass index of 31m² or above	Snuby garment sizing accommodates up to body mass index of 30m²
Having/had a vaginal birth	Having/had Caesarean section in the current pregnancy	Caesarean birth identified barrier for skin-to-skin contact in practice (reducing confounding variables)
Capacity to consent or decline participation	Deprivation of liberties in place	Capacity to consent: safeguard maternal autonomy
Basic spoken and written English	Unable to read and understand study documentation	Maximise accessibility to participate Lack of funding for translation and interpreter services

Table 4.2 Neonatal inclusion and exclusion criteria at enrolment

Inclusion	Exclusion	Rationale
In the care of biological mother	Child protection plan in place or anticipated	Ability to maintain mother-infant closeness Capacity to consent for baby's participation
Born at or after 37 weeks gestation	Premature infants	Adequate neonatal tone and mass to be safely accommodated in Snuby garment
Born at or above 2500g	Low birth weight infants	Adequate neonatal tone and mass to be safely accommodated in Snuby garment
Singleton infants	Twins and higher order multiples	Snuby garment able to accommodate one baby at once
Healthy infants receiving routine care	Infants receiving phototherapy, intravenous antibiotics, or neonatal unit care	Effects of neonatal illness and special care procedures on neonatal thermoregulation, e.g. nursed unclothed

Phase I: The feasibility study

Feasibility study: design

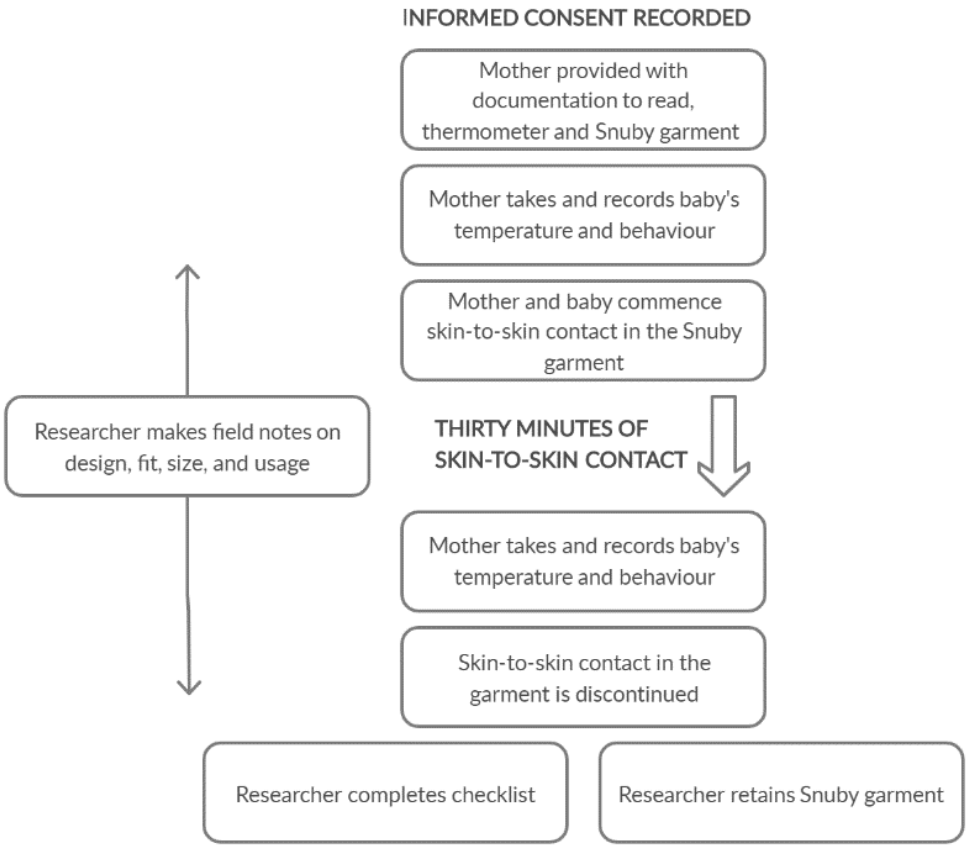
The feasibility study aimed to focus on three areas: acceptability, implementation, and limited-efficacy testing (Bowen et al., 2009). For a limited assessment of the efficacy of the garment, a simple pretest-test design was used to assess the thermoregulatory effects of the Snuby garment with a non-randomised group. This design is low on the hierarchy of research design as it lacks a comparison group, therefore causation should not be inferred (Sim and Wright, 2000). The aim of the feasibility study was not to produce inferential results but to generate descriptive data for a preliminary evaluation of the intervention before a randomised controlled trial (Lancaster et al. 2004). The 'pre-test' aspect of the design collected a baseline neonatal axillary temperature before skin-to-skin contact. The 'test' aspect collected another neonatal axillary temperature following 30 minutes to skin-to-skin contact within the garment.

Dual participant and researcher data collection occurred within a single data collection episode whilst the mother-infant dyad trialled the Snuby garment (Figure 4.1). Data were collected with each participating mother-infant dyad at a mutually convenient time in the participant's home. The data collection episodes ranged from 60 – 90 minutes in duration, and all commenced with confirmation of informed consent, the opportunity to ask any questions, and a recap of the data collection method. Alongside the Snuby garment, the mother was provided with an axillary digital thermometer and usage instructions for both the thermometer and garment. Garments were provided based on the body mass index recorded in early pregnancy and on their pre-pregnancy clothing size. Women's comments on the garment were transcribed while the women tried the garment on. Appropriate measures to maintain the women's dignity were taken, such as offering to leave the room. Once in situ, the garment was checked for fit and any signs of damage. All garments were found to fit appropriately, with no signs of damage.

The mother used the thermometer to take and record the baby's temperature before Snuby usage and repeated after 30 minutes while the baby remained in the garment. Following the episode of Snuby facilitated skin-to-skin contact, the mother completed the provided 'temperature and behaviour chart' (appendix F). To assess the practicality of the

intervention, trialling data collection tools and study documentation is particularly important when participants will self-collect data (Lancaster et al., 2004) as it aims to identify practical problems the participant may face in following the research procedure (Van Teijlingen and Hundley, 2001). Researcher observation was used to complete field notes on the usage, size, fit, and design of the Snuby garment and complete the purpose-made checklist (appendix G) to audit adherence to study protocol and documentation, and maintenance of neonatal thermoregulation and positioning. Following the data collection episode, the Snuby garment was retained by the researcher, and participation was complete.

Figure 4.1 Feasibility study: procedure



Feasibility study: outcome measures

Outcome measures for the feasibility study:

- Score on the purpose-made checklist (n/11)
- Experience of the mother-infant dyad using the Snuby garment

In order to fulfil the aims of the feasibility study, a specific outcome measure was designed to incorporate the range of safety checks necessary before proceeding with a larger study. The researcher checklist (appendix G) was designed to aggregate all safety components and feasibility considerations for trialling the garment without researcher oversight, which included the maintenance of a normothermic neonatal axillary temperature whilst contained within the garment. Dyadic experiences were used as an outcome measure to assess the acceptability of the garment before commencing the randomised controlled trial study. The experience of the mother whilst using the garment was assessed to identify any foreseeable issues with recruiting a larger sample of women to trial the garment in Phase II of the study.

Mothers' experiences were categorised using simple word repetition analysis of their transcribed verbatim comments recorded in researcher field notes to categorise their experiences as positive, neutral, or negative. The experience of the baby was assessed by the mother, who recorded the baby's baseline behavioural state before garment use and following thirty minutes of garment use. Maternal comments on the baby's experience were also transcribed and analysed as per the previous description. For the experience to be classified as 'positive', both maternal and neonatal criteria were met. Maternal descriptors of the experience were categorised as positive, and the behavioural state of the baby was recorded by the mother to be either settled or asleep.

Feasibility study: recruitment

As the feasibility study did not aim to estimate an effect size, the sample size considered the cost and feasibility of recruitment and the inclusion of a diverse range of participants. The feasibility study sought to recruit a minimum of ten participants, a traditional sample size for pilot studies (Nieswiadomy, 2002). Face to face recruitment took place over three months, anticipating a 50% attrition rate between antenatal recruitment and postnatal enrolment. Thirty-three women were recruited antenatally, of which 11 were consented and enrolled postnatally (66% recruitment to enrolment attrition).

Purposive sampling was to recruit a heterogeneous sample of participants which represented the full remits of the inclusion criteria, such as a range of birth modes and neonatal birth weights (Table 4.3). Maximum variation purposive sampling also addresses the lack of socio-economic and ethnic diversity found within clinical research by recruiting participants who reflect the diversity of the local population. Demographic information was collected with informed maternal consent via a verbal history from the mother and verified using the electronic maternity records. Provision of the participants' demographic details also allows for the identification of potentially confounding variables and informs the generalizability of research results. The diversity of participants in the feasibility study sample suggests that the language and documentation used during recruitment was appropriately accessible, and that purposive maximum variation sampling was successful.

Table 4.3 Feasibility study participant characteristics

Dyad subject	Maternal age (years)	Parity	Ethnicity and nationality	Gestation at birth (week+day)	Birth type	Neonatal age (days)	Neonatal birth weight (grams)	Feeding Practice
1	29	3	5	42+2	SVB	20	3050	BF
2	26	2	5	39+6	SVB	9	3240	BF
3	39	1	1	39+4	NBF	5	3320	FF
4	23	2	6	42+2	SVB	12	3840	MF
5	26	1	4	40+4	SVB	4	3300	BF
6	35	3	7	38+3	SVB	6	2900	BF
7	30	2	2	38+4	SVB	14	4000	MF
8	30	1	6	41+6	VEN	7	3160	FF
9	24	1	2	40+5	SVB	10	3320	MF
10	27	2	5	37+5	SVB	11	2500	BF
11	32	2	1	41+0	SVB	9	4300	FF

Table 4.3 Feasibility study participant characteristics: Key

Ethnicity key: 1 White British, 2 White European, 3 Irish Traveller/Roma, 4 Black British, 5 Black African/Caribbean, 6 British Asian – Indian subcontinent, 7 Asian – Indian subcontinent, 8 Asian – other, 9 Mixed ethnicity.

Birth type key: SVB Spontaneous vaginal birth, NBF Neville Barnes forceps assisted birth, VEN Ventouse assisted birth.

Feeding practice key: BF exclusively breastmilk feeding, MF Mixed feeding including breastfeeding and formula feeding, FF exclusively formula feeding.

Feasibility study: results

The results of the feasibility study are summarised as follows; the results were published in full in a peer-reviewed academic journal (Bailey et al., 2017) which is included in Appendix H. The feasibility study identified no issues with the design of the Snuby garment but did identify a manufacturing error with the sizing of the front panels of larger sized garments. This error was rectified before the production of garments for larger-scale trialling. The researcher checklist was scored from 0 -11, with a score of zero indicating that none of the checklist criteria were met, and eleven indicating that all of the checklist criteria were met. A full score of 11 was used as a surrogate outcome to suggest the study design was eligible and appropriate to be scaled up into a larger, randomised controlled trial. Scores of less than eleven were to prompt a review of the data collection episode and study design with the researcher's academic supervisors. Checklists identified no issues with neonatal positioning, study documentation or participant data collection; all checklists scored 11/11. All neonatal temperatures were normothermic following 30 minutes of Snuby-facilitated skin-to-skin contact with a mean pretest- test difference of 0.0°C.

Of the eleven data collection episodes, 10 met the criteria for a positive experience (as per the outcome measures detailed in the previous section). Maternal participants remarked positively on the design, fit, and appearance of the garment. Simple word repetition analysis of field notes identified 'safe', 'secure', and 'comfortable' as the most frequently used descriptors of the garment. Regarding neonatal behaviour, all mothers recorded their baby's behaviour as 'settled' or 'asleep' following 30 minutes of Snuby usage. Unexpectedly, a change in maternal behaviour was also observed following the commencement of Snuby usage; mothers increased their use of infant-directed speech and positive affect towards their baby. Due to the one-group design of the feasibility study, it is unclear whether this change in maternal behaviour results from skin-to-skin contact irrespective of the facilitation strategy or the use of the Snuby garment specifically.

Feasibility study: in summary

The feasibility study met its aims to inform the development of a larger, randomised controlled trial, and provide a trial of the garment within monitored conditions and a safe environment. The researcher checklist demonstrated appropriately developed study

documentation, which was clear and comprehensive. No issues were identified with the terminology, and the study protocol was adhered to. No amendments were made to the study documentation for scaling up to the larger trial, but important amendments were made to the manufacturing process of the garment to standardise the front panel size.

The findings from the feasibility study demonstrated that it is feasible to expect maternal participants to use these study documents and garments in a larger study without direct researcher supervision. The data collection method for taking the baby's temperature was found to be user-friendly and was completed without error by all participants. Maintenance of neonatal temperature and position within clinically acceptable ranges was observed in all participating dyads, providing a rationale for a larger study without researcher presence at data collection episodes. The feasibility study also provided preliminary findings of the relational effects of Snuby-facilitated skin-to-skin contact, which should be further explored following a prolonged period of trialling in the larger study with comparable intervention and control groups. The qualitative data generated from the transcription of maternal comments whilst wearing the garment suggest that the garment is an acceptable intervention for a diverse range of women and their babies, and warrants further participant-initiated trialling to determine maternal uptake, acceptability, and efficacy.

Phase II: The randomised controlled trial

Randomised controlled study: design

Following the feasibility study, a randomised controlled trial (RCT) design was used to assess the effects of the provision of the Snuby garment in the postnatal period. Equally weighted intervention and control groups were created through the opaque sealed envelope method of randomisation. All participating mother-infant dyads received routine pregnancy and postnatal care following local trust guidelines. In addition, dyads randomised to the intervention arm received a Snuby garment for use until they reached six weeks postnatal when the garment was collected back by the researcher. Irrespective of group allocation, all participating dyads recorded their infant feeding methods weekly using provided questionnaires and recorded the frequency and duration of skin-to-skin contact episodes on provided charts alongside the baby's behaviour and temperature (Appendix F).

Randomised controlled trial: outcome measures and variables

The following outcome measures were developed in line with the study aims and objectives. In order to maximise the internal validity of the research design, it is necessary to explicitly specify both how the intervention variable will be manipulated, and the precise way that the outcome variables will be measured in advance of conducting the research (Sim and Wright, 2000). This process of translating concepts into empirical referents is known as operationalizing (Sim and Wright, 2000). Following the description of the study outcomes measures, operational definitions are provided for study variables to provide transparency and clarity.

Primary outcome measures

Outcome measures for the main study: breastfeeding

- Mother-infant dyads feeding *any* breastmilk at six weeks postnatal
- Mother-infant dyads feeding *only* breastmilk at six weeks postnatal

Outcome measures for the main study: neonatal thermoregulation

- Incidence of neonatal *hypo*thermia after thirty minutes of skin-to-skin contact
- Incidence of neonatal *hyper*thermia after thirty minutes of skin-to-skin contact

Outcome measures for the main study: practising of skin-to-skin contact

- Frequency of skin-to-skin contact episodes over the six week postnatal period

For infant feeding outcomes, the six week time point has been used for several reasons. Firstly, 6-8 weeks is the standardized infant feeding data collection point for the Healthy Child Programme (Department of Health 2009). Secondly, 6-8 weeks marks the end of routine maternity care provision in line with national guidance (NICE, 2015) and therefore, the scope of the researcher as a practising midwife. For thermoregulation outcomes, the thirty minute time point for temperature monitoring whilst in skin-to-skin contact reflects the amount of time participants may use the garment for, based on conversations with the PPI group. Intervals of temperature monitoring for babies receiving kangaroo care varies widely in the literature from 5 minutes (de Albuquerque et al., 2016) to six-hourly (World Health Organisation, 2003b). Temperature monitoring at 30 minutes post commencement of skin-to-skin contact demonstrates a judicious approach to swiftly identifying developing neonatal hypothermia and hyperthermia.

Operationalization

Without prior operationalization, data is vulnerable to manipulation based on results, where outcomes are determined based on the research data. The following operational definitions are provided for the study variables as follows (Table 4.4).

Table 4.4 Operational definitions of variables

Variable	Operational definition
Intervention variable:	
Provision of a skin-to-skin facilitating garment	A skin-to-skin facilitating garment is provided to the mother within one week of giving birth. This is in addition to receiving routine postnatal care from the hospital and community midwifery teams. The garment may be used as much or as little as the mother decides until the baby is six weeks old.
Primary outcome variables:	
Normothermic temperature	A neonatal axillary temperature taken after thirty minutes of uninterrupted skin-to-skin contact. The temperature is measured by the mother with a provided electronic axillary Omron EcoTemp thermometer. Normothermic range refers to a temperature of 36.5-37.5°C. Temperatures of less than 36.5°C are categorised as hypothermic, and temperatures exceeding 37.5°C degrees Celsius are categorised as hyperthermic (World Health Organisation 2003b)
Any breastmilk feeding at six weeks	Any feeding of mother's own breastmilk at six weeks post-birth via breastfeeding, or feeding mother's own expressed milk via alternative method such as, but not limited to, syringe, cup, or bottle.

Exclusive breastmilk feeding at six weeks	Exclusive feeding of mother's own breastmilk at six weeks post-birth, without any supplementation of infant formula or alternative food or drinks. Exclusive breastfeeding may include the provision of oral medications but excludes medicated infant formula (World Health Organisation and UNICEF 2014)
Frequency of occasions spent having skin-to-skin contact.	Amount of occasions which the mother and baby have had skin-to-skin contact as recorded by the mother on data collection sheets in the first six postnatal weeks, irrespective of the length of time spent in skin-to-skin contact on each occasion.

Randomised controlled trial: procedure

Recruitment and sample size

As this is the first study of the Snuby garment, no data were available to inform the anticipated effect size of the intervention. The closest applicable research, a study comparing the effects of intermittent kangaroo mother care (KMC) and conventional care on the outcome of exclusive breastfeeding (Conde-Agudelo and Díaz-Rosello 2014), was used to estimate an effect size (0.24). Under the assumptions of 80% power, a critical limit of significance of 0.05, and a two-tailed test, the target sample size for the randomised controlled trial was 184 participants in total (92 per group).

Manca et al. (2013) found that face to face recruitment in clinics and ultrasound facilities was the most successful method for recruiting pregnant women into clinical research. Based on this research, women were initially recruited in the antenatal period by the researcher, who attended maternity clinics and wards within the NHS trust. Women awaiting appointments were approached about the study, and if they expressed interest, were provided with a participant information booklet and follow-up contact details of the researcher. An opportunity to provide consent for study participation was initially offered at a minimum of two weeks after receiving study information. Posters and flyers (Appendix I)

were also displayed by the researcher and community and hospital-based midwives, who were briefed on the study design to recruitment. Face-to-face recruitment aimed to reduce the risk of excluding more marginalised groups of women unintentionally. Women who did not have access to their own means of communication or those who spoke English as a second or additional language were identified as likely to benefit from researcher-initiated face to face interaction rather than participant-initiated interaction via phone or email.

This initial meeting served to establish a relationship with women considering participation, acknowledging the power dynamic between the researcher and the women receiving pregnancy care. Borbasi et al. (2005) advocate minimising the power dynamic between researcher and participant through strategies such as two way information sharing, and providing space for concerns to be raised. Using a feminist lens, Tong (1995) characterises the researcher-participant relationship as one based upon intimacy, self-disclosure, reciprocity, and caring. The characteristics of care and reciprocity in relationship building have been well established in midwifery practice, particularly evident in the work of Kirkham (2010), Deery (2010), Hunter (2006) and Hunter et al. (2008). Two-way information sharing was embedded within the recruitment design, with self-disclosing conversation openers including information about the researcher's name, profession, and role within the research. The researcher continued to work clinically as a hospital midwife throughout the recruiting period, which all women who were considering participation were made aware of. Visibility as a midwife within the research setting sought to demonstrate professional values which women may recognise, and attribute to their view of research.

Recruitment and data collection coincided, as the researcher accommodated the minimum consideration window, and the varying gestations and postnatal ages of the participating dyads. Women who were recruited in the antenatal period were offered a preliminary assessment of inclusion and exclusion criteria, to provide as much information as possible about their likelihood of eligibility once postnatal. Women who were planning a caesarean section birth, carrying a multiple pregnancy, or outside of the body mass index criteria were excluded antenatally. Complete inclusion and exclusion criteria were definitively applied once the woman had given birth. Copies of the study documentation were retained by the participant, and filed in the corresponding episodic records. The original consent forms were stored in the researcher's site file, which was securely held on site as per the

research protocol. Contemporaneous records were kept in the electronic maternity notes, detailing the recruitment to the study and the informed consent process, as per professional standards (Nursing and Midwifery Council, 2015). Actual recruitment figures, alongside a post-hoc power calculation, are presented in the following chapter.

Assessing eligibility

Participants were requested to contact the researcher within 48 hours of the birth of their baby to discuss the details of the birth. Following a conversation with the participant, eligibility was assessed by reviewing electronic maternity records. Participants who did not meet all study criteria were thanked for their time and encouraged to still have as much conventionally-facilitated skin-to-skin contact as they desired, seeking any necessary support from their community midwife as per routine postnatal care. Encouraging the uptake of skin-to-skin contact for excluded participants sought to alleviate any potential feelings of disappointment or failure at not achieving a physiological birth or conventional postnatal experience, and permit participants to still engage in the research topic without data collection.

Randomisation

For all participants who met the study criteria and gave informed consent, the sequentially numbered opaque sealed envelope method of randomisation was used. Randomisation is the process used to give each participant a known chance of being assigned to a treatment or control group (Beller et al., 2002). The randomisation sequence was computer-generated by creating a random binary code with an equal number of both digits using Microsoft Excel. This code was created by a statistician outside of the research project. To conceal the allocation until interventions were assigned, the code was inserted into opaque envelopes which were sequentially numbered. The opaque sealed envelope method is low cost, as it does not require specialist equipment or a subscription to an external randomisation provider. Potential fallibilities of the opaque sealed envelope method were considered, such as the potential for revealing the allocation using bright light before opening the envelope, and opening of envelopes ahead of allocation to change the order in which participants are randomised (Torgerson and Roberts, 1999). Distance randomisation where the allocation is revealed by an external party rather than the recruiting clinician was considered but found to be unfeasible due to funding limitations and lack of available external personnel.

Research integrity was ensured by double sealing the allocation slip within a smaller envelope inside a larger envelope to rule out the use of bright light to subvert the randomisation process. The random binary code was also stored by the external statistician to facilitate an audit of adherence to the randomisation process by academic supervisors. The result of the randomisation process was explained to the participants immediately after randomisation, and an opportunity was provided to ask any questions regarding the randomisation process, including the option to have conventionally facilitated skin-to-skin contact irrespective of group allocation as per usual postnatal care practice. This process of assessing eligibility and randomisation sought to reduce the risk of selection and allocation bias in the research process.

Quantitative data collection

Following the establishment of postnatal eligibility and informed consent, participating dyads were met by the researcher in the maternity unit or at home, dependent on their preference. Demographic details were recorded on a baseline questionnaire which were stored securely, then collated with the rest of the questionnaires once participation was completed. Participants were provided with a participation pack, containing questionnaires to be completed at discharge from hospital care, then weekly from the date of the baby's birth until six weeks postnatal. The questionnaires were labelled with dates for completion and researcher contact details. The questionnaires recorded data on the dyad's feeding method, engagement with skin-to-skin contact, and free text data on the experience of using the Snuby garment or having conventionally-facilitated skin-to-skin contact.

Neonatal behaviour and temperature charts were also provided for completion with each episode of skin-to-skin contact. The pack also contained relevant safety information on recording and acting upon neonatal temperature readings, and a 'how-to' guide for taking an axillary temperature. The intervention group were also provided with a safety guide for the use of the facilitating garment. The participant pack was discussed with each participant to provide verbal instruction in addition to the documentation and clarify data collection requirements. A demonstration was provided on the correct method of taking a neonatal axillary temperature, along with the provision of an Omron EcoTemp axillary thermometer. An opportunity to ask questions was provided, and up to date contact details for weekly liaising were exchanged. Participants were contacted weekly by their preferred method of

communication to provide the opportunity to raise any concerns with study participation or report any incidences of hypothermia or hyperthermia within the garment. A maximum of two attempts to contact the participant were made per week to avoid undue stress or feelings of coercion. An electronic log was maintained of participant contact to monitor the frequency of contact attempts.

Participants collected varying quantities of paired neonatal behaviours and depending upon how frequently they engaged in skin-to-skin contact. Data were not collected by the participants when skin-to-skin contact episodes lasted less than thirty minutes, as skin-to-skin contact was not maintained for long enough to significantly change the neonate's temperature. Additional neonatal temperature and behaviour sheets were offered in weekly conversations and were provided as required. The completed data collection packs were collected from participating dyads following the six week postnatal period. Any temperature and behaviour data collected by the dyad after the six weeks but before the collection of the pack was not included in data analysis.

Assessment of rigour in quantitative research

The assessment of rigour serves to evaluate the extent to which researchers have worked to enhance the quality of a study (Heale and Twycross, 2015). In quantitative research, this is achieved largely through the measurement of validity and reliability (Heale and Twycross, 2015). These concepts will be considered and applied to provide a self-assessment of the rigour of the quantitative aspects of this study.

Assessment of validity

The National Institute for Health and Care Excellence (NICE) (2012) have published a quality appraisal checklist to evaluate the internal and external validity of quantitative intervention studies. This checklist has been used to structure this assessment of validity. Internal validity refers to the outcomes being attributable to the intervention being assessed, rather than another, often unidentified, factor (NICE, 2012). Instead, external validity refers to whether the study findings are generalizable to the source population (NICE, 2012).

The assessment of internal validity considers the procedures of selection and allocation in the study (NICE, 2012). The internal validity of this study is strengthened by the randomisation procedure detailed in the previous section. Randomisation serves to minimise

the risk of allocation confounding the study findings, as neither the participant nor the researcher can influence the allocation. In addition to randomisation, the allocation algorithm was concealed in opaque sequentially numbered envelopes. The concealment of the allocation algorithm is particularly pertinent in undermining the internal validity of a study, as knowledge of the allocation sequence may subvert attempts to randomise. NICE (2012) recognises randomising participants with equal chances of allocation to intervention and control groups as the most reliable way of avoiding selection bias and confounding in clinical trials, as was employed in this study design.

Lack of blinding is a limitation of the internal validity of this study, as there is the potential for the researcher's knowledge of the treatment allocations to bias the analysis or interpretation of the findings. However, NICE (2012) note that blinding is not always possible. Due to the researcher's dual role in enrolling the participants and analysing the data, and the active participation of the study participants in using the Snuby garment, it was not feasible for either single or double blinding. To mitigate the potential for bias, the data analysis procedure has been clearly detailed to maximise transparency.

Low rates of contamination are also necessary to protect the internal validity of the study (NICE, 2012), as contamination between the intervention and control groups risks undermining the accuracy of the calculated effect size. As the researcher controlled the stock of the interventional garment, there was no possibility of contamination between the groups.

Attrition bias may also affect the internal validity of a study. To avoid attrition bias, transparent reporting of attrition rates is necessary, accounting for the large proportion of attrition where necessary. NICE (2012) suggest attrition rates of less than twenty percent are acceptable. The rate for this study was ten percent attrition from enrolment to completion. Further details of this are supplied in the data analysis chapter.

The assessment of external validity considers the populations: the source population and the study population. To maximise the external validity, the study should ensure that the source population is well described (NICE, 2012) to guide the generalisability of the study findings. In this study, the source population is described with reference to the geographical location, socio-demographic make-up, and healthcare provision (as in previous section Methods – Setting). Representation of the source population in the study population also

strengthens the generalisability of the study findings. In this study, the demographic characteristics of the study population are described alongside the data analysis. Representation of participants traditionally under-served by research, and representative of a diverse and transient population, is considered a strength of this study which is discussed further in the reflection chapter.

Assessment of reliability

Reliability is defined as the consistency of a measure (Heale and Twycross, 2015). NICE (2012) considers objective rather than subjective outcome measures in its assessment of reliability, as self-report may not garner reliable data. This study uses a combination of objective and subjective outcome measures. The temperature outcome measure was objective, as it was digitally recorded on the same type of thermometer used in the clinical setting. However, incorrectly used thermometers may record unreliable data. To avoid this, all participants were shown how to use the thermometer correctly, and given a written guide.

The breastfeeding outcome measure was at increased risk of being unreliable, as it was self-reported by participants, and not assessed using a validated tool (NICE, 2012). As self-report was used, rather than the outcome being measured by a researcher, the study did not include reliability scores. Although self-reporting may lack reliability, it is frequently used in breastfeeding studies as the measure of breastfeeding cannot be blinded from the participant, and only the participant accurately knows their feeding practices.

Other data collection options were considered, such as the researcher observing and recording infant feeding practices at the data collection visit. However, this method of data collection would not necessarily produce more reliable data as it may not be representative of the participant's usual infant feeding practices. NICE (2012) reports biochemically validated outcome measures as more reliable than subjective self-report outcome measures, but it was unfeasible to operationalise this into the study design due to the nature of breastfeeding.

Assessment of rigour in the quantitative methodology

Randomised controlled trials support a rigorous approach to quantitative research as the well-defined processes seek to minimise biases and reduce confounding. Overall, this study demonstrates the external and internal validity of research methods through adherence to

recognised best practice protocols, and examination and minimisation of biases. A lack of blinding is recognised as a limitation to the study's internal validity, which has been mitigated through a transparent approach to analyses. Self-reporting via questionnaires which had not been validated limits the reliability of the quantitative breastfeeding data. However, given the limited researcher resources and the dynamic nature of infant feeding practices throughout the data collection period, it was deemed the most appropriate methodology to minimise attrition rates and maximise participation rates.

Quantitative data analysis

Data analysis was undertaken after the completion of the data collection period of the study. However, the researcher reviewed neonatal temperature data in weekly conversations with the participants in order to identify any issues concerning the thermoregulatory properties of the garment. Interim data analysis served to protect participants by identifying potentially harmful interventions and minimise the exposure of participants to harm.

Processing data

Initially, all raw data were extracted from the paper data collection tools which had been completed by participants, and inputted and reformatted in Microsoft Excel (2016). Personally identifiable information was removed, and data sets were attributed to the respective case number of the participant. Data cleaning preceded analysis, involving repeated cycles of screening the data for omissions, inconsistencies, and errors. Following identification through screening, defective data were either amended or deleted. Chart data that did not meet the protocol requirements were excluded, including paired neonatal temperatures taken following less than 30 minutes of skin-to-skin contact, or single temperatures not recorded with a baseline temperature.

Questionnaire data and chart data were reviewed simultaneously to identify any inconsistencies in data entry. The electronic clinical maternity record-keeping system was used to ratify or amend suspect data, for example, when inconsistencies were noted between the questionnaire answer and the screening tool. The data clean identified several occasions where participants had inaccurately recorded their parity by including their current pregnancy, i.e. gravida 1 para 0 recorded as para 1. These inaccuracies were corrected in line with the electronic maternity record. Audio recording transcripts were reviewed when omissions were noted in the questionnaires. Reviewing the transcripts resulted in the

completion of several unanswered questions, often in the case of a single weekly questionnaire having not been completed by the participant, but having been spoken about in the interview.

When discrepancies were noted between the electronic record and the participant's record of the duration of skin-to-skin contact, the data were left unchanged to reflect the participant's record. The decision to leave the participant recorded data unchanged was supported by the research of Blomqvist et al. (2011), who found that parents were able to record skin-to-skin contact episodes as accurately as nursing staff. Progressive versions of the data were saved to provide an audit trail of the changes. The final data set was then divided up into separate spreadsheets according to the method of analysis.

Skin-to-skin contact frequency was collated per participant in Microsoft Excel and uploaded into SPSS for negative binomial regression analysis. Neonatal temperature data were coded as either hypothermic, normothermic, or hyperthermic as per the operational definitions in the previous section. Once coded, the incidences of hypothermia and hyperthermia were calculated to compare the thermoregulatory properties of the skin-to-skin facilitation methods. Infant feeding data were converted into binary variables and uploaded into SPSS statistical analysis programme for binary logistic regression analysis. Participant interviews were used to verify documented infant feeding practice listed on the questionnaires at the time of the interview. Where it was identified that in some cases, mothers' understanding of exclusivity of breastmilk feeding differed from the definition used within the research design, the questionnaire data were amended in order to reflect the definition of the research study. As not all participants were interviewed, at the pack collection visit, the infant feeding method was discussed between the researcher and participant to ensure the questionnaire data were internally valid.

Identifying predictor variables

In the most recent Infant Feeding Survey, McAndrew et al. (2012) identified age, parity, ethnicity, and socio-economic status as key predictor variables in breastfeeding initiation and continuation. Based on this research, age, parity, and ethnicity were included as predictor variables in the regression analysis. However, many participants did not record data on their household salary bracket signifying their socio-economic status; therefore, this predictor variable was removed from the regression analysis. To better understand the relationship

between ethnicity and breastfeeding, demographic data on first spoken language and country of birth were also collected to discriminate between ethnicity and migrant status. However, given the small sample size, these predictors were not included in the regression tests to reduce the risk of overfitting the model.

High pre-pregnancy body mass index has been shown to reduce the odds of initiating breastfeeding (Thompson et al., 2013), and also inversely correlates with the duration of breastfeeding (Oddy et al., 2006). Upon this evidence, the body mass index of participants recorded at their first antenatal appointment was categorised as either 'healthy', from 18 – 25m^2 inclusive, or 'overweight', from 26-30m^2 inclusive, and included in the regression tests. Women with a body mass index over 30m^2 were not included in the study due to the design and sizing of the Snuby garment.

Gibson-Davis and Brooks-Gunn (2007) identified relationship status as an important correlate of breastfeeding. However, there was a low prevalence of women who were not in a relationship within this study sample (single: in a relationship ratio of ~ 1:17). Predictor variables with a low prevalence were not included in the analysis, as a higher events-per-variable, i.e. >20 is needed when low prevalence predictors are present (Ogundimu et al., 2016), which could not be achieved with this sample size. Although there is no defining threshold for high and low prevalence, a conservative threshold of 1:4 was set for low prevalence, given the sample size was less than 100 (N=98). Upon this rationale, the predictive variable of birth mode (assisted: spontaneous birth ratio of ~ 1:5) was removed from the analysis. Birth mode data were primarily collected to assess against the study inclusion and exclusion criteria, and its omission from the regression tests is supported by various studies failing to demonstrate the impact of assisted vaginal birth on breastfeeding continuation (Asole et al., 2009; Bai et al., 2015).

There is a paucity of research identifying the predictor variables informing the practising of skin-to-skin contact, particularly as a participant-led intervention rather than a prescribed intervention such as kangaroo mother care. In the absence of informing research, the predictor variables from the breastfeeding regression models were extrapolated. The included independent variables were: study group, parity, ethnicity, age, and body mass index. In addition, the variable 'initiated breastfeeding' was included as a predictor to explore

the relationship between the decision to breastfeed and the practising of skin-to-skin contact.

Statistical tests and assumptions

To analyse data on skin-to-skin contact frequency, a Poisson regression test was planned. However, early models showed over-dispersed residuals (Pearson $\chi^2/df = 12.19$); therefore, a negative binomial regression test was performed. Negative binomial regression is a generalisation of the Poisson regression, which is appropriate to use to analyse count data when the conditional mean and the conditional variance are not equal (Hilbe 2011).

To analyse data on neonatal temperature, paired temperature data were grouped into three categories: intervention group using Snuby, intervention group not using Snuby, and control group not using Snuby. The incidence and error parameter were calculated using Microsoft Excel to compare the incidences of hypothermia and hyperthermia between the facilitation methods. Mixed effect model regression analysis was considered but found to be outside the scope of this study, given the risk of overfitting when both the prevalence of abnormal temperatures and the sample size is low.

Binary logistic regression tests were performed to predict the probability of breastfeeding uptake, continuation, and exclusivity based upon intervention allocation, and the remaining demographics of age, body mass index, parity and ethnicity. The test was repeated with different dichotomous dependent variables to respond to the research questions. These were: 'commenced breastfeeding', 'giving any breastmilk at six weeks postnatal', 'giving only breastmilk at six weeks postnatal', and 'exclusively breastfeeding at six weeks postnatal'.

A main effects regression analysis test was performed initially to analyse the effect of the provision of the Snuby garment, and the accompanying variables on the outcomes of interest. This test uses a forced entry method of entering the predictors into the model, recognised by Studenmund and Cassidy (1987) as the only appropriate method for theory testing. Next, a stepwise method of regression was performed, to explore the effects of the independent variables on the outcome of interest. Stepwise regression remains contentious in the field of statistics, as it enters predictors into the model using a purely mathematical approach, rather than based upon previous research informing their predictive value on the

outcome of interest (Field 2018). Such an approach may result in a model which has been overly influenced by the sampling process, and as such, lacks generalizability (Field 2018). However, stepwise selection permits the exploration of predictive variables to determine which may warrant further research and is regularly utilized in breastfeeding research (Al-Sahab et al., 2010; Oddy et al., 2006; Sparud-Lundin et al., 2011). This method of regression is helpful to inform the design and focus of subsequent research in the same field. Being the first study of Snuby facilitated skin-to-skin contact, the inclusion of an exploratory style of regression analysis is warranted to identify variables of interest for subsequent research.

In all of the regression tests, p values are reported as a measure of significance; the smaller the p value, the greater the incompatibility of the data with the null hypothesis (Wasserstein and Lazar, 2016). A threshold probability value of 0.05 is widely applied in clinical research, but should not be interpreted without an assessment of the accompanying confidence intervals and sample size (Concato and Hartigan, 2016). As such, the widely utilized threshold of 0.05 was applied following regression tests, alongside the sample size and 95% confidence intervals to aid the interpretation of the results.

Before running logistic regression tests, continuous independent variables must be tested for linearity, as the assumption of linearity is a pre-requisite for logistic regression (Hilbe, 2011). The Box-Tidwell procedure (Box and Tidwell, 1962) was used to determine the type of relationship between the continuous independent variable of age (recorded in years) and the logit of the dependent variables, breastfeeding initiation, continuation, and exclusivity. A Bonferroni correction was applied using all nine terms in the model resulting in statistical significance being accepted when $p < 0.00556$ (Tabachnick and Fidell, 2014).

Collinearity statistics were calculated to test for symptoms of multicollinearity, whereby the predictors are correlated, rather than independent of each other. The variance inflation factor (VIF) indicates whether a predictor has a strong linear relationship with another predictor (Field, 2018). Myers (1990) suggests a value of 10 as a threshold to determine concern about multicollinearity biasing the regression model, which was applied to this research study.

Standardised residuals with a value greater than +/- 2.5 were examined, and Cook's distance was used to determine inclusion or exclusion in the analysis. Cook's distance is used

to identify influential outliers, termed “critical values”, which can be removed to optimise the regression model (Cook, 1977, 15). Standardised residuals over +/- 2.5 with a Cook’s distance of 1 or greater were removed from the analysis, and the regression test was re-run. Although the identification of outliers is important, it is not always desirable to remove outliers (Osborne and Waters, 2002). The removal of outliers should improve the fit of the model, but repeatedly removing cases from the dataset decreases the sample size and may jettison valid cases. As there are no available data from a separate population also using the Snuby garment to compare against the sample data, the removal of residuals was limited to one round per regression test. The results of the statistical assumption testing are presented in the following chapter alongside the data analysis and results.

Phase III: The qualitative follow-up

Qualitative follow-up: design

Following six weeks of quantitative data collection, a subset of participants were invited to participate in one-to-one semi-structured interviews. This follow-up phase aimed to explain the infant feeding and skin-to-skin contact practices which had been recorded by the participating dyads during the six week postnatal period. Semi-structured interviews were used to elicit pertinent information relating to the participant’s experience which responded to the research questions, whilst enabling the participant to maintain some control over the pace and focus of the data collection.

Qualitative follow-up: procedure

Sampling for qualitative data collection

A purposive maximum variation sampling technique was used to create a subgroup of participants for qualitative data collection. The rationale for using this sampling technique is provided at the beginning of this chapter. Fairness is considered to be the most important criterion for achieving authenticity in qualitative research (Guba, 2004). Procedures such as sampling enable fairness through value pluralism: honouring the different values from participants to compare and contrast (Amin et al., 2020). Efforts were made to include women from both the intervention and control group, including women who were

breastfeeding, formula feeding, and mixed feeding, and those who practised varying quantities of skin-to-skin contact through the postnatal period to reduce the potential for selection bias. The continuous informed consent process also underpins the concept of fairness (Amin et al. 2020), as it promotes a shift in power to the participant. This process is discussed in more depth later in this chapter.

Qualitative data collection

Semi-structured interviews were conducted with 44 participants in their homes at a mutually convenient time following the six week postnatal period. Qualitative data were collected following quantitative data collection, in order to permit the participants' retrospective consideration of the entire postnatal period and in keeping with the sequential explanatory research design. The structure of the interviews was informed by the pre-prepared topic guide (Appendix J) and by reviewing the participant data collection pack to add pertinent questions which would explain how and why the participant had engaged with breastfeeding and skin-to-skin contact. Use of the same interview topic guide through all of the interviews was used to promote fairness, a criterion for authenticity in qualitative research, by making equal opportunities for each participant's voice to be heard (Amin et al., 2020). The themes of manageability, comprehensibility, and meaningfulness (Antonvosky 1987) were embedded within the topic guide to explore the participants' experiences using a salutogenic framework. Follow-on questions were created contemporaneously during the interview to further explore developing themes or subject areas mentioned by the participant.

Positionality as a midwife and breastfeeding worker influenced the responses and question development during the semi-structured interviews. Rather than framing women's decisions to use formula milk as negative, an empathic stance was adopted in which responses recognised the challenges women faced in carrying out breastfeeding as their intended feeding method. Following the completion of the topic guide, or upon signs that concentration had been lost by the dyad, an opportunity was provided for any further thoughts on skin-to-skin contact or infant feeding to be voiced. An open-ended prompt was used to ensure that space was created for the mother to share any thoughts or ideas which were not anticipated by the researcher, or to frame ideas which were particularly significant in her experiences.

Interviews were audio-recorded with informed maternal consent using an encrypted digital device. Recordings were stored in line with General Data Protection Regulations (2016) alongside the participant identification number. Recordings were transcribed verbatim and checked for accuracy by the researcher's academic supervisor. The framework method of analysis, described in the following section, requires verbatim transcription without the conventions of dialogic transcription such as pauses or simultaneous speech as it is primarily concerned with the content of the recordings (Gale et al., 2013). Video recording was considered as a qualitative data collection method, in order to record non-verbal dyadic interactions during the interview. A decision was made to use audio-only recording to minimise the formality of the interview, and reduce perceptions of judgement being made on mothering behaviours or infant feeding practices throughout the interview. Audio recording was generally well-received by participants, with no issues raised before or following qualitative data collection.

Assessment of rigour of qualitative methods

The assessment of rigour in qualitative research remains contentious, with scholars disagreeing on the implementation of evaluative criteria which originate in quantitative research (Creswell and Poth, 2018). Specialist appraisal instruments have been developed for qualitative research to assess the methodological quality of studies, such as by Tong et al (2007). However, their usage alone does not necessarily demonstrate the study's rigour (Amin et al, 2020). Rather than using an appraisal instrument alone, Amin et al (2020) suggest that researchers reflect on quality criteria for qualitative research, and consider the strategies for demonstrating rigour in context with the specific research questions.

The principles of trustworthiness and authenticity (Amin et al 2020) are examined with reference to the research aims and method. The practices of researcher reflexivity, positioning, building of respectful, trusting relationships with participants, and researcher debriefing support rigour in qualitative research (Gray, 2019). The application of these practices is described in depth in Chapter Seven, alongside a reflective evaluation of the extent to which they built rigour.

Qualitative research methods have unique characteristics which suit different research aims, philosophies, and research subjects. Their appropriateness for implementation in a research study will affect the rigour of the qualitative data collection

methods (Gray, 2019). This section examines the choice of semi-structured audio-recorded interviews as the primary qualitative method in this mixed method study, and evaluates the strengths and weaknesses of alternative methods.

To achieve the goal of understanding participant perspectives, methods of sampling, data collection and analyses may shift during the study (Creswell and Poth, 2018). Initially, focus groups were planned as the primary qualitative method for both maternal and midwife participants. Focus groups are a "semi-structured group interview" which aims to elicit data on a defined topic of interest (Bracati 2018, 156). These were planned to collect large volumes of data in a short space of time, and were anticipated to be acceptable to participants due to their social aspect. The successful implementation of focus groups for similar subject topics is evident in recent research by Arida et al (2019) in their study of mothering experiences, and by Craig et al (2018) in their study with parents of babies receiving hospital care.

However, the research protocol was amended through the Research Ethics Committee to remove focus groups, and replace them with semi-structured individual interviews. The rationale for this change was the difficulty in coordinating focus group attendance with mothers and their babies. Focus groups require participants to gather away from their home in a neutral space (Gray, 2019), which was unfeasible for mothers with young babies. Instead, individual interviews enabled maximum flexibility for data collection episodes to maximise rates of participation, particularly for participants that did not have the financial means to travel.

There were several methodological advantages to conducting individual interviews. Individual interviews also avoided a heterogeneous group of participants reducing both the trustworthiness and transferability of the findings, as there may have been an imbalance in participation in focus groups based on confidence conversing in English or levels of education (Gray, 2019). Conducting interviews in participants' homes enables data to be socially and environmentally contextualised, which can strengthen the researcher's interpretation of the data, and inform the transferability of the findings. Individual interviews and a longitudinal study design also promote a prolonged engagement with each participant (Lincoln and Guba 1985), which enables the researcher to build trust, and become cognizant of potential distortions emerging from their own prior anticipations about the study findings (Amin et al.,

2020). Focus groups were also planned in the original 'Phase three' of the study as described in the protocol, whereby midwives were invited to participate. This did not take place due to a lack of time, as the data collection for Phase II took longer than anticipated.

In summary, the principles of trustworthiness and authenticity in relation to the qualitative data were embedded in the research process in several ways. Trustworthiness was demonstrated through the processes of negative case analysis and thick contextual description (detailed in Chapter Six) and researcher reflexivity and peer debriefing (detailed in Chapter Seven). By changing the qualitative data collection method from focus groups to interviews, the limitation of heterogeneous participant groups affecting the trustworthiness of the data was negated. To build authenticity, the researcher used prolonged engagement with the study participants, and promoted fairness through the informed consent process, and use of a topic guide, as described earlier in this chapter.

Qualitative data analysis

Identifying characteristics such as names were removed, then transcriptions were uploaded to NVivo software. The process of transcription enabled familiarisation with the qualitative dataset. At this stage, the accuracy of a random sample of transcripts was reviewed by the researcher's supervisor to verify the dependability of the study findings (Amin et al., 2020). A framework method of analysis was used, which included the processes of indexing, charting, mapping, interpreting, and thematic refinement (Ritchie and Spencer, 1994). Framework analysis is particularly suited to larger datasets and, crucially, can facilitate both inductive and deductive methods of analysis (Gale et al. 2013). The framework method of analysis was used to apply salutogenic concepts to the qualitative data and also compare across and within cases. An in-depth description of the process of framework analysis is provided in Chapter Six. The resulting themes were used to explain the findings of the quantitative data by providing context and meaning to dyadic health-promoting behaviours. Negative case analysis was used to enhance the trustworthiness of the thematic analysis, and thick contextual description was used to inform the transferability of the findings (Amin et al., 2020).

Integrating quantitative and qualitative data

The integration of qualitative and quantitative data is key to the value of a mixed methods study (Creswell and Plano Clark 2011). In health services mixed methods research, the integration of qualitative and quantitative methods may occur at several stages, dependent upon the research design and approach (Fetters et al., 2013). This study used two forms of integration. At the methods level, data were integrated through connecting, which occurs when the data are linked by the sampling frame (Fetters et al. 2013). Secondly, quantitative data informed the maximum variation purposive sampling for qualitative data collection.

Primarily, integration occurred at the interpretation and reporting level through narrative. When integrating through narrative, the qualitative and quantitative findings are described in a single report. In this thesis, the qualitative and quantitative findings are integrated in Chapter Eight using the weaving approach, whereby the findings are presented on a concept by concept basis in response to the research aims (Fetters et al. 2013). The rationale for using the weaving approach rather than the contiguous approach, which reports qualitative and quantitative findings separately, was because both qualitative and quantitative findings pertained to each research aim.

Ethical Considerations in Research Design and Conduct

The constituents of ethical research practice vary according to the research discipline, type of research, and the time and place in which it is conducted; Green and Thorogood (2018) suggest it is both impossible and undesirable to define exact criteria to ascertain whether research is ethical. Instead, they consider four frameworks which the researcher can use to determine what can be done ethically: legal and statutory frameworks, disciplinary codes of practices, the local cultural norms of ethical conduct in the institution and fieldwork setting, and formal ethical review through research ethics committees (Green and Thorogood 2018).

These four frameworks were considered when designing the research protocol and undertaking active research. The process of ethical review and approval and the verification of ethical conduct through the audit process is described in the following section. General ethical issues for both the participants and the researcher are explored with reference to the four principles of biomedical ethics: respect for autonomy, beneficence, non-maleficence, and justice (Beauchamp and Childress, 1994).

Ethics training, process, approval, and audit

Before commencing the research process, Good Clinical Practice training was undertaken (National Institute for Health Research, 2016). Mandatory for all NHS researchers, the training provides details of essential measures which must be taken to uphold the integrity of research and protect participants. Following the completion of the training, ethical clearance was sought from Birmingham City University Faculty Academic Ethics Committee (FAEC), which required a written submission of the ethical issues which may be encountered as part of the research process, and mitigations in place to reduce the risk of harm to all involved. Hedgecoe (2016) warns of overly risk-averse ethics committees who work to protect against the risk to the reputation of the institution, rather than the risk to research participants. Such concerns were not substantiated by the FAEC requirements, requesting minor amendments in order to make study documentation clearer for participants.

As the study involved NHS service users, ethical approval was next sought from the local Research Ethics Council (REC) via the completion of an electronic form within the Integrated Research Application System (IRAS). Green and Thorogood (2018) note that RECs are primarily concerned with the safety of clinical research and the ethical principle of non-

maleficence. The REC review outcome reflected this, requiring minor amendments to the wording and photographs on participant information sheets to ensure safe usage of the garment. Following these amendments, Health Research Authority (HRA) approval was issued (Appendix K), and site capacity and capability was confirmed before embarking upon active research. The study was randomly selected for an internal research and development audit by the hosting NHS trust in September 2018. The investigator site file was reviewed alongside source data, case report forms, and study documentation for a randomly selected 10% of participants. Positive feedback was received on the consenting process, and the investigator site file was commended. An action plan of amendments was produced by the research and development department and was duly completed by the researcher within the prescribed time frame, none of which altered the time frame or key features of the study.

Public Involvement

Public involvement in the design of research studies aims to make research more ethical by helping to define what is acceptable to participants, improving the experience of participating in research and making the research more useful to the public (Health Research Authority/ INVOLVE 2016). An open invitation was provided to local student midwives, asking for their collaboration on the research design. Five student midwives, who were also mothers, attended a meeting about the research design. The key points identified were:

- How long the Snuby garment might be used for. The group felt that the Snuby garment would typically be used for 30 minutes, so neonatal temperature monitoring should take place within this time.
- Barriers to data collection. The group felt that the data collection instruments should be as quick and straightforward as possible, as mothers were likely to have competing responsibilities.
- Barriers to recruitment and enrolment in the hospital. The group were concerned that midwives would not have the time to recruit and enrol women on the study. The consent process should be part of the role of the researcher, not the named midwife.

Recruitment of participants

Access to maternity populations

The first stage of the research process posed many ethical considerations. The value of research recruitment relies on the ethical theory of utilitarianism; as a rule, widespread participation in research is likely to produce the best outcome for society through the generation of knowledge to improve health, even if it does not directly benefit the participant. The recruitment of participants presented several ethical issues which are explored in the following section. The first ethical consideration of recruitment was the process of gaining access to the maternity population. Third-party access to pregnant and postnatal women has sparked much media interest and debate, particularly following women's reports of feeling vulnerable and pressured when targeted by companies such as Bounty in the immediate postnatal period (Eleftheriou-Smith, 2018; Garner, 2013; Peck, 2014). In a Mumsnet survey preceding a petition against the presence of Bounty representatives on postnatal wards, 82% of women felt it was unacceptable for the NHS to allow commercial companies to have access to patients (Mumsnet, 2013). The deleterious effects of external commercial pressures in the pregnancy and postnatal period are reflected in The Code of Marketing of Breastmilk Substitutes (World Health Organisation, 1981) which forbids commercial formula milk companies from direct contact with women on the maternity wards. Although research recruitment may not be construed as 'for profit', recruitment may be financially incentivised for individual clinicians or the institution itself.

Several mechanisms are in place to protect maternity service users from commercial or external pressures which do not directly benefit their own health and wellbeing, such as the requirement of permission of access. In order to secure the permission of access from the NHS trust, the researcher sought the views and approval of midwifery leaders within the organisation, including the head of midwifery, consultant midwife, and head of community midwifery. These organisational leaders served as gatekeepers, controlling research access to the organisation (Jupp, 2006). The action, or inaction, of gatekeepers may be influenced by a range of factors, including the level of understanding of the research, their feelings towards the study's outcomes, and their attitudes and beliefs about the subject matter of the study (McFadyen and Rankin, 2016). As such, the researcher sought to convey the benefits of the research to both the hosting trust and its maternity service users.

In conversations with the gatekeepers, the ethical principle of justice arose as a primary concern. The principle of justice in biomedical ethics pertains to equitable access to care and resources (Hay and Marshall, 2019). Before allowing access to the maternity service user population, the gatekeepers required assurances that recruitment and research methods would facilitate the inclusion of women who were traditionally under-represented in research, and also at most risk of poor perinatal outcomes. In particular, gatekeepers sought assurances that women who spoke English as an additional language, and women with a raised body mass index were included in the research, and as such, had equitable access to participation. This gatekeeper requirement led to a review of the proposed study criteria and careful consideration of how to maximise the accessibility of participation. The language used on study documentation was reviewed for simplicity and clarity, and the language requirements were amended from 'proficient' to 'basic' spoken and written English.

The community midwives working for the NHS trust formed an additional layer of gatekeepers. One method of participant recruitment featured community midwives referring women to the researcher, which presented a risk of bias when selecting which women may be interested in participating. The community midwives that referred the most women tended to be professionally aligned with other health-promoting practices, such as pregnancy yoga, and aromatherapy. Women who spoke English as a first language, and identified as British tended to be over-represented in referrals from these midwives. To address this imbalance, the researcher ensured face-to-face recruitment included areas accessible to all women, such as ultrasound scan and phlebotomy departments, which did not require prior engagement in additional maternity services.

Recruiting pregnant women into interventional research: feminist bioethical considerations

Medical research has historically neglected to provide the same attention to women's health issues as that of men (Sheldon, 1998); women's health issues may not have benefitted from medical advancement due to a lack of recruitment into clinical research (Institute of Medicine and C.E.L.I.R.I.W.C. Studies, 1994; Sheldon, 1998). However, with an implemented research agenda and recruitment monitoring, gender parity in research recruitment can be achieved; in the U.S.A., women now represent 49% of participants in National Institutes of Health funded studies following such efforts (Blehar et al., 2013). Despite improved gender representation, there remains widespread reticence to enrol pregnant women into

intervention-based clinical research (Blehar et al., 2013). A feminist perspective of bioethics arose in the 1970s (Hay and Marshall 2019) which challenged the paternalism inherent in the exclusion of women, particularly pregnant women, from clinical research. Feminist bioethicists were principally concerned with social equality and self-determination, challenging the traditional biomedical research recruitment process and contesting the societal norms which regarded the male as the archetypical research subject (Eckenwiler et al., 2008).

Tragedies such as the thalidomide scandal, where a teratogenic drug was prescribed to thousands of pregnant women for the treatment of nausea, further excluded pregnant women from intervention-based studies, despite the acknowledged risks of providing care and treatment without an appropriate evidence base (Blehar et al., 2013). Paradoxically, Macklin (2010) identified the thalidomide scandal as a case in which the harm to the population could have been considerably reduced if the drug was subject to a phase I clinical trial. Rather than avoiding the recruitment of pregnant women into research, women were exposed to risk and harm through lack of research. For pregnant women specifically, the undermining of their autonomy to participate in clinical research trials and determine their own healthcare needs can be partially attributed to the notion of maternal-fetal conflict. Blehar et al. (2013) describe maternal-fetal conflict as a false dichotomisation of the rights of the woman and the fetus, which is commonly cited when women's decision making is curtailed to protect fetal wellbeing (Eckenwiler et al., 2008).

Rejecting the conflict-based model of perinatal ethics, Harris (2000) illustrates an ethical model which focusses on the mutual needs of the woman and fetus and conceptualises the wellbeing of the woman as the most important aspect of fetal wellbeing. This ethical model is in keeping with the midwifery philosophy of woman-centred care which regards the needs of the woman as encompassing those of the fetus, baby, and her wider family (Leap, 2000; Leap, 2009). As this study was not a controlled trial of a medicinal product and did not involve clinical interventions in pregnancy, such risks were negated. However, the overarching themes of paternalism and disempowerment were considered in order to shape a research design which facilitates women's autonomy in deciding whether to partake in research and recognises the mother-infant dyad as an inseparable entity. To protect the

rights of pregnant women to determine their own, and their baby's, involvement in clinical research, the process and ethical implications of informed consent are examined.

Informed consent

The informed consent process has been key to supporting the shift away from medical paternalism and towards individual autonomy (Jefford and Moore, 2008). Informed consent is an ethical and legal concept which requires the person to be capable of understanding and assessing the information provided about the treatment or intervention, including the potential risks, benefits, and alternatives, and not coerced into making a decision whether to accept or decline the treatment or intervention (Cocanour, 2017). Informed consent is enshrined in professional codes of practice; midwifery registration requires the practitioner to be competent at providing evidence-based, non-biased information and gaining consent before providing care and treatment (Nursing and Midwifery Council, 2015). Although often described as gaining consent, it is essential that both the practitioner and researcher recognise the right for informed refusal or declination as fundamental to the consent process.

Consent – maternal participants

In order to provide informed consent, the decision must be free from coercion (Cocanour 2017). Pregnant women may be particularly vulnerable to coercion as they may make altruistic decisions based upon the perception of the risk to the fetus, which has been conveyed by professionals (Kukla, 2005). With responsibility for their own health and the health of the fetus, pregnant women may rely on professionals' opinions when making decisions about care and treatment (Kukla 2005). Pregnancy is also regarded as a crucial period for health education and promotion (McNeill et al., 2012), with pregnant women exposed to large volumes of information regarding disease prevention, identifying pathophysiology, and education for birth and parenthood. As such, pregnant women have reported information overload, unable to retain or use the knowledge they had learnt in antenatal education classes (Nolan, 2009). It is therefore essential that women are given adequate time and resources to revisit and digest the information which is required to make an informed decision about participation in a research study. Upon this basis, a minimum

consideration period was implemented in the study design following the provision of the participant information sheet and researcher contact details.

The purpose of the research, potential risks and potential benefits, as well as the alternatives to participation, were shared verbally, via the participant information booklet (Appendix L), and the informed consent form (Appendix M). Flory and Emanuel (2004) assessed interventions used to improve participant understanding through the informed consent process and found ambiguous results for most interventions, including a multimedia presentation of information and enhanced consent forms. However, they found that extended one-to-one discussion with participants increased participant understanding with both clinical and statistical significance. These findings were integrated into the research recruitment design which maximised face to face time spent with participants following an opportunity to read the study documentation.

Consent – children unable to consent

Although active participants in the research study, the neonates could not provide consent or assent for the research study. Much has been written about the consent process for children, generally assuming some degree of understanding, and appropriately tailored information provision (De Lourdes Levy et al., 2003). However, with no ability to consent or assent to research involvement, neonatal participation was subject to the mother's wishes. Mothers, as primary caregivers and sole legal guardians before birth registration, were considered best placed to determine whether the mother-infant dyad participated in the research study. Having already made numerous decisions regarding care and treatment before and after birth, mothers were expected to act in the baby's best interests when determining whether to participate or not. The potential for differing parental opinions on research participation was acknowledged; however, this was not observed by the researcher during the recruitment or data collecting process.

Despite being unable to consent, the neonates were able to exhibit behaviour which suggested whether participation in skin-to-skin contact was a stressful or calming event for them. The notion of assessing neonatal behaviour as an ethical consideration of neonatal participation in research studies is a new phenomenon, recently described by Orrmalm (2020) as part of their ethnographic research. Neonatal behaviour was monitored and recorded by the mother during skin-to-skin contact, to evaluate the baby's perception of the

research intervention, and allow the mother to determine the dyad's practising of skin-to-skin contact in line with both the mother and baby's experience.

Research Participation

Respondent burden

The process of participation in the research study presented several ethical considerations, mainly related to the psychological experience of the participant. Ulrich et al. (2005) note that although respondent burden has not been clearly articulated in the field of bioethics, the term has been extended from the context of survey research in the social sciences into the field of clinical research. By reapplying the concept of respondent burden to clinical research, Ulrich et al. (2005, 17) define respondent burden as "a subjective phenomenon that describes the perception by the subject of the psychological, physical and/or economic hardships associated with participation in the research process". Bradburn (1977) first explored the concept of respondent burden in health survey research, attributing the burden to four factors: interview length, participant effort requirement, sensitivity of the questions, and frequency of participation. These factors were considered in the research design to minimise the burden on participants.

Ulrich et al. (2005) describe the concern voiced by clinicians who are reticent in facilitating research enrolment for fear of overburdening patients, often those with a new diagnosis and accompanying symptoms. With the existing burden associated with the diagnoses, including symptoms, side effects, and appointments, patients are vulnerable to increased strain when partaking in one or more research studies concurrently alongside their illness (Ulrich at el., 2005). However, restricting concurrent research participation in pregnancy is at odds with respect for autonomy. During the study design process, the researcher considered whether or not to exclude participants who were already participating in other research. Upon evaluation, as adults with the capacity to self-determine their care, it was considered paternalistic to exclude current research participants on a presumptive basis.

The likelihood of clinical respondent burden may be reduced with a population of pregnant women, as the existing burden of clinical care is minimal in healthy, low-risk pregnancies. However, as clinical respondent burden is subjective (Ulrich et al., 2005), it is prudent to take appropriate steps to minimise the risk further. Considering this, consenting

appointments for this study were offered before or after the participant's existing antenatal appointments, in the same location, to minimise the burden of additional travel. Participants were able to determine the quantity of data they collected, providing flexibility for the time required to participate. Participant effort was minimised through scheduling interviews at mutually convenient times and within the participant's home. The length of the interviews was determined by the length and clarity of participant responses to identify respondent fatigue. Questionnaires were provided with labelled dates for completion and were collected in a single visit, reducing the financial burden of postage, and the time burden of returning them to the researcher.

Sensitive subject matter – participant responses

Cowles (1988) defines sensitive subjects as those that have the potential to elicit powerful emotional responses, such as anger, embarrassment, and sadness. Although breastfeeding does not feature on the list of common sensitive topics in health research (Elmir et al., 2011), feelings of shame and failure are regularly cited in qualitative studies on women's breastfeeding experience (Taylor and Wallace, 2012). Coupled with the knowledge that midwives have a professional responsibility to encourage and support breastfeeding (Royal College of Midwives, 2018), participants may feel judged upon their infant feeding practices, especially if they are outside of a social convention or public health recommendations. To mitigate the risk of distress to the participant, women were informed of the topics prior to the interview, enabling them to collect their thoughts and reflect upon their experience before sharing it with the researcher. The participant was able to select the location and timing of the interview to reduce their sense of vulnerability (Elmir et al., 2011).

Erlich (2001) describes the discomfort research participants may feel when the research agenda does not recognise the concerns of the interviewees. To avoid the alienation of the participant in the research agenda, open questions were used to enable the participant to acknowledge the experiences which were most salient to them and participate in steering the interview. Questions were developed before the interview, which avoided emotionally loaded terms such as 'failed' and 'succeeded' in regards to breastfeeding continuation. Instead, the participant was able to frame their own experience of infant feeding in terms of their own perception and expectation, rather than by external measures of breastfeeding 'success'. Periods of silence were held to allow the participant to explore

their experience before vocalising their response (Elmir et al., 2011), and to avoid unnecessary anxiety about providing answers rapidly. Following the interviews, the researcher was able to provide infant feeding support details for participants seeking reassurance or support with their infant feeding method. Provision of follow-up support services is essential in providing aftercare when eliciting potentially sensitive information (Baker, 2006).

Sensitive subject matter – researcher responses

Researching sensitive topics has the potential to cause vicarious traumatisation and researcher burnout (Elmir et al. 2011). As the researcher is exposed to the traumatic lived experiences of the participants, the researcher may too develop symptoms of post-traumatic stress disorder (Dunkley and Whelan, 2006) or emotional exhaustion and cognitive weariness (Shirom and Melamed, 2006). To safeguard against these negative effects of collecting sensitive data, Elmir et al. (2011) suggest staggering interviews over a period of time and debriefing with colleagues. In keeping with these recommendations, interviews were scheduled throughout the data collection period, amongst other research activities. Academic supervisions were also utilized to discuss any troubling themes which had arisen from interviews.

Researcher practices

Confidentiality and disclosure

The right to a private life is enshrined in international law (U.N. General Assembly 1948), a feature of the professional midwifery code of conduct (Nursing and Midwifery Council 2015) and the Declaration of Helsinki (World Medical Association, 1964). However, judicious information sharing within the healthcare system is fundamental to the safe delivery of care (General Medical Council, 2017). Green and Thorogood (2018) separate the ethical requirement of confidentiality into two criteria. Firstly, information gained from research must not be disclosed in other settings. Particular care must be taken if the researcher is recruiting colleagues or friends, or the area of interest originates from a personal or professional conversation. Both instances may lead to research data and participant information being shared through informal conversations through a blurring of the boundaries between professional life, personal life, and research.

Participation in the research study was not shared with the participant's general practitioner, as there was no rationale for such information sharing, given the non-medical nature of the research. In order to comply with record-keeping regulations (Nursing and Midwifery Council 2015), information about study participation was documented within the electronic maternity record and hospital notes, to ensure study participants were traceable, and information regarding the study was accessible to the relevant professionals within the maternity services. Similarly, care was taken not to share personally attributable research findings in the clinical area, where the researcher both practised as a midwife and recruited and enrolled participants.

Secondly, the identity of individuals should be protected in published accounts of the research (Green and Thorogood 2018). Within the consenting process, participants were made aware that direct quotes may be used in conference publications, journals, and academic writing, but would never be attributed to a recognisable individual (Appendix H). To safeguard the identity of the participants, names and potential identifiers were changed in all research output, and identifier numbers were generated to avoid personally identifiable information on data collection documents. In interviews, participants were encouraged to omit the names of professionals when reflecting on infant feeding support they may have received, to enable them to provide accurate accounts without fear of the practitioner identifying them from the research. For participants who mentioned the name of a professional, a pseudonym was attributed in all research output. Participant confidentiality was ensured unless the researcher suspected a participant, or a member of their family, was at risk of significant harm. The participant's right to confidentiality was superseded by the researcher's duty to safeguard people from harm (Nursing and Midwifery Council 2015, General Medical Council, 2017). Such issues were discussed at the outset to ensure that confidentiality assurances were realistic, and met the expectations of the participant (Green and Thorogood 2018), however, the duty to safeguard was not encountered in the research process.

Data protection and storage

Misuse or mishandling of personal data may result in personal distress to the participants and may damage the integrity of scientific research. The Caldicott Principles were used to inform appropriate collection, storage, and protection of all data, ensuring that all data collected and

stored could be justified as both appropriate and necessary. During the consenting process, participants were informed of what data would be collected, and for how long it would be stored (Appendix L; M). Participants were also informed of the process of removing their details, or data, from the research study, and reassured that withdrawal of data would not affect their clinical care provision. Password protection and encryption were used to safeguard the data electronically, in abidance with the institution's policy on data storage.

During the study time span, the Data Protection Act (1998) was superseded by General Data Protection Regulation (GDPR) (European Parliament and Council of the European Union, 2016) which required the reconsideration of original measures taken to store and protect data. Initially, research data and personally identifiable documents were stored securely within a locked cabinet in the researcher's office. Following the introduction of GDPR (European Parliament and Council of the European Union, 2016), storage of personally identifiable data (PID) was transferred to the Doctoral Research Centre of the university, and source data were electronically uploaded and stored securely on an encrypted cloud system. As data are stored for five years following completion of the study, institutional rather than personal storage is necessary to ensure data can be accessed if needed following the doctoral study period.

Role conflict

Working in the roles of researcher and practitioner within the same setting requires careful consideration of professional boundaries to reduce the risk of role ambiguity. Although practising as a midwife within the research setting offers many advantages, including knowledge of the setting and population, and improving communication with staff, it may also confuse staff and maternity service users as to the role and responsibilities of the researcher. As well as safeguarding considerations, covered in the section titled 'confidentiality and disclosure', dual role professionals may feel obliged to offer care or advice when requested by research participants, or as required by their professional duty of care (Nursing and Midwifery Council 2015). For women recruited into the research study, professional boundaries were discussed at the time of consenting, including disclosure of the researcher's midwifery registration, and the role of the researcher being specifically related to the research study. Women were requested to use the routine contact pathways for their

community midwife and triage unit for questions or concerns which did not relate specifically to the research study.

As the study considered key midwifery areas of health promotion, there was overlap in information shared in a researcher capacity and a practitioner capacity. When visiting women to enrol them in the study in the postnatal period, there was a strong desire to use clinical skills to assess breastfeeding, mainly when the participant shared concerns about positioning or attachment. Rather than partaking in clinical care, signposting was used to ensure the participant received the appropriate care and infant feeding support, without confusing the researcher's role, or potentially biasing data on infant feeding decisions made by the participating dyads. The differentiation between uniform and plain clothes was also used to maintain professional boundaries, and enable staff and maternity service users to identify the professional role easily. Further considerations of researcher positionality are described in Chapter Eight.

Lone working

Lone working presents a risk to the researcher, particularly when working in a community setting. Lone working practices vary by institution and environment, but generally, lone worker policies consist of personalised risk assessments, development of contingency plans, and communication pathways (Health and Safety Executive 2013). Measures were taken to ensure researcher safety, such as risk assessment planning, and documentation of visit location and anticipated timings shared securely via an electronic calendar. A contact system was used to confirm the researcher's safety with their supervisor following lone visits. An e-module by the Royal College of Midwives titled 'Lone Working' was completed by the researcher before active research to inform the development of the risk assessment.

Conflict of interest

Although the general public benefit from collaborations between researchers and pharmaceutical companies and medical device manufacturers to develop products which benefit public health, conflicts of interest between researchers and industry undermine the public's trust in research and medicine and threaten the integrity of science (Institute of Medicine et al., 2009). Unethical relationships between researchers, institutions, and industry have failed to disclose substantial financial payments from pharmaceutical companies, non-declaration of gifts, delayed or omitted publications based upon perceived favourability of

results, and unmerited academic accolade through false authorship on publications (Institute of Medicine et al., 2009).

In the field of infant feeding, formula milk companies have historically offered free samples and gifts to institutions, instigating unsustainable formula feeding practices which resulted in unsafe formula milk provision, and the irreversible undermining of breastfeeding (World Health Organisation 1981). Now regulated by the International Code of Marketing of Breast-milk Substitutes (World Health Organisation 1981), all midwives have a professional responsibility to refuse gifts and favours (Nursing and Midwifery Council 2015), including from formula milk companies. The researcher has no financial ties to the manufacture or provision of the skin-to-skin facilitating garment and does not own the intellectual property of the intervention. Efforts were made to distance the researcher from the manufacturer, liaising only regarding stock delivery. No financial incentives nor gifts were offered by participants which could be interpreted as bribes to influence the randomisation result, but such actions were considered as possible before the research. As such, the impartiality of the randomisation process was discussed with the participant before gaining informed consent.

Conclusion

The ethical considerations related to interventional healthcare research are complex, as both the intervention itself and a paucity of interventional research have the propensity to cause harm. The research design and conduct sought to address the four primary ethical principles of health research: respect for autonomy, beneficence, non-maleficence, and justice (Beauchamp and Childress 1994). Respect for autonomy was enshrined within the recruitment and informed consent process, which aimed to avoid coercive or paternalistic behaviour by enabling ample consideration time and the ability to withdraw from the research study at any point. The principle of beneficence was the focus of the intervention design and the underpinning theoretical framework; all participants were supported to practise health-promoting behaviours such as skin-to-skin contact irrespective of group allocation. The principle of non-maleficence was assessed through statutory frameworks of ethical review and approval to ensure that the likelihood of harm had been rigorously evaluated and mitigated. Finally, the principle of justice was considered through research design and recruitment to address the potential marginalisation of women traditionally

excluded from research and at risk of poor perinatal outcomes. The research study design and conduct were subject to review, approval, and audit, which verified that appropriate and necessary ethical issues had been considered and mitigated.

Chapter summary

This study used a multi-phase mixed methods intervention design, which consisted of a feasibility study (Phase I), a randomised controlled trial (Phase II), and a qualitative interview follow-up (Phase III). The feasibility study was used to trial the study documentation and data collection instruments and assess the acceptability of the intervention before full-scale manufacture and trialling. The feasibility study identified a manufacturing amendment to the garment, but no necessary amendments to study documentation or design. The descriptive data collected in the feasibility study suggested that the garment was safe for unsupervised trialling, as it maintained normothermic temperatures and neonatal positioning within stipulated parameters.

Following the feasibility study, a randomised controlled trial design was used to compare the provision of the Snuby garment with routine postnatal and neonatal care. Quantitative data collection instruments were purpose-made for the study as no pre-existing, validated instruments were found which responded to the specific study objectives. Quantitative data were used to inform the questions included in the semi-structured interviews in Phase III of the study. A range of ethical issues were considered in the development of the multi-phase study design, with particular consideration of the process of recruitment and consent, and the ethical principles of autonomy, beneficence, non-maleficence, and justice. The following two chapters describe the process of data analysis for the quantitative and qualitative data respectively, integrating the findings in Chapter Eight.

5. Quantitative data analysis and results

Introduction

This chapter details the analysis process for the quantitative arm of this mixed method study and presents the results of the quantitative data analysis. Quantitative data analysis was used to understand the effect of the Snuby garment on the practices of breastfeeding and skin-to-skin contact, as well as its effect on neonatal thermoregulation. The chapter is divided into four sections, detailing the data collection and analysis process. Firstly, the outcome of the recruitment strategy is described alongside the achieved sample size. Next, the three following research questions are addressed:

1) What effect does the provision of a Snuby garment have on breastfeeding initiation, continuation, and exclusivity?
2) What effect does the provision of a Snuby garment have on the frequency of practising skin-to-skin contact?
3) What effect does the Snuby garment have on the incidence of abnormal neonatal temperatures during skin-to-skin contact, in comparison to conventionally facilitated skin-to-skin contact?

Recruitment and sample size

When examining recruitment and retention strategies for studies with pregnant, ethnically diverse women, Gilliss et al. (2001) found face to face recruitment maximised eligible women recruited, and also minimised attrition rates. However, face to face recruitment required significant researcher time and resources, to both meet and follow up potential participants. A significant proportion of potential participants who were offered information in the antenatal period would be more than one week postnatal after the mandatory consideration period, and therefore would be unable to participate. This consideration period similarly excluded the recruitment of postnatal women, given the enrolment period taking place within the first postnatal week.

The initial consideration period of two weeks was subsequently reduced to twenty-four hours with ethical approval from the university's Faculty Academic Ethics Committee,

the local Research Ethics Council, the Health Research Authority, and the hosting NHS Trust. The rationale for reducing the minimum consideration period was to ensure consent was fully informed while reducing the rate of women who were outside of the eligibility criteria following the two week consideration period. Similar studies of interventions which are time and gestation dependent, such as trials of kangaroo mother care, exercise a consideration period of 24 hours or less (Flacking et al., 2011; Ramani et al., 2018; Silva et al., 2016), setting a precedent for the amendment. Following the amendment to the research protocol, the proportion of women who were eligible to participate following consideration increased, therefore increasing the efficiency of researcher recruitment, and reducing the time and resources needed. When requested by women, further consideration time was provided.

Recruitment commenced in April 2018. However, due to a change in garment manufacturer, recruitment was then postponed for three months. During this period, thirty participants were removed from the study, as the researcher had no available garments during their six week postnatal window, so they could not be randomised. The researcher contacted the participants to inform them of the study's postponement and offered apologies. This was generally well-received, and the researcher's integrity was maintained by employing open and honest communication. In total, 385 women were screened for participation, 168 of which were consented, 98 enrolled and randomised, and 89 completed the data collection period. The reasons given for deciding not to participate in the study following an initial expression of interest included concern over the time required to collect data, the perception that participation may be stressful in the postnatal period, and the randomisation process. Reasons for not completing the data collection episode are not known, as contact was lost between the researcher and the participant. The implications of the study sample size are presented at the end of this chapter, alongside a post-hoc power calculation.

Research question one: What effect does the provision of a Snuby garment have on breastfeeding, initiation, continuation, and exclusivity?

For the questionnaire data on infant feeding outcomes, the demographic and infant feeding data were converted into binary dummy variables, except age, which was maintained as a

continuous variable. Once the conversion to binary dummy variables was complete, the data set was uploaded into SPSS version 25.0 (IBM Corp., 2017), and formatted ready for analysis.

Using the Box-Tidwell procedure as described in the previous chapter, the continuous independent variable of age was found to be linearly related to the logit of breastfeeding initiation (p=0.139), breastfeeding continuation (p=0.056), and breastfeeding exclusivity (p=0.911), thus suitable for logistic regression analysis.

Initiation of breastfeeding - one or more breastfeeds in the six week postnatal period

Initiation of breastfeeding was defined as one or more breastfeeding attempts in the six week postnatal period. Complete data on breastfeeding initiation were available for 96 of the 98 cases; one case was not included due to missing data on breastfeeding initiation status. Overall, 88 of the 97 dyads initiated breastfeeding. Demographic details were missing for 1 of the 97 cases; therefore, 96 cases were included in the analysis. The age range of the sample was 16 – 40 years old, mean age 29 years old. Rates of breastfeeding initiation were similar between the intervention and control groups; 90.4% vs 91.1% respectively.

There were three standardised residuals, with values of -3.150, -4.136, and -2.684 standard deviations. The Cook's distance was calculated, with values of 0.78, 1.24, and 1.16 respectively. The residuals with a Cook's distance over 1 were removed from the analysis, and the regression test was re-run. As such, 94 cases were included in the analysis. There were two standardised residuals of -3.650 and -2.670, with a Cook's distance of 1.12 and 1.17 respectively. However, these residuals were kept in the analysis, as per the rationale previously detailed. The categorical sample characteristics are detailed below (Table 5.1). When testing for multicollinearity, no evidence of a linear relationship between independent variables was found, as all VIF values were less than 10 (Myers 1990) (Table 5.2).

Table 5.1 Initiation of breastfeeding - participant characteristics

Characteristic	Category	N
Ethnicity	White	33
	BAME	61
Parity	Multiparous	58
	Primiparous	36
Body mass index	Healthy weight	62
	Overweight	32
Study arm	Control group	44
	Intervention group	50

Table 5.2 Collinearity statistics – Initiation of breastfeeding

Independent variable	Tolerance	VIF
Age	0.850	1.176
High BMI	0.942	1.062
Provision of Snuby garment	0.950	1.053
Primiparity	0.847	1.181
BAME ethnicity	0.970	1.031

The logistic regression model was statistically significant, $\chi^2(5)$= 23.199, p = 0.000. The model explained 53.2% (Nagelkerke R2) of the variance in breastfeeding initiation and correctly classified 93.6% of cases. Of the five predictor variables, provision of the Snuby garment, age, parity, body mass index, and ethnicity, two were statistically significant. Increasing age, and being from an ethnic minority were both associated with an increased likelihood of initiating breastfeeding, a finding which is supported by the research by McAndrew et al. (2012). For each increasing year in maternal age, there appears to be a 39% increase in the odds of initiating breastfeeding. Women from an ethnic minority were significantly more likely to initiate breastfeeding, although the wide confidence interval suggests the true effect of ethnicity should be interpreted with caution (Table 5.3).

Table 5.3 Initiation of breastfeeding – main effects regression analysis

Variable	B	S.E.	Sig.	Exp(B)	95% C.I. for Exp(B)	
					Lower	Upper
Provision of Snuby garment	0.13	1.05	0.902	1.14	0.15	8.82
Age	0.33	0.12	0.008	1.39	1.09	1.77
Primiparity	0.38	1.10	0.731	1.46	0.17	12.61
High body mass index	n/a	6000.00	0.997	n/a	n/a	n/a
BAME classification	2.64	1.12	0.018	13.98	1.57	124.43

As the incidence of not initiating breastfeeding is low, the “one in ten” rule of thumb, whereby one predictor can be fitted to every ten events (Peduzzi et al., 1996) has been exceeded, as five predictors have been fitted to seven events of not initiating breastfeeding, which increases the chance of bias. Vittinghoff and McCulloch (2006) found that although larger samples and more events are preferable, it is often necessary to violate the rule to address confounding. However, this limits the reliability of the model, and its ability to make predictions on a new dataset, evident in very large standard errors, i.e. for high body mass index, and wide-ranging confidence intervals.

Next, a stepwise method of regression was performed using the backwards stepwise selection, with variable removal based upon the probability of the Wald statistic, i.e. Backwards Wald method. Three standardised residuals were identified, with values of -3.842 (Cook’s distance 0.50), -4.224 (Cook’s distance 1.08), and -3.142 (Cook’s distance 1.01). Those with a Cook’s distance over 1 were removed from the analysis, and the regression test was re-run. One standardised residual with a value of -3.910 (Cook’s distance 0.55) was identified and kept in the analysis. The optimal stepwise model was statistically significant, $\chi 2$ (2) = 14.862, p = .001. The model explained 35.5% (Nagelkerke R2) of the variance in breastfeeding initiation and correctly classified 94.7% of cases. Two predictor variables, BAME classification and age, were included in the model. Each increasing year of maternal age appeared to increase the rates of initiating breastfeeding (OR per unit step: 1.32, 95% CI

1.08– 1.63, p=0.007). Being from an ethnic minority also appeared to be positively associated with breastfeeding initiation, although this was not statistically significant (OR: 6.03, 95% CI 0.96- 38.0, p=0.056).

The results from the two methods of regression analysis suggest that age and ethnicity are possibly important predictive variables in the initiation of breastfeeding. The true effects of these demographics would benefit from further exploration in subsequent research with a larger sample size. The provision of the Snuby garment appears to have no significant effect on breastfeeding initiation, possibly due to high rates of breastfeeding initiation within the sample, and the Snuby garment being provided *after* the first feed, when women may have already chosen whether or not to initiate breastfeeding.

Continuation of breastmilk feeding – provision of any breastmilk at six weeks postnatal

A binary logistic regression test was used to determine if the provision of the Snuby garment, or the accompanying predictors, affects the likelihood of continuing to breastmilk feed. Continuation of breastmilk feeding was defined as the dyad partaking in breastfeeding or feeding of breastmilk at six weeks postnatal, including exclusive breastfeeding, partial breastfeeding, exclusive expressed milk feeding, or partial expressed milk feeding. Of the 98 cases, 85 were included in the analysis. Data on breastfeeding continuation were missing for 13 of the cases, which were not included. Overall, 59 of the 84 participants were continuing to breastmilk feed at six weeks postnatal. The categorical sample characteristics are detailed below (Table 5.4). There were three standardised residuals, with values of -3.588, -2.952, and -3.866 standard deviations. The Cook's distance was calculated, with values of 0.36, 0.43 and 0.40 respectively; therefore, all three residuals were kept in the analysis. When testing for multicollinearity, no evidence of a linear relationship between independent variables was found, as all VIF values were less than 10 (Myers 1990) (Table 5.5).

Table 5.4 Sample characteristics – Continuation of breastmilk feeding

Characteristic	Category	N
Ethnicity	White	33
	BAME	52
Parity	Multiparous	53
	Primiparous	32
Body mass index	Healthy weight	56
	Overweight	29
Study arm	Control group	37
	Intervention group	48

Table 5.5 Collinearity statistics – Continuation of breastfeeding

Independent variable	Tolerance	VIF
Age	0.863	1.158
High BMI	0.947	1.056
Provision of a Snuby garment	0.937	1.068
Primiparity	0.848	1.179
BAME ethnicity	0.959	1.042

The logistic regression model was statistically significant, χ^2 (5) = 20.286, p = .001. The model explained 30.0% (Nagelkerke R^2) of the variance in breastmilk feeding continuation, and correctly classified 77.6% of cases. Of the five predictor variables, provision of Snuby garment, age, parity, ethnicity, and body mass index, two were statistically significant.

Table 5.6 Continuation of breastmilk feeding – main effects regression analysis

Variable	B	S.E.	Sig.	Exp(B)	95% C.I. for Exp(B)	
					Lower	Upper
Provision of Snuby garment	0.22	0.55	0.689	1.25	0.42	3.69
Age	0.15	0.06	0.010	1.16	1.04	1.30
Primiparity	-0.09	0.58	0.881	0.92	0.29	2.86
High BMI	0.21	0.59	0.725	1.23	0.39	3.87
BAME ethnicity	1.93	0.58	0.001	6.87	2.22	21.22

As well as being more likely to initiate breastfeeding, women from an ethnic minority appeared to be over six times more likely to still be breastmilk feeding at six weeks postnatal, compared to white women (OR: 6.87, 95% CI 2.22-21.22). The confidence interval suggests that there is a 95% likelihood of the true effect of ethnicity on breastfeeding continuation lying between a two-times increase and a twenty-one times increase. The wide range of the confidence interval suggests the true effect size should be interpreted with caution. Increasing maternal age was also associated with higher odds of breastmilk feeding continuation. With each increasing year of maternal age, the odds of continuing to breastmilk feed at six weeks postnatal increased by 16%. It does not appear that the provision of the Snuby garment had a significant effect on the likelihood of breastmilk feeding at six weeks postnatal (p = 0.689), or that the continuation of breastmilk feeding was significantly affected by body mass index (p = 0.725), or parity (p = 0.881). The confidence intervals of these parameters cross the line of no effect, meaning the true effect of the parameter may be positive, negative, or it may have no effect on the outcome.

The backwards Wald method of stepwise regression was performed. This method yielded three standardised residuals with values of -3.490 (Cook's distance 0.26), -2.572 (Cook's distance 0.13), and -3.768 (Cook's distance 0.31), all of which were kept in the analysis. The optimal stepwise model was statistically significant, χ^2 (2) = 20.017, p = .000. The model explained 29.6% (Nagelkerke R2) of the variance in breastmilk feeding continuation and correctly classified 76.5% of cases. Two predictor variables, BAME classification and age, were included in the model. Women from an ethnic minority were

significantly more likely to be continuing to breastmilk feed at six weeks postnatal (OR: 6.80, 95% CI 2.26- 20.51, p=0.001). Increasing maternal age was also associated with a significant albeit modest increase in the odds of continuing to breastmilk feed at six weeks postnatal (OR per unit step: 1.17, 95% CI 1.06- 1.30, p=0.006).

These results from the two methods of regression analysis suggest that age and ethnicity are important predictor variables in the continuation of breastmilk feeding, as well as the initiation of breastfeeding. Both methods of regression analysis produced very similar odds ratios for the predictors of statistical significance. The provision of a Snuby garment does not appear to have a significant effect on breastmilk feeding continuation at six weeks postnatal.

Exclusivity of breastmilk feeding – exclusive breastfeeding with or without expressed breastmilk supplementation at six weeks postnatal

A binary logistic regression test was used to determine if the provision of the Snuby garment, or the accompanying predictors, affects the likelihood of exclusive breastmilk feeding. Exclusive breastmilk feeding is defined as the dyad solely feeding breastmilk, whether directly from the breast or with expressed breastmilk, without the supplementation of other foods or drinks, such as formula milk, at six weeks postnatal. 85 of the 98 cases were included in the analysis. Data on breastmilk feeding exclusivity were missing for 13 of the cases, which were not included. Overall, 34 of the 86 dyads were exclusively breastmilk feeding. The sample characteristics remain the same as those detailed in Table 5.4. There were no standardised residuals identified as outliers. When testing for multicollinearity, no evidence of a linear relationship between independent variables was found, as all VIF values were less than 10 (Myers 1990) (Table 5.7).

Table 5.7 Collinearity statistics – Exclusive breastmilk feeding

Independent variable	Tolerance	VIF
Age	0.863	1.158
High BMI	0.947	1.056
Provision of Snuby garment	0.937	1.068
Primiparity	0.848	1.179
BAME ethnicity	0.959	1.042

The logistic regression model was not statistically significant, χ^2 (5) = 9.504, p = .091, which means that it could not provide a significantly better prediction of the categorisation of the dependent variable than a model without the predictor variables. Using a backwards Wald stepwise method of regression, the optimal model was statistically significant, χ^2 (1) = 4.968, p = 0.026. The model explained 7.7% (Nagelkerke R^2) of the variance in breastmilk feeding exclusivity at six weeks postnatal. A single predictor variable, primiparity, was included, which was statistically significant. Although primiparity did not have a significant effect on the continuation of breastfeeding, it appears that primiparity significantly reduced the odds of breastmilk exclusivity at six weeks postnatal (OR: 0.35, 95% CI 0.13-0.91, p= 0.031). This suggests that although there is no significant difference in continuation rates, primiparous women are significantly more likely to supplement with formula milk than multiparous women. Multiparous women may have previous feeding experience, which increases the likelihood of exclusively breastmilk feeding, possibly through physiological changes to lactation or developing breastfeeding as a learnt skill. These hypotheses are explored by participants through interviews in the qualitative arm of this study.

Exclusivity of breastfeeding – exclusive breastfeeding at six weeks postnatal

A binary logistic regression test was used to determine if the provision of a Snuby garment, or the accompanying predictors, affects the likelihood of exclusively breastfeeding. Exclusive breastfeeding is defined as the dyad solely breastfeeding, with no supplementation from other foods or drinks, including formula milk and expressed breastmilk at six weeks postnatal. 85 of the 98 cases were included in the analysis. Data on breastfeeding exclusivity were missing for 13 of the cases, which were not included. Of the 85 cases, 29 were exclusively

breastfeeding at six weeks postnatal. The sample characteristics remain the same as those detailed in Table 5.4. There were no standardised residuals identified. When testing for multicollinearity, no evidence of a linear relationship between independent variables was found, as all VIF values were less than 10 (Myers 1990). Collinearity statistics remained the same as detailed in Table 5.7.

The logistic regression model was not statistically significant, χ^2 (5) = 10.787, p = 0.056. Next, a stepwise approach was taken. The optimal model was statistically significant, χ^2 (2) = 7.466, p = 0.024. The model explained 11.6% (Nagelkerke R^2) of the variance in breastfeeding exclusivity at six weeks postnatal. Two predictor variables were included in the model, one of which was statistically significant. Contrary to previous research, raised body mass index appeared to significantly increase the odds of exclusive breastfeeding at six weeks postnatal (OR: 3.07, 95% CI 1.14-8.26, p= 0.027). Being from an ethnic minority appeared to increase the odds of exclusive breastfeeding, although this was not statistically significant (OR: 2.63, 95% CI 0.94- 7.36, p= 0.067).

Findings

Provision of the Snuby garment does not appear to significantly affect the likelihood of initiating, or continuing to breastfeed, either exclusively or partially. The provision of the Snuby garment may have a varying effect on women dependent upon their demographics, such as parity or ethnicity, but the group sizes are too small to produce results on the interaction of the independent variables. As the provision of the garment occurs after the first feed, it is unlikely to affect the initiation of breastfeeding, given that initiation rates are already relatively high.

It appears that women from an ethnic minority are both more likely to initiate breastfeeding, and continue to breastfeed at six weeks postnatal. Possible explanations for this difference include differing cultural expectations, societal norms, or migration from a country with a high prevalence of breastfeeding. Increasing maternal age also appears to be associated with an increase in breastfeeding initiation and continuation. Based upon these findings, the qualitative arm of this study explores the impact of women's knowledge of breastfeeding, motivations to breastfeed, and social and practical resources used to support breastfeeding through interviews with an ethnically diverse subset of the study sample to offer a contextualised interpretation of these results.

Research question two: What effect does the provision of a Snuby garment have on the frequency of practising skin-to-skin contact?

Participants recorded each episode of skin-to-skin contact on purpose-made charts (Appendix F), which were analysed according to their allocated arm of the study. At the data collection visit, the charts were checked with the participant to ensure accuracy and identify if any skin-to-skin contact episodes had not been recorded. Generally, participants were found to have followed the study design and completed the charts to record temperature data. In one case, the participant had misplaced the data collection tool and had recorded episodes on her mobile phone. This data was reformatted and included in the analysis. All skin-to-skin contact frequency data were digitised via Microsoft Excel (2016) and attributed to participants with their study ID number and group allocation code.

Of the 98 participants, 84 collected frequency data on their skin-to-skin contact practices and were included in the analysis. The age range of the sample was 16 – 40 years old, mean age 29 years old. Four standardized Pearson's residuals were identified, with values of 3.355 (Cook's distance: 0.12), 3.688 (Cook's distance: 0.11), 2.698 (Cook's distance: 0.249), and 4.418 (Cook's distance: 0.225). As all of the Cook's distances were less than 1, all four residuals were included in the analysis. The categorical characteristics of the sample are detailed below in Table 5.8.

Table 5.8 Skin-to-skin contact frequency: sample characteristics

Characteristic	Category	N
Ethnicity	White	33
	BAME	51
Parity	Multiparous	52
	Primiparous	32
Body mass index	Healthy weight	55
	Overweight	29
Study arm	Control group	37
	Intervention group	47
Initiated breastfeeding	Did initiate	77
	Did not initiate	7

The negative binomial regression model was not statistically significant when including only the study group allocation and not adjusting for the other predictor variables, (χ^2 (1) = 0.402, p = 0.526), or when including the study group allocation alongside the predictor variables (χ^2 (6) = 8.538, p = 0.201). This suggests that the inclusion of the predictor variables does not significantly improve the ability of the model to predict the frequency of skin-to-skin contact episodes when compared to a model without the predictor variables. Next, a backwards selection stepwise method of negative binomial regression was used to explore the effects of these predictor variables. The optimal negative binomial regression model was statistically significant with the inclusion of one predictor variable, ethnicity: χ^2 (1) =5.155, p =0.023. Women who identified as BAME had a significantly reduced frequency of skin-to-skin episodes compared to white women; on average, they had 38% fewer skin-to-skin episodes during the postnatal period (95% CI: 58-6% reduction, β=-0.47 +/- 0.2).

Secondary analyses were conducted to explore whether the provision of the Snuby garment affected whether or not participants engaged in any skin-to-skin contact episodes after the first hour post-birth. For the control group, 74% of participants engaged in one or

more episodes of ongoing skin-to-skin contact, compared to 87% of participants in the intervention group. Binary logistic regression testing found that the difference in engagement with ongoing skin-to-skin contact was not significant between the intervention and control groups when unadjusted for predictor variables (χ^2 (1) = 2.500, p = 0.114). Likewise, the inclusion of the predictor variables did not result in a statistically significant model (χ^2 (5) = 6.815, p = 0.235). Exploratory stepwise binary logistic regression testing did not find a statistically significant model; none of the included predictor variables explained the small difference in skin-to-skin contact engagement.

Findings

These findings suggest that the provision of a Snuby garment does not have a significant effect on the frequency of skin-to-skin contact episodes in the postnatal period, nor whether or not participants engage in any episodes of skin-to-skin contact after the immediate period post-birth. Negative binomial regression testing has failed to reject the null hypothesis, $H_{0:}$ the provision of a Snuby garment does not affect the frequency of skin-to-skin contact episodes. Exploratory stepwise modelling identified ethnicity as a variable of interest. Stepwise negative binomial regression suggests that being from an ethnic minority is negatively correlated with the frequency of skin-to-skin contact episodes. The under-representation of BAME women in the sample who collected skin-to-skin frequency data suggests that proportionately more BAME women than white women decided not to record any skin-to-skin contact episodes, possibly as they did not engage in skin-to-skin contact. The finding that women from an ethnic minority had significantly fewer skin-to-skin contact episodes with their baby than white women is surprising given that minority ethnic status is positively correlated with breastfeeding initiation and continuation. There is a dearth of research which examines the relationship between ethnicity, breastfeeding, and the practising of skin-to-skin contact. These findings are explored in the qualitative aspect of the study, as reported in Chapter Six.

Research question three: What effect does the Snuby garment have on the incidence of abnormal neonatal temperatures during skin-to-skin contact, in comparison to conventionally facilitated skin-to-skin contact?

Of the 52 participants, 28 from the intervention group recorded paired temperatures during skin-to-skin contact, which were included in the analysis. The intervention group recorded a combined total of 147 paired temperatures during Snuby garment facilitated skin-to-skin contact and 106 paired temperatures during conventionally facilitated skin-to-skin contact. Of the 46 participants from the control group, 19 recorded paired temperatures during skin-to-skin contact, which were included in the analysis. The control group recorded a combined total of 125 paired temperatures during conventionally facilitated skin-to-skin contact.

Hyperthermia

Hyperthermia is defined as a temperature over 37.5°C. (World Health Organisation and Maternal and Newborn Health, 1997). There were no episodes of hyperthermia preceding skin-to-skin contact recorded in either group, as the neonatal baseline temperature was required to be 37.5°C or less to commence skin-to-skin contact as per the study protocol. One participating dyad in the intervention group had two incidences of neonatal hyperthermia, both while using the Snuby. For the intervention group, the incidence of hyperthermia during Snuby facilitated skin-to-skin contact was 1.4% +/- 1%. One participating dyad in the control group had one incidence of hyperthermia when having conventionally-facilitated skin-to-skin contact. For the control group, the incidence of hyperthermia during conventionally facilitated skin-to-skin contact was 0.8% +/- 0.8%. A binary logistic regression was performed, which demonstrated that the skin to skin facilitation method did not have a significant effect on the incidence of hyperthermia ($p = 0.64$). This suggests that the Snuby garment is as safe as conventionally facilitated skin-to-skin contact in avoiding over-heating during skin-to-skin contact.

Hypothermia

Hypothermia is defined as a temperature below 36.5°C (World Health Organisation 1997). Hypothermia preceding skin-to-skin contact was a common occurrence in both groups: in the control group, the incidence of hypothermia preceding skin-to-skin contact was 41.9% +/-

0.2%, and in the intervention group, the incidence of hypothermia preceding skin-to-skin contact was 32.8% +/- 0.1%. The data were analysed to compare the incidences of hypothermia in skin-to-skin contact, when the baseline temperature was normothermic, to assess the incidence of skin-to-skin contact resulting in hypothermia.

The control group collected 75 paired temperatures with a normal baseline temperature. The incidence of developing hypothermia during conventionally facilitated skin-to-skin contact was 1.3% =/- 0.2%. The intervention group collected 100 paired temperatures with a normal baseline temperature preceding Snuby facilitated skin-to-skin contact. The incidence of developing hypothermia during Snuby facilitated skin-to-skin contact was 8% +/- 0.7%. A binary logistic regression was performed, which demonstrated that this was not statistically significant ($p = 0.08$). This suggests that although there was a higher incidence of hypothermia in the Snuby garment than in conventionally facilitated skin-to-skin contact, there is no significant difference between the methods of skin to skin facilitation in regards to the incidence of developing hypothermia.

Temperatures were collected at 30 minutes post commencement of skin-to-skin contact to identify temperatures becoming abnormal through rapid heat loss or overheating, which required intervention. As such, this analysis provides a safety evaluation of the skin-to-skin contact facilitation methods from a normal baseline temperature, rather than as a therapeutic device to correct baseline hypothermia. To understand the role of skin to skin facilitation methods in correcting hypothermia, additional data points would be required at 60 minutes post commencement of skin-to-skin contact, to allow adequate time for thermoregulation. These additional data collection requirements and the additional monitoring were outside of the scope of this study, as the skin-to-skin contact duration is participant-led, and on average lasted less than the duration required to achieve thermostasis (mean duration of all skin to skin episodes: 39 minutes).

Findings

The Snuby garment appears to be as safe as conventionally facilitated skin-to-skin contact regarding the incidence of developing an abnormal neonatal temperature. Episodes of hyperthermia were very rare in both the control and intervention arm of the study. Episodes of hypothermia in skin-to-skin contact were more common in Snuby facilitated skin-to-skin

contact than conventionally facilitated skin-to-skin contact, but this difference was not significant. Should the Snuby garment be intended to be used therapeutically to rectify hypothermia, further research with extended data points would be warranted to investigate the effect of skin to skin facilitation method on achieving thermostasis.

Conclusion

The analysis was conducted to explore the effects of the Snuby garment on infant feeding and skin-to-skin contact practices made by healthy mother-infant dyads at home. For infant feeding outcomes, a range of predictor variables was sourced from relevant literature and included in the analysis to account for confounding. For the outcome of frequency of skin-to-skin contact episodes, no relevant literature was identified to inform the inclusion of relevant predictor variables alongside the provision of the intervention. Therefore, the same predictor variables were included as those on the infant feeding regression tests with the addition of breastfeeding initiation status.

Due to unexpected issues with study recruitment, the achieved sample size was 98 participants. Upon this basis, the analysis may lack the necessary power to reject the null hypothesis, meaning that there may be an effect, but it may not have been found.

A post-hoc power calculation can be used to post-analysis when non-significant results have been found, and it has not been possible to reject the null hypothesis. Post-hoc power calculations seek to aid the interpretation of experimental results, as well as to inform the planning of subsequent research. Using the power package implemented in R, a post-hoc power calculation was performed using the observed prevalence of exclusive breastfeeding in the control group. Under the assumptions of 80% power, a critical limit of significance of 0.05, and a two-tailed test, the intervention group would need to demonstrate a prevalence of exclusive breastfeeding in excess of 67.0% or less than 8.5% to be detectable in this study. The rates of exclusive breastfeeding between the intervention and control group were very similar (35 vs 34%), with no significant change to rates of exclusive breastfeeding with the provision of the Snuby garment (p=0.96). However, the local rates of exclusive breastfeeding at 6-8 weeks post-birth were 25%, significantly lower than the overall average in the study (p=0.03). Several reasons for this are suggested. Firstly, selection bias may have resulted in the recruitment of participants who were intending to breastfeed exclusively. Secondly,

participating in the study may have increased the rate of exclusive breastfeeding through increased skin-to-skin contact. Although rates of SSC are not collected in the general population, they may be significantly changed by study participation through increased awareness and knowledge mobilisation.

Assessing the effects of the garment on breastfeeding, it appears that the Snuby garment does not have a significant effect on breastfeeding initiation, continuation, or exclusivity. However, a study with increased power may detect an effect which has not been detected in this study. Equally, it is possible that the facilitation method of skin-to-skin contact does not significantly affect infant feeding practices. The ways in which breastfeeding and formula feeding dyads use the garment, and the relationship between the Snuby garment and their infant feeding practices, are explored further through the qualitative findings to offer a contextualised interpretation of these results.

Although participants with the Snuby garment had more episodes of skin-to-skin contact than those in the control group, this difference was not statistically significant. It appears that the provision of the Snuby garment makes no significant difference to the frequency of skin-to-skin contact episodes in the six week postnatal period. However, the exploratory stepwise analyses identified that BAME identity and skin-to-skin contact frequency were inversely correlated. By recruiting an ethnically diverse study population, this study has identified that ethnicity is a significant predictive factor in both infant feeding and skin-to-skin contact practices, surprisingly in inverse directions. These findings warrant further exploration to understand the role of minority ethnic status in health-promoting practices to identify the social, environmental, or cultural factors behind a higher uptake of breastfeeding and lower uptake of skin-to-skin contact. These results also identified a significant correlation between increasing maternal age and breastfeeding initiation and continuation. This study confirms that these predictive variables are important to include in any subsequent studies which evaluate the effect of the Snuby garment on infant feeding practices to account for confounding.

The analysis of the paired neonatal temperatures demonstrates that the Snuby garment does not have a significant effect on the incidence of abnormal temperatures in skin-to-skin contact compared to the conventional method of facilitating skin-to-skin contact. As there was no significant difference in the prevalence of hypothermia and hyperthermia

between the two methods of facilitation, the garment appears to be as efficacious as conventional facilitation at maintaining neonatal normothermia. This preliminary safety analysis suggests that further research and usage of the Snuby garment is safe to conduct without additional neonatal temperature monitoring.

Collectively, these results demonstrate that the Snuby garment is safe to use when facilitating skin-to-skin contact, as it does not significantly affect the rates of abnormal temperatures. Provision of the garment appears to have no significant effect on infant feeding practices, with similar rates of breastfeeding between the intervention and control arms. Similarly, regular skin-to-skin contact appears to be practised irrespective of feeding method, or skin-to-skin contact facilitation method. To explain and contextualise these results, the ways in which participating dyads engaged with skin-to-skin contact and breastfeeding are explored in the qualitative aspect of this study with particular reference to the identified variables of interest.

6. Qualitative data analysis and results

Introduction to the framework method

A framework method of data analysis was used in order to analyse the interview transcripts systematically and methodically. Originating in large scale social policy research (Ritchie and Spencer 1994), the framework method is particularly useful when analysing a large number of cases, permitting the researcher to compare both across and within cases, without losing the contextual positioning of the data (Gale et al., 2013). The method enables a deductive or inductive approach to analysis. The analysis can be led by pre-defined categories and codes generated through literature, theory, or research questions, or the analysis may be led by open coding and emergent themes (Gale et al., 2013). However, these approaches are not exclusive. Framework analysis permits a combined inductive and deductive approach (Gale et al., 2013), which makes it well suited to responding to specific research questions while making room for unexpected findings. This chapter describes the process of framework analysis following the method published by Ritchie and Spencer (1994) and Gale et al. (2013). This method of analysis involves a five step process: familiarisation, identifying a thematic framework, indexing, charting, and mapping and interpretation (Ritchie and Spencer 1994). The findings of the qualitative analysis are reported in three overarching themes and thirteen integrated subthemes.

The process of the framework method

Familiarisation

Following the initial transcription of audio recordings, familiarisation is the first step of framework analysis (Gale et al., 2013). Transcriptions were proof-read by the researcher to identify any potential inaccuracies in transcription, and audio recordings were replayed several times to confirm or correct transcriptions; simultaneously revisiting the transcriptions and audio recordings helps to immerse the researcher in the data. To verify the accuracy of the transcriptions, a sample of the audio recordings and the transcriptions were reviewed by the researcher's academic supervisor, and no issues were identified. By using a research supervisor to audit the process of data analysis, the dependability of the study findings can be corroborated (Nowell et al., 2017). The process of familiarisation continued as audio

recordings were replayed while revisiting and adding to the contemporaneously-kept reflective notes about the interview content (Gale et al., 2013). Pseudonyms were attributed to each interviewee to anonymise the data, but it was ensured that the pseudonyms were suggestive of a similar socio-cultural background to the interviewee. This built coherence for the researcher and maintained important aspects of the socio-cultural context of the interview.

Developing an analytical framework: coding

From a pragmatist perspective, the framework method enables the researcher to begin with the research questions, and from there, develop the structure of the analytical framework. The analytical framework exists to facilitate the sifting and sorting of data (Ritchie and Spencer 1994). As suggested by Ritchie and Spencer (1994), a subset of research questions which were used to develop the interview topic guide was revisited. These research questions were adapted to form succinct, abbreviated codes.

Table 6.1 Research question developed into codes in analytical framework

Research question	Code in analytical framework
How is the Snuby used by mother-infant dyads?	Snuby usage – timings
	Snuby usage - patterns
What motivates skin-to-skin contact?	SSC motivations

Next, the theoretical framework (as described in Chapter Three) was used to continue to build the analytical framework. The same key terms and concepts from Antonovsky's theory of salutogenesis (1979, 1987), which informed the production of the research protocol and interview topic guide were used to generate codes in the analytical framework. The example below shows the application of Antonovsky's (1987) Generalized Resistance Resources – Resistance Deficits (GRR-RD) continuum. Although Antonovsky conceptualises the GRR-RD as a continuum (1987), GRRs and GRDs were separated into distinct codes in the thematic framework, divided again for application to breastfeeding and skin-to-skin contact.

Deconstructing the theory allowed the researcher to make sense of the theoretical application, and categorise data systematically.

Table 6.2 Theoretical component developed into codes in analytical framework

Theoretical component	Application to study	Code in analytical framework
generalised resistance resources (GRRs)	Characteristics that facilitate the individual to cope with the stressors of breastfeeding and early motherhood	Resources for breastfeeding
		Resources to facilitate SSC
generalised resistance deficits (GRDs)	Absence of resources to cope with the stressors of breastfeeding and early motherhood	Barriers to breastfeeding
		Barriers to skin-to-skin contact

The identification of themes coincided with the development and adaptation of the analytical framework. Through a deductive approach, the initial set of a priori themes were generated from the characteristics of the phenomenon (Ryan and Bernard, 2003), and the values and theoretical orientation of the researcher (Bulmer, 1979; Strauss, 1987). Dey (1993) suggests that the interview protocol and the researcher's approach for eliciting the data are rich sources of a priori themes. Beginning with this method of thematic identification, initial themes of 'barriers', 'resources', and 'motivations' to breastfeeding and skin-to-skin contact were identified from the theoretical framework of the research. Research objectives led to the identification of themes related to the Snuby garment, as no prior research on the garment existed.

Table 6.3 Research objectives developed into codes in analytical framework

Research objective	Generated theme
To understand the mothers' perspectives regarding the value of a SSC facilitating garment	Acceptability and value of using Snuby garment
To explore mothers' views on the acceptability of using a SSC facilitating garment	
To determine if a SSC facilitating garment affects breastfeeding initiation, continuation and exclusivity rates.	Role of Snuby in infant feeding

A skeleton structure of the analytical framework was formed using Computer-Assisted Qualitative Data Analysis Software (CAQDAS) (NVivo Pro 11). CAQDAS was used through the data analysis process, as it permitted the researcher to keep track of new codes and emerging themes automatically, and electronically link quotations, codes, and categories. Following this deductive stage, an inductive approach of open coding was used for the first five transcripts. Gale et al. (2013) recognise the benefits of this period of open coding, even with predominantly deductive studies, to ensure important aspects of the data are not overlooked.

Several methods of coding were employed during the open coding stage, including descriptive, in vivo, and emotion coding. These three methods of coding were used to identify what the interviewee is saying (descriptive coding), begin to interpret the specific words and phrases they use to describe their experiences (in vivo coding) and record any emotion portrayed through their words or body language (emotion coding). Miles et al. (2014, 74) suggest several methods of coding can be "mixed and matched", which is particularly helpful to respond to a wide-ranging set of research questions. Simultaneous coding was employed when multiple interpretations were suggested by a single datum (Miles et al., 2014). This process was helpful in recording the emotional and non-verbal

interpretations, as well as descriptive events. Following open coding of the first five transcripts, new codes continued to emerge, which informed the decision to continue to open code an additional five transcripts. At this stage, codes were grouped into categories, which were defined to add structure to the working framework. The CAQDAS software enabled the codes to be grouped electronically, permitting easy visualisation of codes and categories. To summarise the process of developing the analytical framework, a combined inductive and deductive approach was used. Initially, a deductive approach identified codes from the research questions, objectives, and theoretical framework. This approach ensured that the data analysis would respond to the aims of the research study. Secondly, an inductive approach was taken, whereby the first ten transcripts were open coded to ensure important aspects of the data were not overlooked, and to make room for unexpected findings. Following the development of the analytical framework, the remaining transcripts were indexed against the codes and categories.

Indexing

Indexing is the process of applying the analytic framework to the data, making judgements about the significance and meaning of the data (Ritchie and Spencer 1994). A 'miscellaneous' category was utilized to hold tangential or unwieldy data to avoid finalising the framework until it had been applied to all of the transcripts (Gale et al., 2013). During the application of the framework to the transcripts, the researcher made electronic analytic memos to record thoughts and emerging concepts, linked electronically to the respective transcripts. As suggested by Miles et al. (2014), the memos explored the possible networks among the codes, including similarities and divergence in the data, and to record the related theories which were emerging from the data. At this stage, containment theory (Douglas, 2007), Maslow's (1943) hierarchy of needs, and Engel's (1977) biopsychosocial model were identified as tangential theories to be explored when interpreting the data.

Charting

Having applied the framework to the transcripts, CAQDAS software was used to develop a framework matrix to 'chart' the data. The framework matrix is a spread-sheet style matrix which facilitates the filtering and summarising of data, attributed to cases in the rows and categories in the columns. Pertinent quotes were extracted from the memos and transcripts

and embedded into the matrix to illustrate codes and provide context. From the wide-ranging matrix, which covered all interview topics, individual charts were drawn up for each key subject, so the experiences of multiple participants could be held on each chart. Ritchie and Spencer (1994) demonstrate that chart headings may derive from framework categories or emergent themes identified whilst indexing the data. Seven subject charts were constructed from a priori framework categories: barriers to breastfeeding, resources for breastfeeding, motivations to breastfeed, barriers for skin-to-skin contact, resources for skin-to-skin contact, motivations for skin-to-skin contact and Snuby. Two subject charts were constructed from emergent themes: decision making, and motherhood and parenting. Charting can either be made using numerical or textual entries. In this study, textual entries were made to aid the interpretation of the data.

Mapping and interpreting

Mapping and interpreting is the process of "piecing together the overall picture" (Ritchie and Spencer 1994, 186). The method of this complex process is dependent upon the objectives of the analysis. Of the six objectives of qualitative analysis (Ritchie and Spencer 1994), three were identified as in keeping with the objectives of this research study: mapping the nature of the phenomena, finding associations, and providing explanations. The first stage of mapping and interpreting is returning to the notes, memos, charts, and framework matrix. In their example of using the mapping and interpreting process to explore the motivations to volunteer, Ritchie and Spencer (1994) suggest reviewing charts on experiences and deterrents in order to map the nature of the phenomena. In keeping with this process, charts were reviewed and collated on motivations, as well as barriers, to begin to map the key dimensions in practising health-promoting behaviours.

Ryan and Bernard (2003) suggest using a combination of techniques to identify themes and sub-themes, dependent upon the nature of the data. To find associations within the data, two techniques were used. Firstly, a constant comparison method (Glaser and Strauss, 2017) was used to identify similarities and differences between cases. The constant comparison method (Glaser and Strauss, 2017) was used to compare the views of participants across the matrix categories, identifying recurring expressions, and divergent perspectives. This method resulted in the identification of the majority of themes. Secondly,

the researcher searched for missing information, seeking to identify the themes that are missing in the data which may have been intentionally or unintentionally omitted. This technique was used to ensure any 'holes' in the matrix were interrogated. For example, searching for missing data identified the subtheme of primiparity as a resource for engaging in skin-to-skin contact. Multiparous women recognised their parity as a barrier to skin-to-skin contact. However, primiparous women did not identify the significance of their parity in regards to their ongoing practice of skin-to-skin contact. Although reference to their primiparity was unlikely to be omitted intentionally, it suggested that primiparity is likely an important resource utilized in practising ongoing skin-to-skin contact, which was not recognised by primiparous participants as they could not compare their experiences with having one or more children. Combined, these methods of thematic identification resulted in the production of eight thematic categories and twenty-six sub-themes (Table 6.4).

Table 6.4 Eight thematic categories and twenty-six subthemes

Initial themes	Initial sub-themes
Motivations to use skin-to-skin contact	Securing attachment and building the bond
	Responding to baby's behavioural cues
	Enjoying time as a mother-infant dyad
Motivations to breastfeed	Securing attachment and building the bond
	Knowledge of maternal and neonatal health outcomes
	Social expectation, support, and role modelling
	Beliefs and conceptualisations about breastfeeding
Role of the Snuby in infant feeding	Establishment of breastfeeding
	Optimising breastmilk supply
	Maintain a unique breastfeeding-type relationship
Barriers to having skin-to-skin contact	Competing demands and responsibilities
	Fear of a cold baby
	Social acceptability and environment
Barriers to the establishment and continuation of breastfeeding	Lack of accurate knowledge and working understanding
	Paucity of effective support from trained HCP
	Social attitudes and life outside the home
Resources and factors associated with using skin-to-skin contact	Primiparity
	Delegation of usual responsibilities
	Privacy and personal space

Resources and factors associated with breastfeeding establishment and continuation	Professional support and referrals
	Understanding the challenge and knowing when it is working
	Using a problem-solving mentality to enable perseverance
Acceptability and value of using the Snuby for skin-to-skin contact	Offers security to maintain safe neonatal positioning
	Permits mobility and multi-tasking
	Design and the preservation of modesty
	Validates quiet time to connect and bond

Thematic refinement and making theoretical coherence

Once the data had been analysed as described, the thematic categories and emergent themes were re-examined to address overlap and repetition between the study arms (intervention and control groups), and between health-promoting behaviours (breastfeeding and skin-to-skin contact). This refinement led to the merging of several thematic categories and subthemes, resulting in four themes, with eighteen sub-themes.

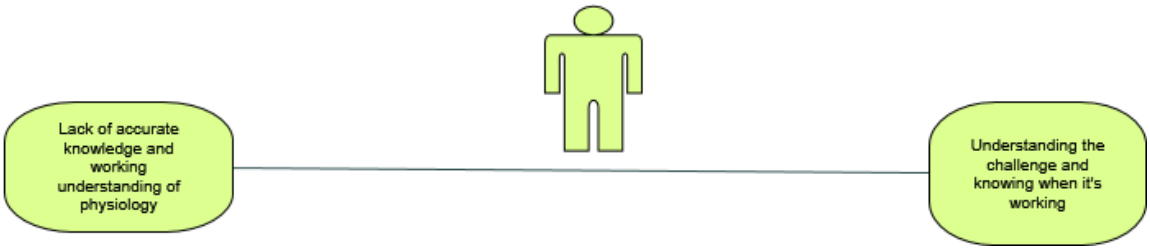
Table 6.5 Thematic refinement

Working themes	Working sub-themes
Motivations for health-promoting behaviours	Knowledge of health benefits Beliefs, attitudes, and conceptualisations Social expectation, support, and role modelling Attachment and bonding Responding to the baby's needs
Barriers to health-promoting behaviours	Social attitudes and acceptability Competing demands and responsibilities within the home Lack of accurate knowledge and working understanding of physiology Paucity of effective support from healthcare professionals
Resources used to facilitate health-promoting behaviours	Professional support and referrals Problem-solving mentality to enable perseverance Understanding the challenge and knowing when it is working Privacy, time, and personal space
Snuby garment as a health-promoting device	Security and mobility Dyadic bonding and reciprocity Preservation of modesty and bodily exposure Prompting and validating quiet time Facilitating breastfeeding and lactation

Miles et al. (2014) suggest that making theoretical coherence is an important part of the drawing and verifying of conclusions, either from a bottom-up or top-down approach. By returning to the theoretical framework, several sub-themes were amended by integrating two sub-themes to become one. For example, Antonovsky's (1987) recurring conceptualisations of continuums, rather than distinct states, positions two sub-themes at opposite ends of a single resource-deficit scale, rather than as individual sub-themes. Antonovsky (1987, 28) proposed that "we can speak of 'major psychosocial generalized resistance resources—resistance deficits' (GRR-RDs) as one unified concept. In each case—

wealth, ego strength, cultural stability, and so on—a person can be ranked on a continuum." This theoretical concept led to the subthemes 'lack of accurate knowledge and working understanding of physiology' from the 'barriers' theme and 'understanding the challenge, and knowing when it is working' from the 'resources' theme becoming a continuum of 'knowledge and understanding' (Figure 6.1).

Figure 6.1 GRR-RD Knowledge and Understanding



Through continued thematic refinement, the four themes and eighteen sub-themes became the final three themes and thirteen sub-themes. Dey (1993, 110) accepted that "there is no single set of categories waiting to be discovered", and there may be no ultimate demonstration of validity in qualitative data analysis (Ryan and Bernard 2003). However, by following a structured analytical process such as the framework method, and outlining the techniques used to identify and refine the themes, clarity and transparency are demonstrated to build trustworthiness in the research findings.

Table 6.6 Final themes and subthemes

Themes	Sub-themes
Theme one: Resources used to facilitate health-promoting behaviours (incorporating 'barriers for health-promoting behaviours')	Knowledge and understanding Professional support and referrals Social support and role modelling Problem-solving and seeking help to enable perseverance Agency and autonomy
Theme two: Motivations for health-promoting behaviours	Beliefs, attitudes, and conceptualisations Reciprocity, attachment, and bonding Social acceptability and expectation
Theme three: Snuby garment as a health-promoting device	Security and mobility Dyadic bonding and reciprocity Preservation of modesty and bodily exposure Prompting and validating quiet time Facilitating breastfeeding and lactation

Findings: Providing explanations through exploration of themes

This section seeks to respond to the research aims of understanding the mothers' perspectives of initiating and continuing to breastfeed, the practising of skin-to-skin contact, and understanding how the Snuby may be used, and for what purpose. These research aims will be addressed through the exploration of themes and sub-themes to illuminate people's experiences and behaviour (Ritchie and Spencer 1994). Although the themes and sub-themes are explored in sequence, the themes are inextricably linked through the sub-themes. Several sub-themes are identified in a single datum, and as such, have been only loosely grouped under sub-headings, to avoid repetition.

These explanations are supported by various theoretical components. Antonovsky's (1979) theory of salutogenesis has been embedded through the research process, and as such, featured heavily in the thematic categorization. Other more tangential theories which emerged in the data analysis are referenced to offer further explanation of the phenomena. Participant quotes are used throughout to support and illustrate the research findings. Pseudonyms are used for participants and their family, the names of organisations and geographic locations to ensure anonymity. A summary of each theme is presented at the end of each subsection; themes and subthemes are referenced in the summaries using abbreviations, e.g. T1S1: theme 1 subtheme 1.

Theme one: Resources used to facilitate health-promoting behaviours

As described in the section 'thematic refinement', the resources used to facilitate health-promoting behaviours of breastfeeding and skin-to-skin contact were conceptualised as a continuum. However, during the interviews, participants were asked by the researcher about the resources used to support them in these behaviours, as well as any barriers they had experienced. By asking about resources and barriers separately, women were able to share their experiences, whether or not they went on to establish or continue to breastfeed, or to practise skin-to-skin contact. The resources used to facilitate these health-promoting behaviours included physical, cognitive, psychological and social resources.

Theme one, subtheme one: Knowledge and understanding

Women's establishment and continuation of breastfeeding hinged on knowledge and understanding (see diagram 'GRR-RD – knowledge and understanding), often concerning professional support. Women who attempted breastfeeding, but ceased before they wanted to, reported lacking an understanding of how breastfeeding works, and how to determine whether breastfeeding was going well. This was often confounded by contradictory and confusing advice from healthcare professionals. Amira, a primiparous woman, describes her confusion leading to stress and informing her decision to cease breastfeeding.

> *Amira: "That's why I also got confused, because I thought 'oh, I can see her cheeks moving, as if she's taking it', but then one midwife said to me, 'she might just be sucking your nipple as comfort, she might not be actually drinking', because they can just suck, but not necessarily take in milk. So then I was like, really confused. Then it got to the point when I just got really stressed, and I was like, I don't want to get depressed, or anything like that, to be honest with you. And I thought, 'actually, do you know what? Bottle feed her instead'."*

When women were able to apply their knowledge of breastfeeding by recognising signs of effective feeding, they were able to identify and challenge myths which advocated unnecessary formula supplementation. Although Aisha described her family as "supportive", she described her elders encouraging her to supplement breastfeeding with formula milk on the basis that baby's crying was a sign that breastfeeding was insufficient. Due to her knowledge base, Aisha was able to navigate this misinformation to protect the exclusivity of her breastfeeding. Similarly, Sumaya found that her elders were dismayed at her choice to breastfeed exclusively. Her formal education was identified as a key resource to challenging the myths around breastfeeding exclusivity, and in turn, facilitate her decision to continue to breastfeed.

> *Sumaya: "In our culture we have a lot of children. My mum has ten, my auntie has nine. So everyone has, like, five, minimum. And I thought to myself, 'none of you exclusively breastfed'. So they all breastfeed, all of them, but combine [with formula]. Even my auntie who was anti exclusively breastfeeding… She agrees breastfeed 'til, like, long, up to two years she breastfeeds, 'cause that's what she does with her children, but combine with it. She feels like the breast alone cannot be enough. She even told me this whole*

> *theory that apparently babies that are exclusively breastfed are very thirsty, and then it's funny she said that, because when she came, she saw his lips like that, and she was like 'you see what I mean?! Look! Oh my god, get me water, I'm gonna give him water' and I was like 'Noooo! Don't do that!' and she was just driving me so insane… I feel like friends, a new generation now, more knowledge, we've all gone to uni, they know a lot more. So some of them have chosen to exclusively breastfeed… Obviously going to uni, learning everything, I can't ignore that information I learnt. I feel like, when you have education, your mind gets developed a bit more, and you ask more questions, you want to find out more."*

This quotation illustrates an inter-generational distrust for exclusive breastfeeding. Sumaya considers the reasons behind this distrust in exclusivity, considering the role that migrating from poverty in Somalia may play on women's understanding of the value of breastfeeding, as well as the effects of the infiltration of formula milk marketing. The following passage shows Sumaya grappling with the cognitive disconnect between a generational lineage of breastfeeding knowledge, and distrust for exclusivity:

> *Sumaya: "I feel like back home, people are quite poor, and they only breastfeed anyway, and their children still grow. So I don't know where this mentality of thinking formula is better came from. I know the ladies I've seen weren't in the best financial situation, but they looked happy and their babies looked content, and I thought our mothers and everyone that came from there you'd think would have that mentality, but it's completely the opposite… In my culture, food and drink is a big thing. Something a lady said actually the other day, she was like, you know, 'we don't like our people to be hungry, because we already came from poverty'. So is it something linked to that? You know, they just want to fill, fill, fill?"*

Knowledge and understanding were also evident in women's decisions to engage in skin-to-skin contact. Women who practised skin-to-skin contact tended to demonstrate an understanding of how skin-to-skin contact works, which challenged a common fear of the baby becoming cold. Women who did not practise skin-to-skin contact frequently cited cold weather and having a "winter baby" as barriers. Amira recalled sharing the information she was given about skin-to-skin contact and thermoregulation with her husband:

> *Amira: "When I told my husband initially, he was like, 'what're you doing? You know, you shouldn't, she'll get cold', but then, you know, I gave him stuff I'd had to read, and he went to the antenatal classes as well. I said, 'well, remember they said skin to skin? This is skin to skin. It literally means skin to skin'"*

Understanding the role of skin-to-skin contact in relation to breastfeeding also informed how and when women used skin-to-skin contact. Referring to advice from a breastfeeding peer-supporter, Gina, a primiparous woman, described the learning curve needed to understand her baby's needs through his behavioural cues, whilst working to establish breastfeeding with a baby who was reluctant to feed.

> *Gina: "They'd said, 'if he's hungry, don't use skin to skin to settle him, and ignore that hunger sign. You should be feeding him'. So, I had to, yeah, kind of learn what was a hunger cry and what was just a cry that meant 'I want a cuddle'."*

Similarly, Reshmi also found that understanding her baby's behavioural cues helped her to establish breastfeeding.

> *Reshmi*: *"There was this one particular midwife… when she explained to me about breastfeeding and how it works, that really, truly did help. She goes, for me to read what the baby is saying to me with the hands or mouth, you'll know straight away what that means and what this means."*

For multiparous women like Amarjit, transferring knowledge from previous breastfeeding experiences was a key resource in continuing breastfeeding. For women who had breastfed before, they understood the challenge of breastfeeding and knew the challenge to be both achievable and finite. Katie also relied upon *"knowing that it would get better at some point"*. She describes the importance of knowing the difficult stage does not last forever.

> *Amarjit: "I just thought, 'right, I could do it with one, I could do it with two'… I knew that I had done it before, so I could do it again, so that was my sort of rationale to 'I'm going to carry on'."*

> *Katie: "So yeah, I think knowing that there was like, a light at the end of the tunnel, kind of thing"*

In summary, the concept of knowledge and understanding enabled the continuation of health-promoting behaviours in three ways. Firstly, a combined understanding of how breastfeeding and skin-to-skin contact worked and what baby's behavioural cues meant enabled women to make sense of what they were experiencing. Secondly, a working understanding of the physiological effects of breastfeeding and skin-to-skin contact enabled women to both challenge commonly encountered misconceptions, such as inadequate milk supply, or baby becoming cold. Finally, multiparous women were able to transfer knowledge from previous breastfeeding experiences. This transferable knowledge was not necessarily related to the technique of breastfeeding; multiparous women drew on their knowledge of the challenge as achievable and finite to enable them to persevere through difficulties.

Theme one, subtheme two: Professional support and referrals

The subtheme of professional support and referrals generally pertained to breastfeeding rather than skin-to-skin contact. Professional support and referrals were resources that almost all women utilized while breastfeeding, although women shared both positive and negative experiences of seeking professional support. Often, women described the establishment and continuation of breastfeeding *despite* the professional support they received, rather than as a result of it. Common experiences were shared of hands-on breastfeeding support being either ineffective or offering a short-term fix which they could not replicate when they were discharged home. This is illustrated in Sarah's experience of receiving professional support, in contrast to support from her sister.

> *Sarah: "The other two times that he latched, one was the woman who did the tongue tie, she did a similar thing, she kind of like grabbed my boob, and stuck it in the mouth, and like... Obviously, they need to stop the bleeding, so they need them to feed, so it was a case of, you know, this needs to happen, and it did. And the other time was when I was in postnatal ward, and an older midwife came up, and did the same thing. Grabbed my boob, grabbed the baby, whacked it in there, kind of thing."*

Neither episode of professional support enabled Sarah to latch her baby to the breast herself. It was Sarah's sister's advice on bringing the baby swiftly into the breast which led to the establishment of breastfeeding.

Sarah: "And from that point on, it was fine."

Professional support appeared to be often undermined by the professional's attitude to breastfeeding. This was sometimes recognised by women or was otherwise evident from their testimony. Gina identified a "*judgey*" attitude from her health visitor, which she felt to be in contrast to the positive attitude of a breastfeeding peer-supporter.

> *Gina: "The health visitor wasn't supportive at all… She did a kind of '*deep intake of breath* Ooh, you don't want to get him on bottles too soon, you know, be careful with that, because, you know, he'll get confused, he won't be able to latch, blah, blah, blah' and I was like, 'well, he can't latch anyway. How do you want me to feed him? I'm feeding him. I keep trying him, but actually, breastfeeding network have been really positive about it'… I'd had breastfeeding network in the morning, and she'd been really positive, making me feel really empowered, and 'OK, it could be tongue tie, it's going to be difficult, he might not learn to latch whilst he's got that, but he's showing an interest, he does keep trying, he's not completely turning away, he's really trying to latch on, and that's really positive', and then health visitor came out and kind of turned her nose up, you know 'Oh, giving him bottles, be careful'. Umm, so I tried to feed him when she was here, and then she changed, and said, 'Oh, he is really difficult to latch, isn't he? I don't think you're going to persist with that, if I'm honest' and almost completely switched, and was almost saying 'put him on bottles!'"*

In turn, this perception of a negative attitude in response to Gina continuing to try to establish breastfeeding resulted in a self-proclaimed "*crisis of confidence*", and Gina feeling she needed to be "*defensive*", in order to prove she was adequately feeding her baby. Generally, professional support was found to be enabling of breastfeeding continuation when a healthcare professional observed a breastfeed with a positive attitude. Debby, a breastfeeding peer-supporter herself, explained the value of a peer supporter observing her breastfeed. Like Debby, many women valued the reassurance given when a healthcare professional observed a breastfeed, in addition to "*tweaks*" to optimise positioning and attachment.

> *Debby: "I found it really reassuring and helpful. It's given me something... It's just reassuring to have someone else come and make sure, yep, you're doing fine, or maybe tweak that... Like, another pair of eyes."*

Regarding referrals, of the forty-two dyads who initiated breastfeeding, ten babies were identified as having a tongue tie, of which nine obtained a tongue tie referral and a frenulotomy. One dyad ceased breastfeeding before the referral was made. The incidence of tongue tie diagnosis in this sample was considerably higher than the 4-10% incidence reported by Segal et al. (2007); the implications of this are explored in the following chapter. Without exception, women regarded the frenulotomy as a significant resource for the continuation of breastfeeding, despite it not resolving all breastfeeding issues. Women often cited a delay in the referrals being made or followed up, commonly attributed to the Christmas period, missed opportunities to diagnose the tongue tie, and long waiting lists. Women used persistence and perseverance to access the required services.

> Clare: *"After the tongue tie was cut at two weeks, over the course of the next week, it got gradually better each day, really. Being able to open his mouth wide enough, I think, was the main thing."*

> Farida: *"We did a self-referral, which was what we were told to do at [local hospital]. And they couldn't give us an appointment until April 4th. And this was when she was three weeks, it was early March time. So then I went to a breastfeeding support group, and they tried to help me out. And then they said they'd put me on [different local hospital] clinic list, but that was for April 14th or something. So then [local hospital] suggested I just go private. So we had that done March 19th, I think."*

Although professional support from midwives and health visitors aimed to enable the continuation of breastfeeding, professional support was not perceived to be wholly positive. Conceptualising this subtheme as a continuum, poor professional support (GRD) was characterised by a practitioner's negative attitude, hands-on technique, and untimely provision. These three factors appear to be underpinned by the practitioner's knowledge, beliefs, and understanding: of the value of breastfeeding, how breastfeeding works, and recognition of common complications, congruent with the resources used by women in T1S1.

Professional support which positively enabled the continuation of breastfeeding was typically characterised by a practitioner's positive attitude, time spent observing a breastfeed while providing hands-off support, and timely attention to arising issues.

Theme one, subtheme three: Problem-solving and seeking help to enable perseverance

When problems arose, women who continued with health-promoting behaviours demonstrated an ability to problem-solve. The ability to problem solve related to physiological issues, such as milk supply and latching, as well as social and environmental issues which hindered the ability to breastfeed or have skin-to-skin contact. Women who continued to breastfeed through the first six weeks commonly instigated self-help measures outside of professional support to solve breastfeeding-associated problems. These predominantly included internet-based resources such as watching videos, following and participating in forums, and use of search engines, as well as physical measures such as nipple shields and breastfeeding pillows. Expressing breastmilk was commonly used to remedy physiological issues with perceived low supply, and maintain breastmilk feeding and supply whilst working to establish an effective latch. However, the ability to express breastmilk did not enable all women to continue with breastfeeding or breastmilk feeding. Jodie describes pumping regularly for her baby who had a tongue tie and a significant weight loss.

> *Jodie: "I had the breast pump on me the first night I was there, all night, really, didn't I? 'Cause obviously I was up with him, the two hours, I had it on me all night. And I was doing maybe one feed formula, one feed breastmilk, because I couldn't produce as much as every two hours. But then the second time, that's when I did ask for the breast pump, didn't I? I went and asked for it, and they were like, 'no, no, let's just stick to one thing now'… because of the weight loss, they made me just exclusively formula feed him. So they knew exactly what he was having, and it wasn't messing up his body, or... So they made me stop."*

Jodie's account suggests that advice from a healthcare professional may disempower personal proactivity to solve breastfeeding-associated issues, possibly due to the inherent power dynamic between women and healthcare professionals, evident in Jodie's permission-seeking to use a breast pump. The notion of the practitioner/service user power dynamic

affected women's abilities to seek support in resolving breastfeeding issues. Habbah described the fear of authority and a language barrier hindering women's abilities to seek support.

> *"Women need to be taught that… you can actually hold your hands up and say 'I don't know how to breastfeed, I need to be taught'… Women that can't communicate in their language, they're stuck. They're going to look as you as intimidating. That you're the authority, you know, I think that's how they look at you."*

Help seeking behaviours which enabled the continuation of skin-to-skin contact tended to rely on social and practical support rather than seeking professional support. Multiparous women who continued to engage in skin-to-skin contact sought help with childcare and delegated specific responsibilities to their family members.

> *Sarah: "I definitely did [skin-to-skin] around Christmas time, because there was loads of people in the house, so loads of people to distract my toddler. When my husband was home, that was the important thing, because he could look after [older child] and I could just be like, 'OK, my baby's screaming, what do I do about it?' I was basically in charge of [baby] and my husband was in charge of [older child] so it freed up loads of time for me, for [baby]."*

The following subtheme explores social support as a resource for health-promoting behaviours in more depth.

Theme one, subtheme four: Social support and role modelling

Social support was identified as a key dimension in women's decisions to begin or continue to practise health-promoting behaviours. For both the practice of breastfeeding and skin-to-skin contact, women largely drew on support and validation from their partner. Partners encouraged and engaged in skin-to-skin contact after seeing the calming effects on the baby, learnt through observing mother-infant skin-to-skin contact.

> *Taifa: [he does skin-to-skin contact] to be more close, and he really... With [daughter], because she used to cry a lot, but with him, he's calmer, so whenever I'm cooking or doing something, he just takes his clothes off, and puts him next to him. He'd never do it with [daughter], but this one, when I had the top on, and I told him, he did it, but never before did he do it. He has two other kids, and he never did it before."*

Of the women who were continuing to breastfeed at six weeks, many described consistent encouragement and unwavering support for their choice to breastfeed from their partner. Clare exclusively breastmilk-fed her first child, who was unable to breastfeed and was exclusively breastfeeding her second child at the time of the interview. Explaining the effect that her husband had on her resolution to continue to breastmilk feed, Clare identifies the importance of social support which believed breastfeeding to be normal and achievable.

> *Clare: "I'd got the support of my husband. He's from Sweden and their breastfeeding rates are sky high. So, again, it was just the normal thing to do… He had never sort of said, 'this is too difficult, let's just go and buy some formula', that sort of thing. He was just always quite supportive, and as well, never really considered any other option to be honest. He'd not pushed, 'this looks really difficult for you, let's do something else', it was always just 'well, let's keep going'. Because I suppose it's just normal for him and his family."*

Women who continued to breastfeed despite encountering difficulties rarely did so without the support and encouragement from a partner or immediate relative. Inga's experience proved an exception to the rule. As a mother of two, Inga achieved her aim of exclusive breastmilk feeding with her second child, despite her husband's distrust in her ability, based on Inga's difficulties breastfeeding their first child. Instead, Inga relied upon making a plan and resolving to stick to it, supporting herself through breastfeeding challenges.

> *Inga: "I'm happy that I have stuck with my plan. Because my husband sitting next to me and you know, 'when it's not going to work, we had that before, it's just not going to work. Formula is not a poison'. And I'm just looking at him, like 'no, I'm going to breastfeed'."*

Women also demonstrated forethought and planning to develop the appropriate social support they would need to be able to breastfeed and parent their baby in the way that they wanted to. Aneesa described social isolation and loneliness following the birth of her first child, and postponed having her next child until she had moved into her own home with her husband, and established a social support network. The tenets of containment theory (Douglas 2007) are evident through Aneesa's account. She identified the importance of

taking care of herself, both socially and emotionally, in order to be able to respond to her child the way she wants to. In this case, Aneesa used social support to enable her to practise reciprocal and responsive caregiving, in keeping with Douglas' (2007) theory of containment and reciprocity.

> *Aneesa: "It was very tough for me with my eldest one, because I legit just got married. And, umm, not so long later, I was pregnant, about four, five months after I got married, and it was unexpected… I felt so lonely after I had my eldest son, because I had no one around. My mum, my sisters, everyone lives in London. So I was actually alone here… I didn't jump from one baby to another. It took seven years to understand, you know, how a child needs attention, or how important it is that I'm mentally OK, to be able to look after my child, in a way, like, I'm not upset, the surroundings are OK."*

Another form of social support which enabled women to establish and continue breastfeeding was the sharing of stories and experiences with other women who had experienced breastfeeding. Women living with their immediate family, predominantly with their partner and children, accessed support and shared experiences with 'mum-friends': existing or newly-established groups of women who were also breastfeeding similarly aged children. Generally, the sharing of stories and experiences was highly regarded by women who attended parent education classes; women expressed their enjoyment at offering breastfeeding support to other women that they had met at parent education classes, as well as receiving the same in return. Aoife's problem-solving mentality appeared to be validated by offering support to other women having similar experiences, in this case, referring to how she managed mastitis:

> *Aoife: "I think I'm finding that people are more open to just talking about it, especially with other mums - they're just like, 'whatever it is, just talk!' - than I thought they would be to begin with. One of them is experiencing the exact same thing at the moment, so I was like 'this is what I tried' and we talked together about it. And she tried a couple of other things, and was like 'that's a really good idea' so that was nice."*

Women who were continuing to breastfeed often identified a breastfeeding role model, frequently a sister or sister-in-law, who had successfully breastfed. Knowing somebody who

had a positive experience of breastfeeding appeared to be associated with the continuation of breastfeeding. Sumaya described her breastfeeding role model and how she drew on the sharing of metaphors to support her resolution to breastfeed.

> *Sumaya: "My sister in law… How stubborn she was, and how her daughter still cried, and how today her daughter is turning 1 next month, and her daughter is so chubby and healthy. And I thought 'you've done it!' And I thought 'if she can do, I feel like I should try it… The example she gave me which made so much sense was, she was like, 'imagine you own a farm' she said, and she was like 'imagine the animals on the farm', she was like, 'the artificial ones would get really big very quickly because you give artificial things to the baby... to the chickens and stuff'. She was like 'organic animals would take time to put the weight on but eventually they will put the weight on, but it will just take time, and that's breastmilk for you', and yeah, and she was like, 'so think of it like that'. And I was like 'OK, then!' She goes, 'because with organic and natural things you don't see things straight away, but if you give formula, you might see your baby put weight on a lot more quicker'. So I thought I'm gonna keep that theory in mind."*

Absence of a breastfeeding role model, or knowledge that their mother did not, or could not, breastfeed, appeared to undermine women's beliefs in their own ability. In her pregnancy, Jade had planned to "*give it a go*", and anticipated having difficulties with breastfeeding. Jade decided to stop breastfeeding when her baby was a few days old.

> *Jade: "I thought, I know with my mum trying, when she tried to breastfeed me, it didn't work, so I thought she might not even latch on to me, she might not like it, or stuff."*

In summary, social support and role modelling worked in two ways to facilitate health-promoting behaviours. Firstly, support and encouragement validated women's decisions to breastfeed and have skin-to-skin contact, particularly when their partners shared a belief in the positive effects. Secondly, social support and role modelling enabled women to seek help from other breastfeeding women to solve commonly encountered issues (T1S3) through the sharing of their own knowledge and experiences (T1S1).

Theme one, subtheme five: Agency and autonomy

Agency and autonomy is the final subtheme of theme one. This subtheme relates predominantly to women's ability to determine and delegate the time, space, and resources within the home. Living as an extended family unit, most often with parents-in-law, emerged as a barrier to responsive behaviours of breastfeeding and skin-to-skin contact. Almost all women who were living with their parents-in-law, or had been living with their parents-in-law, found that a lack of personal time and space inhibited their ability to respond to their baby with breastfeeds or skin-to-skin contact when they had wished to. This inability tended to relate to a lack of input in the delegation of household duties, competing demands between childcare for other children, and feeling unable to expose their chest to breastfeed or have skin-to-skin contact. Saira described being warned about the difficulties of exclusively breastfeeding whilst living in an extended family:

> *Saira: "It's mainly from households like mine, so people who are living in extended families. Due to their circumstances, you know, because of household responsibilities, they can't tend to their child. And people say, in no time you'll end up going to the formula because you're busy… Obviously the stress of being upstairs whilst there's work to do downstairs. Because I could be upstairs, all comfortable with him, then my elderly mother-in-law might be doing work downstairs, so I'd need to be downstairs. If I was in my own place, I don't think there'd be any barriers."*

Habbah shares similar thoughts about the lack of personal space. The agency to move freely within the home and utilize various spaces to tend to the baby was a sought-after resource for women who lived permanently in extended family units.

> *Habbah: "It was about privacy, yeah. I think, a lot of people are not open to the idea of breastfeeding. You know, I think for me personally, in the sense, just in case I would accidentally reveal myself whilst breastfeeding. That's what I was always conscious about… I don't think personally that living in a household, especially with an extended family, in certain cultures, is acceptable, breastfeeding. Especially when you haven't got a private space. I think being in your own home, and just having your own family, would've helped me breastfeed her more. Because I would have had a household routine, a private space, where I can do what I want, sit how I want, you know. Having*

the experience of lying down, side to side and breastfeeding her on the sofa or even on the floor, that would've been a lot more better."

Contrarily, for women who had their own mother staying in their home temporarily, the presence of their mother was identified as an enabler for the continuation of breastfeeding and responsive behaviours. By comparing the experiences of these two groups of women, it appears that the social hierarchy within the extended family unit inhibited women's autonomy to parent responsively. Women who permanently lived in extended family units used various methods to establish and maintain their parental autonomy. This is evident in Saira's use of performative compliance, in which she pretends to follow the advice of community elders about discarding colostrum, then makes contrary decisions in private. Women developed various strategies to protect the exclusivity of breastfeeding when formula supplementation was advised, and continue with skin-to-skin contact when it was discouraged for fear of a cold baby.

Saira: "*Someone called me when he was 5 weeks, a very close person to my mother-in-law… She was giving me advice on breastfeeding… She said make sure you squeeze it all out, don't feed him that, that's the bad stuff… I've just learnt to say 'OK, OK,' to all the comments. But it's all contradicting… She's an elderly person, she was like 'I've raised this many children, they've never had any infections, they've had no issues, make sure you just feed him the milk, don't give him the colostrum, it's not good for them.' But I'd obviously heard the opposite… Just say 'yes, yes, yes' to everything. I know what I'm doing. I could be on the phone arguing with her, they're going to take it wrong. Because obviously I've just given birth to my first child. They've had 5, 6 children, they've got grandchildren. So they don't take it like 'she acts like she knows everything but really she doesn't know what she's doing, and later on she'll realise' so I know to say 'yes, yes, yes', because if anything does happen to him, they'd love to say 'I told you so', so I just say 'yes, yes, yes'.*"

Women sought the agency to determine how and when they engaged in breastfeeding and skin-to-skin contact, which was frequently inhibited by living in an extended family unit. The presence of extended family was not necessarily a barrier for health-promoting behaviours when women had their own mother staying in their home. Women's agency and autonomy appeared to be dependent upon their place on the social hierarchy of living within an

extended family. When living with their parents-in-law, women's agency in moving freely around the home and determining their own use of time appeared to be reduced. In these circumstances, women developed strategies to navigate unwanted parenting advice exercise their decision-making capacity. When living in their own home with their mother, women were able to self-determine their time and were less concerned with privacy or modesty.

Summary of theme one

In summary, theme one demonstrates the resources that women used to facilitate breastfeeding and skin-to-skin contact as health-promoting behaviours. There was considerable congruence between the resources used to facilitate breastfeeding and skin-to-skin contact. The resources required to facilitate breastfeeding and skin-to-skin contact were elicited through women's descriptions of both the barriers and the enablers that they encountered in the postnatal period, which included cognitive, social, and environmental factors. A working understanding of the physiological mechanisms of both skin-to-skin contact and breastfeeding underpinned women's decision making to engage in and continue health-promoting behaviours (T1S1). This working understanding was rarely gleaned from healthcare professional support provided by midwives or health visitors (T1S2). Instead, women sought help from social networks (T1S4), internet resources (T1S3), and specialist referrals (T1S2) to solve their own perception of issues (T1S3).

Theme two: motivations for health-promoting behaviours

The motivations for partaking in breastfeeding and skin-to-skin contact ranged much more broadly than the often-cited short- and long-term health benefits for the baby and mother. When asked about their motivation to breastfeed, most women recognised general health benefits to both themselves and their babies but went on to discuss social, cognitive, and psychological motivations in more breadth and depth.

Theme two, subtheme one: Beliefs, attitudes, and conceptualisations

For Muslim women, Islamic beliefs provided a source of motivation to breastfeed. However, Sumaya identified that religious beliefs tended to motivate women to breastfeed but often not exclusively.

> *Sumaya: "Breastfeeding is a religious thing as well. In the Koran, it says we have to breastfeed. In fact, the woman that chooses not to breastfeed, not for health reasons, but says 'no I don't want to ruin my body or anything', she can face, like, punishment in the here-after. It's actually that severe regarding breastfeeding. So breastfeeding is big religiously so they all breastfeed but never exclusively."*

Saira, another Muslim woman, suggests that other women in her religious community are motivated to breastfeed based upon their religious beliefs, but combination feed due to pragmatic considerations, such as childcare.

> *Saira: "In our religion, they're only entitled to it [breastfeeding] for two years. And I wanted to make the most of it, and they do as well, but because they've got other kids as well that they've got to attend to, you know, they feel like they can't do that. So they are breastfeeding as well as giving them the formula."*

Two dominant conceptualisations of breastfeeding were expressed by women when describing their motivation to breastfeed. Women tended to conceptualise breastfeeding as either 'normal and natural', or using the well-established motto 'breast is best'. The conceptualisation of breastfeeding as normal and natural supported women's beliefs in their ability to breastfeed. Clare exclusively breastmilk-fed her older child as he had difficulty latching. Despite not establishing breastfeeding with her older child, Clare maintained the belief that the challenge was achievable, and was exclusively breastfeeding her baby at the

time of interview. The conceptualisation of breastfeeding as normal and natural was supported by the conceptualisation of formula milk as a medical intervention, rather than a second choice, in her husband's country of origin.

> *Clare: "When I was pregnant with [older child], it just seemed like this is the normal, natural thing to do, and I never really questioned that I wouldn't be able to do it. First time mum, you've never done it before. You just think, 'well, why wouldn't I be able to breastfeed?' That's all that I wanted to do… In Sweden, you can only really get formula on prescription, when there's a need for it, so it's sort of seen as a last resort, really."*

Subscribing to the beliefs and attitudes of a society which has much higher breastfeeding rates seemed to motivate Clare to work to solve problems, and persevere with breastfeeding. This perspective was shared by other women whose families originated from societies with higher breastfeeding rates. Kabita, a Nepalese woman, also discussed the normalisation and visibility of breastfeeding being a motivation for her.

> *Kabita: "In our culture, like, we don't even think about bottle, it's like a natural thing. So in the community, women are breastfeeding, talking to each other, it's like more than 95% of women that might breastfeed. It's something natural. If a baby's born, it's natural to just put it to boob. And if somebody doesn't, it's like, 'what's wrong with that woman?' it's like that culture. It was my culture, and I never thought I would bottle feed my baby."*

Women such as Kabita and Clare who regarded breastfeeding as normal and natural demonstrated a closed-minded attitude to their chosen method of infant feeding. This attitude appeared to have motivated them to continue to breastfeed or breastmilk-feed despite encountering difficulties. Despite calls to drop the slogan 'breast is best' (Berry and Gribble 2007), women continue to cite it as a rationale for choosing to breastfeed. Women who cited the 'breast is best' motto tended to display a more open-minded attitude about methods of infant feeding. This was more closely associated with women who planned to combination feed, or who were combination or exclusively formula feeding at the time of interview.

Women who conceptualised skin-to-skin contact as an added extra, or as an intervention needed only in particular circumstances, tended to report having less skin-to-skin contact. Johanna regards skin-to-skin contact as an intervention for premature or unwell babies and suggests that:

> *Johanna: "It may really differ with premature babies, but because none of my children were prematurely born or had any health difficulties, I think that it didn't really make any difference on them."*

Women who believed skin-to-skin contact to be fundamental to securing attachment and bonding tended to report engaging in skin-to-skin contact more frequently. Their belief in the value of skin-to-skin contact was reinforced by the perception of tangible results, such as their baby recognising them as their mother, settling quickly, and sleeping better. By comparing her experiences with her two children, Sarah demonstrates a shifting conceptualisation of skin-to-skin contact, which can be understood through Maslow's (1943) hierarchy of needs. With her first child, Sarah found skin-to-skin contact to be a fundamental need of the mother-infant dyad, needed to stimulate her diminishing milk supply. This situates skin-to-skin contact at the bottom of Maslow's (1943) hierarchy. However, having had an easier time establishing breastfeeding with her second child, Sarah's conceptualisation of skin-to-skin contact shifts, no longer positioning it as a physiological need, but as a higher level need as part of love and belonging (Maslow 1943). This interpretation of Sarah's conceptualisation of skin-to-skin contact may explain the variance of Sarah's engagement with skin-to-skin contact between her two children.

> *Sarah: "With [older child]… it was that I had to do skin to skin, I had to have my milk back, I was putting him in skin to skin constantly in the hope that he would latch, and things like that, so it was kind of more... More intense, I guess, the first time round, my relationship with skin to skin… Whereas with [baby], it's been a breeze, by comparison, with the feeding and everything. So I suppose it was more... yeah, to calm him down, but also, I mean, I wish I had been able to do more skin to skin with [baby] for the bonding."*

Women's positive beliefs, attitudes, and conceptualisations about breastfeeding and skin-to-skin contact motivated them to continue to practise these health-promoting behaviours. This motivation appeared to be particularly powerful when it was shared by the woman's family and wider social network. A belief that breastfeeding was normal and natural motivated women to initiate and continue breastfeeding. Inversely, a belief that skin-to-skin contact was not a fundamental aspect of mothering led to the conceptualisation of skin-to-skin contact as an added extra, useful for sick or unwell babies. Women who tried skin-to-skin contact tended to be motivated to continue with it based on their experiences, as they perceived it to be beneficial for the development of the mother-infant relationship.

Theme two, subtheme two: Reciprocity, attachment, and bonding

Securing attachment and developing a unique bond was a key motivator for both breastfeeding and skin-to-skin contact. Women were motivated to begin breastfeeding and skin-to-skin contact on a theoretical basis, but were motivated to continue to breastfeed and have skin-to-skin contact based upon the effects that it generated. Women frequently reported using skin-to-skin contact to respond to their baby's behaviour, most often to settle an upset or fussy baby, or to soothe a tired baby to sleep. Jasprit describes learning about the benefits of skin-to-skin contact from her own reading and research,

> *Jasprit: "It was like, this is something I've gotta do. But then, when I started doing it, I was like, 'oh, the baby's settled'."*

Women used the terms 'to bond' and 'bonding' frequently when reporting their motivations to breastfeed and have skin-to-skin contact. The notion of bonding appears to feature two key components: establishing themselves as the mother and feeling closer to their baby. Taifa describes her motivation for breastfeeding as:

Taifa: "to get to know my son more. And also I want him to know that I'm actually his mum."

The notion of securing attachment reoccurs within most women's motivations to breastfeed and have skin-to-skin contact. This appears to be encouraged by the development of the baby's unique response to their mother, which encourages ongoing breastfeeding and skin-to-skin contact. Most women conceptualised relational bonding as a developing process

rather than a single event. However, for Driti, once the bond had been established in the first few days, skin-to-skin contact was no longer thought to be necessary.

> *Driti: "They [my children] know me from day one, as soon as they come out in this world, skin-to-skin contact is the best thing… Because he [baby] stays with my chest a lot of time, a long time, he can smell me, he knows who I am. I did first few days… After then, he knows me now, so wherever I'm going, he's looking at me. If I give him to somebody, he'll cry for me. He can smell me. When I go inside the room, he can smell me. When he's staying with his dad, he's looking at me, he knows me, he knows my voice as well! I think I don't need any more skin to skin!"*

All of the women who had ongoing skin-to-skin contact at home found it to be enjoyable, which motivated the continuation of the practice. When examining women's motivations to continue to breastfeed, many women found the establishment of breastfeeding to be either stressful or painful. Women's motivations to breastfeed tended to be more long-sighted, rather than for the immediate experience. For multiparous women like Amarjit, reflecting on their bond with their older children who were breastfed motivated them to persevere in establishing and continuing with breastfeeding:

> *Amarjit: "It's a nice way to bond with the baby as well, and especially with her [older child], because I did it for a year, I feel like we've got quite a strong bond now, and I want the same thing with him as well. So that was the other motivation as well, I suppose."*

Women's motivations to engage with breastfeeding and skin-to-skin contact were more closely aligned with the social and psychological process of bonding and relationship development, rather than physical health benefits for either the mother or baby. Engagement in skin-to-skin contact provided instantaneous gratification, as skin-to-skin contact was found to be effective at soothing an unsettled baby. Motivations for breastfeeding tended to rely on retrospective impressions from breastfeeding previous children, including general good health, sociability, and a close bond with their mother. This longsighted motivation marries with multiparous women's ability to understand the

challenge of breastfeeding as achievable and finite (T1S1), generating motivation as a psychological resource to continue breastfeeding despite the challenges.

Theme two, subtheme three: Social acceptability and expectation

Encouragement and reassurance from healthcare professionals, including breastfeeding peer-supporters, midwives and doctors, motivated women to begin and continue breastfeeding and to engage in skin-to-skin contact. Although this may be construed as a component of professional support, it appeared that the psychological aspect of encouragement and reassurance was a motivator of behaviours, whereas specific practical support was often an ineffective facilitator. Beth describes the value of reassurance to encourage perseverance:

> *Beth: "Sometimes you're like, 'I'm doing this, is this... Is this the best thing to be doing?' Because initially, like in the first week, when he was tongue tie, and he was struggling with his latch, and I was expressing, and he was having bottles, I was really scared that he was just going to get so used to the bottle, he wouldn't go back on to the breast. So just having some, like, reassurance over the phone, that what I was doing was suitable."*

Both the practice of breastfeeding and skin-to-skin contact varied in acceptability across the social circles of the women interviewed. Where women perceived the behaviour to be considered acceptable or desirable, they felt supported in practising the behaviour. Jasprit describes the conversation with her father-in-law shortly after her baby's birth which gave her the confidence to move past the social discomfort, and continue to breastfeed her daughter.

> *Jasprit: "It was my father-in-law that asked me at the hospital, soon after my oldest daughter was born, he goes 'what's your intention on feeding?', and I said I intend on breastfeeding, and he was just like, 'you know, it's good to give your kids the natural food', and so then I kind of thought I have got that support, because babies feed constantly, feed constantly, and I never felt like I had to go and hide away in a room, or you know… I could cover myself up with a muslin cloth, and be comfortable feeding around family. And I think at first, they found it a bit uncomfortable, because, you know, my daughter was the first baby in generations… to kind of, you know, be breastfed.*

Because my husband and cousins, they weren't. So it took a bit of getting used to, but they were fine with it, and I felt comfortable doing it."

For some women, the perceived social expectation of breastfeeding motivated both the commencement and continuation of breastfeeding. However, social expectation alone was not enough to enable women to continue to breastfeed for as long as they wanted to. Despite an expectation to breastfeed her baby, Wahida stopped breastfeeding before she had planned to. She attributed the cessation of breastfeeding to being encouraged to supplement her baby's diet with formula milk in order to keep the baby content. Wahida compares the support she received from their family in comparison to the support that her sister-law received:

Wahida: "With her [sister-in-law], when she didn't have that supply of milk, her husband did not get the extra formula feeds, he's like, 'you just latch the baby on your breast and then that will just bring the milk', and that helped her, whereas me, I get those, like... For example, when my baby didn't have enough, my brother was like 'oh well, we'll just go and get some formula feeds, and we'll just feed the baby, you can't just leave the baby hungry' and I think it's those side thoughts that just like... don't help, because yes, fair enough, the baby's going to be quiet for now, but in the long run, your breast is going to dry up, 'cause the baby will just rely on the formula feed, and that's what happened with me, whereas her, her husband [Wahida's brother] just looked at her and said 'I'm sorry, I won't get you anything, the baby will cry today, but tomorrow, it'll have some breastmilk'. And now she's got enough breastmilk to feed her baby."

Wahida's account illustrates the complexity of breastfeeding continuation when the social expectation is to breastfeed, but breastfeeding is undermined by the social circle failing to support the mother. Although Wahida's brother had the knowledge and understanding to support his own wife, this logic did not apply to Wahida. As identified in theme one, subtheme five (agency and autonomy), it appears that familial social hierarchy determined the support for health-promoting behaviours, particularly if they required time and perseverance.

Summary of theme two

In summary, women's motivations to engage with and continue health-promoting behaviours comprised primarily of cognitive and social factors. Social factors, such as exposure to a culture where breastfeeding was considered normal (T2S1, T2S3), fed into cognitive factors, including a belief that breastfeeding was achievable and desirable (T2S1). The perception of social acceptability in the home environment encouraged women to engage in breastfeeding and skin-to-skin contact (T3S3). Once women were motivated to engage in these behaviours, experiential factors motivated them to maintain these behaviours (T2S2). Women were motivated to continue breastfeeding and skin-to-skin contact through their experience of bonding and responding to their baby, which appeared to develop over time (T2S2).

Theme three: Snuby garment as a health-promoting device

Of the forty-four women interviewed, twenty-seven were from the intervention arm of the study. Only the interviews from women who received the garment fulfilled the aim of understanding how the Snuby garment was used, and to what effect. However, the remaining seventeen interviews were included in the interpretation to offer context and comparison of the two different methods of skin-to-skin facilitation. All quotes about the Snuby garment are from women in the intervention arm unless stated otherwise.

Theme three, subtheme one: Security and mobility

Women mostly felt that the Snuby garment offered increased security to maintain safer neonatal positioning than conventionally facilitated skin-to-skin contact. For primiparous women, this was a frequently cited reason for using the garment rather conventional facilitation.

> *Amira: "Once or twice, I did it without [the Snuby], and I was more, like, wary, she might fall off, even though she was covered, and I put a blanket on her, I didn't feel she was that secure."*

> *Gina: "When he was really, really tiny, when he'd just come home, it was helpful to have something that wrapped him in and kept him there. Rather than just trying to do it with nothing to support you, if that makes sense. It kept him in one place. And he loves this tree frog position."*

Multiparous women tended to value being able to multi-task, having their hands free to tend to their other children or complete household chores. Keisha, a mother of three, describes the increased security of the Snuby maintaining her baby's position whilst her other children were present. Harbeer, a mother of two, also found the garment to offer security, which enabled older children to interact with the new baby safely.

> *Keisha: "It just feels more secure, and also just having my hands-free, so I know that she's sat in there, especially like when my boys have come, I've just been able to plop her in there, and still have my hands-free when my son would want me to play action*

figures or still kind of have a free hand doing that, whereas if I just had her in my dressing gown, it doesn't sit, whereas in the top, she just sits there."

Harbeer: "It's also really nice again, as I have an older daughter, she can play with him, and I know she's not going to sit on him, or get too- accidentally- aggressive, as they're a bit heavy handed at that age."

Of the twenty-seven women who were provided with the garment, one felt that it would benefit from an adaptation to increase the security. Harbeer's baby was born at 2.5kg, the minimum weight for study inclusion. She used the garment regularly throughout the six week period. Describing more in-built support at the bottom of the pouch, Harbeer suggested:

"I just think it just needs to be… supported at the bottom, I think, if your baby's a little bit on the smaller side. Other than that, perfect. Absolutely perfect."

Both primiparous and multiparous women used the Snuby to increase their mobility, enabling them to change and adjust their position, sway and jiggle baby, and make short trips to the kitchen and bathroom whilst holding the baby in the garment. Although not designed to facilitate mobility, the women valued the containment of the garment when needing to mobilise around the house whilst using their arms to support the baby in the Snuby. Beth, a mother of two, describes the benefit of the containment of the garment when needing to mobilise:

Beth: "I could get up, if there was something I needed to do for her [older child], I could. Or, if he [baby] was unsettled, I could walk around with him. He seems to settle a bit more when you're moving around with him, when he's being fussy. So it [the benefit] was mainly having my hands."

However, three of the multiparous women interviewed did not find added value in the garment, preferring conventional facilitation for ease when having opportunistic episodes of skin-to-skin contact.

Katie: *"I found it easier to not use it. I think it was just the whole 'oh, I'm gonna have to get changed to do skin to skin now' whereas I found it easier, like I said, to do it once*

> *he'd had a bath, and he would settle, and it was just easier to cover us with just the blanket."*

The majority of primiparous and multiparous women found value in the Snuby garment, albeit for different reasons. Primiparous women were more concerned with neonatal security during skin-to-skin contact, whereas multiparous women were more concerned with mobility. The differences between the findings from primiparous and multiparous women are likely due to the increased demands on multiparous women to care for other children, and remain mobile and active.

Theme three, subtheme two: Dyadic bonding and reciprocity

Relational bonding was both a motivation for Snuby-facilitated skin-to-skin contact (as described in T2S2) and an outcome of using the Snuby garment, irrespective of whether the mother-infant dyad was breastfeeding. However, multiparous women who had had fewer breastfeeding-associated problems and who were breastfeeding at the time of interview were less motivated to use the Snuby as a way to bond with their baby. This difference may be due to women feeling that the act of breastfeeding sufficed in establishing the mother-infant bond, negating the requirement for additional time spent in skin-to-skin contact. The equating of breastfeeding and skin-to-skin contact as a tool for bonding is evident in Zahra's explanation of why she did not feel the need to use the Snuby garment frequently with her second baby.

> *Zahra: "I think, like, because I'm exclusively breastfeeding her [baby], it's balanced it out. With him [older child], like, I was, even though I wasn't breastfeeding him all the time, giving him a bottle, someone else would give it, then I would spend time with him skin to skin. Whereas with her, because I'm not, I'm not, like, giving her to somebody else, I've got that time with her anyway."*

Women who used the Snuby often described using it to understand and communicate with their baby. Sumaya described the process of connecting with her baby through skin-to-skin contact, which she engaged in because she had a Snuby garment. As multiparous women, both Keisha and Sumaya were able to compare the process of relational development between their children.

> *Sumaya: "I don't know if it's the skin to skin, which I've been doing a lot more of, because I've been doing this [indicates to the Snuby] – but I just feel more connected. Because I remember with my first child… It was my first child, and I loved him and everything, but people would say 'how does it feel to be a mother?' And I'd say to them 'it's nice, but I feel like…' and they'd say to me 'what kind of love do you feel?' My friends that haven't had children that were pregnant would ask me that question, and I'd say to them 'it feels like a sibling that I really love'. I didn't know what is a mother's love, I didn't know, but with [baby], I feel… different… I feel like I connected with him better, and understood him better."*

Having not engaged with skin-to-skin contact with her previous children, Keisha described the process of using the Snuby to respond to her baby, which enabled her to understand her baby's needs and behaviour:

> *Keisha: "A couple of time, when she's been unsettled, I've thought, 'let me just try, let me just see if it works' and literally, as soon as I put her in it, she's calmed down, and then afterwards she'll kind of say why she's unsettled, whether it was a case of, 'well, I was hungry' or 'I needed changing', or 'I just wanted some love'."*

A pattern is identified where women use the Snuby as a response to their baby, which enabled a process of reciprocal communication between themselves and their baby. The notion of being able to interpret what the baby is communicating and understanding what the baby needs is encapsulated in Amira's testimony:

> *Amira: "I definitely think that it helped me as well, to learn about my daughter. She doesn't just cry because she wants to be fed, or a nappy change. She literally just wants mum's cuddles - that's what I say - 'you just want mum's cuddles!'… I learnt that via Snuby, I think. You know, you're just always told that 'oh, you know, check she needs burping, or needs feeding, she's hungry', but you don't ever think, 'oh, they just want to be cuddled and held, and talked to'. So when she was in the Snuby, I used to tell her stories, like 'this is about your grandma' and 'this is how your mum and dad met'. I used to just babble on. So, I think that's when she heard my voice properly as well, that probably helped with the recognition as well. It's been really good."*

In keeping with the findings on motivations to engage in skin-to-skin contact (T2S2), women found that using the Snuby garment regularly resulted in their baby recognising them, which appears to be fundamental to their perception of dyadic relational development. Taifa partially breastfed both of her children and compared her skin-to-skin experiences with her older daughter and her baby son.

> *Taifa: "Ever since I started doing this skin to skin with the top, I've realised he knows me more than he did before. Because she didn't know, and she wouldn't... When I'd come in the house, like, from somewhere, or when I come from college, he knows my voice. So he looks around, puts his head up, that I am actually in the house. When I say 'hello mummy', he literally looks around. I kept him more on my skin than I did with [daughter]… I've seen a lot of difference."*

For women who chose not to breastfeed, or were no longer breastfeeding, the Snuby was perceived to offer an opportunity to develop or maintain a breastfeeding-type relationship, which was unique to the mother and baby. Amira goes on to share her experience of this:

> *Amira: "I wanted to breastfeed as a bonding thing, just between me and her. But then obviously, now it's bottles, her dad has obviously been feeding her, her grandma has been feeding her, so I kind of lost that thing. I just wanted to have that time with her. So I thought that if I do skin to skin, at least that'll be something that's personal between us two as well, so. It just kind of gave me something… I think having the Snuby definitely helped, because I didn't have that... breastfeeding relationship I wanted. So I think I got it somewhere else, if that makes sense, via the Snuby. So I think I'm quite satisfied with that."*

Rachel also describes the calming effect of using the Snuby top to bond with her baby when she stopped breastfeeding.

> *Rachel: "Because I've not been able to breastfeed, I have found that it has helped, kind of, I suppose, calming me, calming him, the bonding a bit more. Because obviously we're not having that time together that we would normally if we were breastfeeding."*

However, the Snuby did not appear to encourage women to cease breastfeeding and replace it with skin-to-skin contact. For women like Gina, who had struggled to establish breastfeeding, and persevered despite many barriers, the Snuby acted as a way of reconnecting, and maintaining a positive relationship with their baby. She describes how using the Snuby alleviated stress and frustration, and provided a way to positively mother her baby:

> *Gina: "I was trying to make sure that every time he was with me, wasn't stressful. Because that's how I started to feel, a bit. Like, because [husband] was off work at that point as well, and we would both sleep when we could, and take it in turns. But my turn was always feeding, which then meant stress, him getting frustrated, and I was like, I don't want our time to always be like that. So one of the ways of overcoming that was just to have some nice skin to skin sometimes, just for the sake of it. Not for trying to feed, not for any purpose, just for lying down and having a cuddle."*

The intimacy and intensity of relationship-building in the Snuby were predominantly positively regarded by women, who recognised feelings of protectiveness and possessiveness over their baby from birth. Women frequently described using skin-to-skin contact to reconnect with their baby following times of stress, including the presence of visitors. However, not all women easily adapted to an unfamiliar sense of attachment to their baby. Niomi presents a unique case, divergent from the experiences of the other participants, and as such, is examined here in further depth. Negative case analysis is an important tool to understand the whole phenomenon of the research topic, and to reinforce the trustworthiness of the study findings (Amin et al., 2020). Thick contextual description accompanies Niomi's quotes to inform the transferability of the data (Amin et al., 2020).

Niomi, a mother of two, portrayed feelings of ambivalence related to the unique relationship she had built with her baby through exclusive breastfeeding and frequent and consistent use of the Snuby. Niomi suffered from postnatal depression after the birth of her first child, whom she formula-fed. She described establishing a high degree of independence between herself and her first child, whereby feeding and care would often be outsourced between family members to enable Niomi to maintain her own personal space. With this baby, Niomi went on to exclusively breastfeed and practise ongoing skin-to-skin contact in the Snuby. Niomi examined the notion of attachment and explained how she used the Snuby

as a tool to protect the integrity of the mother-infant dyad. Niomi's experience is explored further in the following chapter with reference to Bowlby's (1997) attachment theory.

> *Niomi:* "[It's] *been a blessing and a curse all in one… I don't know. I think I've got mixed feelings on it. Simply because I like my own space, I like my own company. Even with my [older] son, I've got that 'alright, you need your space, I need my space', whereas this one, we sleep together, we wake up together, it's like having another partner. And this one, you can't tell off, this one doesn't go to work. So we just… we're in it together. [It's] A very different, a very, very different relationship. I think the Snuby has definitely had an impact, because I don't think I had much skin to skin with my son… I'd have visitors, and I wouldn't take him out of it. I'd purposely put the Snuby on, just so I didn't have to give my baby to anybody."*

The Snuby garment appeared to promote relational bonding in three ways. Firstly, the garment was used to protect the integrity of the mother-infant dyad, either by creating a physical layer of containment or as a mechanism to reconnect with each other following episodes of stress. Secondly, the garment worked to preserve a unique mother-infant relationship which fulfilled women's identities as a primary caregiver, especially when exclusive breastfeeding was no longer part of their identity as a mother. Finally, the garment was used as part of dyadic communication, both to interpret and respond to baby's needs for love and comfort.

Theme three, subtheme three: Preservation of modesty and bodily exposure

Women generally shared one of two perspectives on the Snuby's role in preserving modesty, apparently divided by their family's country of origin. Women from a South Asian country of origin who lived in an extended family unit, whether first or subsequent generation migrants, found the Snuby to be inappropriate to wear around their extended family. This was found to be a limitation for Snuby facilitated skin-to-skin contact. South Asian women who lived with their immediate family generally reported feeling comfortable wearing the Snuby at home, but shared the views of women who lived with their extended family unit, that it would not be appropriate in company. Driti, who lived in an adjoining house to her parents-in-law preferred wearing the Snuby for skin-to-skin contact, but could not do so in the presence of her in-laws:

> *Driti: "The top is better, because nobody else in the house, you can wear your top, and don't have to worry about nothing. But because I'm living in the in-laws' house, I have to come down, I have to dress over the top. Because we are Asian people, we can't stay like that without clothes."*

Kam felt the Snuby offered some preservation of modesty for women living in extended family units. However, she still refrained from using the Snuby in the presence of her extended family whilst they were staying with her and only engaged in skin-to-skin contact in her bedroom.

> *Kam: "I didn't find it as hard to do skin to skin with him but you know people that live with in-laws or other people, it's not as easy to just take everything off to have skin to skin, just in case, what if someone walks in, but in the top, you're covered. So that helps, in that sense, modest-wise… After my in-laws left - my mum and my mother-in-law were around - so during that time I couldn't walk around much in the top because I'd find it quite awkward, that's just me though. But once they left, I was able to come down with him and stuff."*

Concerns about the preservation of modesty were not unique to any religious group, migrant generation, nor seemingly linked to bodily exposure in front of specifically male relatives. For the women from South Asian countries of origin, living in an extended family was the key dimension identified in the acceptability of the Snuby garment. Migrant women from non-South Asian countries of origin, and non-migrant women reported feeling comfortable whilst wearing the Snuby in front of their families. Taifa and Sumaya, both British Somali Muslim women, described a surprised reaction from their families about using the Snuby garment but found it to be acceptable to use in company and went on to use the garment frequently. For non-migrant women, the Snuby was felt to offer an appropriate degree of modesty to be able to use in the company of visitors.

> Rachel: *"The nice thing about it as well… I thought it was going to be kind of a bit more skin tight, so if people came round, I'd have to quickly change, and things like that,*

because obviously not having a bra on... But I quite happily sat quite a few times with visitors coming round and things, and I felt completely, like, covered with it."

These findings suggest that the Snuby garment is not considered to be socially acceptable for women of a South Asian heritage when living in an extended family unit, although all women found it to be acceptable for use around their partners. Although the premise of modesty arises in Islamic teachings (Boulanouar, 2006), these findings indicate that culture and environment, rather than religion, informed women's views of modesty and bodily exposure. The requirement for further research to develop culturally acceptable skin-to-skin facilitation strategies is addressed in the following chapter.

Theme three, subtheme four: Prompting and validating quiet time

The Snuby garment acted as a prompt for skin-to-skin contact, apparently validating quiet time spent together as a dyad, as well as enabling multi-tasking and activity. Gina used the Snuby regularly for myriad reasons, including to calm her baby, maintain a positive relationship with her baby despite feeding difficulties, optimise breastmilk expression, and encourage her baby to latch to the breast.

Gina: "It [Snuby] just prompted me about the importance of skin to skin. I could've come away from the hospital being told 'oh, have skin to skin, that'll help your bonding, that'll help your feeding', whatever, but I might not have done it had I not had the top to prompt me to think. I think it just prompted me to remember to use it as a method for calming him down or whatever. I don't think I'd have necessarily came home and, I don't know, lay on the sofa with him with a blanket over us or whatever. I don't think I'd have necessarily thought to do that, had I not been prompted with the top being there."

Women often reported feeling comfortable wearing the Snuby throughout the day as they would an ordinary top, which prompted them to practise skin-to-skin contact regularly. Taifa wore the Snuby regularly and used Snuby facilitated skin-to-skin contact to soothe and settle her baby.

Taifa: "Instead of thinking, 'oh, I've got to put a blanket on, I've gotta do this, I've gotta do that, you're gonna feel cold', it's just easier, it's like wearing one of your normal tops, you just put it on. I was cuddling him when he was crying, and instead of cuddling him, I took the clothes off and put the top on. He'd either fall asleep, settle, or calmer, being

awake. Settled, always. And then I'd check him, and he was asleep. Literally, after like maybe fifteen minutes later, he's gone to sleep."

Amy, a primiparous woman, described herself as "*a bit of a control freak*", and followed a parenting guide aimed at establishing a routine from birth. Amy described how the Snuby garment prompted her to take time out to be with her baby. However, the implementation of a sleeping routine prohibited Amy from using the Snuby more, as enjoying quiet time with her baby was limited by adherence to a set routine.

Amy: "That 'everything just has to stop' time, because you've got to sit still. And I'm too much of a busy body. I think it made me sit still for a bit… The only thing that's probably stopped me from using it more is the routine, because she falls asleep in it. I guess because I want her asleep at set times, the other sleeps in the day, I find it harder like, now for the afternoon sleeps, to just sit still and put it on when she will sleep at the time, because I tend to go and get things done, wash up, and sterilise. So I've tended to use it in the morning, because I'm sat still anyway, we'll be upstairs until after her first sleep."

Women's utilization of the Snuby garment to facilitate quiet time with their baby appeared to depend on their parenting style. As apparent in Niomi's use of the garment in T3S2, the Snuby appeared to facilitate a responsive, attachment style of parenting, where the dyad came together to reconnect and spend time together regularly. The relationship between skin-to-skin contact and attachment parenting is explored in the following chapter.

Theme three, subtheme five: Facilitating breastfeeding and lactation

Women were asked to share their thoughts about any relationship between using the Snuby and their infant feeding practices, irrespective of their intended method of feeding. Most women who were breastfeeding did not identify a relationship between using the garment and establishing or maintaining breastfeeding. Instead, they often referred to the enabling of relationship building and bonding as a key feature of Snuby usage, especially when they encountered breastfeeding issues. The five women who found the Snuby garment to positively impact on their breastfeeding establishment or continuation cited various reasons. These reasons included the encouragement of baby-led attachment, optimization of

breastmilk supply for breastfeeding or expression, and maintaining closeness for responsive breastfeeding.

> *Gina: "I've noticed I do express quite a lot more when he's skin to skin. So it's very helpful for getting bottles ready, because when he's in the sling, I can express a lot more, even, like this, but when it's actually skin to skin, it's better."*

When examining the Snuby garment as a tool to support positioning for breastfeeding, women's views were polarised. Women tended to either regard the Snuby as restricting their ability to establish and maintain an effective position for breastfeeding, or as a facilitator for responsive breastfeeding when using the garment throughout the day. There did not appear to be an association between the perceptions of the Snuby as a positioning aid, and women's parity, breastfeeding experience, or breastfeeding continuation. Jasprit describes learning to position her baby for breastfeeding using the Snuby in order to establish breastfeeding:

> *Jasprit: "It took us a while to get the grasp of feeding whilst she was in the top, just because of positioning, but once we'd got that, she was OK. I think I used it for the first four, four and a half weeks, but then after that, I kind of just thought, 'oh, you know what, feeding's now established, she's got into a regular bit of a pattern'.*

Gina also used the Snuby in the establishment of breastfeeding, to maintain close proximity to the breast whilst awaiting feeding cues:

> *"In the mornings, so in between that first morning and mid-morning feed, I'd put him in the top, skin to skin, and just wait for him to wake up. And as soon as he started showing signs, I'd be like, just inching him over."*

In contrast, Aoife and Estela found that skin-to-skin contact, irrespective of facilitation method, over-elicited feeding cues.

> Aoife: *"Every time we have skin to skin, she's like 'food!' She goes crazy for it! So she didn't end up trying it [Snuby] on again, because I knew she wasn't settled anyway, just doing regular skin to skin, so I figured she'd be really fidgety in the top. When I did skin to skin with her without the top, she was as fidgety, because wanted to eat."*

The Snuby was also adapted to maintain a breastfeeding position, evident in Jasprit and Taifa's description of using a bathrobe over the top. Describing how she breastfed in the Snuby, Taifa reported that:

> *Taifa: "It was easy. I just kept him a bit up, so I put my bath robe [cord], and I lifted it up, so he could actually grab it and keep it. He did a lot of feeding in the top."*

On the contrary, some women found the Snuby to inhibit their ability to position and attach their baby to the breast, finding it to restrict the freedom of movement. Karen had anticipated using the Snuby to facilitate breastfeeding but did not find it helpful.

> *Karen: "[I] found that positioning him wasn't... It was more of a hindrance than a help… Because it keeps his bottom down, doesn't it?"*

As the Snuby garment maintained one neonatal position, it did not negate the need for a working understanding of the principles of positioning and attachment (T1S1) and an individualised application for each mother-infant dyad. For dyads who used a laid back position for breastfeeding, the Snuby garment sustained the position required for breastfeeding. For dyads who actively positioned their baby for breastfeeding, the Snuby appeared to inhibit their range of movement. Irrespective of the positioning, the garment was useful in stimulating and maintaining lactation for breastfeeding and expression of breastmilk.

Summary of theme three

On a practical level, the Snuby garment facilitated security for neonatal positioning and enabled increased maternal mobility (T3S1). For women of South Asian heritage, the garment was not considered to be socially acceptable for use within extended family units (T3S3). Without social support (T1S4) and agency to self-determine the use of time and space in the home environment (T1S5), women did not find the Snuby garment to enable breastfeeding and skin-to-skin contact. However, when women had adequate privacy and personal space at home, the Snuby garment was found to be useful in facilitating skin-to-skin contact.

The Snuby garment was used in a variety of ways to support breastfeeding and lactation, including as a positioning aid and to maintain closeness in order to respond to feeding cues (T3S5). However, the garment was not found to be beneficial for all

breastfeeding women; for some dyads, the Snuby garment inhibited their ability to find and maintain a position for breastfeeding, and for others, skin-to-skin contact was perceived to over-stimulate feeding cues (T3S5). Considering these findings in the context of theme one, it appears that without a working understanding of breastfeeding and lactation (T1S1), the provision of a Snuby garment was not sufficient in affecting dyadic infant feeding practices.

Unexpectedly, the primary value attributed to the Snuby garment was related to its facilitation of dyadic relationship building and relationship preservation following periods of breastfeeding-associated stress or cessation (T3S2). The Snuby garment was used by mothers to interpret, understand, and respond to their baby's needs for comfort, love, and closeness, particularly when women were struggling to achieve or maintain exclusive breastfeeding (T3S2). The effect of the Snuby garment on mother-infant relational bonding appears to be bidirectional; as well as responding to their baby's needs, mothers also used the garment to relieve their own stress associated with parenting, and meet their own expectations of themselves as a caregiver who can comfort and respond to their baby.

Summary of findings with reference to the theoretical framework

Dyadic engagement in the Snuby garment, skin-to-skin contact, and breastfeeding was interpreted in line with Antonovsky's (1979) theory of salutogenesis. The transition to new motherhood was a natural but stressful event for women; in Antonovsky's (1996) metaphor, stress is an unavoidable occurrence in the river of life. This life stage had the propensity to generate social, physical, and emotional health for women and their families through breastfeeding and skin-to-skin contact. However, the engagement in and continuation of health-promoting behaviours depended upon the resources available to the individual, or as Antonovsky (1979, 1987) termed them: generalised resistance resources.

Theme one depicted the generalised resistance resources and deficits (GRR-RDs), which were involved in women's engagement in breastfeeding and skin-to-skin contact. These resources included cognitive, social, psychological and social factors which enabled women to navigate the stress of feeding and nurturing their baby and generate dyadic health. Women who generated health through breastfeeding and skin-to-skin contact were able to utilize a working understanding of the mechanism of breastfeeding and skin-to-skin

contact; they were able to make sense of the challenge. The subtheme of knowledge and understanding marries with Antonovsky's (1987) sense of coherence concept of comprehensibility: a sense that life events can be understood, and are reasonably predictable. Women also relied on their skills and ability to problem-solve, especially to maintain health-promoting behaviours. This subtheme is underpinned by Antonovsky's (1987) concept of manageability: a belief that you have the skills, abilities, support, and resources to manage and respond to challenges. In terms of the support needed to maintain breastfeeding, women primarily sought breastfeeding-specific support from other women with experience of breastfeeding, either from breastfeeding peer supporters, a breastfeeding role model, or mum-friends. To maintain skin-to-skin contact throughout the postnatal period, women required social support from other members of their household, including the provision of space and privacy in the home environment.

The role of the Snuby garment as a resource for generating health was explored in theme three. The garment was found to be a useful resource in the facilitation of skin-to-skin contact, predominantly based upon its ability to maintain neonatal positioning, in turn making the practising of skin-to-skin contact safe and sustainable. The strengths of the garment as a resource for health promotion centred on its impact on parenting practices. The garment stimulated responsive parenting practices, as women used the garment to interpret and respond to their baby's behaviour, and as a way to soothe their own and their baby's emotions in times of stress. Two limitations of the Snuby garment were identified, which reduced its efficacy to support health-promoting behaviours. Firstly, the garment was not considered to be wholly socially acceptable for use for women living in extended family units as it did not adequately preserve modesty. Secondly, some women found the garment to negatively impact on their ability to position their baby for breastfeeding. However, the majority of breastfeeding women found the garment useful in laid back positioning (Colson, 2008), stimulating lactation, and enabling responsive breastfeeding throughout the day.

The third and final tenet of Antonovsky's (1987) sense of coherence concept is meaningfulness: the belief that challenges in life are worthwhile, and that there is a good reason to care about what happens. To fully understand how women generate health in the stress of new motherhood, the meanings that women attributed to breastfeeding and skin-to-skin contact were explored in theme two: motivations for health-promoting behaviours.

Women's motivations to engage in breastfeeding and skin-to-skin contact tended to focus on social, emotional, and psychological health, rather than physical health outcomes. Women were primarily motivated by the development of the mother-infant bond. Women described several ways in which they measured the developing bond. Firstly, the mother-infant relationship was evident through the baby's recognition of its mother. Secondly, women remarked upon their own understanding of their baby, including interpreting and responding to its needs for love and comfort. Finally, women compared their experiences of bonding with their other children with reference to their previous engagement in breastfeeding and skin-to-skin contact.

The meaning which women attributed to breastfeeding and skin-to-skin contact was also dependent upon their own, and their family's, conceptualisations of the behaviours. When breastfeeding and skin-to-skin contact were considered to be normal, natural, and fundamental to motherhood, women worked hard to overcome any barriers that they encountered. However, when women's social circle did not share in a belief in the value of breastfeeding or skin-to-skin contact, the social support that women received was undermined, and their own engagement in these behaviours was affected. With the application of salutogenic theory (Antonovsky 1979, 1987, 1996), a thematic analysis of women's experiences of skin-to-skin contact and breastfeeding has been produced. In the following chapters, study limitations are critically evaluated, the positionality of the researcher is revisited, and these findings are integrated with those from the quantitative stage of the study in response to the study aims.

7. Reflection and reflexivity

Reflecting on my positionality

Introduction of the process of reflexivity in research

Reflexivity is the process associated with developing researchers' self-awareness of how they impact and transform the research that they undertake (Kingdon, 2005). Teh and Lek (2018) describe reflexivity as the gold standard for determining the trustworthiness of qualitative research. The rationale for reflexivity is based upon the subjectivity of qualitative research. All qualitative research is contextual; it is situated in time, space, and between people (Dodgson, 2019). In order to add credibility to the research findings, demonstrate rigour, assess the relevance and applicability of the research, and deepen the understanding of the research, Dodgson (2019) suggests researchers should be reflexive, describing the contextual intersection between themselves and the participants.

Reflexivity is critical when considering how unconscious bias may affect the research process and the generation of research findings, as pre-existing beliefs and expectations may influence what is found in the data, and how highly it is regarded (Buetow, 2019). Buetow (2019) describes the risk of apophenia, a cognitive bias in which patterns are perceived amongst things that are not meaningfully related, and suggests that reflexivity can be used to identify and address unconscious biases. Reflexivity seeks to address these biases to avoid the perpetuation of stereotypes and preconceptions, which are ingrained in the cultural unconscious (Finlay, 2002).

Dodgson (2019) suggests that as the process of reflexivity applies to the entire research process, researchers should demonstrate the effects of a "continual internal dialogue" and "self-evaluation of the researcher's positionality" (Mitchell et al., 2018: 678). As such, the relevance of the positionality of the researcher is interwoven in several chapters, such as theoretical framework, methodology, and methods. Following the data analysis process, a reflexive approach was taken to examine the effects of the positionality of the researcher on the research findings, and likewise, examine the effects of the research process on the researcher themselves. These effects are examined in the subsequent sub-

sections, which integrate the researcher's view of their positionality before, during, and after the research process as recorded within a reflexive diary.

Personal issues: gender, race, and socio-economic status

Midwives must reflect upon and examine their value lens to identify strengths and weaknesses of the values they hold and to identify potentially discrimination behaviours based on gender, culture, or societal norms (Hay and Marshall 2019). Working as a woman with other women is typical in midwifery practice and research, although the issue of gender in obstetrics and midwifery has historically been fraught with tension (Drife, 2002). Although not all midwives or maternity service users are women, being within the majority afforded me access to a setting in which I was both inconspicuous and comfortable. I considered being of the same sex as the participants as a benefit, as it mitigated the power imbalance between the researcher and participant, avoiding historical notions of research done *to* women, not *with* women.

Through the recruitment process, I began to consider the effect that being a white, English-speaking, educated woman might have on the research process. As the population served by the hosting hospital was predominantly from a black or minority ethnic background (Office for National Statistics, 2015), I found myself researching in an environment where I was not representative of the demographic. This challenged my original assumption that I would be part of the community I was researching in based on my gender. It left me feeling uncomfortable about 'doing' research as an outsider as I felt I was holding the power to develop the narrative about phenomena which were situated outside of my experiences, and about which I could not truly embody. I particularly reflected on the significance of race and migrant status on both perinatal morbidity and mortality and breastfeeding outcomes. I felt strongly that maternity research should seek to include a diverse, representative sample of participants as one way to address racial health inequities. But was I the right person to do it? When I examined the demographics of the hospital's catchment population, I realised that there was no 'right' person to recruit a representative sample of participants, as the local population was itself transient and varied.

However, feelings of discomfort arose again as I began to analyse the interviews and identify culturally specific narratives. I identified a pattern between the family origin of

participants who lived in extended family units and their perceptions of modesty. I questioned whether unconscious bias might be affecting my pattern-detection in the data; have I found what I expected to find? To address this tension, I returned to the dataset once the preliminary analysis was complete and cross-checked my findings, asking myself whether I could provide evidence of a pattern. Secondly, I asked a research colleague from the same family origin to engage with my preliminary findings, and identify any issues that she saw. Buetow (2019) describes this process as intersubjective reflection, whereby a sceptical peer perspective stimulates dialogue around signs of unconscious bias. It resulted in the reformation of a general working theme 'South Asian culture' into several more specific and nuanced sub-themes including 'agency and autonomy', 'beliefs, attitudes and conceptualisations' and 'social acceptability and expectation'. I found the process nerve-wracking, as peer reflexivity leaves the researcher open to criticism, but I highly benefitted from the process of articulating my thoughts and enquiring where they had come from.

I also considered how my socio-economic privilege might affect the design and recruitment of the research study. The city ward served by the hosting hospital is in the top fifth quintile of social deprivation (Office for National Statistics, 2015). As a resident in another part of the city with the use of a car, I considered whether I was assuming that participants would have the same resources available to them to participate in the research. Following this, I made attempts to make study participation as accessible as possible to the population surrounding the hospital. I initially considered recruiting from private antenatal classes conducted across the city but decided to avoid recruitment sites which were cost-prohibitive. I also conducted all visits whilst the participants were already visiting the hospital, or at their own homes to avoid additional transport or childcare associated costs.

Finally, I considered my status as a non-mother. As Kingdon (2005) describes in her reflexive account of conducting maternity research as a non-mother, I too benefitted from the ability to deflect and defer questions about what decisions I had made in the participants' situation. Although participating women did not often overtly ask me what decisions I would make, I was frequently asked if I had children. I had initially anticipated this question as I expected women to challenge my credibility as a non-mother researching the lived experience of mothering. However, when the question arose, it actually felt that women were more reassured to share their own experience of motherhood as I did not have any

experience to contradict their own story. I felt that my position of a non-mother enabled the experiences of participating women to take shape and form the themes of the analysis.

I identified the impact of my positionality from the perspective of an insider, in terms of my gender, and as an outsider, in terms of the community I was recruiting in, and my non-mother status. Considering the multifaceted and interwoven aspects of identity and positionality, my own identity presented both issues and enablers to conducting research and led me to believe that there is no perfect fit for the characteristics of a researcher. I went on to consider the impact of my professional status as part of my positionality in conducting clinical research.

Professional issues: dual clinical role

As a midwife within the NHS Trust hosting the research, I initially considered my dual role of midwife and researcher as vulnerable to establishing a power imbalance between myself and the women approached to participate, which could affect the recruitment process. Maternity care is laden with moral imperatives (Lothian, 2012); despite frequently cited notions of empowerment and autonomy, women's decision-making capacity is often curtailed by recommendations and advice from midwives and other healthcare professionals (O'Cathain et al., 2002). I was conscious that I did not want to use my professional status to imply that participation is recommended or that participation is the right thing to do. As women are already altruistic in their decision making when pregnant, I was concerned that opening conversations with my professional status might be akin to pulling rank, whereby I exerted my professional status as the decision-maker. I was aware the knowing that I worked as a midwife in the hospital hosting the research may reduce women's confidence in declining participation, in case they faced embarrassment if they saw me again in a clinical role. However, knowledge of my profession added information to inform women's choices about participation. As the recruitment process progressed, I began to feel that women were reassured by the research being non-profit for researcher and being conducted within the National Health Service, particularly as it involved product testing.

Being recognised as a midwife did open up issues with information sharing and professional duty. Fortunately, I did not encounter safeguarding issues which I would have had a professional duty to report, but I did frequently encounter situations where women

were seeking information and support from me as a midwife rather than as a researcher. I had planned to navigate these situations with signposting to appropriate professionals, but in reality, I found it challenging to manage women's expectations for information and advice in a way which met their needs for timely and accurate information. In one interview in particular, I was directly asked about the role of formula milk in breastfeeding, and how and when to introduce solids. I hesitated then paused the recording and gave a 'midwife' answer, aiming to provide evidence-based and non-judgemental information. Although I had planned to signpost, in reality, it was not feasible as rapport had been established. I also felt a debt to the participant; she had given me her time and shared her experience with me, and I felt that she was entitled to something from me. I switched roles, then returned to that of the researcher, recommencing the recording and asking my next interview question.

Kingdon (2005) also grapples with the impact of information sharing, especially where it might affect clinical care or the woman's decision making. Rather than avoid or deflect the implications of my information sharing on the data, I chose to examine the impact of my behaviour throughout the research process. Although it was the final data collection episode, and the woman's decisions would not affect the integrity of the data that I had collected, I considered the impact that even subtle, and often overt, encouragement about breastfeeding might have had on the decision making of participants throughout the study. As a researcher, I strived to be impartial and non-judgemental. But as part of my professional role as a midwife, and holding my own internalised beliefs about the value of breastfeeding, I was aware that I was not neutral about breastfeeding. I had felt that in order to support women with breastfeeding, which is fundamental to the role and identity of a midwife, you must be more than neutral about breastfeeding.

During the study, I was conscious that I celebrated women's breastfeeding achievements and sat with their sadness when it had not worked out. I felt framed by women as a breastfeeding 'expert' who could validate their decisions to persevere with breastfeeding or corroborate the difficulties which they had experiences. I tried to reflect the experiences of women back to them, in order to centre their voice as the expert in their experience, whether breastfeeding had been successful or not. Centring the experiences and voices of participants should not be overshadowed by the researcher's own examination of their positionality (Kingdon, 2005), so I tried to avoid integrating my own positionality into the

qualitative data analysis process in order to preserve the voices of participants. Instead, I addressed my own positionality after preliminary data analysis to begin to unpick the effects of my professional role and beliefs on the data collection and analysis.

Reflecting back on the value associated with having a dual clinical research role, it is difficult to imagine gaining access to the hosting organisation and areas, navigating gatekeepers, and establishing trust and rapport with participants without having recognised credentials and clinical affiliation. Having a dual role provided a basis of trust and accountability from which to build on with both gatekeepers and participants, and came with insider knowledge of the maternity care system within the NHS. The dual role proved crucial in developing and maintaining relationships throughout the research development process and the research study itself.

Conclusion on my positionality

My gender, ethnicity, and socio-economic status enabled me to research in the closed setting of NHS maternity services; similarly, my professional status conferred privileges in my role as a researcher. However, these privileges resulted in feelings of discomfort and tension in researching within an environment as an outsider and left me questioning the ethics of researching with a population which I was not a part of, nor representative of. To address these feelings of discomfort, I used introspection and intersubjective reflection to develop a self-evaluation of the impact of my positionality. I have come to conclude that the positionality of the researcher is not problem-free, but attempts to make the positionality of the researcher and the process of reflexivity explicit demonstrates transparency and integrity in the research process.

Reflecting on the research process

Introduction to reflection in research

Reflection is an essential tool for midwives to facilitate self-awareness and inform continuous professional development (Nursing and Midwifery Council, 2019). Similarly, the ability to reflect upon the research process facilitates the researcher's continuing professional development, and makes the process of learning to research more transparent. Although study limitations are often briefly described in research publications, an opaque image of the research process is often depicted, with little room made for reflection and critique of the

journey from research protocol to research output. This section details a reflection of key stages of the research process with the use of Gibbs' (1988) reflective cycle. Given that the study has been described in previous chapters, the reflection focusses on evaluating the strengths, weaknesses, and limitations of the research design, analysis of the research process, conclusion of what has been learnt in the process, and action planning for subsequent research.

Recruitment

The recruitment of participants has an ongoing impact on the integrity of the research data and findings, and as such, was one of the most challenging aspects of the research process. The main strength of the recruitment process was the development of a sample which was representative of the local population in its diversity. Research with a representative sample produces results which are generalizable to the wider population. The sample in Phase II of the study included women aged 16-40 years old, approximately one-third of whom were primiparous, two-thirds of whom identified as BAME, and over one quarter of whom were non-British nationals. The recruitment of a representative population was likely due to several factors, including concentrated efforts recruiting within the communities that these women lived in, and researcher reflexivity addressing the potential for unconscious bias in not approaching women traditionally considered 'hard to reach'.

The recruitment of women for follow-up interviews was very successful, with over forty women taking part. Although qualitative research does not rely on large sample sizes, interviewing a large sample of women enabled more nuanced themes to be detected in subsets of the participants and provided more scope to centre the experiences of the participants alongside the quantitative data. Recruiting for follow-up interviews was likely successful as a relationship and rapport had been developed through the antenatal and postnatal period, which built trust and investment between the participant and the researcher. Conducting the interviews in the participants' home also removed common barriers to research engagement by minimising the burden of participation (Adams et al., 2015) and enabled the mother-infant dyad to remain together at home in the postnatal period.

The main challenge to recruitment was consenting and randomising enough participants to reach the calculated sample size of 184 participants for the quantitative aspect of the main study. The recruitment phase ended with 98 participants having successfully completed this aspect of the study. Several barriers to meeting the recruitment target were identified: biphasic eligibility assessment in the antenatal and postnatal period, limited time and resources for labour-intensive face-to-face recruitment, and maintaining interest following randomisation. Such barriers to recruitment and retention are well documented in the literature, particularly pertaining to interventional trials, as unconcealed randomisation may lead to high rates of attrition with participants not receiving the intervention (Dumville et al., 2006; West et al., 2008). It is difficult to situate the strengths and weaknesses of the recruitment strategy within a field of similar studies, as many do not publish sample size calculations alongside actual recruitment figures (Bigelow et al., 2014; Flacking et al., 2011; Owusu-Ansah et al., 2019).

Considering the recruitment process as a whole, including for the feasibility study, and quantitative and qualitative aspects of the main study, it was effective in producing a diverse and representative sample of participants to appropriately respond to the research questions. For future research recruitment, it is suggested that face-to-face recruitment in community settings is used to recruit a sample which is representative of the local population. Face-to-face recruitment also served to be effective in developing researcher-participant relationships which effectively minimised participant drop-out associated with longitudinal and interventional studies. To improve subsequent recruitment strategies, additional researcher time and resources should be factored into funding and ethics applications which considers the resources required for requesting, writing in, and filing hospital notes and consent forms. Recruitment strategies in similar studies may use a 4:1 screening to completion ratio as calculated following the recruitment process in this study for planning recruitment time and resources to meet the desired sample size.

Methodology and analysis

Use of a mixed methods design enabled the collection of quantitative and qualitative data in order to respond to the research questions. A sequential explanatory type of design produced findings on both the ‘what’ and the ‘why’: what are the effects of this intervention, and why have those effects been found? This multiphase approach was a key strength of the

research methodology, as a staged approach ensured that the design responded to each of the research outcomes. Another strength of this mixed method design was the epistemological and philosophical congruence. Firstly from a pragmatist perspective, mixed methods enable the researcher to address the research questions. Secondly, in keeping with a midwifery philosophy, mixed methods research enabled a holistic and multifaceted examination of an intervention, considering both quantitative and qualitative outcomes as equally weighted and inextricable from each other.

The process of operationalising the research protocol was complicated and required amending during the data collection stage. The questionnaires were developed electronically to reduce time and expenses associated with printing and to streamline the extraction of data. Following negotiations with institutional gatekeepers, the questionnaires were produced in a paper format to widen accessibility to a population with a lower level of information and English literacy. McFadyen and Rankin (2016) suggest that researchers engage with gatekeepers early in the research process, although the process of seeking ethical approval for the study design often runs concurrently with negotiating access with institutional gatekeepers. The adjustment from electronic to paper data collection significantly increased the researcher time spent per participant, as all data were collected in person from the participants' homes then manually extracted and formatted onto electronic spreadsheets. As this additional time was not accounted for in the project planning, it resulted in less time available for recruitment.

Another potential limitation of the quantitative data collection method was the completeness and accuracy of the data. Questionnaires were labelled with dates for completion, and the bundle of six questionnaires was provided to participants on the first postnatal visit. However, women may not have completed the questionnaires on the requested dates, which introduces the prospect of recall bias, and could reduce the internal validity of the findings. Similarly, if temperature data were not recorded by participants immediately, it may have been omitted from the data collection charts. For these reasons, participant-led data collection may be considered a study limitation as there is limited opportunity to corroborate the validity of the data. However, participant-led data collection enabled community trialling of the intervention rather than institution-based trialling with healthcare professional oversight. The setting of the trialling is particularly important when

considering the intended use of the intervention; data collected in a hospital on neonatal thermoregulation lacks transferability to the typical home setting. Using validated data collection instruments and objective measurements would have increased the reliability of the quantitative study design, but was not compatible with the outcomes of interest.

Regarding the collection of qualitative data, a semi-structured interview design targeted data in response to outcomes of interest, including maternal perceptions on the interaction between skin-to-skin contact, breastfeeding, and relational bonding. Flexibility with the order and emphasis of the interview questions also enabled emergent themes to be explored with subsequent participants, developing interviewing and analytic skills through the repeated process of interviewing and transcribing. Although interviewing and transcribing requires considerable time and practice, the process of one researcher conducting all of the interviewing and transcribing enables familiarisation with the data and hones qualitative research skills. As the researcher had engaged with the participants weekly as part of the quantitative data collection, respectful and trusting relationships had been formed prior to the qualitative data collection, which is key in collecting authentic data (Amin et al., 2020). A limitation of the use of semi-structured interviews in this study was the lack of professional interpreting facilities needed to include some women who spoke English as a second or additional language. Subsequent studies should consider the feasibility of costing and providing professional interpreting services to widen the inclusion criteria and ensure the voices and experiences of women are included in the data, irrespective of their spoken language. Used effectively, interpreting services may have further increased the authenticity of the qualitative data collection, by ensuring that all values and views were represented (Amin et al., 2020)

The time required for recruitment and data collection in Phase II of the study left the proposed Phase III of the study, qualitative exploration of the views of midwives, as unfeasible. The evaluation of the intervention is somewhat limited without the inclusion of the views and experiences of midwives working with the participants. However, as the majority of participants were enrolled in the home setting, midwives had little input or experience with the use of the Snuby garment in the hospital or the community. If the garment is to be trialled for primary usage in an inpatient setting, subsequent research should consider seeking the views of midwives and other healthcare professionals who might

support the implementation of the garment, especially as the various perceptions of healthcare professionals in the facilitation of kangaroo mother care has been identified as a potential enabler and a potential barrier to its implementation (Seidman et al., 2015).

Conclusion

The strength of this mixed methods study is in its epistemological, philosophical and methodological congruence: the research design addressed research outcomes central to the midwifery philosophy of care using a pragmatist stance by focussing on the pertinent research questions. As the study included quantitative and qualitative data collection and analysis, the results provide a thorough and holistic evaluation of the Snuby garment. To complement the findings from this study, subsequent research should examine the perspectives of the midwives and other healthcare professionals involved in the usage and implementation of the garment in an inpatient setting. Limited time and resources proved a barrier to both recruitment and data collection. In future research, rigorous scoping and costing of researcher time and resources should be completed early in the study design process to maximise the likelihood of recruiting the pre-calculated sample size. Although a diverse and representative sample of women were recruited from the local population, funding for translating and interpreting services would further increase the accessibility of study participation, particularly for the qualitative aspect of the study.

8. Discussion

Introduction

The purpose of this chapter is to situate the findings of this research study in the context of the literature field and the theoretical framework of salutogenesis. The chapter is subdivided by research finding, integrating the relevant quantitative and qualitative findings in response to the research aims. The original contributions to knowledge are described, and the implications of the findings are detailed. In the following chapter, concluding remarks are made regarding the conduction of the research and the subsequent research findings.

Research finding one: The safety of the Snuby garment

Introduction

The ethical principle of non-maleficence is fundamental to healthcare practice, and as such, medical research must seek to ensure that healthcare interventions are evaluated for their safety (World Medical Association 2013). A primary aim of this research was to assess the safety of a baby-wearing garment which facilitated skin-to-skin contact given its novel nature and a lack of prior research. A multi-method approach was used to assess the safety of the intervention in both the feasibility and the main study. In addition to primary data collection of neonatal temperature, reference is made to the occurrence of adverse incidences. The findings related to the safety of the garment are discussed with reference to the paucity of existing literature on the topic, and implications are considered for the use of the garment in a hospital and community setting.

Temperature

Bailey and Rose (2001) note that the safety, efficacy and ease of use of various methods of temperature measurement have been long disputed, with preferences generally divided between rectal, tympanic, temporal artery, and axillary methods. Although axillary methods may take more time (Bailey and Rose, 2001), the risks associated with rectal methods have long been documented (Frank and Brown, 1978; Greenbaum et al., 1969), and the method lacks acceptability to parents (Thomas et al., 1995). Tympanic membrane thermometers may be difficult to accurately position in small babies (Bailey and Rose 2001), and alongside

temporal artery thermometers, they are generally more expensive. For safety, ease of use, interpretability, and availability, digital electronic axillary thermometers were provided to parents, identical to those used by midwives within the hospital setting. This decision is supported by the research of Charafeddine et al. (2014), who found that axillary thermometry is as reliable as rectal thermometry in clinically stable infants, especially those born at term and by vaginal birth. Through the direct observation in the feasibility study, all participating mothers were able to demonstrate the correct technique of thermometer usage and recording, therefore the method was continued in Phase II of the study.

Regarding the prevalence of abnormal neonatal temperatures, no incidences of hypothermia nor hyperthermia occurred during the feasibility study. When trialled in Phase II without researcher presence, the garment was as efficacious as conventional facilitation in the avoidance of hyperthermia whilst conducting skin-to-skin contact. One dyad each from the intervention and control groups reported an episode of neonatal hyperthermia during skin-to-skin contact. The method of skin-to-skin facilitation did not have a significant effect on the incidence of neonatal hyperthermia (intervention 1.4% vs control 0.8%, p=0.644). Similarly, the method of facilitation did not have a significant effect on the incidence of hypothermia (intervention 8% vs control 1.3%, p=0.082). This finding is the first contribution to the previously unaddressed issue of the safety of skin-to-skin facilitation methods relating to thermoregulation. Considering this finding alongside the results of the study by de Albuquerque et al. (2016) which compared garment-facilitated skin-to-skin contact with radiant warmer care, it appears that garment facilitation methods of skin-to-skin contact promote neonatal thermoregulation, and that containment by the garments does not interfere with the thermoregulatory properties of skin-to-skin contact.

Meta-analysis has demonstrated that skin-to-skin contact results in a slightly higher mean axillary temperature than conventional care in term infants receiving early skin-to-skin contact (Moore et al. 2016), and a reduction in hypothermia in preterm infants receiving kangaroo care (Conde-Agudelo and Díaz-Rossello 2014). This study did not compare rates of hypothermia between babies receiving skin-to-skin contact and cot care, as all participating dyads were able to engage in skin-to-skin contact. However, this study identified that cold weather and giving birth in winter were perceived barriers to engaging in skin-to-skin contact for women in both the intervention and control groups, despite the evidence on the benefits

of skin-to-skin contact for neonatal thermoregulation. This finding contributed to the theme of knowledge and understanding as an underpinning principle of engagement in health-promoting action, such as skin-to-skin contact and breastfeeding.

Similarly, in a systematic review of the enablers and barriers to engagement with Kangaroo Mother Care in a population of low birth weight babies, Seidman et al. (2015) also found that a lack of knowledge and understanding of neonatal health and hypothermia was a significant barrier for mothers undertaking Kangaroo Mother Care. Hill et al. (2010) identified potential measures for behaviour change to promote thermal care of newborns in Ghana, including the sharing of knowledge of skin-to-skin contact. Further research is needed to develop an understanding of common beliefs held by women in the United Kingdom related to thermal care in order to address this barrier with cultural specificity and sensitivity.

Positioning

Appropriate and secure neonatal positioning is necessary to avoid acute events such as falls and slips, and the serious but rare occurrence of sudden unexpected postnatal collapse (SUPC), as well as chronic conditions such as developmental dysplasia of the hips (DDH). Feldman-Winter and Goldsmith (2016) cite several case reports and case series of fatal or near-fatal events in the postnatal period related to sleep, suffocation, and falls when rooming-in or skin-to-skin contact has been conducted. Also termed apparent life-threatening events (ALTE), causality between the practices and the adverse events has not been established, and the tendency to blame evolutionary behaviours such as skin-to-skin contact and maintaining close proximity has been challenged (Wickham, 2016). However, given the gravity of the consequences, it is prudent to follow the components of safe positioning whilst skin-to-skin (Ludington-Hoe and Morgan, 2014).

In the feasibility study, appropriate neonatal positioning was established and maintained with all participating dyads, consistent with the criteria developed by Ludington-Hoe and Morgan (2014). In Phase II of the study, a flowchart for adverse incidences was developed and implemented to identify and act upon findings of insecure neonatal positioning resulting in neonatal drops or falls. Little data exist on the incidence of neonatal falls in the United Kingdom; in the U.S.A, Helsley et al. (2010) estimate the incidence to be

approximately 4/10,000. There were no incidences of neonatal falls in this study, nor reports of any near-misses.

The interview data evidenced that the garment provided security for dyads practising skin-to-skin contact. Similar findings were reported by Thapa et al. (2016) in their evaluation of an ergonomic baby wrap for low birth weight babies; the authors reported that women felt more secure engaging in skin-to-skin contact than when using traditional methods of facilitation. This study identified that primiparous and multiparous women provided differing rationales relating to security and containment, suggesting that the garment is used differently by women dependent upon their parity. Primiparous mothers found the garment to provide support and containment to maintain the baby's frog position (World Health Organisation 2003b), and valued the feeling of security. Multiparous mothers valued the establishment of a safe space to enable other children to interact with the baby and themselves, and the security to use their hands for other household jobs and multitasking. Further research is required to understand the positioning and security requirements for low birth weight babies which may be accommodated by an adapted Snuby design, as a participating dyad with a birth weight of close to 2.5kg identified that the size and structure of the pouch would benefit from adjustment for smaller babies.

Summary of findings on the safety of the Snuby garment

When considering the safety of the garment, several parameters were evaluated to provide a holistic and rigorous safety assessment. The evaluation of all parameters, including neonatal temperature, positioning and security, demonstrates that the garment fulfils the primary requirement to do no harm. Secondly, the security and containment of the garment enabled mother-infant dyads to engage with skin-to-skin contact in a way that they felt to be safe and preferable to conventional facilitation. These findings are the first published safety evaluation of a skin-to-skin baby-wearing garment with reference to the garment's effects on neonatal thermoregulation and positioning.

The results of this study should not be applied to other skin-to-skin facilitating garments. Further research is required to evaluate the safety of other skin-to-skin facilitation strategies in order to develop an evidence base to inform best practice and to minimise the potential for harm.

Research finding two: Barriers, resources, and motivations to engaging in skin-to-skin contact

Practising skin-to-skin contact has the potential to promote physical, emotional and social health in the mother-infant dyad, evident through the plethora of studies examining the health, social and emotional benefits (Moore et al. 2016; Bigelow et al. 2012; Bigelow and Power 2012). Considered within the framework of salutogenesis, skin-to-skin contact may function as a resource to buffer stress and promote health, which applies to the maternity population as a whole. The facilitating garment may be positioned as an enabling resource or a barrier to the practising of skin-to-skin contact.

To test the hypothesis that the facilitating garment would increase the frequency of skin-to-skin contact episodes, a quantitative evaluation was conducted to determine if the provision of a garment affected the frequency of engagement with skin-to-skin contact. To explore how mothers situated both skin-to-skin contact and the facilitating garment within the salutogenic paradigm, interviews were conducted with participating mothers from both the intervention and control groups, with particular reference made to the barriers and enabling resources that they encountered when engaging with skin-to-skin contact.

Frequency of skin-to-skin contact episodes

Although participants with the facilitating garment engaged in slightly more skin-to-skin contact episodes on average, the difference between the study groups was not statistically significant. In their study comparing two methods of skin-to-skin contact facilitation, Thapa et al. (2018) also found that participants using a new ergonomic carrier engaged in slightly more skin-to-skin contact, although the difference was not statistically significant. The similarities between these findings suggest that the provision of a new facilitation method is not enough *on its own* to significantly affect the frequency of engagement in skin-to-skin contact, as barriers may still exist which are not overcome with the use of a new facilitation method.

Barriers to engagement in skin-to-skin contact

In his theory of salutogenesis, Antonovsky (1979) described a continuum of generalised resistance resources and resistance deficits (GRR-RD) by way of theorizing what factors are used to deal with stressors and cultivate health. Interviews were conducted to explore what

factors acted as a barrier to health-promoting behaviours such as skin-to-skin contact, identifying deficits or the absence of resources which contributed to not engaging in skin-to-skin contact. These interviews sought to understand women's perceptions of barriers to engagement in skin-to-skin contact and explain the comparable frequency of engagement in skin-to-skin contact between the intervention and control groups.

In keeping with the experiences of participants Driti and Kam, the notion of modesty and bodily exposure was identified as a perceived barrier for engagement in skin-to-skin contact, which was not comprehensively addressed with the use of a facilitating garment (theme three, subtheme three). The preservation of modesty has been cited as a rationale for the development of facilitating garments such as the Top Maternal (de Alberquerque et al. 2016), although the acceptability and preservation of modesty are not frequently examined as a research outcome. For women of South Asian heritage who lived within an extended family unit, such as Driti and Kam, engagement in skin-to-skin contact with or without a facilitating garment was generally considered to be socially unacceptable as it risked bodily exposure, particularly in the presence of family members other than their partner.

Prior research by Wennerberg et al. (2018) on the practice of caregiving has identified a lack of solitude and feeling restrained or regulated by people within the home environment as a generalized resistance deficit (GRD). This GRD is closely aligned to the identified barrier of preserving modesty and avoiding bodily exposure, as the perception of social regulation within the home environment was found to inhibit women's abilities to engage freely and openly in skin-to-skin contact. This finding is further supported by the accounts of women of South Asian heritage that did not live in an extended family unit, alongside women from other backgrounds, such as Taifa, Sumaya, and Rachel, who generally found the Snuby garment to adequately protect their modesty when the home environment was regulated by themselves and their partner, rather than an elder generation. These women identified the Snuby garment as an enabling resource for practising skin-to-skin contact on this basis.

The concept of 'birth dirt', the bodily fluids associated with birth, is frequently cited as a perceived barrier to skin-to-skin contact (Finigan and Long 2014). When researching the concept of 'birth dirt' with a cohort of largely South Asian women, Finigan and Long (2014) found that stereotypical responses related to cultural background often characterize

professional responses to the instigation of skin-to-skin contact. Considering the risk of depicting inaccurate stereotypes of South Asian women, culturally competent research is needed to explore notions of modesty and bodily exposure with women that perceived this to be a barrier. This research should aim to centre the experiences of these women and co-develop practical and culturally appropriate strategies to overcome this barrier.

Household obligations and responsibilities were also identified as a barrier to engagement in skin-to-skin contact, apparently irrespective of all demographic characteristics. Additionally, almost all multiparous women cited childcare responsibilities as a primary barrier to skin-to-skin contact. In their study comparing skin-to-skin facilitation methods for low birth weight babies, Thapa et al. (2016) also identified household obligations as a barrier to skin-to-skin contact which was not comprehensively overcome through skin-to-skin facilitation methods, even when the skin-to-skin carrier was designed to permit maternal mobility. This finding is in keeping with the experiences of participants Saira and Habbah, who both pertinently described the competing demands of household responsibilities and obligations. This study identified that women's ability to determine and delegate household jobs and responsibilities was closely linked to engagement in skin-to-skin contact. These findings are supported by the results of a systematic review by Seidman et al. (2015) who found that other tasks and obligations were ranked in the top five barriers to engagement in skin-to-skin contact identified across all included publications, irrespective of whether they were conducted in a low, middle, or high-income country.

Enabling resources for engagement in skin-to-skin contact

Many of the factors that enabled dyadic engagement in skin-to-skin contact also presented in their inverse form as barriers to engagement. In addition to the preservation of modesty and facilitation of multi-tasking discussed in the previous section, several enabling resources were identified that supported the dyad to engage in and continue to practise skin-to-skin contact. The identified enabling resources comprised of physical resources, such as the facilitating garment, emotional resources, and social resources. The role of these resources is explored with reference to the underpinning theoretical framework and surrounding evidence base.

Social support was a key factor in women's decisions to engage with and continue to practice skin-to-skin contact, particularly evident in Taifa and Aneesa's experiences of

parenting. In their systematic review, Seidman et al. (2015) identified support from family and friends as a key enabler for engagement in skin-to-skin contact, although there is a paucity of research which explores the mechanism of social support as an enabler for continued engagement in skin-to-skin contact. Using regression analysis, Calais et al. (2010) identified support for skin-to-skin contact in the hospital and support in the transition to motherhood as promoting factors for skin-to-skin engagement in their study of Swedish and Norwegian mothers.

In this study, the resource of social support was observed outside of the hospital environment and was closely linked to the theme of knowledge and understanding. Women found their actions to be validated by their partner, whose own experience of observing and conducting skin-to-skin contact had developed an understanding of the value and the effects of skin-to-skin contact. This finding is evident in Taifa's description of her partner engaging in skin to skin contact with their baby after seeing Taifa do the same. Mirroring or encouraging health promoting behaviours predominantly related to a reduction or cessation in the baby's crying. The initiation of skin-to-skin contact was attributed by women to a theoretical understanding originating from healthcare professionals or research. However, the continuation of skin-to-skin contact was attributed to tacit knowledge developed through the experience of parenting and coping with distress, which was shared between the parents.

When examining this finding within the framework of salutogenesis, the theme of knowledge and understanding as a resource for health promotion marries with Antonovsky's (1987) concept of comprehensibility as a tenet of the sense of coherence. Antonovsky (1987) describes the concept of comprehensibility as the ability to make sense of life events and reasonably predict what might happen in the future. Through engagement in skin-to-skin contact, women and their partners were able to make sense of their baby's needs and responses, and predict what resources may be likely to work in a stressful situation in the future. Antonovsky's (1979) concept of unavoidable stress is applicable on both a micro and macro scale, evident in acute episodes of distress exhibited by the baby or mother, and also the chronic stress of new parenthood. Irrespective of the scale of the stressor, women utilized skin-to-skin contact as a resource for coping, as it was found to mitigate dyadic distress.

The Snuby garment was also identified as an enabling resource for engaging in skin-to-skin contact. As well as its uses in securing neonatal position and avoiding maternal bodily exposure, participants such as Gina and Amy found the garment to prompt and validate quiet time with their baby. Hays (1996) describes the mothering ideal, which includes the concepts that child-rearing requires extensive time and energy, and also that mothers experience social pressure to be productive in a capitalist culture. A key finding of this research study is that the provision of a skin-to-skin facilitating garment was interpreted by women to challenge this mothering ideal, as it required the mother to engage in quiet time which was not quantified by notions of productivity. Amy's description of regret about not using the Snuby garment as much as she wanted as she tried to create a productive routine is particularly pertinent in light of the research by Henderson et al. (2016), who found that the pervasive ideologies of motherhood can breed feelings of guilt and lower self-efficacy in mothers, whether or not they consciously subscribe to the dominant ideology.

Motivations for skin-to-skin contact

Interviews sought to provide an understanding of women's decisions to engage in health-promoting behaviours such as skin-to-skin contact, the findings of which were synthesised into three subthemes as described in Chapter Six, theme two. These subthemes are 'beliefs, attitudes, and conceptualisations', 'reciprocity, attachment and bonding', and 'social acceptability and expectation'. The first two of these subthemes feature most predominantly in women's motivations for engaging in skin-to-skin contact and reflect Antonovsky's (1979) concept of meaningfulness, which he acknowledges to be the most important element of the sense of coherence. Antonovsky's (1979) concept of meaningfulness consists of the idea that the challenges and stressors of life, such as the transition to new parenthood, are buffered by the individual's ability to make sense of and provide meaning to life challenges.

The primary rationale which motivated women to engage with skin-to-skin contact was the desire to form secure bonds and a reciprocal pattern of communication between themselves and their baby. Women made sense of the challenge of parenthood by seeking out this reciprocal pattern of communication which validated their identity as a mother who is responsive and understanding of her baby's needs. This finding is corroborated by the work of Dalbye et al. (2011), who identified that skin-to-skin contact was perceived by mothers to

be a mutual interaction between them and their babies from which mothers interpreted their baby's demeanour and behaviour as signifying satisfaction. This mutual interaction described by Dalbye et al. (2011) is evident in Amira's description of chatting to her baby, and interpreting her baby's needs whilst they used the Snuby garment,

Women's motivations for engaging in skin-to-skin contact were embedded in their conceptualisation of skin-to-skin contact. In their research with women who engaged in skin-to-skin contact, Dalbye et al. (2011, 109) describe women's conceptualisations of skin-to-skin contact as an "obvious, logical continuation" of the closeness between a mother and baby during pregnancy. In this study, women such as Clare, who conceptualised skin-to-skin contact as an intrinsic and fundamental aspect of motherhood to establish the mother-infant relationship tended to be motivated to engage more in skin-to-skin contact. Inversely, women such as Johanna, who conceptualised skin-to-skin contact as an intervention necessary only for premature or unwell babies, were less likely to engage with skin-to-skin contact. This finding suggests that in addition to the findings of Dalbye et al. (2011) that women perceive skin-to-skin contact as logical, they are also motivated by the belief that skin-to-skin contact is the physiological norm for dyadic social development.

It is recognised that women's motivations to engage in skin-to-skin contact may have been affected by participation in the trial. MacNeill et al. (2016) describe the potential effects of participating in a behaviour change study and suggest that participation in the research process may influence the behaviours of the participants, thus biasing the estimation of effects. Following this rationale, study participation including the recruitment process, access to study documentation, and the process of data collection may have motivated women to engage in more skin-to-skin contact than women who were not participating in the study. This potential source of bias was addressed in two ways. Firstly, the comparison between an intervention and control group who had both been exposed to the same research process aimed to isolate the estimation of effects to the intervention, rather than study participation. Additionally, qualitative techniques were used to explain women's motivations to engage in skin-to-skin contact rather than rely on a solely quantitative estimation of whether the women's engagement in skin-to-skin contact was influenced by the intervention. A summary is provided in the following subsection, which provides a succinct interpretation of the mixed

method findings on women's practising of skin-to-skin contact with reference to the Snuby garment.

Summary of findings on the effect of the Snuby garment on the practising of skin-to-skin contact, and the barriers and enabling resources to engagement.

The initial hypothesis proposed that the provision of the Snuby garment would increase the frequency of skin-to-skin contact episodes. This hypothesis is supported by the concept of nudging, whereby interventions shape the environment to cue certain desirable behaviours (Marteau et al., 2011). The results of the quantitative analysis of skin-to-skin contact frequency fail to reject the null hypothesis, therefore there is not adequate evidence to suggest that the garment has a significant effect on the frequency of skin-to-skin contact episodes. By interpreting the results from the skin-to-skin contact frequency charts and the semi-structured interviews together, it is apparent that multiple factors affect women's engagement in skin-to-skin contact.

Thapa et al. (2018) also found that the provision of a new facilitation garment did not affect the engagement in skin-to-skin contact despite the majority of women positively evaluating the garment. In this study, the absence of a significant effect on engagement in skin-to-skin contact is explained by the interviews with a subset of the study population. The primary barriers to engagement in skin-to-skin contact were a lack of privacy and concerns about the preservation of modesty, and competing household obligations, both of which were not comprehensively overcome through the provision of the Snuby garment.

When women had the support of their partners, found their partners to recognise the positive effects of skin-to-skin contact, and had agency over the home environment, women engaged in more skin-to-skin contact with their baby. Women found many benefits to conducting skin-to-skin contact in the garment. These benefits included the garment legitimizing quiet time between the mother and baby, and acting as a prompt to engage in skin-to-skin contact.

Two strategies are proposed to increase dyadic engagement in skin-to-skin contact in the wider population. Firstly, further research should be co-developed with women to identify strategies to overcome perceived household barriers such as competing obligations, childcare, and a lack of privacy infringing on their modesty. Secondly, professional bodies

engaged in the facilitation of skin-to-skin contact, such as healthcare professionals and researchers, should work to shift the societal position on ongoing engagement in skin-to-skin contact from an intervention for sick or vulnerable babies to an integral part of parenting all babies. This conceptual repositioning is reflective of the theory of salutogenesis (Antonovsky, 1979), aiming to promote health across the maternity population rather than focussing on a subset of the maternity population according to risk factors or pathology. This conceptual repositioning would encompass the design and conduction of salutogenically-orientated research on skin-to-skin contact, and the development of health-promotion strategies which apply to the wider population of maternity service users.

Research finding three: The effect of the Snuby garment on breastfeeding outcomes

Introduction

There is a paucity of literature examining the effects of ongoing skin-to-skin contact on breastfeeding rates for healthy term mother-infant dyads, as discussed in the findings of the integrative review (Chapter Two). In order to respond to this paucity, quantitative research was conducted to test the hypothesis that the provision of a garment to facilitate ongoing skin-to-skin contact would increase rates of breastfeeding continuation and exclusivity in healthy, term dyads. To explain the quantitative findings on breastfeeding rates, qualitative interviews were conducted with mother-infant dyads to identify and explain the motivations, resources, and barriers that they encountered when making decisions about their infant feeding practices. These interviews generated unexpected findings relating to the role of skin-to-skin contact for dyads who were struggling to breastfeed, detailed in Chapter Six.

Feasibility of breastfeeding in the Snuby

Prior to the investigation into the effect of the garment on rates of breastfeeding continuation and exclusivity, a feasibility study was conducted to assess the feasibility of breastfeeding whilst using the garment. Direct observation was used to assess any instinctual behaviours of the mother and baby in relation to breastfeeding. Direct observation is an established data collection method in breastfeeding research, used alone or alongside other data collection methods to identify barriers to breastfeeding (Awi and Alikor, 2006) and

assess breastfeeding efficiency (Furman and Minich, 2004). Direct observation is considered to be the least intrusive form of data collection for breastfeeding dyads, which is essential when considering infants' sensitivity to sensory stimuli (Nyqvist et al., 1999). These observations were recorded in field notes and collated following the end of the data collection period.

The feasibility study identified that Snuby-facilitated skin-to-skin contact elicited neonatal feeding cues much like those recorded during conventionally facilitated skin-to-skin contact (Widström et al., 2011). Of eleven participating babies, eight babies demonstrated feeding cues such as mouthing and rooting whilst in the garment, seven of which were breastfed whilst using the Snuby garment. Porter (2004) suggests that exposure to maternal odours during skin-to-skin contact may be responsible for the elicitation of such neonatal behaviours.

When breastfeeding was instigated by the seven dyads, no issues were identified in establishing and maintaining the neonate's position for breastfeeding, or with achieving an adequate breastfeeding latch. This finding is in keeping with the work of Colson et al. (2008), who identified that a semi-recumbent maternal position and a prone neonatal position, like those adopted by dyads in the Snuby garment, optimised the release of primitive neonatal reflexes which enables the establishment and maintenance of a successful breastfeeding latch. Based upon the observation of these behaviours, it was evident that it was feasible for mothers to use the Snuby garment for skin-to-skin contact as it did not restrict or inhibit breastfeeding, thus it is suitable to be trialled on a larger scale to understand the effects of a facilitating garment on infant feeding practices.

To understand the role of the Snuby garment on the facilitation of breastfeeding, women's experiences were explored via semi-structured interviews. Participant responses detailing experiences using the Snuby for breastfeeding varied; women's views were polarised on the effect of the Snuby garment in establishing and maintaining a breastfeeding position, which was not explained by parity or breastfeeding experience. Although many women used the garment to facilitate breastfeeding whilst in skin-to-skin as found in the feasibility study, one mother in the intervention group found that skin-to-skin contact in the Snuby resulted in the over-stimulation of feeding cues, which left her baby unsettled. Similarly, one mother in the control group also perceived that skin-to-skin contact resulted in

the over-stimulation of feeding cues. Both of these mothers decided to stop practising skin-to-skin contact within the first week, and both perceived a transient or chronic breastmilk insufficiency.

In a review of maternal perceptions of insufficient milk supply (PIM), Gatti (2008) identified that insufficient milk supply is one of the most commonly cited reasons for discontinuing breastfeeding. Signs of infant insatiety and dissatisfaction, such as persistent feeding cues, are perceived as evidence of PIM despite a paucity of research defining or measuring these characteristics. Of the two women previously mentioned who experienced PIM and perceived an over-stimulation of feeding cues in skin-to-skin contact, both were primiparous. Gatti (2008) identifies that there is a lack of research evaluating the effect of previous breastfeeding experience and multiparity on PIM, although women with little breastfeeding experience are reported to be at higher risk of PIM. By situating the experiences of these women in the context of the PIM research field, PIM may likely have been correlated with the perception of over-stimulated feeding cues, rather than the over-stimulation of feeding cues being directly attributed to skin-to-skin contact. More research is needed to understand women's perceptions of breastmilk insufficiency, and to establish a rigorous mechanism to measure and report breastmilk insufficiency working to integrate the perceptions and experience of the mother with an evidence-based evaluation of infant behaviour.

Breastfeeding initiation

Immediate or early skin-to-skin contact has been found to reduce the time between the baby being born and the first breastfeed (Mahmood et al., 2011), but there is a paucity of research investigating the effect of skin-to-skin contact on rates of breastfeeding initiation. This paucity may be due to relatively high rates of breastfeeding initiation in the United Kingdom; in the last national survey, breastfeeding initiation rates were over 80% (McAndrew et al., 2012). Given the high rates of breastfeeding initiation, it was not feasible to conduct a study adequately powered to detect a meaningful change in rates of breastfeeding initiation between the two groups. Additionally, as the Snuby garment was provided to the intervention group after the first hour post-birth, initial decisions on infant feeding practices had already been made.

Rates of breastfeeding initiation, defined as one or more attempts to instigate breastfeeding, were calculated for the study sample as a whole and between the two groups to control for breastfeeding initiation as a potential confounder when analysing data on breastfeeding exclusivity and continuity. For the study sample included in the analysis, 88 out of 97 dyads initiated breastfeeding, resulting in a breastfeeding initiation rate of 90.7% for participating dyads. This is over 15% higher than breastfeeding initiation rates in the hosting NHS Trust over the first year of data collection (NHS England, 2017). This difference may be attributable to recruitment as women who plan to breastfeed may be more motivated to engage in health-promoting behaviours such as skin-to-skin contact, and decide to participate in the study. Another contributing factor may have been the inclusion and exclusion criteria, as women who have a full-term vaginal birth are more likely to initiate breastfeeding than unwell or preterm infant-mother dyads (Radtke, 2011).

The rates of breastfeeding initiation between the intervention and control groups were very similar; 90.4% vs 91.1% respectively. Logistic regression demonstrated that the provision of the garment did not affect breastfeeding initiation; $p=0.902$. Similar rates of breastfeeding initiation between the study arms are useful in excluding breastfeeding initiation as a confounding factor when assessing breastfeeding continuation and exclusivity at six weeks postnatal. Exploratory stepwise regression analysis identified that increasing maternal age and belonging to an ethnic minority were correlated with breastfeeding initiation. In their analysis of socio-demographic predictors of breastfeeding initiation across all primary care trusts in the U.K., Oakley et al. (2013) also identified increasing maternal age and a high proportion of the local population from a BAME background to be strongly associated with higher rates of breastfeeding initiation. Qualitative research conducted with a diverse sample of women in areas of high breastfeeding initiation is required to understand the role of these socio-demographics on infant feeding practices and formulate health promotion strategies for the initiation of breastfeeding.

Breastfeeding continuation

Although a wealth of evidence exists on the positive effects of early skin-to-skin contact on breastfeeding duration with healthy, term mother-infant dyads (Moore et al., 2016), research on the effects of ongoing skin-to-skin contact with the same population is not conclusive, as

demonstrated in Chapter Two. In their study examining the effects of ongoing skin-to-skin contact on breastfeeding continuation, Bigelow et al. (2014) found that an intervention group engaging in ongoing skin-to-skin contact had significantly higher rates of breastfeeding exclusivity compared to the control group. However, this study found no significant difference in rates of breastfeeding continuation (any breastfeeding at six weeks postnatal) between the study groups. Several factors may explain the comparable breastfeeding rates between the study groups. Firstly, study participants had a significantly higher rate of breastfeeding continuation overall than the local population (34% vs 25%, p=0.03). This difference may be attributable to a combination of factors: the inclusion criteria, and recruitment of a health-orientated sample as previously described, or an effect of increased awareness and knowledge mobilisation through the study participation information. Another possible explanation for the difference in breastfeeding continuation between study participants and the general population is skin-to-skin contact. Study participants are likely to have engaged in more skin-to-skin contact than the general population, due to an increased awareness and motivation. This theory is supported by the comparable rates of skin-to-skin contact frequency and breastfeeding between the control and intervention groups.

Differences between these research findings and the work of Bigelow et al. (2014) can also be explained by divergent methodologies: Bigelow et al. (2014) compare two groups receiving differing quantities of skin-to-skin contact, >4000 minutes of skin-to-skin contact vs <4000 minutes of skin-to-skin contact in the first month. Contrastingly, this study compares the provision of a facilitating garment with standard care, irrespective of the quantity of skin-to-skin contact each mother-infant dyad has. Comparable rates of breastfeeding continuation are unsurprising as the frequency of skin-to-skin contact episodes between the intervention and control groups was not significantly different, as detailed in Chapter Five.

Subsequent research should address the demographics identified in exploratory stepwise analysis as possible factors in breastfeeding continuation. BAME identity and increasing maternal age were identified as correlates with breastfeeding continuation, which should be addressed in subsequent research to determine the effect size of these predictor variables accurately.

Breastfeeding exclusivity

There is a considerable lack of research on the effect of ongoing skin-to-skin contact on breastfeeding exclusivity of healthy, term mother-infant dyads, as demonstrated in Chapter Two. In their study into a potential dose-response relationship between breastfeeding exclusivity and ongoing skin-to-skin contact, Ruxer et al. (2013a) found no significant difference in rates of exclusive breastfeeding when measured at four and eight weeks postnatal, although this may have been attributable to a small study sample size. Similarly, this research study found no significant difference between rates of breastfeeding exclusivity at six weeks postnatal when comparing groups with and without the provision of the Snuby garment.

As described in the previous section, comparable breastfeeding exclusivity rates between the two groups may be due to comparable rates of skin-to-skin contact between the two groups, or due to an underpowered study sample. The sample size target was calculated based upon research by Conde-Agudelo and Díaz-Rossello (2014) with a sample of low birth weight infant-mother dyads receiving intermittent kangaroo mother care. The rationale for using this research study to calculate an estimated effect size was it having the most comparable methodology and intervention, despite the different study population. However, due to unforeseen issues with study recruitment, as described in Chapter Five, 98 participants were recruited and randomised rather than the anticipated 184 participants. Despite this shortfall, the study power still exceeded 50% in respect of the a priori effect size, as advocated by Bird (Turner et al., 2013). Turner et al. (2013) also found that although underpowered studies are not desirable, they make up the entirety of the evidence in most Cochrane reviews, suggesting that they are extremely common. The sample size in this study exceeded comparable studies (Bigelow et al., 2014; Ruxer et al., 2013a).

An exploration into the barriers that women in both the intervention and control group experienced with breastfeeding revealed common and complex factors which were not comprehensively overcome through the provision of a skin-to-skin facilitating garment. A common barrier to both the continuation of any breastfeeding and the continuation of exclusive breastfeeding was a lack of knowledge and working understanding of lactation and breastfeeding, particularly in relation to the mechanism of breastmilk supply and demand.

Women frequently grappled with contradictory information from relatives, healthcare professionals, and the internet and struggled to make sense of the effects of formula milk supplementation on the longevity and exclusivity of breastfeeding. This finding illustrates the requirement for breastfeeding knowledge mobilisation throughout society, including specialist knowledge for healthcare professionals, and policy implementation to challenge misleading and inaccurate formula milk marketing claims.

Comprehensibility, to understand life's challenges, is recognised as a fundamental aspect of the individual's ability to cope with stress and move towards health (Antonovsky, 1979). The theme of knowledge and understanding mirrors one of Antonovsky's (1979; 1987) examples of a generalised resistance resource – resistance deficits (GRR-GD) continuum: knowledge and intelligence. In this study, women at the higher end of the continuum, such as Sumaya and Saira, had a working understanding of the physiology of breastfeeding, and the knowledge to challenge or dismiss misinformation, which enabled them to cope with the stress of learning to breastfeed and work to achieve their breastfeeding intention. However, women at the lower end of the knowledge and understanding continuum, such as Wahida and Amira, were unable to reconcile seemingly contradictory information on breastfeeding, and frequently made the decision to stop breastfeeding in order to engage in feeding practices that they could make sense of, such as the provision and measurement of formula milk intake, and timed and planned feeding routines.

Manageability, to have the resources to deal with life's challenges, is another core tenet of the theory of the sense of coherence (Antonovsky, 1979; 1987) which enables the individual to manage stress. Problem-solving and help-seeking behaviours have been identified in this study as a theme which underpins women's management of breastfeeding challenges. This theme follows the salutogenic concept of the GRR-GD continuum (Antonovsky, 1987), combining Antonovsky's (1979; 1987) factors of coping strategies and knowledge and understanding. An example of a commonly encountered breastfeeding problem which women worked to resolve was tongue tie. Of the 42 interviewed breastfeeding mothers, ten reported that their baby had a tongue tie requiring intervention. Segal et al. (2007) estimate the prevalence of ankyloglossia to be between 4-10%, although diagnostic criteria remain heterogeneous. Although the sample of interviewed women was not designed to be representative, it is noteworthy that a considerably higher proportion of

interviewed women perceived tongue tie to be a barrier to breastfeeding (24%) than the estimated proportion of infants with tongue tie in the general population (4-10%). This finding is particularly pertinent as nine of the ten babies with a suspected tongue tie underwent a frenulotomy, a procedure that surgically divides the lingual frenulum with an aim to improve breastfeeding capability (NICE, 2005).

By comparing the incidence of maternally-diagnosed tongue tie with the incidence of professionally-diagnosed tongue tie in Segal's (2007) review, it is suggested that the diagnosis and treatment of perceived breastfeeding problems remain subjective. The National Institute for Health and Care Excellence (2005) recognise the controversy associated with tongue tie division, given the limited research on the efficacy of the procedure, the multitude of other factors which affect the dyad's ability to breastfeed, and the inconsistent use of conservative breastfeeding support measures before the procedure. The efficacy of frenulotomy is currently being investigated by the FROSTTIE trial, which will provide a rigorous assessment of frenulotomy as a resource for breastfeeding problems.

When women suspected that tongue tie was negatively affecting breastfeeding, they used self-referral mechanisms to enlist specialist services, most commonly outside of the NHS. Women also sought help from breastfeeding professionals, working to develop their own skills in positioning, attachment, and breastmilk expression to manage perceived tongue tie related issues. Irrespective of whether issues were associated with tongue tie, this study found that women's ability to solve breastfeeding-related problems was underpinned by their access to information and finances, as well as social support which validated the meaning they attributed to establishing or continuing to breastfeed.

The role of material resources such as money was recognised by Antonovsky (1979; 1987) as a factor which affects the individual's ability to cope with stressors, in this case, breastfeeding problems, and engage in health-promoting behaviours. In this study, services which women frequently used to resolve breastfeeding problems, such as peer groups formed in private antenatal classes, private frenulotomy services, and commercial breast pump hire, were accessible exclusively to women with the financial means and information literacy skills needed to identify and access them. This finding explains the inverse correlation observed between socioeconomic deprivation and breastfeeding continuation in the Infant Feeding Survey (McAndrew et al., 2012). This finding also contributes evidence in support of

the growing narrative which challenges the frequently cited adage that breastfeeding is free and accessible to all (Bregal, 2018; Rippeyoung and Noonan, 2012; Seals Allers, 2017).

Explorative stepwise regression analysis was used to identify potential predictor variables for breastfeeding exclusivity to inform subsequent research. Multiparity and raised body mass index were identified as potential variables of interest regarding rates of breastfeeding exclusivity. Multiparity may be associated with prior breastfeeding experience; this is significant, as Bai et al. (2015) found that previous breastfeeding practices are predictive of women's breastfeeding practices with subsequent children. Raised body mass index has been identified as a factor inversely related to the duration of breastfeeding (Li et al., 2003), although the effects of raised body mass index may depend on other demographic factors such as ethnicity and the presence of comorbidities (Wojcicki, 2011). Conversely, this study identified that raised body mass index might be positively associated with exclusive breastfeeding at six weeks postnatal. Further research should work to understand the effects of body mass index and multiparity on women's infant feeding practices in the United Kingdom, as previous research with American and Danish women (Bai et al., 2015; Li et al., 2003) may lack generalisability to a national context.

Summary of findings on the effect of the Snuby garment on breastfeeding

There was no significant difference in rates of any breastfeeding or exclusive breastfeeding between the two study arms. Both quantitative and qualitative methods provided an explanation of these findings. Comparable frequency of skin-to-skin contact episodes between the intervention and control groups provides an explanation of the comparable rates of breastfeeding exclusivity and continuation between the two groups on the basis that the frequency of skin-to-skin contact correlates with breastfeeding continuation. Via analysis of the 44 interview transcripts, barriers to the continuation of partial and exclusive breastfeeding were identified which were not mitigated by the provision of a skin-to-skin contact facilitating garment.

Women's infant feeding experiences were examined through the application of the theory of salutogenesis (Antonovsky, 1979; 1987), as it offers a theoretical interpretation of how people cope with life's stressors and move towards health. The theory of salutogenesis (Antonovsky, 1979; 1987) is well aligned with the research outcome for two reasons. Firstly,

the theory recognises that sources of stress, such as breastfeeding, have the capacity to generate health. Secondly, the theory recognises the role of barriers and resources in health-promoting behaviours, which are well addressed in breastfeeding research (Balogun et al., 2015; Callen and Pinelli, 2005; Whalen and Cramton, 2010).

Generalised resistance resources – resistance deficits (GRR-GDs) (Antonovsky, 1987) were identified which explained the factors associated with the continuation of partial and exclusive breastfeeding. Compared to women who stopped breastfeeding before they intended to, women who continued to breastfeeding either partially or exclusively demonstrated working knowledge and understanding of breastfeeding. This knowledge and understanding was often underpinned by their ability to access information on the internet, from a social peer group, or specialist services.

Unexpectedly, women who continued to breastfeed primarily reported continuing to do so *despite* healthcare professional support, rather than as a result of it. Women frequently found themselves faced with contradictory information on breastfeeding from healthcare professionals; those who were able to make sense of lactation and breastfeeding using their own resources tended to continue. Another identified GRR-GD was problem-solving and help-seeking behaviour. Women who continued to breastfeed demonstrated an ability to resolve their breastfeeding problems which was underpinned by information literacy and material resources. By exploring the barriers and resources associated with infant feeding practices, an explanation for the results of the quantitative arm of the study has been provided. Subsequent research should aim to explore the role of demographics such as economic status and information and language literacy on breastfeeding continuation and exclusivity to corroborate these findings.

Research finding four: The effect of the Snuby garment on relational bonding

Ongoing skin-to-skin contact cultivates maternal feelings of closeness (Dalbye et al., 2011) and more positive dyadic interactions (Bigelow et al., 2014). Anisfeld et al. (1990) found that maintaining close mother-infant proximity through baby-wearing promoted security of attachment between mothers and their babies. However, little research exists on the effects of baby-wearing in skin-to-skin contact on the development of the dyadic bond. To address

this paucity, interviews were conducted with women from both the intervention and control groups to explore their experiences of bonding, and any contribution of skin-to-skin contact with or without the Snuby garment.

Fostering the mother-infant bond

Although there has been much research into the barriers and enablers surrounding the practice of skin-to-skin contact (Alenchery et al., 2018; Blomqvist et al., 2013; Ferrarello and Hatfield, 2014; Seidman et al., 2015), there has been little focus on understanding women's motivations to engage in skin-to-skin contact, beyond measuring their understanding of the benefits. The primary motivation for mothers to engage in skin-to-skin contact and use the Snuby garment was to develop the mother-infant bond. This motivation was particularly evident in the accounts of primiparous women, and women encountering breastfeeding-related difficulties.

The development of the mother-infant bond in the postnatal period challenges a recognised master narrative: that all mothers should have an experience of instant and positive feeling for their baby at first sight (Kerrick and Henry, 2017). In their research with primiparous mothers, Kerrick and Henry (2017) found that although just over half of mothers report 'at first sight' connection with their baby, a third of mothers exclusively reported the way that they built a connection with their baby as a gradual and continual process, coded by the authors as 'it takes time'. The findings generated from inductive thematic analysis by Kerrick and Henry (2017) are mirrored by early survey research by Macfarlane et al. (1978), who reported that around a third of mothers fell in love with their baby for the first time in the postnatal period rather than in pregnancy or at the birth. In this study, Sumaya describes her varying experiences bonding with her children, herself challenging the master narrative of instant bonding in conversations with her friends.

The development of the mother-infant bond was reported by women to be both a motivator and an outcome of ongoing skin-to-skin contact with the Snuby garment. Women reported that skin-to-skin contact increased feelings of closeness and connection with their baby and that they felt more able to deal with emotional stressors on their relationship with their baby. In particular, Gina describes using skin to skin contact to deal with the emotional stressor of having difficulty establishing breastfeeding. This finding extends the work of

Tessier et al. (1998) on the bonding hypothesis which identified that ongoing skin-to-skin contact in the form of Kangaroo Mother Care (KMC) produced a resilience effect in mothers, whereby they felt more competent in stressful situations with their baby than those who did not engage in KMC. The resilience effect reported by Tessier et al. (1998) is demonstrated in this study with a population of healthy mother-infant dyads undergoing typical stresses of motherhood, rather than the specific stresses of prematurity and extended hospital stay associated with the KMC intervention. The extension of the resilience effect into the population of healthy mother-infant dyads suggests that ongoing skin-to-skin contact plays an important role in stress management of the wider population. Considering Antonovsky's river of life metaphor, empirical evidence from women's experiences has been provided to reposition ongoing skin-to-skin contact from a disease-specific treatment to a resource used to buffer life's intrinsic and inevitable stressors such as the transition to motherhood and the establishment of breastfeeding.

An unexpected finding arose from interviews with women about their experiences with skin-to-skin contact and bonding, which has not previously been documented. In addition to buffering the stress associated with the establishment of breastfeeding, women such as Amira, who stopped breastfeeding before they had planned to, used Snuby-facilitated skin-to-skin contact as a tool to reinstate a unique relationship between them and their baby. The use of skin-to-skin contact as a mechanism to protect the unique mother-infant relationship was particularly evident when women reported feelings of guilt, failure, and self-blame related to not being able to breastfeed. The use of skin-to-skin contact as a protective mechanism for the unique mother-infant relationship was identified only in women in the intervention group; women who had not had the Snuby garment did not report using skin-to-skin contact to preserve the unique relationship.

Crossley (2009) describes breastfeeding as a normalized moral imperative, whereby women are under strong cultural pressure to breastfeed and experience negative psychological and emotional effects when they 'fail' to do so. This narrative is evident in women's description of their feelings of guilt and self-blame after they stopped breastfeeding (Labbok, 2008). Despite a plethora of research on the predictors of breastfeeding cessation (Agboado et al., 2010; Ertem et al., 2001; Semenic et al., 2008), and some research on women's experiences of breastfeeding cessation (Bailey et al., 2004; Mozingo et al., 2000),

little research has been conducted which practically addresses feelings of guilt and failure that accompanies breastfeeding cessation. Brown (2018) calls for practitioners to recognise, rather than belittle, women's breastfeeding goals, whether or not they were achieved. This study presents skin-to-skin baby-wearing as an additional strategy to counter negative feelings associated with earlier than planned breastfeeding cessation.

Promotion of skin-to-skin baby-wearing as a strategy to address negative feelings and loss of maternal identity associated with breastfeeding cessation is of particular relevance in a national context, as eight out of ten women in the United Kingdom report that they stopped breastfeeding before they wanted to (McAndrew et al., 2012). Although not all of these women may have experienced such negative feelings associated with the cessation of breastfeeding, the work by Kerrick and Henry (2017) suggests that women may be hesitant in voicing experiences which deviate from the master narrative. In respect of the early cessation of breastfeeding, this study identified a recurring narrative that the transition to formula feeding usually worked out for the best. Further research is needed to identify if this theme is a master narrative associated with breastfeeding cessation in order to understand how women describe their experiences of breastfeeding cessation.

Invoking reciprocal communication

In both Phases I and II, Snuby-facilitated skin-to-skin contact invoked reciprocal dyadic communication. In Phase I, direct researcher observation recorded an increase in infant-directed speech following the commencement of skin-to-skin contact with all eleven participating mothers. An increase in infant-directed speech has also been reported in studies of infants receiving skin-to-skin contact after a caesarean birth (Velandia et al., 2010). In this study, Amira described how she would take time to tell stories to her baby when practising skin to skin contact. Infant-directed speech, historically termed motherese, is linguistically simplified and characterized by a high pitch and exaggerated intonation (Fernald, 1985). Studies into infant-directed speech have found that infants show a strong preference for it over adult-directed speech (Cooper and Aslin, 1990; Fernald, 1985). Infant-directed speech also offers several benefits; it communicates affect and facilitates social interaction (Werker and McLeod, 1989), supports physiological regulation for premature infants (Filippa et al., 2013), and facilitates language acquisition (Golinkoff et al., 2015).

The benefits of an increase in infant-directed speech are particularly pertinent to infants growing up in areas of high socio-economic deprivation. Socio-economic deprivation is highly correlated with a reduction in the amount that parents talk to their infants, which is in turn correlated with the size of the child's vocabulary (Golinkoff et al., 2015). In the feasibility study, nine of the eleven participating dyads had an Index of Multiple Deprivation score in the 5th centile of most deprived areas in the United Kingdom. Given the marked increase in mother-infant vocalisations in this study sample, the facilitation of skin-to-skin contact provides an accessible intervention which supports infants' social and linguistic development and addresses health and social inequities associated with socio-economic deprivation. Further research should follow up on the effects of ongoing skin-to-skin contact on infant language development and vocabulary to corroborate the findings of the feasibility study.

In Phase II, participants such as Keisha and Amira found skin-to-skin contact to elicit reciprocal communication, in which they used Snuby-facilitated skin-to-skin contact both to interpret and to respond to their baby's behaviour. Reciprocity is a relatively recent focus of maternity and neonatal care standards which encourages two-way mother-infant communication to enable responsive feeding and parenting (UNICEF UK, 2017). The tenets of a reciprocal approach are that mothers can recognise and respond to their baby's hunger and satiety cues, and their baby's need for love and comfort via breastfeeding, closeness, touch, and responsiveness. Similarly, mothers can recognise and respond to their own needs, such as their desire for closeness with their baby, or their need to breastfeed for their own comfort or convenience.

The focus on reciprocity deviates from previous infant feeding and parenting advice which advocated a scheduled, routine-based approach (Millard, 1990) as seen in Amy's description of her parenting practices, then a baby-led, demand feeding approach (Rapley and Murkett, 2012). In their systematic review, Fallon et al. (2016) identified no studies which compared the two approaches and recommended that robust research was undertaken which includes many patterns of breastfeeding and not limited to baby-led and scheduled approaches. However, the current focus on reciprocal feeding and parenting is underpinned by research on the effects of responsive feeding and parenting on brain development

(Walker, 2010) and developmental outcomes, which is even more marked in more socially and economically deprived populations (Engle et al., 2011).

Women used the Snuby garment as a facilitator for verbal and tactile communication in recognition of and response to their baby's needs. The Snuby garment was used by women to reduce the stress associated with parenting which enabled women to learn to interpret their baby's cues for closeness, food, and love and communicate with their baby through skin-to-skin touching and vocalisations. In keeping with the increase in infant-directed speech reported in the feasibility study, story-telling and talking to the baby whilst in skin-to-skin contact were used by women with the Snuby garment to promote recognition as being the baby's mother, and as a response to baby's needs for comfort. A baby's recognition of and preference for its own mother's voice is well documented (DeCasper and Fifer, 1980; Mills and Melhuish, 1974; Standley and Madsen, 1990), which appears to be understood by women on an instinctual basis when engaging with skin-to-skin contact.

Development of dyadic relationships and attachment

The majority of women that engaged with the Snuby continued to do so to promote relational bonding. Whether women engaged with skin-to-skin contact for days or weeks, almost all women perceived it to be beneficial to the development of the mother-infant relationship. However, Niomi, who engaged in frequent and consistent skin-to-skin contact using the Snuby garment and exclusive breastfeeding described ambivalent feelings regarding the development of the dyadic relationship. Niomi contrasted this experience with that of her first child with whom she worked to develop a mutual sense of independence. Niomi was concerned that frequent Snuby usage accompanied by exclusive breastfeeding and co-sleeping could cause an over-reliance on close mother-infant proximity. For this mother, the provision of the Snuby garment appeared to have inadvertently led to the adoption of an attachment parenting style.

The attachment parenting method advocates parental responsiveness to the baby's dependency needs which are interpreted and responded to through the maintenance of close mother-infant proximity (Sears and Sears, 2014). The attachment parenting approach draws upon Bowlby's (1997) theory of attachment behaviour. Bowlby (1997) theorised that the infant's behavioural mechanisms were primarily seeking to establish and maintain close

proximity to the caregiver for survival, security, and protection. When the caregiver is consistently responsive in social engagement with the infant and reciprocates behaviours which maintain proximity, the infant develops a secure attachment to the caregiver, underpinning and predicting attachment-related behaviour over the life course (Bowlby, 1988; Bowlby, 1997). Although Bowlby (1997) described the first six weeks of an infant's life as the pre-attachment phase where the infant seeks social interaction with anyone in their proximity, tenets of this theory arose in the exploration of the mother-infant relationship over the first six weeks, and as such, are used to theoretically situate the experiences of this mother.

Feelings of mutual over-reliance on the maintenance of close proximity were explored by Niomi; the desire to maintain such closeness with her baby was a novel experience which she compared and contrasted to the relationship she had with her partner. Although this mother had "mixed feelings" on the developing relationship with her baby, Bowlby's (1997) theory of attachment suggests that her actions are in keeping with evolutionarily adaptive behaviours linked to survival and that close proximity and responsiveness in infancy facilitate secure attachment patterns in childhood. It is suggested that endocrine mechanisms may be responsible for eliciting this behaviour in this mother in contrast to her parenting practises with her first child. Engagement in both skin-to-skin contact and breastfeeding are both stimulants of endogenous oxytocin, the neuropeptide responsible for feelings of protectiveness and social bonding behaviours (Lim and Young, 2006). The stimulation of oxytocin may have perpetuated the maternal desire for continuous close proximity with her baby, resulting in co-sleeping, and the continuation of skin-to-skin contact and breastfeeding, thus further stimulating oxytocin release. Although higher levels of oxytocin in the postnatal period are physiologically expected (Eapen et al., 2014), they may have been in contrast to the mother's previous experience as postnatal depression has been associated with lower levels of oxytocin (Skrundz et al., 2011). Kendall-Tackett (2007) suggests that breastfeeding attenuates the inflammatory effects of stress by reducing cortisol; it is suggested that this mechanism may also apply to skin-to-skin contact.

Although the role of oxytocin is well recognised as playing an important part in early bonding and parent-infant interactions (Eapen et al., 2014), the existence or direction of a relationship between oxytocin-releasing behaviours such as skin-to-skin contact and

parenting behaviours to maintain close proximity is unclear. However, the provision of a Snuby garment has been generally perceived to positively affect the development of the mother-infant relationship. Collectively, these findings indicate that women should be reassured about experiencing evolutionarily expected feelings of protectiveness over their babies and be supported to understand the physiological basis for these feelings.

Summary of findings on the effect of the Snuby garment on relational bonding

The concept of relational bonding is both complex and ill-defined; Eyer (1992) goes as far as to call the concept a scientific fiction, fraught with poorly grounded research. Relational bonding has previously been assessed through the use of various data collection tools (Perrelli et al., 2014) including a scale (Taylor et al., 2005), a questionnaire (Brockington et al., 2006) and interviews (Bicking Kinsey et al., 2014). To understand the effect that the provision of a Snuby garment has on relational bonding, interviews were conducted to explore women's experiences and perceptions of dyadic bonding. This study sought to centre women's experiences of relational bonding with their baby without a theoretical assumption that the process of bonding is either instant or accumulative over time, as Kerrick and Henry (2017) identified both 'at first sight' and 'it takes time' narratives in women's descriptions of bonding with their baby.

Women used the Snuby garment to engage in skin-to-skin contact in various ways: to establish a bond, to develop a bond, and to safeguard the bond. For multiparous women without breastfeeding issues, such as Driti, the process of establishing the bond was perceived to be finite; therefore, these women generally engaged with the Snuby garment for a shorter time. For primiparous women and women encountering breastfeeding difficulties, such as Gina and Amira, the Snuby was used as a tool to develop a bond with their baby and to counteract stressors on the mother-infant relationship such as breastfeeding difficulties. Little comparable research exists to situate these findings within the research field. However, similarities can be drawn between women's use of the Snuby to counteract the stress associated with breastfeeding and the resilience effect identified by Tessier et al. (1998) in dyads using skin-to-skin contact to counteract the stressors of prematurity and neonatal unit admission.

The use of the Snuby garment invoked reciprocal communication between mothers and their babies. The initial finding of an increase in infant-directed speech in the feasibility study is corroborated through interviews conducted in Phase III of study, where the development of reciprocity and dyadic communication was identified as a sub-theme. Snuby facilitation does not appear to interfere with the effects of skin-to-skin contact on mother to infant verbal communication as documented by Velandia et al. (2010). On the contrary, mothers found the Snuby garment enabled the interpretation of their baby's behaviour and was used to understand and respond to the baby's needs for love and comfort.

For almost all women, the development of the mother-infant bond was positively regarded. However, for one mother, the intense feelings of protectiveness and the resulting intensity of the mother-infant relationship was challenging. This finding suggests that women may benefit from an understanding of the underpinning physiology associated with oxytocin, breastfeeding, and skin-to-skin contact in order to interpret their feelings of maternal protectiveness. Further research is required to assess the existence of a directional relationship between skin-to-skin contact facilitating behaviours and other components of attachment parenting, such as exclusive breastfeeding and co-sleeping.

Research finding five: Presenting a new paradigm

A paradigm can be defined as an overarching philosophical or ideological stance which forms the assumptive base for the production of knowledge (Rubin and Rubin, 2005). Paradigms contain the epistemological, ontological, and methodological premises that guide the actions and approach of the researcher (Denzin and Lincoln, 2017). As well as relating to methodological traditions, paradigms serve as philosophical underpinnings for explaining a phenomenon of interest to a discipline (Parse, 2000). This section describes the current neonatal care paradigm in relation to skin-to-skin contact and calls for the adoption of a new paradigm which fundamentally reconceptualises skin-to-skin contact.

Models of health and illness which underpin research are seldom made explicit (Wade and Halligan, 2004). The dominant paradigm of biomedicine underpins much of the research into ongoing skin-to-skin contact, evident in the use of quantifiable health markers as the primary research outcomes and research conducted in populations characterized by pathophysiology (Conde-Agudelo and Díaz-Rossello, 2014). The principles of the biomedical

model of illness include health as the absence of disease, mental phenomena as distinct from bodily function, and the patient as a passive recipient of treatment and care (Wade and Halligan 2004). By drawing upon the concepts and background described in Chapters One and Two, the following tenets aim to describe the current conceptualisation of ongoing skin-to-skin contact in the biomedical model of illness (Table 7.1).

Table 8.1 Conceptualisation of ongoing skin-to-skin contact using the biomedical model of illness: kangaroo mother care

Theoretical perspective:	Disease prevention, i.e. ongoing skin-to-skin contact as a quantified intervention to prevent disease
Practise of ongoing SSC:	Intervention. Prescriptive and standardized, i.e. determined 'dose' in hours or days
Epistemology:	Post-positivist, hypothetical-deductive, in keeping with the Western scientific method
Applicable to:	A subset of the population defined by pathophysiology, i.e. low birth weight and premature infants
Methodology:	Reductionist, quantitative, i.e. randomised controlled trials
Outcomes:	Absence of disease, i.e. morbidity and mortality

The application of the theoretical framework of salutogenesis and the resulting findings of this research study provides scope to reconceptualise the phenomenon of ongoing skin-to-skin contact and shift the paradigm (Kuhn, 1970) into the field of salutogenic health promotion (Table 7.2).

Table 8.2 Re-conceptualisation of ongoing skin-to-skin contact using the salutogenic model of health promotion: continued and responsive skin-to-skin contact

Theoretical perspective:	Health promotion, i.e. ongoing skin-to-skin contact as a salutogenic behaviour to generate health and manage stress
Practise of ongoing SSC:	Behaviour. Self-determined and individualised. Reversing the socio-cultural intervention of mother-infant separation.

Epistemology:	Integration of post-positivist theory testing and constructivist understanding of health and wellbeing. Respects knowledge acquisition outside of academic and scientific hegemony which pre-dates Industrial maternal-infant separation, i.e. matriarchal generational wisdom, maternal intuitive and tacit knowledge.
Applicable to:	All mother-infant dyads, irrespective of disease categorisation. Maintains dyadic integrity, but not exclusive to the mother-infant dyad.
Methodology:	Mixed methods, i.e. responding to numerous and broad-ranging research questions. Rejects the false dichotomisation of health and experience.
Outcomes:	Responsive to mother-infant dyads, generated by mother-infant dyads, i.e. health and wellbeing outcomes relevant to the population

Through the study design, conduct, and application of the theoretical framework, this study has demonstrated the contribution of a new approach to skin-to-skin contact research. This study began with an intervention, a baby-wearing garment to facilitate ongoing skin-to-skin contact. Moore et al. (2016) note the irony in conceptualising ongoing skin-to-skin contact as an intervention, as maternal-infant separation is a relatively new practice, and unique to humans amongst the practices of other mammals. The practice of skin-to-skin contact has been re-examined in light of the study findings. Rather than positioning ongoing skin-to-skin contact as an intervention to be administered, this study conceptualises skin-to-skin contact as a behaviour influenced by resources, understanding, and beliefs. This study has demonstrated the feasibility and acceptability of exploring the phenomenon of skin-to-skin contact with respect for maternal autonomy and self-determinism. Mothers and their babies were able to self-determine their engagement in skin-to-skin contact, avoiding a prescriptive administration of skin-to-skin contact, which positions the participant as a passive recipient in their care.

By using a mixed methodology, this study challenged the traditional single method approach, which was evident in the studies identified in Chapter Two. By integrating quantitative and qualitative findings, this study produced results which were both contextually situated and responsive to a range of health and wellbeing outcomes. Use of

qualitative methods made room for emergent data on the dyadic experience of the postnatal period, ensuring knowledge production was woman-centred. Finally, this study has repositioned the facilitation of skin-to-skin contact back into the profession of midwives: experts in the care of mother-infant dyads, and promoters of health and wellbeing. The following chapter examines the professional and personal positionality of the researcher in further depth.

Conclusion

In conclusion, the Snuby garment presents a safe method of skin-to-skin facilitation. The garment is comparable to conventional facilitation in the maintenance of normothermia in the neonate and maintained the neonate's position with no adverse events. Provision of the Snuby garment does not appear to significantly affect the frequency of skin-to-skin contact episodes or the incidence of exclusive or partial breastfeeding at six weeks postnatal. Although every effort was made to test these hypotheses, definitive testing was not possible, and therefore further research in this field is urgently needed.

Reasons for comparable skin-to-skin contact engagement and breastfeeding rates between the intervention and control group have been explored, and key themes have been identified, including shared concerns regarding privacy, modesty, and competing social and emotional demands. Although the Snuby garment did not have a quantifiable effect on breastfeeding exclusivity or continuation rates, women who encountered breastfeeding difficulties employed the Snuby to re-establish the role of the mother, and as a buffer for the stress that they experienced during and after breastfeeding difficulties.

Women were motivated to use the Snuby garment to establish and develop the mother-infant relational bond and identified relational bonding as an outcome of Snuby usage. The Snuby garment aided dyadic communication and was used by mothers to both respond to and interpret their baby's behaviour. The Snuby garment presents a health-promotion intervention which is used by women as a resource to buffer the stressors associated with the transition to parenthood and establishment of breastfeeding, which is widely applicable to a population of mothers and their babies. The study design, conduct, and application of the theoretical framework frame a new paradigm for research and understanding of ongoing

skin-to-skin contact outside of the KMC care package: one of continued and responsive skin-to-skin contact for all babies and their mothers.

9. Summary

Introduction

This chapter provides a review of the study aims, objectives and methodology, and summarises the study findings. The implications for healthcare policy and practice are outlined, and the original contributions to knowledge made in the thesis are illustrated. Finally, recommendations for further research are summarised, and the thesis is briefly concluded.

Review of the research aims, objectives, and methodology

Study aims and hypotheses

This study has taken a mixed methods salutogenic approach to evaluate the health-promoting capacity of a novel intervention, the Snuby garment. The study produced a holistic examination of the garment from several perspectives, including its role in the facilitation of skin-to-skin contact, preservation of neonatal physiological and positional stability, in infant feeding practices, and the formation of the mother-infant relational bond. More specifically, it was hypothesised that the provision of the garment would increase the uptake of skin-to-skin contact between the mother and her baby in the postnatal period as the garment would address commonly cited barriers to skin-to-skin contact including the preservation of modesty (de Albuquerque et al., 2016), and difficulty maintaining the baby's position (Thapa et al., 2018).

Upon this premise, it was also hypothesised that the provision of the garment would result in increased breastfeeding duration and exclusivity related to the increase in skin-to-skin contact resulting in higher rates of maternal oxytocin, and maintenance of closeness required for frequent, responsive breastfeeding. Given the lack of prior research on the relationship and potential mechanism between baby-wearing in skin-to-skin contact and mother-infant relational bonding, qualitative data collection was used to explore dyadic experiences of relational bonding.

Data collection and analysis

Breastfeeding initiation, exclusivity, and duration were measured following the six week period in which mother-infant skin-to-skin contact can be facilitated by the garment. The six week outcome measurement is in line with local and national data collection, enabling comparisons to be drawn both within the study and in the broader local and national contexts. Participating women recorded their infant feeding practices weekly on questionnaires which were verbally corroborated when the researcher collected the data packs at the six week point to increase the accuracy of the data. This method of data collection resulted in low rates of enrolment to completion attrition and high rates of questionnaire completion.

Neonatal temperature stability was assessed through the recording and analysis of paired neonatal temperatures taken before and after thirty minutes of skin-to-skin contact. This study demonstrated that participant-led data collection is both feasible and reliable in studies with mother-infant dyads in the home setting when the data collection method is carefully piloted. Methods involving parents in the care and monitoring of their baby mirror the principles of family-centred care, which are implemented in neonatal units. Research into family-centred care has found that parents can safely perform tasks such as recording a temperature and that involvement in their baby's care increases parental self-efficacy and decreases parental stress (O'Brien et al., 2013).

Semi-structured interviews were conducted with 44 participating women, which explored their experiences of early motherhood in relation to their practices of skin-to-skin contact and breastfeeding. Participating women were asked about the process of bonding with their baby, and mechanisms of relational bonding were explored in accordance with the mother's experiences. A framework method of analysis was used to enable the systematic and comprehensive comparison of experiences related to the outcomes of interest. The framework method of analysis was also considered to be the most appropriate choice for this study as it enables the data to be charted in accordance with the research questions, in keeping with the pragmatist approach, and permits both top-down and bottom-up thematic formation arising from the theoretical framework or the data itself (Gale et al., 2013). In this study, the framework approach was used to apply Antonovsky's (1979) theory of

salutogenesis, a theory of health promotion, to women's experiences of motherhood. This application was in recognition of the health-promoting capacity of dyadic behaviours in the early postnatal period, including skin-to-skin contact, breastfeeding, and the formation of relational bonds.

Review of the findings

The findings of the study demonstrated that the Snuby garment was safe for healthy, term babies and their mothers. The safety of the garment was demonstrated through the integration of research findings from the feasibility study and main study, including paired temperature data, and recording of adverse incidences. This study found that the Snuby garment is comparable to conventional skin-to-skin contact in its thermoregulatory abilities, and does not inhibit the thermoregulatory properties of skin-to-skin contact.

These results are the first robust evaluation of the thermoregulatory properties of a skin-to-skin contact facilitating garment, despite several other products being commercially marketed and used in acute and home settings. In this way, this study addresses the considerable gap in the research field of skin-to-skin contact facilitation which was identified in Chapter Two by addressing neonatal safety as a primary outcome.

Investigating the effects of the provision of the Snuby garment on breastfeeding outcomes, this study found that the provision of the Snuby garment did not significantly affect rates of breastfeeding initiation, exclusivity, or duration. Qualitative data analysis using Antonovsky's (1979) theory of salutogenesis was used to produce an explanation of engagement in breastfeeding and skin-to-skin contact as health-promoting behaviours. The transition to motherhood and caregiving was conceptualised as a stressor, with the capacity to generate a move towards or away from health.

Through thematic analysis, generalised resistance resources – resistance deficits (GRR-RDs) were identified which explained the barriers and enablers encountered by women in engaging in health-promoting behaviours of breastfeeding and skin-to-skin contact. These GRR-RD continuums included knowledge and understanding, problem-solving and help-seeking, social support and role modelling, and agency and autonomy. Identification of GRR-RDs associated with breastfeeding and skin-to-skin contact enables the development of theoretically situated health-promoting approaches to increase the practising of

breastfeeding and skin-to-skin contact in line with Baby Friendly Initiative goals to remove barriers to enable breastfeeding (UNICEF UK, 2017).

Secondly, motivations for engaging in health-promoting behaviours were thematised to provide an understanding of the meaning that women attributed to health-promoting behaviours of breastfeeding and skin-to-skin contact. Women were motivated by their internal belief system, which included their conceptualisations of breastfeeding and skin-to-skin contact as fundamental and physiological behaviours of motherhood. Women's motivations were also outcome-driven through their theoretical and tacit knowledge of the beneficial effects of breastfeeding and skin-to-skin contact, especially in relation to its effect on the development of the mother-infant bond. Finally, women were motivated by a culture of expectation and acceptability, where engagement in breastfeeding and skin-to-skin contact was normalised by their social circle and family network.

The acceptability and value of the Snuby garment were assessed through a comparison of experiences between women in the intervention and control group. Overall, the Snuby garment was found to be acceptable for usage in the home setting, although for some women, the preservation of modesty remained a barrier to engagement in skin-to-skin contact irrespective of the provision of the garment. Primiparous women with the garment favoured its ability to maintain safe neonatal positioning and security when compared to conventional facilitation, whereas multiparous women valued the additional mobility that the garment facilitated.

Surprisingly, the primary value of the garment related to its role in the facilitation of the mother-infant relationship, rather than as a breastfeeding aid. The Snuby garment prompted and validated quiet time spent as a mother-infant dyad, used proactively and reactively by mothers to promote calmness and rest as a dyad. During this time, mothers tuned in to their baby's cues and learnt the value of touch, communication, and reciprocity. Unexpectedly, the Snuby garment was most valued when breastfeeding was stressful or had ceased. In these situations, the Snuby garment provided a mechanism to reconnect with the baby and safeguarded a unique mother-infant relationship in place of the anticipated unique breastfeeding relationship.

These findings show that the Snuby garment is a safe skin-to-skin contact facilitation strategy for mothers and their healthy, term infants which is largely acceptable to women for use at home. Barriers and resources have been identified which explain the comparable rates of skin-to-skin contact frequency and breastfeeding duration and exclusivity between women with the garment, and those without. The barriers, resources, and motivations to engage in skin-to-skin contact and breastfeeding have implications for healthcare policy and clinical practice.

The findings of this study are to be disseminated in several ways. Firstly, study participants will receive a summary of the research findings alongside researcher contact details, following open access publication of the thesis. Initial plans to also conduct a discussion group with participants have been postponed due to social distancing measures being in place at the time of completion (2020). Material from this study has been published in practitioner journals (Appendices C and I) to inform midwifery practice and research, and the published thesis will also be shared directly with the hosting NHS Trust. The specific implications for healthcare policy and practice are described in the following section.

Implications for healthcare policy and practice

The findings from this study should be used to inform the development of clinical midwifery practice and healthcare policy in several ways. Theoretically, this study has demonstrated the congruence between the underpinning philosophy of salutogenesis (Antonovsky, 1979) and the underpinning philosophy of midwifery care, specifically in relation to breastfeeding and skin-to-skin contact as health-promoting behaviours. As health promotion is a crucial aspect of midwifery practice (Bowden and Manning, 2016), clinicians should consider the use of a salutogenic framework to address, develop, and interpret barriers and resources to health-promoting behaviours.

This study has demonstrated the applicability and relevance of the theory of salutogenesis in supporting breastfeeding and skin-to-skin contact in clinical practice. Its application to the topic of skin-to-skin contact confers that skin-to-skin contact should be promoted by clinicians as integral to the development of health through the formation of responsive, close, and loving relationships, rather than solely in a reactionary manner to pathophysiology, such as in cases of neonatal hypothermia.

This study has identified several barriers to engagement in skin-to-skin contact and breastfeeding, which should be addressed through education, training, and research:

- To combat contradictory and inaccurate information sharing, infant feeding support provided by healthcare professionals should be locally audited to identify and correct individual or institutional sources of misinformation which disempower women to achieve their breastfeeding goals.
- An audit of second and additional episodes of skin-to-skin contact should be conducted to ascertain local rates of ongoing skin-to-skin contact outside of the research study. This data should be used as a baseline to gauge subsequent efforts to improve engagement in ongoing skin-to-skin contact.
- To address women's concerns related to the preservation of modesty and privacy, institutions and individual clinicians should seek the views of individual women in how best to promote their dignity, and work with women to develop strategies which meet their individual requirements for modesty.
- Clinicians should use reflexive practice to consider their positionality, including their views on modesty and bodily exposure in order to avoid unconscious biases negatively affecting their decisions to withhold encouragement of skin-to-skin contact.

Based on the findings of mothers' experiences engaging in ongoing skin-to-skin contact, midwives, health visitors, and other relevant healthcare professionals should consider advocating the practice of ongoing and plentiful skin-to-skin contact through baby-wearing for all healthy babies and their mothers in recognition of the value mothers attributed to skin-to-skin contact. The key action points for healthcare professionals include:

- Discussing ongoing and plentiful skin-to-skin contact in routine antenatal appointments, in addition to existing conversations about the value of immediate skin-to-skin contact. This discussion should seek to normalise the practice of ongoing skin-to-skin contact and share knowledge of the value of skin-to-skin contact before the inevitable stressor of new motherhood is encountered.

- When working with postnatal women encountering breastfeeding-associated difficulties or early cessation, healthcare professionals should share information on the value of ongoing skin-to-skin contact for the preservation of the unique mother-infant relationship.

Regarding the key recommendation for healthcare policy, the Baby Friendly Initiative and the World Health Organisation standards (UNICEF UK, 2017; World Health Organisation, 2015) should:

- Consider making their support of ongoing and plentiful skin-to-skin contact for healthy, term babies and their mothers both more explicit and more specific. The Baby Friendly Initiative and the World Health Organisation, alongside collaborating organisations, should work to define and operationalise the concept of ongoing and plentiful skin-to-skin contact in a similar way to the development and refinement of the concept of kangaroo mother care.

This process would illustrate and advocate for the new paradigm of ongoing and plentiful skin-to-skin contact as fundamental to the formation of close and loving relationships for all babies and their mothers.

Original contribution to knowledge

This thesis makes several original contributions to knowledge, which are summarised as follows:

- On a theoretical basis, this thesis showcases the novel application of a salutogenic framework used to explore the phenomenon of skin-to-skin contact as a health-promoting mechanism in the transition to new motherhood.

Previous research on skin-to-skin contact has either sidestepped theoretical integration by using a positivist biomedical epistemology or has used a theoretical framework which excludes the integration of quantitative data. This study contributes an example of using a

salutogenic theoretical framework to cultivate a holistic understanding of the phenomenon of skin-to-skin contact inclusive of qualitative and quantitative research outcomes.

- This study conceptualises a new paradigm of skin-to-skin contact.

Currently, skin-to-skin contact is positioned as a long-term intervention for premature infants in the form of kangaroo mother care, or a time-specific intervention for the stabilisation and care of infants immediately after birth. This thesis progresses the current conceptualisations of skin-to-skin contact, and identifies a new paradigm of skin-to-skin contact, *continued and responsive skin-to-skin contact*. Progressing Miller's (2018) suggestion of baby-wearing being a natural extension of kangaroo mother care in NICU graduates, this study extends the notion of skin-to-skin contact beyond its role a medical intervention, and repositions skin-to-skin contact as a fundamental part of motherhood, demonstrating its role in the development of dyadic reciprocity, communication, and bonding for healthy babies and their mothers.

Empirical contributions have also been made to the research field of skin-to-skin contact:

- This is the first study which compares the thermoregulatory properties of skin-to-skin contact facilitation methods, demonstrating that garment facilitated skin-to-skin contact is as safe and efficacious as conventional facilitation in promoting neonatal normothermia.
- This study contributes a theoretically framed understanding of the barriers and enablers to engagement in ongoing skin-to-skin contact and the continuation of breastfeeding as components of health-promoting behaviour, where previous research has focussed exclusively on either barriers and enablers to breastfeeding or barriers and enablers to kangaroo mother care.

The findings of this study are novel as they position and interpret both breastfeeding and skin-to-skin contact as health-promoting behaviours. They thus provide evidence to inform holistic, rather than isolated, health promotion measures.

- This study identified unanticipated and novel effects of baby-wearing in skin-to-skin contact for healthy babies and their mothers. It was demonstrated that skin-to-skin contact in the Snuby garment facilitates the development of dyadic reciprocal

communication, facilitating both the identification and interpretation of the infant's needs for closeness and love and providing an environment which responded to the infant's needs.

Additionally, the findings of this study contribute to a new interpretation of the relationship between skin-to-skin contact and breastfeeding. Prior to this research study, skin-to-skin contact is positioned as a breastfeeding aid to facilitate positioning, attachment, or lactation.

- This study identifies a new relationship between skin-to-skin contact and breastfeeding, whereby skin-to-skin contact is used to preserve, repair, and safeguard the mother-infant relationship usually developed through breastfeeding in the face of breastfeeding-associated problems.

Summary of recommendations for further research

The contributions of this study suggest several areas of the skin-to-skin contact research field for exploration and development, which are summarised as follows.

- Subsequent research designed to test interventions to increase breastfeeding and skin-to-skin contact rates should address the identified GRR-RDs which inform the barriers and enablers women encounter when engaging in health-promoting behaviours such as breastfeeding and skin-to-skin contact.

Subsequent research using a collaborative design approach is recommended to respond to the barriers of privacy and modesty in order to develop acceptable strategies to facilitate breastfeeding and skin-to-skin contact in the hospital and home environment.

- Given the results of the explorative stepwise regression analysis, subsequent research should seek to corroborate the effects of socio-demographics such as ethnicity, parity, and maternal age in decisions to continue breastfeeding and skin-to-skin contact.

The study design should be adequately powered and demographically representative to accurately establish the estimated effect sizes of the identified coefficients. This research

should also include a qualitative aspect to provide an understanding of the relationship between socio-demographics and engagement in health-promoting behaviours.

- Further research should also explore whether the positive effects of Snuby provision on the relational development of mother-infant dyads are replicated in dyads at risk of attachment or bonding issues, such as postnatal depression.

- Finally, subsequent research on the Snuby garment should explore the value and acceptability of the garment from the perspectives of those who contribute to the support of women and their babies in the postnatal period.

This should include midwives and other healthcare workers who facilitate and advocate for mother-infant skin-to-skin contact, and partners and families who inform women's decisions about skin-to-skin contact and breastfeeding. As research on kangaroo mother care has identified the views of healthcare workers and partners and family as potential barriers and enablers to engagement in skin-to-skin contact (Cattaneo et al., 2018), the views of these groups should be sought in relation to baby-wearing in skin-to-skin contact for healthy babies and their mothers to broaden the evaluation of the Snuby garment.

Conclusion

This chapter has reviewed the research aims and hypotheses and provided an overview of how the study has responded to the research aims and objectives. The findings of the study have been reviewed, and the implications for practice and policy have been detailed. The theoretical and empirical contributions to the research field have been summarised, and recommendations have been made to further progress the findings from this research and inform the development of the research field.

Reference List

Adams, M., Caffrey, L. and McKevitt, C. (2015) Barriers and opportunities for enhancing patient recruitment and retention in clinical research: findings from an interview study in an NHS academic health science centre. *Health Research Policy and Systems,* 13(1), p. 8.

Agboado, G., Michel, E., Jackson, E. and Verma, A. (2010) Factors associated with breastfeeding cessation in nursing mothers in a peer support programme in Eastern Lancashire. *BMC Pediatrics,* 10(1), p. 3.

Al-Sahab, B., Lanes, A., Feldman, M. and Tamim, H. (2010) Prevalence and predictors of 6-month exclusive breastfeeding among Canadian women: a national survey. *BMC Pediatrics,* 10(1), p. 20.

Alberts, J. R. (1994) Learning as adaptation of the infant. *Acta Paediatrica,* 83(s397), pp. 77-85.

Alenchery, A. J., Thoppil, J., Britto, C. D., de Onis, J. V., Fernandez, L. and Suman Rao, P. N. (2018) Barriers and enablers to skin-to-skin contact at birth in healthy neonates - a qualitative study. *BMC Pediatrics,* 18(1), p. 48.

Amaliya, S., Rustina, Y. and Agustini, N. (2017) Comparison of Various Kangaroo Mother Care Carriers on Maternal Comfort: A Pilot Study. *Comprehensive Child And Adolescent Nursing,* 40(sup1), pp. 52-61.

Amin, M. E. K., Nørgaard, L. S., Cavako, A. M., Witrey, M. J., Hillman, L., Cernasev, A., and Desselle, S. P. (2020) Establishing trustworthiness and authenticity in qualitative pharmacy research. *Research in Social and Administrative Pharmacy*. 16 Pp. 1472-1482

Anderson, G.C. (1977) The Mother and Her Newborn: Mutual Caregivers. *Journal of Obstetric, Gynecologic, & Neonatal Nursing,* 6(5), pp. 50-57.

Anisfeld, E., Casper, V., Nozyce, M. and Cunningham, N. (1990) Does Infant Carrying Promote Attachment? An Experimental Study of the Effects of Increased Physical Contact on the Development of Attachment. *Child Development,* 61(5), pp. 1617-1627.

Antonovsky, A. (1976) Conceptual and methodological problems in the study of resistance resources and stressful life events. In: B. Dohrenwend and B. Dohrenwend, eds. *Stressful life events: Their nature and effects.* New York: Wiley.

Antonovsky, A. (1979) *Health, stress and coping.* San Francisco: Jossey-Bass.

Antonovsky, A. (1980) Implications of socio-economic differentials in mortality for the health system. *Popul Bull,*(13), pp. 42-52.

Antonovsky, A. (1987) *Unraveling the mystery of health : how people manage stress and stay well.* 1st ed. San Francisco: Jossey-Bass.

Antonovsky, A. (1993a) Complexity, conflict, chaos, coherence, coercion and civility. *Soc Sci Med,* 37(8), pp. 969-974.

Antonovsky, A. (1993b) The structure and properties of the sense of coherence scale. *Soc Sci Med,* 36(6), pp. 725-733.

Antonovsky, A. (1996) The salutogenic model as a theory to guide health promotion. *Health Promotion International,* 11(1), pp. 11-18.

Arida, J., Bressler, T., Moran, S., D'Arpino, S., Carr, A., & Hagan, T.Arida J, Bressler T, Moran S, D'Arpino S, Carr A, and Hagan T. (2019) Mothering with advanced ovarian cancer. *Cancer Nursing* 42 pp. e54-e60

Asole, S., Spinelli, A., Antinucci, L. E. and Di Lallo, D. (2009) Effect of Hospital Practices on Breastfeeding: A Survey in the Italian Region of Lazio. *Journal of Human Lactation,* 25(3), pp. 333-340.

Awi, D. and Alikor, E. (2006) Barriers to timely initiation of breastfeeding among mothers of healthy full-term babies who deliver at the University of Port Harcourt Teaching Hospital. *Nigerian Journal of Clinical Practice,* 9(1), pp. 57-64.

Bai, D., Fong, D. and Tarrant, M. (2015) Previous Breastfeeding Experience and Duration of Any and Exclusive Breastfeeding among Multiparous Mothers. *Birth,* 42(1), pp. 70-77.

Bailey, R., McIntyre, H. and Harvey, M. (2017) Piloting Kangaroo Mother Care in the Community: dyadic responses to a novel innovation facilitating skin-to-skin contact. *MIDIRS Midwifery Digest* 27(4) pp. 518-522.

Bailey, C., Pain, R. H. and Aarvold, J. E. (2004) A 'give it a go'breast-feeding culture and early cessation among low-income mothers. *Midwifery,* 20(3), pp. 240-250.

Bailey, J. and Rose, P. (2001) Axillary and tympanic membrane temperature recording in the preterm neonate: a comparative study. *Journal of Advanced Nursing,* 34(4), pp. 465-474.

Baker, L. (2006) Ten common pitfalls to avoid when conducting qualitative research. *British Journal of Midwifery,* 14(9), pp. 530-531.

Balogun, O. O., Dagvadorj, A., Anigo, K. M., Ota, E. and Sasaki, S. (2015) Factors influencing breastfeeding exclusivity during the first 6 months of life in developing countries: a quantitative and qualitative systematic review. *Maternal & Child Nutrition,* 11(4), pp. 433-451.

Banerjee, A., Chitnis, U. B., Jadhav, S. L., Bhawalkar, J. S. and Chaudhury, S. (2009) Hypothesis testing, type I and type II errors. *Industrial psychiatry journal,* 18(2), pp. 127-131.

Beauchamp, T. L. and Childress, J. F. (1994) *Principles of biomedical ethics.* New York: Oxford University Press.

Beller, E. M., Gebski, V. and Keech, A. C. (2002) Randomisation in clinical trials. *Medical Journal of Australia,* 177(10), pp. 565-567.

Bergman, N. (2000) 'Kangaroo Mother Care: Restoring the Original Paradigm for Infant Care and Breastfeeding' (VHS). South Africa: N. Bergman.

Bergman, N. J. (2014) The neuroscience of birth - and the case for Zero Separation. *Curationis,* 37, pp. 1-4.

Bhaskar, R. (2008) *A Realist Theory of Science.* 3rd edn. London: Verso.

Bicking Kinsey, C., Baptiste-Roberts, K., Zhu, J. and Kjerulff, K. H. (2014) Birth-related, psychosocial, and emotional correlates of positive maternal–infant bonding in a cohort of first-time mothers. *Midwifery,* 30(5), pp. e188-e194.

Bigelow, A. E. and Power, M. (2012) The effect of mother–infant skin-to-skin contact on infants' response to the Still Face Task from newborn to three months of age. *Infant Behavior and Development,* 35(2), pp. 240-251.

Bigelow, A. E., Power, M., Gillis, D. E., Maclellan-Peters, J., Alex, M. and McDonald, C. (2014) Breastfeeding, skin-to-skin contact, and mother-infant interactions over infants' first three months. *Infant Mental Health Journal,* 35(1), pp. 51-62.

Blaffer-Hrdy, S. (2000) *Mother Nature: Maternal Instincts and how They Shape the Human Species.* New York: Ballantine Books.

Blehar, M. C., Spong, C., Grady, C., Goldkind, S. F., Sahin, L. and Clayton, J. A. (2013) Enrolling Pregnant Women: Issues in Clinical Research. *Women's Health Issues,* 23(1), pp. e39-e45.

Blois, M. (2005) *Babywearing: The Benefits and Beauty of this Ancient Tradition.* Pharmasoft Pub.

Blomqvist, Y., Rubertsson, C. and Nyqvist, K. (2011) Parent-infant skin-to-skin contact; How do parent records compare to nurse records? *Acta paediatrica,* 100, pp. 773-775.

Blomqvist, Y. T., Frölund, L., Rubertsson, C. and Nyqvist, K. H. (2013) Provision of Kangaroo Mother Care: supportive factors and barriers perceived by parents. *Scandinavian Journal of Caring Sciences,* 27(2), pp. 345-353.

Booth, A. (2004) Formulating answerable questions. *Evidence Based Practice: An Information Professional's Handbook. Eds. Andrew Booth and Anne Brice. London: Facet,* 200, pp. 61-70.

Booth, A., Sutton, A. and Papaioannou, D. (2016) *Systematic Approaches to a Successful Literature Review.* London: SAGE Publications.

Borbasi, S., Jackson, D. and Wilkes, L. (2005) Fieldwork in nursing research: positionality, practicalities and predicaments. *Journal of Advanced Nursing,* 51(5), pp. 493-501.

Boulanouar, A. W. (2006) The Notion of Modesty in Muslim Women's Clothing: An Islamic Point of View. *New Zealand Journal of Asian Studies,* 8(2), pp. 134-156.

Bowden, J. and Manning, V. (2016) *Health Promotion in Midwifery: Principles and Practice, Third Edition.* Florida: Taylor & Francis.

Bowlby, J. (1988) *A Secure Base: Clinical Applications of Attachment Theory.* London: Routledge.

Bowlby, J. (1997) *Attachment and Loss: Attachment.* London: Pimlico.

Box, G. E. and Tidwell, P. W. (1962) Transformation of the independent variables. *Technometrics,* 4(4), pp. 531-550.

Bradburn, N. (1977) Respondent burden. *Proceedings of the Survey Research Methods Section of the American Statistical Association,* pp. 35-40.

Bregal, S. (2018) If Breastfeeding Is Supposed to Be Free, Why Is It So Expensive? *Glamour Magazine*.

Brockington, I. F., Fraser, C. and Wilson, D. (2006) The Postpartum Bonding Questionnaire: a validation. *Archives of Women's Mental Health,* 9(5), pp. 233-242.

Buetow, S. (2019) Apophenia, unconscious bias and reflexivity in nursing qualitative research. *International Journal of Nursing Studies,* 89, pp. 8-13.

Bulmer, M. (1979) Concepts in the analysis of qualitative data. *The Sociological Review,* 27(4), pp. 651-677.

Bystrova, K., Widström, A.M., Matthiesen, A.S., Ransjö-Arvidson, A.B., Welles-Nyström, B., Wassberg, C., Vorontsov, I. and Uvnäs-Moberg, K. (2003) Skin-to-skin contact may reduce negative consequences of "the stress of being born": a study on temperature in newborn infants, subjected to different ward routines in St. Petersburg. *Acta Paediatrica,* 92(3) pp. 320-326.

Calais, E., Dalbye, R., Nyqvist, K. and Berg, M. (2010) Skin-to-skin contact of fullterm infants: an explorative study of promoting and hindering factors in two Nordic childbirth settings. *Acta Paediatrica,* 99(7), pp. 1080-1090.

Callen, J. and Pinelli, J. (2005) A Review of the literature examining the benefits and challenges, incidence and duration, and barriers to breastfeeding in preterm infants. *Advances in Neonatal Care,* 5(2), pp. 72-88.

Cartwright, J., Atz, T., Newman, S., Mueller, M. and Demirci, J. R. (2017) Integrative Review of Interventions to Promote Breastfeeding in the Late Preterm Infant. *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 46(3), pp. 347-356.

Critical Appraisal Skills Programme (CASP) (2018) *CASP: About Us.* Available at: https://casp-uk.net/aboutus/ [Accessed 05/02/2020].

Cattaneo, A., Adidja, A., Charpak, N., Leon-Mendoza, S., Moxon, S., Nimbalkar, S., Tamburlini, G., Villegas, J. and Bergh, A.-M. (2018) Report on an international workshop on kangaroo mother care: Lessons learned and a vision for the future. *BMC Pregnancy and Childbirth,* 18, Art. no. 170.

Chan, G. J., Valsangkar, B., Kajeepeta, S., Boundy, E. O. and Wall, S. (2016) What is kangaroo mother care? Systematic review of the literature. *Journal of Global Health,* 6(1), pp. 1-9.

Charafeddine, L., Tamim, H., Hassouna, H., Akel, R. and Nabulsi, M. (2014) Axillary and rectal thermometry in the newborn: do they agree? *BMC Research Notes,* 7, pp. 584-584.

Château, P. and Wiberg, B. (1977). Long-term effect on mother-infant behaviour of extra contact during the first hour post partum. II. A follow-up at three months. *Acta Paediatrica*. 66 Pp. 145-151.

Chiu, S.-H., Anderson, G. C. and Burkhammer, M. D. (2005) Newborn temperature during skin-to-skin breastfeeding in couples having breastfeeding difficulties. *Birth,* 32(2), pp. 115-121.

Christensson K, Siles C, Moreno L, et al. (1992) Temperature, metabolic adaptation and crying in healthy full-term newborns cared for skin-to-skin or in a cot. *Acta Paediatrica,* 81(6-7), pp. 488-493.

Chowdhury, R., Sinha, B., Sankar, M.J., Taneja, S. Bhandari, N., Rollins, N., Bahl, R. and Martines, J. (2015) Breastfeeding and maternal health outcomes: a systematic review and meta-analysis. *Acta Paediatrica,* 104 (467), pp. 96-113.

Ciulla, T. A. (2017) *How to Interpret Clinical Trial Outcomes.* Available at: https://www.reviewofophthalmology.com/article/how-to-interpret-clinical-trial-outcomes [Accessed 04/12/2019].

Cluett, E. R. and Bluff, R. (2006) *Principles and Practice of Research in Midiwfery.* Edinburgh: Churchill Livingstone Elsevier.

Cocanour, C. (2017) Informed Consent: It's More Than a Signature on a Piece of Paper. *The American Journal of Surgery,* 214(6), pp. 993-997.

Colson, S. D., Meek, J. H. and Hawdon, J. M. (2008) Optimal positions for the release of primitive neonatal reflexes stimulating breastfeeding. *Early Human Development,* 84(7), pp. 441-449.

Concato, J. and Hartigan, J. A. (2016) P values: from suggestion to superstition. *Journal of Investigative Medicine,* 64(7), pp. 1166-1171.

Conde-Agudelo, A. and Díaz-Rossello, J. L. (2014) Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *Cochrane Database of Systematic Reviews,*(4).

Cong, X., Ludington-Hoe, S. M., Hussain, N., Cusson, R. M., Walsh, S., Vazquez, V., Briere, C.-E. and Vittner, D. (2015) Parental oxytocin responses during skin-to-skin contact in pre-term infants. *Early Human Development,* 91(7), pp. 401-406.

Cook, R. D. (1977) Detection of Influential Observation in Linear Regression. *Technometrics,* 19(1), pp. 15-18.

Cooke, A., Smith, D. and Booth, A. (2012) Beyond PICO: the SPIDER tool for qualitative evidence synthesis. *Qualitative health research,* 22(10), pp. 1435-1443.

Cooper, H. M. (1998) *Synthesizing Research: A Guide for Literature Reviews.* London: SAGE Publications.

Cooper, R. P. and Aslin, R. N. (1990) Preference for Infant-directed Speech in the First Month after Birth. *Child Development,* 61(5), pp. 1584-1595.

Cowles, K. V. (1988) Issues in qualitative research on sensitive topics. *West J Nurs Res,* 10(2), pp. 163-179.

Craig, A., Gerwin, R., Bainter, J., Evans, S. and James, C. (2019) Exploring parent experience of communication about therapeutic hypothermia in the neonatal intensive care unit. *Advances in Neonatal Care* 18 pp. 136-143

Creswell, J. W. and Creswell, J. D. (2018) *Research Design: Qualitative, Quantitative & Mixed Methods Approaches.* 5th edn. Los Angeles: SAGE

Creswell, J. and Plano Clark, V. (2018) *Designing and Conducting Mixed Methods Research.* 3rd edn. California: SAGE.

Creswell, J. and Poth, C. (2018) *Qualitative inquiry & research design*. California, USA: SAGE.

Crossan, F. (2003) Research philosophy: towards an understanding. *Nurse Researcher,* 11(1), pp. 46-55.

Crossley, M. L. (2009) Breastfeeding as a Moral Imperative: An Autoethnographic Study. *Feminism & Psychology,* 19(1), pp. 71-87.

Dalbye, R., Calais, E. and Berg, M. (2011) Mothers' experiences of skin-to-skin care of healthy full-term newborns – A phenomenology study. *Sexual & Reproductive HealthCare,* 2(3), pp. 107-111.

Davis-Floyd, R. (2001) The Technocratic, Humanistic, and Holistic Models of Birth. *International Journal of Gynecology & Obstetrics,* 75, pp. S5-S23.

Davis-Floyd, R. (2008) Foreword. In: S. Downe, ed. *Normal Childbirth Evidence and Debate*. 2nd edn. Edinburgh: Churchill Livingstone Elsevier, pp. ix-xv.

de Albuquerque, R. S., Mariani Neto, C., Bersusa, A. A. S., Dias, V. M. and da Silva, M. I. M. (2016) Newborns' temperature submitted to radiant heat and to the Top Maternal device at birth. *Revista Latino-Americana de Enfermagem,* 24.

De Lourdes Levy, M., Larcher, V., Kurz, R. and CESP, t. m. o. t. E. W. G. o. t. (2003) Informed consent/assent in children. Statement of the Ethics Working Group of the Confederation of European Specialists in Paediatrics (CESP). *European Journal of Pediatrics,* 162(9), pp. 629-633.

DeCasper, A. and Fifer, W. (1980) Of human bonding: newborns prefer their mothers' voices. *Science,* 208(4448), pp. 1174-1176.

Denyer, D. and Tranfield, D. (2009) Producing a systematic review. In: Buchanan; D. and Bryman, A., Eds., The Sage Handbook of Organizational Research Methods, London: SAGE, pp. 671-689.

Denzin, N. K. and Lincoln, Y. S. (2017) *The SAGE Handbook of Qualitative Research.* 5th edn. California: SAGE Publications.

Dey, I. (1993) Qualitative data analysis: A user friendly guide for social scientists. London: Routledge and Kegan Paul.

Dodgson, J. E. (2019) Reflexivity in Qualitative Research. *Journal of Human Lactation,* 35(2), pp. 220-222.

Donovan, P. (2006) Alternative approaches to research. In: E. R. Cluett and R. Bluff, eds. *Principles and Practice of Research in Midwifery*. 2nd edn. Edinburgh: Churchill Livingstone Elsevier.

Douglas, H. (2007) *Containment and Reciprocity: Integrating Psychoanalytic Theory and Child Development Research for Work with Children.* London: Taylor & Francis.

Downe, S. (2005) Rebirthing midwifery. *RCM Midwives,* 8(8), pp. 346-349.

Downe, S. and McCourt, C. (2008) From being to becoming: reconstructing childbirth knowledges. In: S. Downe, ed. *Normal childbirth evidence and debate*. 2nd edn. Edinburgh: Churchill Livingstone Elsevier, pp. 3-28.

Drife, J. (2002) The start of life: a history of obstetrics. *Postgraduate Medical Journal,* 78(919), pp. 311-315.

Dumville, J. C., Torgerson, D. J. and Hewitt, C. E. (2006) Reporting attrition in randomised controlled trials. *BMJ,* 332(7547), pp. 969-971.

Dunkley, J. and Whelan, T. (2006) *Vicarious traumatisation: Current status and future directions.* British Journal of Guidance & Counselling, 34(1), pp. 107-116

Eapen, V., Dadds, M., Barnett, B., Kohlhoff, J., Khan, F., Radom, N. and Silove, D. M. (2014) Separation anxiety, attachment and inter-personal representations: disentangling the role of oxytocin in the perinatal period. *PLOS ONE,* 9(9), pp. e107745-e107745.

Easterby-Smith, M., Thorpe, R. and Lowe, A. (2002) *Management Research: An Introduction.* 2nd edn. California: SAGE Publications.

Eckenwiler, L., Feinholz, D., Ells, C. and Schonfeld, T. (2008) The Declaration of Helsinki through a Feminist Lens. *International Journal of Feminist Approaches to Bioethics,* 1(1), pp. 161-177.

Eleftheriou-Smith, L. (2018) New Mum Wants 'Intrusive And Inappropriate' Bounty Reps Banned From Postnatal Wards. *HuffPost UK*.

Elmir, R., Schmied, V., Jackson, D. and Wilkes, L. (2011) Interviewing people about potentially sensitive topics. *Nurse Res,* 19(1), pp. 12-16.

Engel, G. L. (1977) The Need for a New Medical Model: A Challenge for Biomedicine. *Science,* 196, p. 129.

Engle, P. L., Fernald, L. C. H., Alderman, H., Behrman, J., O'Gara, C., Yousafzai, A., de Mello, M. C., Hidrobo, M., Ulkuer, N., Ertem, I., et al. (2011) Strategies for reducing inequalities and improving developmental outcomes for young children in low-income and middle-income countries. *The Lancet,* 378(9799), pp. 1339-1353.

Eriksson, M. (2017) The Sense of Coherence in the Salutogenic Model of Health. In: Maurice B. Mittelmark, Shifra. Sagy, Monica. Eriksson, Georg F. Bauer, Jurgen M. Pelikan, Bengt. Lindstrom and Geir Arild. Espnes, eds. *The Handbook of Salutogenesis*. 1 edn. Switzerland: Springer International Publishing, pp. 91-97.

Eriksson, M. and Lindström, B. (2005) Validity of Antonovsky's sense of coherence scale: a systematic review. *Journal of Epidemiology and Community Health,* 59(6), pp. 460-466.

Eriksson, M. and Mittelmark, M. B. (2017) The Sense of Coherence and Its Measurement. In: Maurice B. Mittelmark, Shifra Sagy, Monica Eriksson, Georg F. Bauer, Jürgen M. Pelikan, Bengt Lindström and Geir Arild Espnes, eds. *The Handbook of Salutogenesis*. Cham: Springer International Publishing, pp. 97-106.

Erlandsson, K., Dsilna, A., Fagerberg, I. and Christensson, K. (2007) Skin-to-Skin Care with the Father after Cesarean Birth and Its Effect on Newborn Crying and Prefeeding Behavior. *Birth,* 34(2), pp. 105-114.

Ertem, I. O., Votto, N. and Leventhal, J. M. (2001) The timing and predictors of the early termination of breastfeeding. *Pediatrics,* 107(3), pp. 543-548.

European Parliament and Council of the European Union (2016) *General Data Protection Regulation.* [Regulation]

Evereklian, M. and Posmontier, B. (2017) The Impact of Kangaroo Care on Premature Infant Weight Gain. *Journal of Pediatric Nursing,* 34, pp. e10-e16.

Eyer, D. E. (1992) *Mother-infant Bonding: A Scientific Fiction.* New Haven: Yale University Press.

Fallon, A., Van der Putten, D., Dring, C., Moylett, E. H., Fealy, G. and Devane, D. (2016) Baby-led compared with scheduled (or mixed) breastfeeding for successful breastfeeding. *Cochrane Database of Systematic Reviews,* (9).

Feldman-Winter, L. and Goldsmith, J. P. (2016) Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns. *Pediatrics,* 138(3), pp. e1-e10.

Ferber, S. G. and Makhoul, I. R. (2004) The Effect of Skin-to-Skin Contact (Kangaroo Care) Shortly After Birth on the Neurobehavioral Responses of the Term Newborn: A Randomized, Controlled Trial. *Pediatrics,* 113(4), pp. 858-865.

Fergusson, D., Aaron, S. D., Guyatt, G. and Hébert, P. (2002) Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. *BMJ (Clinical research ed.),* 325(7365), pp. 652-654.

Fernald, A. (1985) Four-month-old infants prefer to listen to motherese. *Infant Behavior and Development,* 8(2), pp. 181-195.

Ferrarello, D. and Hatfield, L. (2014) Barriers to Skin-to-Skin care during the postpartum stay. *The American Journal of Maternal Child Nursing,* 39(1), pp. 56-61.

Fetters, M. D., Curry, L. A. and Creswell, J. W. (2013) Achieving Integration in Mixed Methods Designs—Principles and Practices. *Health Services Research,* 48(6pt2), pp. 2134-2156.

Field, A. (2018) *Discovering Statistics Using IBM Statistics.* 5th edn. Ed: J. Seaman. London: Sage Publications.

Filippa, M., Devouche, E., Arioni, C., Imberty, M. and Gratier, M. (2013) Live maternal speech and singing have beneficial effects on hospitalized preterm infants. *Acta Paediatrica,* 102(10), pp. 1017-1020.

Finigan, V. and Long, T. (2014) Skin-to-skin contact: multicultural perspectives on birth fluids and birth 'dirt'. *International nursing review,* 61(2), pp. 270-277.

Finlay, L. (2002) Negotiating the Swamp: The Opportunity and Challenge of Reflexivity in Research Practice. *Qualitative Research - QUAL RES,* 2, pp. 209-230.

Flacking, R., Ewald, U. and Wallin, L. (2011) Positive Effect of Kangaroo Mother Care on Long-Term Breastfeeding in Very Preterm Infants. *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 40(2), pp. 190-197.

Flory, J. and Emanuel, E. (2004) Interventions to improve research participants' understanding in informed consent for research: A Systematic Review. *Journal of the American Medical Association (JAMA),* 292(13), pp. 1593-1601.

Frank, J. D. and Brown, S. (1978) Thermometers and rectal perforations in the neonate. *Archives of Disease in Childhood,* 53(10), pp. 824-825.

Furman, L. and Minich, N. (2004) Efficiency of Breastfeeding as Compared to Bottle-Feeding in Very Low Birth Weight (VLBW, <1.5 kg) Infants. *Journal of Perinatology,* 24(11), pp. 706-713.

Furniss, D., Blandford, A. and Curzon, P. (2011) Confessions from a grounded theory PhD: experiences and lessons learnt. In: *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*. Vancouver, BC, Canada. 1978960: ACM, pp. 113-122.

Galbally, M., Lewis, A.J., van Ijzendoorn, M. and Permezel, M. (2011) The Role of Oxytocin in Mother-Infant Relations: A Systematic Review of Human Studies. *Harvard Review of Psychiatry,* 19(1), pp. 1-14

Gale, N. K., Heath, G., Cameron, E., Rashid, S. and Redwood, S. (2013) Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology,* 13, pp. 117-117.

Garg, R. (2016) Methodology for research I. *Indian journal of anaesthesia,* 60(9), pp. 640-645.

Garner, V. (2013) It's time to kick Bounty out of maternity wards. *The Guardian*.

Gatti, L. (2008) Maternal perceptions of insufficient milk supply in breastfeeding. *Journal of nursing scholarship : an official publication of Sigma Theta Tau International Honor Society of Nursing,* 40(4), pp. 355-363.

General Medical Council (2017) Confidentiality: good practice in handling patient information. 1-78. Available at: https://www.gmc-uk.org/-/media/documents/confidentiality-good-practice-in-handling-patient-information---english-0417_pdf-70080105.pdf [Accessed 21/09/18].

Gibbs, G. (1988) *Learning by Doing: A guide to teaching and learning methods. .* Oxford: Further Education Unit (FEU) Oxford Polytechnic.

Gibson-Davis, C. M. and Brooks-Gunn, J. (2007) The Association of Couples' Relationship Status and Quality With Breastfeeding Initiation. *Journal of Marriage and Family,* 69(5), pp. 1107-1117.

Gilliss, C. L., Lee, K. A., Gutierrez, Y., Taylor, D., Beyene, Y., Neuhaus, J. and Murrell, N. (2001) Recruitment and Retention of Healthy Minority Women into Community-Based Longitudinal Research. *Journal of Women's Health & Gender-Based Medicine,* 10(1), pp. 77-85.

Glaser, B. G. and Strauss, A. L. (2017) *Discovery of grounded theory: Strategies for qualitative research.* Abingdon, Oxon; Routledge.

Golinkoff, R. M., Can, D. D., Soderstrom, M. and Hirsh-Pasek, K. (2015) (Baby)Talk to Me:The Social Context of Infant-Directed Speech and Its Effects on Early Language Acquisition. *Current Directions in Psychological Science,* 24(5), pp. 339-344.

Grady, K. and Wallston, B. (1988) *Research in Health Care Settings.* Newbury: Sage Publications.

Grant, C. and Osanloo, A. (2015) Understanding, selecting, and integrating a theoretical framework in dissertation research: Developing a 'blueprint' for your "house". *Administrative Issues Journal,* 4, pp. 12-26.

Gray, J. (2019) *Qualitative research methods: Chapter 12*. IN: Gray, J. and Grove, S. (eds). *Burns and Grove's The Practice of Nursing Research*. 9th edn. Missouri, USA: Elsevier.

Green, H. E. (2014) Use of theoretical and conceptual frameworks in qualitative research. *Nurse Res,* 21(6), pp. 34-38.

Green, J. and Thorogood, N. (2018) *Qualitative Methods for Health Research.* 4th edn. Los Angeles: SAGE.

Greenbaum, E. I., Carson, M., Kincannon, W. N. and O'Loughlin, B. J. (1969) Rectal thermometer induced pneumoperitoneum in the newborn. *Report of Two Cases,* 44(4), pp. 539-542.

Greer, J., Lazenbatt, A. and Dunne, L. (2014) 'Fear of childbirth' and ways of coping for pregnant women and their partners during the birthing process: a salutogenic analysis. *Evidence Based Midwifery,* 12(3), pp. 95-100.

Gregson, S. and Blacker, J. (2011) Kangaroo care in pre-term or low birth weight babies in a postnatal ward. *British Journal of Midwifery*, 19(9), pp. 568-577.

Greynet (1999) Fourth International Conference on Grey Literature: New Frontiers in Grey Literature. In: *GL'99*. Washington D.C. Grey Literature Network Service.

Guba, E. (2004) *Authenticity Criteria*. In: Lewis-Beck, M., Bryman, A. and Futing, L. T. (eds) *The Sage Encyclopedia of Social Science Research Methods*. Vol 26. California, USA: Sage Publications.

Gupta, S. K. (2011) Intention-to-treat concept: A review. *Perspectives in clinical research,* 2(3), pp. 109-112.

Hall, R. (2013) Mixed Methods: In search of a paradigm. In: T. Le and Q. Le (eds.) *Conducting Research in a Changing and Challenging World.* New York: Nova Science Publishers.

Harris, A. D., McGregor, J. C., Perencevich, E. N., Furuno, J. P., Zhu, J., Peterson, D. E. and Finkelstein, J. (2006) The Use and Interpretation of Quasi-Experimental Studies in Medical Informatics. *Journal of the American Medical Informatics Association,* 13(1), pp. 16-23.

Harris, L. H. (2000) Rethinking maternal-fetal conflict: gender and equality in perinatal ethics. *Obstetrics & Gynecology,* 96(5, Part 1), pp. 786-791.

Harvey, M. and Land, L. (2017) *Research Methods for Nurses and Midwives: Theory and Practice. .* London: SAGE.

Hay, S. and Marshall, J. E. (2019) Ethical Decision-Making in Midwifery Education and Practice. . In: J. Marshall, ed. *Myles Professional Studies for Midwifery Education and Practice*. 1st edn. Edinburgh: Elsevier.

Hays, S. (1996) *The Cultural Contradictions of Motherhood.* New Haven: Yale University Press.

Heale, R. and Twycross, A. (2015) Validity and Reliability in Quantitative Studies. *Evidence based Nursing,* 18(3), pp. 66-67.

Health Research Authority/ INVOLVE (2016) *Impact of public involvement on ethical aspects of research*. Available at: www.invo.org.uk/posttypepublication/public-involvement-in-researchimpact-on-ethical-aspects-ofresearch [Accessed: 22/05/2020]

Hedgecoe, A. (2016) Reputational Risk, Academic Freedom and Research Ethics Review. *Sociology,* 50(3), pp. 486-501.

Hekman, S. J. (1990) *Gender and Knowledge: elements of a postmodern feminism.* Cambridge: Polity Press.

Helsley, L., McDonald, J. V. and Stewart, V. T. (2010) Addressing In-Hospital Falls of Newborn Infants. *Joint Commission Journal on Quality and Patient Safety,* 36(7), pp. AP1-AP3.

Henderson, A., Harmon, S. and Newman, H. (2016) The Price Mothers Pay, Even When They Are Not Buying It: Mental Health Consequences of Idealized Motherhood. *Sex Roles,* 74(11), pp. 512-526.

Hilbe, J. M. (2011) *Negative Binomial Regression.* Cambridge: Cambridge University Press.

Hill, Z., Tawiah-Agyemang, C., Manu, A., Okyere, E. and Kirkwood, B. R. (2010) Keeping newborns warm: beliefs, practices and potential for behaviour change in rural Ghana. *Tropical Medicine & International Health,* 15(10), pp. 1118-1124.

Hofer, M. A. (2005) The psychobiology of early attachment. *Clinical Neuroscience Research,* 4(5), pp. 291-300.

Horst, J. F. (2017) Effect of Multiple Skin-to-Skin Experiences on Exclusive Breastfeeding Rates. *Effect of Multiple Skin-to-Skin Experiences on Exclusive Breastfeeding Rates*, pp. 1-1.

Hsu, H.-C., Fogel, A. and Messinger, D. S. (2001) Infant non-distress vocalization during mother-infant face-to-face interaction: Factors associated with quantitative and qualitative differences *Infant Behavior and Development,* 24(1), pp. 107-128.

Hunter, B. (2006) The importance of reciprocity in relationships between community-based midwives and mothers. *Midwifery,* 22(4), pp. 308-322.

Hunter, B., Berg, M., Lundgren, I., Ólafsdóttir, Ó. Á. and Kirkham, M. (2008) Relationships: The hidden threads in the tapestry of maternity care. *Midwifery,* 24(2), pp. 132-137.

Institute of Medicine and C.E.L.I.R.I.W.C. Studies (1994) *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies.* Edited by D. Federman, R. Faden and A.C. Mastroianni. Washington D.C.: National Academies Press.

Institute of Medicine, Policy, B. H. S., Committee on Conflict of Interest in Medical Research, E. P., Field, M. J. and Lo, B. (2009) *Conflict of Interest in Medical Research, Education, and Practice.* National Academies Press.

International Confederation of Midwives (2017) *ICM International Definition of the Midwife.* Available at: http://internationalmidwives.org/who-we-are/policy-and-practice/icm-international-definition-of-the-midwife/ [Accessed 31/08/2017].

Jefford, M. and Moore, R. (2008) Improvement of informed consent and the quality of consent documents. *The Lancet Oncology,* 9(5), pp. 485-493.

Joanna Briggs Institute (2017a) Checklist for Qualitative Research. Available at: https://joannabriggs.org/sites/default/files/2019-05/JBI_Critical_Appraisal-Checklist_for_Qualitative_Research2017_0.pdf [Accessed 22/01/2020].

Joanna Briggs Institute (2017b) Checklist for Quasi-Experimental Studies (non-randomized experimental studies). Available at: https://joannabriggs.org/sites/default/files/2019-05/JBI_Quasi-Experimental_Appraisal_Tool2017_0.pdf [Accessed 22/01/2020].

Joanna Briggs Institute (2017c) Critical Appraisal Checklist for Randomized Controlled Trials. Available at: https://joannabriggs.org/sites/default/files/2019-05/JBI_RCTs_Appraisal_tool2017_0.pdf [Accessed 22/01/2020].

Johnston, C., Campbell-Yeo, M., Disher, T., Benoit, B., Fernandes, A., Streiner, D., Inglis, D. and Zee, R. (2017) Skin-to-skin care for procedural pain in neonates. *Cochrane Database of Systematic Reviews,*(2).

Joint Neonatal Guidelines Group (2019) *Neonatal Guidelines 2017-2019*. Available at: https://www.networks.nhs.uk/nhs-networks/staffordshire-shropshire-and-black-country-newborn/neonatal-guidelines.

Jupp, V (ed). (2006) *The SAGE Dictionary of Social Research Methods*. London: Sage Publications.

Kang, H. (2013) The prevention and handling of the missing data. *Korean journal of anesthesiology,* 64(5), pp. 402-406.

Karanicolas, P. J., Farrokhyar, F. and Bhandari, M. (2010) Practical tips for surgical research: blinding: who, what, when, why, how? *Canadian journal of surgery,* 53(5), pp. 345-348.

Kendall, J. M. (2003) Designing a research project: randomised controlled trials and their principles. *Emergency medicine journal : EMJ,* 20(2), pp. 164-168.

Kendall-Tackett, K. (2007) A new paradigm for depression in new mothers: the central role of inflammation and how breastfeeding and anti-inflammatory treatments protect maternal mental health. *International Breastfeeding Journal*. 2 (6) pp. 1-14.

Kerrick, M. R. and Henry, R. L. (2017) "Totally in Love": Evidence of a Master Narrative for How New Mothers Should Feel About Their Babies. *Sex Roles,* 76(1), pp. 1-16.

Kingdon, C. (2005) Reflexivity: Not just a qualitative methodological research tool. *British Journal of Midwifery,* 13.

Kirkham, M (ed). (2010) *The Midwife-Mother Relationship.* Basingstoke: Macmillan Press.

Kolanen, H., Välimäki, T. and Vehviläinen-Julkunen, K. (2016) Breastfeeding Among Somali Mother's Living in Finland Under Salutogenic Approach. *International Journal of Caring Sciences,* 9(2), pp. 384-392.

Kommers, D. R., Joshi, R., van Pul, C., Feijs, L., Bambang Oetomo, S. and Andriessen, P. (2019) Changes in autonomic regulation due to Kangaroo care remain unaffected by using a swaddling device. *Acta Paediatrica,* 108(2), pp. 258-265.

Kuhn, T. S. (1970) *The Structure of Scientific Revolutions.* 2nd edn. Chicago: University of Chicago Press.

Kukla, R. (2005) Conscientious Autonomy: Displacing Decisions in Health Care. *Hastings Center Report,* 35(2), pp. 34-44.

Lancaster, G. A., Dodd, S. and Williamson, P. R. (2004) Design and analysis of pilot studies: recommendations for good practice. *Journal of Evaluation in Clinical Practice,* 10(2), pp. 307-312.

Lau, Y., Tha, P. H., Ho-Lim, S. S. T., Wong, L. Y., Lim, P. I., Citra Nurfarah, B. Z. M. and Shorey, S. (2018) An analysis of the effects of intrapartum factors, neonatal characteristics, and skin-to-skin contact on early breastfeeding initiation. *Maternal & Child Nutrition,* 14(1), p. e12492.

Lavrakas, P. (2008) *Encyclopedia of Survey Research Methods.* California: Sage Publications.

Lawn, J. E., Mwansa-Kambafwile, J., Horta, B. L., Barros, F. C. and Cousens, S. (2010) 'Kangaroo mother care' to prevent neonatal deaths due to preterm birth complications. *International Journal of Epidemiology,* 39 Suppl 1(Suppl 1), pp. i144-i154.

Leap, N. (2000) The less we do, the more we give. . In: M. Kirkum, ed. *The Midwife/Mother Relationship*. Basingstoke: Macmillan Press.

Leap, N. (2009) Woman-centred or women-centred care: does it matter? *British Journal of Midwifery,* 17(1), pp. 12-16.

Lee, H.-J., Macbeth, A. H., Pagani, J. H. and Scott Young, W. (2009) Oxytocin: The great facilitator of life. *Progress in Neurobiology,* 88(2), pp. 127-151.

Li, R., Jewell, S. and Grummer-Strawn, L. (2003) Maternal obesity and breast-feeding practices. *The American Journal of Clinical Nutrition,* 77(4), pp. 931-936.

Lim, M. M. and Young, L. J. (2006) Neuropeptidergic regulation of affiliative behavior and social bonding in animals. *Hormones and Behavior,* 50(4), pp. 506-517.

Lincoln, Y. and Guba, E. (1985) *Naturalist Enquiry.* California, USA: Sage Publications.

Lincoln, Y., Lynham, S. and Guba, E. (2017) paradigmatic controversies, contradictions, and emerging confluences, revisited. In: N. Denzin and Y. Lincoln, eds. *The SAGE Handbook of Qualitative Research*. 5th edn. Los Angeles: SAGE

Lindström, B. and Eriksson, M. (2005) Salutogenesis. *Journal of Epidemiology and Community Health,* 59(6), pp. 440-442.

Lothian, J. A. (2012) Risk, Safety, and Choice in Childbirth. *J Perinat Educ,*(1), pp. 45-47.

Ludington-Hoe, S.M., Lewis, T., Morgan, K., Cong, X., Anderson, L. and Reese, S. (2006) Breast and infant temperatures with twins during shared Kangaroo Care. *Journal of Obstetric, Gynecologic, and Neonatal nursing,* 35(2), pp. 223-231.

Ludington-Hoe, S. M. and Morgan, K. (2014) Infant Assessment and Reduction of Sudden Unexpected Postnatal Collapse Risk During Skin-to-Skin Contact. *Newborn and Infant Nursing Reviews,* 14(1), pp. 28-33.

Macfarlane, J., Smith, D. and Garrow, D. (1978) The relationship between mother and neonate. In: S. Kitzinger and JA. Davis, eds. *The Place of Birth*. New York: Oxford University Press.

Macklin, R. (2010) Enrolling pregnant women in biomedical research. *The Lancet,* 375(9715), pp. 632-633.

MacNeill, V., Foley, M., Quirk, A. and McCambridge, J. (2016) Shedding light on research participation effects in behaviour change trials: a qualitative study examining research participant experiences. *BMC Public Health,* 16, pp. 91-91.

Mahmood, I., Jamal, M. and Khan, N. (2011) Effect of mother-infant early skin-to-skin contact on breastfeeding status: a randomized controlled trial. *J Coll Physicians Surg Pak,* 21(10), pp. 601-605.

Manca, D. P., O'Beirne, M., Lightbody, T., Johnston, D. W., Dymianiw, D.-L., Nastalska, K., Anis, L., Loehr, S., Gilbert, A. and Kaplan, B. J. (2013) The most effective strategy for recruiting a pregnancy cohort: a tale of two cities. *BMC Pregnancy and Childbirth,* 13(75).

Marteau, T.M., Ogilvie, D., Roland, M., Suhrcke, M. and Kelly, M.P. (2011) Judging nudging: can nudging improve population health? *BMJ,* 342, d228.

Maslow, A. H. (1943) A theory of human motivation. *Psychological Review,* 50(4), pp. 370-396.

Maternal and Child Health Integrated Programme (2012) *Kangaroo Mother Care Implementation Guide* Available at: https://www.mchip.net/sites/default/files/MCHIP%20KMC%20Guide_English.pdf [Accessed 19/12/2019].

McAndrew, F., Thompson, J., Fellows, L., Large, A., Speed, M. and Renfrew, M. (2012) *Infant Feeding Survey 2010*. London: NHS Digital.

McAuley, L., Pham, B., Tugwell, P. and Moher, D. (2000) Does the inclusion of grey literature influence estimates of intervention effectiveness reported in meta-analyses? *The Lancet,* 356(9237), pp. 1228-1231.

McFadyen, J. and Rankin, J. (2016) The Role of Gatekeepers in Research: Learning from Reflexivity and Reflection. *GSTF Journal of Nursing and Health Care,* 4(1), pp. 82-88.

McKenna, J. J. (2018) Afterword: Breastfeeding: in search of the right questions. In: Cecelia. Tomori, Aunchalee E.L. Palmquist and E.A. Quinn, eds. *Breastfeeding: New Anthropological Approaches*. 1st edn. Abingdon, Oxon: Routledge, pp. 212-218.

McNeill, J., Lynn, F. and Alderdice, F. (2012) Public health interventions in midwifery: a systematic review of systematic reviews. *BMC Public Health,* 12(1), p. 955.

Miles, M. B. and Huberman, A. M. (1994) *Qualitative Data Analysis: An Expanded Sourcebook.* California: SAGE Publications.

Miles, M. B., Huberman, A. M. and Saldana, J. (2014) *Qualitative Data Analysis: A Methods Sourcebook.* 3rd edn. California: SAGE Publications.

Millard, A. V. (1990) The place of the clock in pediatric advice: Rationales, cultural themes, and impediments to breastfeeding. *Social Science & Medicine,* 31(2), pp. 211-221.

Miller, R. (2018) What is the experience of babywearing a NICU graduate? (Masters' thesis) Oklahoma: University of Oklahoma.

Mills, M. and Melhuish, E. (1974) Recognition of mother's voice in early infancy. *Nature,* 252(5479), pp. 123-124.

Mitchell, J., Boettcher-Sheard, N., Duque, C. and Lashewicz, B. (2018) Who Do We Think We Are? Disrupting Notions of Quality in Qualitative Research. *Qualitative health research,* 28(4), pp. 673-680.

Moher, D., Schulz, K. F., Altman, D. G. and Group*, f. t. C. (2001) The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials. *Annals of Internal Medicine,* 134(8), pp. 657-662.

Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., Shekelle, P. and Stewart, L. A. (2015) Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic reviews,* 4(1), p. 1.

Moinester, M. and Gottfried, R. (2014) Sample size estimation for correlations with pre-specified confidence interval. *The Quantitative Methods for Psychology,* 10, pp. 124-130.

Moore, E. R., Bergman, N., Anderson, G. C. and Medley, N. (2016) Early skin-to-skin contact for mothers and their healthy newborn infants. *Cochrane Database of Systematic Reviews,*(11).

Moore, G. A., Cohn, J. F. and Campbell, S. B. (2001) Infant affective responses to mother's still face at 6 months differentially predict externalizing and internalizing behaviors at 18 months. *Developmental Psychology,* 37(5), pp. 706-714.

Mozingo, J. N., Davis, M. W., Droppleman, P. G. and Merideth, A. (2000) " It Wasn't Working": Women's Experiences with Short-Term Breastfeeding. *MCN: The American Journal of Maternal/Child Nursing,* 25(3), pp. 120-126.

Mumsnet (2013) *Mumsnet Bounty survey: full results.* [Accessed 08/04/2020].

Munblit, D., Crawley, H., Hyde, R. and Boyle, R.J. (2020) Health and nutrition claims for infant formula are poorly substantiated and potentially harmful. *BMJ,* 369, m875.

Myers, R. H. (1990) *Classical and Modern Regression with Applications.* Duxbury/Thompson Learning.

National Institute for Health and Care Excellence (NICE) (2005) *Division of ankyloglossia (tongue-tie) for breastfeeding Interventional procedures guidance [IPG149*]. Available at: https://www.nice.org.uk/Guidance/IPG149 [Accessed 21/01/2020].

National Institute of Health and Care Excellence (NICE) (2012) *Quality appraisal checklist – quantitative intervention studies. Process and methods [PMG4].* Available at: https://www.nice.org.uk/process/pmg4/chapter/appendix-f-quality-appraisal-checklist-quantitative-intervention-studies [Accessed 17/11/2020]

National Institute for Health and Care Excellence (NICE) (2015) Intrapartum Care Quality Standard - Quality statement 7: Skin-to-skin contact. Available at: https://www.nice.org.uk/guidance/qs105/chapter/quality-statement-7-skin-to-skin-contact [Accessed:21/01/2020]

National Institute for Health Research (NIHR) (2016) Good Clinical Practice (GCP) Reference Guide. 3.1, 1-24. Available at: https://www.nihr.ac.uk/our-faculty/documents/GCP%20Reference%20Guide.pdf [Accessed 20/09/2018].

Neu, M. and Robinson, J. (2010) Maternal Holding of Preterm Infants During the Early Weeks After Birth and Dyad Interaction at Six Months. *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 39(4), pp. 401-414.

Newborn Services Clinical Practice Committee (2015) *Kangaroo Care*. Available at: https://www.starship.org.nz/guidelines/kangaroo-care/ [Accessed 19/12/2019].

NHS England (2017) *Initiation of Breastfeeding Annual Outturn by NHS Trust*. Online.

NHS England (2019) *The NHS Long Term Plan.* Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf [Accessed 08/04/2020].

Nieswiadomy, R. M. (2002) *Foundations of Nursing Research.* Prentice Hall.

Nolan, M. L. (2009) Information Giving and Education in Pregnancy: A Review of Qualitative Studies. *The Journal of Perinatal Education,* 18(4), pp. 21-30.

Nowell, L., Norris, J., White, D., and Moules, N. (2017) Thematic Analysis: Striving to Meet the Trustworthiness Criteria. *International Journal of Qualitative Methods.* 16 (1) pp. 1-13.

NuRoo (2016) *Skin-to-skin newborn carrier for hands-free babywearing.* Available at: https://nuroobaby.com/ [Accessed 09/12/2019].

Nursing and Midwifery Council (2015) *The Code: Professional Standards of Practice and Behaviour for Nurses and Midwives*. London: Nursing and Midwifery Council.

Nursing and Midwifery Council (2019) *Revalidation: how to revalidate with the NMC.* Available at: https://www.nmc.org.uk/globalassets/sitedocuments/revalidation/how-to-revalidate-booklet.pdf#page=27 [Accessed 13/02/2020].

Nyqvist, K. H., Sjödén, P.-O. and Ewald, U. (1999) The development of preterm infants' breastfeeding behavior. *Early Human Development,* 55(3), pp. 247-264.

O'Cathain, A., Thomas, K., Walters, S. J., Nicholl, J. and Kirkham, M. (2002) Women's perceptions of informed choice in maternity care. *Midwifery,* 18(2), pp. 136-144.

O'Connor, D., Director, S. and Fellow, J. (2008) Defining the Review Question and Developing Criteria for Including Studies. In: *Cochrane Handbook for Systematic Reviews of Interventions* V5.1.0, Eds: J. Higgins and S. Green. pp. 81-94.

O'Brien, K., Bracht, M., Macdonell, K., McBride, T., Robson, K., O'Leary, L., Christie, K., Galarza, M., Dicky, T. and Levin, A. (2013) A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit. *BMC Pregnancy and Childbirth,* 13(S1), p. S12.

Oakley, L. L., Renfrew, M. J., Kurinczuk, J. J. and Quigley, M. A. (2013) Factors associated with breastfeeding in England: an analysis by primary care trust. *BMJ Open,* 3(6), p. e002765.

Oddy, W. H., Li, J., Landsborough, L., Kendall, G. E., Henderson, S. and Downie, J. (2006) The association of maternal overweight and obesity with breastfeeding duration. *The Journal of Pediatrics,* 149(2), pp. 185-191.

Office for National Statistics (2012) *Ethnicity and National Identity in England and Wales: 2011.* London: Department for Communities and Local Government.

Office for National Statistics (2015) *The English Indices of Deprivation 2015 Statistical Release.* London: Department for Communities and Local Government.

Office for National Statistics (2018) Child Mortality in England and Wales: 2016. London: Department for Communities and Local Government.

Ogundimu, E. O., Altman, D. G. and Collins, G. S. (2016) Adequate sample size for developing prediction models is not simply related to events per variable. *Journal of Clinical Epidemiology,* 76, pp. 175-182.

Osborne, J. and Waters, E. (2002) Four Assumptions of Multiple Regression That Researchers Should Always Test. *Practical Assessment, Research & Evaluation,* 8.

Owusu-Ansah, F., Bigelow, A. and Power, M. (2019) The effect of mother-infant skin-to-skin contact on Ghanaian infants' response to the Still Face Task: Comparison between Ghanaian and Canadian mother-infant dyads. *Infant behavior & development,* 57, p. 101367.

Parse, R. R. (2000) Paradigms: A Reprise. *Nursing Science Quarterly,* 13(4), pp. 275-276.

Peck, S. (2014) Bounty Mutiny victory for Mumsnet: sales reps should be banned from NHS maternity wards. *The Telegraph*.

Peduzzi, P., Concato, J., Kemper, E., Holford, T. R. and Feinstein, A. R. (1996) A simulation study of the number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology,* 49(12), pp. 1373-1379.

Perez-Botella, M., Downe, S., Magistretti, C. M., Lindstrom, B. and Berg, M. (2015) The use of salutogenesis theory in empirical studies of maternity care for healthy mothers and babies. *Sex Reprod Healthc,* 6(1), pp. 33-39.

Perrelli, J. G. A., Zambaldi, C. F., Cantilino, A. and Sougey, E. B. (2014) Mother-child bonding assessment tools. *Revista Paulista de Pediatria (English Edition),* 32(3), pp. 257-265.

Phillips, P. D. C., Phillips, D. C. and Burbules, N. C. (2000) *Postpositivism and Educational Research.* Maryland: Rowman & Littlefield Publishers.

Pisacane, A., Continisio, P., Filosa, C., Tagliamonte, V. and Continisio, G. I. (2012) Use of baby carriers to increase breastfeeding duration among term infants: the effects of an educational intervention in Italy. *Acta Paediatrica,* 101(10), pp. e434-e438.

Polit, D. F. and Beck, C. T. (2014) *Essentials of Nursing Research: Appraising Evidence for Nursing Practice.* 8th edn. Philadelphia: Wolters Kluwer Health /Lippincott Williams & Wilkins.

Porter, R. (2004) The biological significance of skin-to-skin contact and maternal odours. *Acta Paediatrica,* 93(12), pp. 1560-1562.

Radtke, J. V. (2011) The paradox of breastfeeding-associated morbidity among late preterm infants. *Journal of obstetric, gynecologic, and neonatal nursing : JOGNN,* 40(1), pp. 9-24.

Ramani, M., Choe, E. A., Major, M., Newton, R., Mwenechanya, M., Travers, C. P., Chomba, E., Ambalavanan, N. and Carlo, W. A. (2018) Kangaroo mother care for the prevention of neonatal hypothermia: a randomised controlled trial in term neonates. *Archives of Disease in Childhood,* 103(5), pp. 492-497.

Rapley, G. and Murkett, T. (2012) *Baby-led Breastfeeding: How to make breastfeeding work - with your baby's help.* London: Vermilion

Redshaw, M. and Martin, C. (2013) Babies, 'bonding' and ideas about parental 'attachment'. *Journal of Reproductive and Infant Psychology*, 31(3), pp. 219-221.

Rey, E. and Martinez, H. (1983) Rational management of the premature infant [Manejo racional del niño prematuro]. *Curso de Medicina Fetal y Neonatal Bogota, Colombia: Universidad Nacional*, pp. 137-151.

Rippeyoung, P. L. F. and Noonan, M. C. (2012) Is Breastfeeding Truly Cost Free? Income Consequences of Breastfeeding for Women. *American Sociological Review,* 77(2), pp. 244-267.

Ritchie, J. and Spencer, L. (1994) Qualitative data analysis for applied policy research In: A. Bryman and RG. Burgess, eds. *Analyzing qualitative data*. London and New York: Routledge, pp. pp173-194.

Robson, C. (2011) *Real World Research.* 3rd edn. New York: Wiley.

Ross, H. E. and Young, L. J. (2009) Oxytocin and the neural mechanisms regulating social cognition and affiliative behavior. *Frontiers in Neuroendocrinology,* 30(4), pp. 534-547.

Rothwell, P. M. (2006) Factors that can affect the external validity of randomised controlled trials. *PLoS clinical trials,* 1(1), pp. e9-e9.

Royal College of Midwives (2018) Position Statement: Infant Feeding. Available at: https://www.rcm.org.uk/sites/default/files/Infant%20Feeding.pdf [Accessed 21/09/18].

Rubin, H. and Rubin, I. (2005) *Qualitative Interviewing: The Art of Hearing Data.* 2nd edn. London: Sage.

Ruxer, D. J., Burkhardt, M., Brewer, T., Leakeas, T., Shay, M., Mateer, K. and Seipel, B. (2013) The Impact of Increased Skin-to-Skin Contact on Breastfeeding Neonates on Exclusive Breastfeeding at 4 and 8 Weeks Postpartum. *JOGNN: Journal of Obstetric, Gynecologic & Neonatal Nursing,* 42, pp. S85-86.

Ryan, G. W. and Bernard, H. R. (2003) Techniques to identify themes. *Field methods,* 15(1), pp. 85-109.

Sakano, J. and Yajima, Y. (2005) Factor structure of the SOC scale 13-item version in Japanese university students*. Japanese Journal of Public Health,* 52(1), pp. 34-45.

Sandell, R., Blomberg, J. and Lazar, A. (1998) The factor structure of Antonovsky's sense of coherence scale in swedish clinical and nonclinical samples. *Personality and Individual Differences,* 24(5), pp. 701-711.

Saunders, L. (2009) The Policy and Organisational Context for Commissioned Research. *London: British Educational Research Association, TLRP,* 29.

Save The Children (2018) *Don't push it: Why the formula milk industry must clean up its act.* London: Save The Children.

Seals Allers, K. (2017) *The Big Letdown: How Medicine, Big Business, and Feminism Undermine Breastfeeding.* New York: St. Martin's Press.

Sears, W. and Sears, M. (2014) *The Attachment Parenting Book: A Commonsense Guide to Understanding and Nurturing Your Baby.* New York: Little Brown.

Segal, L. M., Stephenson, R., Dawes, M. and Feldman, P. (2007) Prevalence, diagnosis, and treatment of ankyloglossia: methodologic review. *Canadian family physician Medecin de famille canadien,* 53(6), pp. 1027-1033.

Seidman, G., Unnikrishnan, S., Kenny, E., Myslinski, S., Cairns-Smith, S., Mulligan, B. and Engmann, C. (2015) Barriers and Enablers of Kangaroo Mother Care Practice: A Systematic Review. *PLOS ONE,* 10(5), p. e0125643.

Semenic, S., Loiselle, C. and Gottlieb, L. (2008) Predictors of the duration of exclusive breastfeeding among first-time mothers. *Research in nursing & health,* 31(5), pp. 428-441.

Seraphine (2019) *Skin to skin clothing*. Available at: https://www.seraphine.com/en-gb/baby-clothes/skin-to-skin-clothing.html [Accessed: 15/06/2020]

Shadish, W. R., Cook, T. D. and Campbell, D. T. (2002) *Experimental and Quasi-experimental Designs for Generalized Causal Inference.* Massachusetts: Wadsworth Publishing.

Sheldon, S. (1998) *Feminist Perspectives on Health Care Law.* 1st edn. London: Routledge-Cavendish.

Shirom, A. and Melamed, S. (2006) A comparison of the construct validity of two burnout measures in two groups of professionals. *International Journal of Stress Management,* 13(2), pp. 176-200.

Shorey, S., He, H.-G. and Morelius, E. (2016) Skin-to-skin contact by fathers and the impact on infant and paternal outcomes: an integrative review. *Midwifery,* 40, pp. 207-217.

Silva, M. G. d. C., Barros, M. C. d. M., Pessoa, Ú. M. L. and Guinsburg, R. (2016) Kangaroo–mother care method and neurobehavior of preterm infants. *Early Human Development,* 95, pp. 55-59.

Sim, J. and Wright, C. (2000) *Research in Health Care: Concepts, Designs and Methods.* Cheltenham: Stanley Thornes Publishers.

Sinclair, M. and Stockdale, J. (2011) Achieving optimal birth using salutogenesis in routine antenatal education. *Evidence Based Midwifery,* 9(3), p. 75.

Skrundz, M., Bolten, M., Nast, I., Hellhammer, D. H. and Meinlschmidt, G. (2011) Plasma Oxytocin Concentration during Pregnancy is associated with Development of Postpartum Depression. *Neuropsychopharmacology,* 36(9), pp. 1886-1893.

Smith, V., Daly, D., Lundgren, I., Eri, T., Begley, C., Gross, M. M., Downe, S., Alfirevic, Z. and Devane, D. (2017) Protocol for the development of a salutogenic intrapartum core outcome set (SIPCOS). *BMC Med Res Methodol,* 17(1), p. 61.

Smith, V., Daly, D., Lundgren, I., Eri, T., Benstoem, C. and Devane, D. (2014) Salutogenically focused outcomes in systematic reviews of intrapartum interventions: a systematic review of systematic reviews. *Midwifery,* 30(4), pp. e151-156.

Smith, G., Sylva, K., Smith, T., Sammons, P. and Omonigho, A. (2018) *Stop Start. Survival, decline or closure? Children's centres in England, 2018.* London: The Sutton Trust.

Sparud-Lundin, C., Wennergren, M., Elfvin, A. and Berg, M. (2011) Breastfeeding in Women With Type 1 Diabetes. *Exploration of predictive factors,* 34(2), pp. 296-301.

Spriestersbach, A., Röhrig, B., du Prel, J.-B., Gerhold-Ay, A. and Blettner, M. (2009) Descriptive statistics: the specification of statistical measures and their presentation in tables and graphs. Part 7 of a series on evaluation of scientific publications. *Deutsches Arzteblatt international,* 106(36), pp. 578-583.

Standley, J. M. and Madsen, C. K. (1990) Comparison of Infant Preferences and Responses to Auditory Stimuli: Music, Mother, and Other Female Voice. *Journal of Music Therapy,* 27(2), pp. 54-97.

Strauss, A. L. (1987) *Qualitative analysis for social scientists.* Cambridge: Cambridge university press.

Strümpfer, D. (2006) The Strengths Perspective: Fortigenesis in Adult Life*. Soc Indic Res,* 77, pp. 11-36.

Strümpfer, D. J. W. (1995) The Origins of Health and Strength: From 'Salutogenesis' to 'Fortigenesis'. *South African Journal of Psychology,* 25(2), pp. 81-89.

Svensson, K. E., Velandia, M. I., Matthiesen, A.-S. T., Welles-Nyström, B. L. and Widström, A.-M. E. (2013) Effects of mother-infant skin-to-skin contact on severe latch-on problems in older infants: a randomized trial. *International Breastfeeding Journal,* 8(1), p. 1.

Tabachnick, B. and Fidell, L. (2014) Using multivariate statistics . Harlow. *Essex: Pearson Education Limited*.

Tariq, S. and Woodman, J. (2013) Using mixed methods in health research. *JRSM Short Reports,* 4(6), pp. 1-8.

Tashakkori, A. and Teddlie, C. (eds) (2010) *SAGE Handbook of Mixed Methods in Social & Behavioral Research.* 2nd edn*.* California: SAGE Publications.

Tashakkori, A. and Teddlie, C. (2003) *Handbook of Mixed Methods in Social & Behavioral Research.* California: SAGE Publications.

Taylor, A., Atkins, R., Kumar, R., Adams, D. and Glover, V. (2005) A new Mother-to-Infant Bonding Scale: links with early maternal mood. *Archives of Women's Mental Health,* 8(1), pp. 45-51.

Taylor, E. N. and Wallace, L. E. (2012) For Shame: Feminism, Breastfeeding Advocacy, and Maternal Guilt. *Hypatia,* 27(1), pp. 76-98.

Teh, Y. Y. and Lek, E. (2018) Culture and reflexivity: systemic journeys with a British Chinese family. *Journal of Family Therapy,* 40(4), pp. 520-536.

Tessier, R., Cristo, M., Velez, S., Girón, M., de Calume, S., Figueroa, Z., Ruiz-Paláez, J. G., Charpak, Y. and Charpak, N. (1998) Kangaroo Mother Care and the Bonding Hypothesis. *Pediatrics,* 102(2), pp. e17-e17.

Thapa, K., Mohan, D., Williams, E., Rai, C., Bista, S., Mishra, S. and Hamal, P. K. (2018) Feasibility assessment of an ergonomic baby wrap for kangaroo mother care: A mixed methods study from Nepal. *PLOS ONE,* 13(11), pp. e0207206-e0207206.

Thomas, V., Riegel, B., Andrea, J., Murray, P., Gerhart, A. and Gocka, I. (1995) National survey of pediatric fever management practices among emergency department nurses. *Journal of emergency nursing: JEN : official publication of the Emergency Department Nurses Association,* 20, pp. 505-510.

Thompson, L. A., Zhang, S., Black, E., Das, R., Ryngaert, M., Sullivan, S. and Roth, J. (2013) The Association of Maternal Pre-pregnancy Body Mass Index with Breastfeeding Initiation. *Maternal and Child Health Journal,* 17(10), pp. 1842-1851.

Thomson, G. and Dykes, F. (2011) Women's Sense of Coherence related to their infant feeding experiences. *Maternal & Child Nutrition,* 7(2), pp. 160-174.

Tong, R. (1995) Feminist Philosophy. In: R Audi, ed. *The Cambridge Dictionary of Philosophy*. New York: Cambridge University Press.

Tong, A., Sainsbury, P., Craig, J. (2007) Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care,* 19 (6) Pp 349–357

Torgerson, D. J. and Roberts, C. (1999) Randomisation methods: concealment. *BMJ,* 319(7206), pp. 375-376.

Torraco, R. (2005) Writing Integrative Literature Reviews: Guidelines and Examples. *Human Resource Development Review,* 4(3), pp. 356-367.

Tronick, E., Adamson, L. B., Als, H. and Brazelton, T. B. (1975) Infant emotions in normal and pertubated interactions. In: *biennial meeting of the Society for Research in Child Development*. Denver, Colorado.

Turner, R. M., Bird, S. M. and Higgins, J. P. T. (2013) The Impact of Study Size on Meta-analyses: Examination of Underpowered Studies in Cochrane Reviews. *PLOS ONE,* 8(3), p. e59202.

Ulrich, C. M., Wallen, G. R., Feister, A. and Grady, C. (2005) Respondent Burden in Clinical Research: When Are We Asking Too Much of Subjects? *IRB: Ethics & Human Research,* 27(4), pp. 17-20.

UNICEF UK (2017) Guide to the UNICEF UK Baby Friendly Initiative Standards. Available at: https://www.unicef.org.uk/babyfriendly/wp-content/uploads/sites/2/2014/02/Guide-to-the-Unicef-UK-Baby-Friendly-Initiative-Standards.pdf [Accessed 09/12/2019].

Upton, M. (2018) *Avoiding Term Infants Into Neonatal units: Insights from the Atain programme.* Available at: https://www.npeu.ox.ac.uk/downloads/files/ukmidss/Study-day-2018-

presentations/03%20Study%20Day%202018%20-%20Michele%20Upton%20-%20Insights%20from%20the%20Atain%20Programme.pdf [Accessed 08/04/2020].
Van Teijlingen, E. R. and Hundley, V. (2001) The importance of conducting and reporting pilot studies: the example of the Scottish Births Survey. *Journal of Advanced Nursing*, 34, pp. 289-295.
Velandia, M., Matthisen, A.-S., Uvnäs-Moberg, K. and Nissen, E. (2010) Onset of Vocal Interaction Between Parents and Newborns in Skin-to-Skin Contact Immediately After Elective Cesarean Section. *Birth,* 37(3), pp. 192-201.
VIJA (2019) *Simply skin to skin*. Available at: https://www.vija-design.co.uk/ [Accessed: 15/06/2020]
Vittinghoff, E. and McCulloch, C. E. (2006) Relaxing the Rule of Ten Events per Variable in Logistic and Cox Regression. *American Journal of Epidemiology,* 165(6), pp. 710-718.
Vittner, D., McGrath, J., Robinson, J., Lawhon, G., Cusson, R., Eisenfeld, L., Walsh, S., Young, E. and Cong, X. (2017) Increase in Oxytocin From Skin-to-Skin Contact Enhances Development of Parent–Infant Relationship. *Biological Research For Nursing,* 20(1), pp. 54-62.
Wade, D. T. and Halligan, P. W. (2004) Do biomedical models of illness make for good healthcare systems? *BMJ (Clinical research ed.),* 329(7479), pp. 1398-1401.
Walker, C. D. (2010) Maternal touch and feed as critical regulators of behavioral and stress responses in the offspring. *Developmental Psychobiology,* 52(7), pp. 638-650.
Walsh, D. and Evans, K. (2014) Critical realism: An important theoretical perspective for midwifery research. *Midwifery,* 30(1), pp. e1-e6.
Wasserstein, R. L. and Lazar, N. A. (2016) The ASA Statement on p-Values: Context, Process, and Purpose. *The American Statistician,* 70(2), pp. 129-133.
Watkins, D. and Gioia, D. (2015) *Mixed Methods Research.* Oxford: Oxford University Press.
Weber Cannon, L., Higginbotham, E. and Leung, M. L. A. (1988) Race and Class Bias in Qualitative Research on Women. *Gender and Society,* 2(4), pp. 449-462.
Wennerberg, M. M. T., Eriksson, M., Lundgren, S. M. and Danielson, E. (2018) Unravelling Swedish informal caregivers' Generalised Resistance Deficits. *Scandinavian Journal of Caring Sciences,* 32(1), pp. 186-196.
Werker, J. F. and McLeod, P. J. (1989) Infant preference for both male and female infant-directed talk: A developmental study of attentional and affective responsiveness. *Canadian Journal of Psychology/Revue canadienne de psychologie,* 43(2), pp. 230-246.
West, S. G., Duan, N., Pequegnat, W., Gaist, P., Jarlais, D. C. D., Holtgrave, D., Szapocznik, J., Fishbein, M., Rapkin, B., Clatts, M., et al. (2008) Alternatives to the Randomized Controlled Trial. *American Journal of Public Health,* 98(8), pp. 1359-1366.
Whalen, B. and Cramton, R. (2010) Overcoming barriers to breastfeeding continuation and exclusivity. *Current Opinion in Pediatrics,* 22(5), pp. 655-663.
Whittemore, R. and Knafl, K. (2005) The integrative review: updated methodology. *Journal of Advanced Nursing,* 52(5), pp. 546-553.
Wickham, S. (2016) The ALTE mysteries: who's to blame? *The Practising Midwife,* 19(2), pp. 35-36.
Widström, A.-M., Lilja, G., Aaltomaa-Michalias, P., Dahllöf, A., Lintula, M. and Nissen, E. (2011) Newborn behaviour to locate the breast when skin-to-skin: a possible method for enabling early self-regulation. *Acta Paediatrica,* 100(1), pp. 79-85.

Wojcicki, J. M. (2011) Maternal prepregnancy body mass index and initiation and duration of breastfeeding: a review of the literature. *Journal of women's health (2002),* 20(3), pp. 341-347.

World Health Organisation (1981) *International Code of Marketing of Breast-milk Substitutes.* Geneva: World Health Organisation.

World Health Organisation (2003a) *Global Strategy for Infant and Young Child Feeding.* Geneva: World Health Organisation.

World Health Organisation (2003b) Kangaroo Mother Care: A Practical Guide. Available at: https://www.who.int/maternal_child_adolescent/documents/9241590351/en/ [Accessed: 15/06/2020]

World Health Organisation (2009) Session Two: The physiological basis of breastfeeding. In: *Infant and Young Child Feeding: Model Chapter for Textbooks for Medical Students and Allied Health Professionals*. Geneva: World Health Organization.

World Health Organisation (2012) *Recommendations for management of common childhood conditions: evidence for technical update of pocket book recommendations.* Available at: https://apps.who.int/iris/bitstream/handle/10665/44774/9789241502825_eng.pdf;sequence=1 [Accessed: 15/06/2020]

World Health Organisation (2013) *Long-term effects of breastfeeding: a systematic review.* Available at: https://www.who.int/maternal_child_adolescent/documents/breastfeeding_long_term_effects/en/ {Accessed: 12/05/2020]

World Health Organisation (2015) *WHO recommendations on interventions to improve preterm birth outcomes.* Available at: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/preterm-birth-highlights/en/ [Accessed: 15/06/2020]

World Health Organisation (2017) *Exclusive breastfeeding to reduce the risk of childhood overweight and obesity: Biological, behavioural and contextual rationale.* Available at: http://www.who.int/elena/titles/bbc/breastfeeding_childhood_obesity/en/ [Accessed 31/08/2018].

World Health Organisation 1997) *Thermal Protection of the Newborn: a practical guide*. Available at: https://www.who.int/maternal_child_adolescent/documents/ws42097th/en/ [Accessed: 15/06/2020]

World Health Organisation and UNICEF (2014) *Global Nutrition Targets 2025 Breastfeeding Policy Brief.* Available at: https://apps.who.int/iris/bitstream/handle/10665/149022/WHO_NMH_NHD_14.7_eng.pdf?ua=1. [Accessed: 15/06/2020]

World Medical Association (1964) *Declaration of Helsinki*. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [Accessed 21/09/18].

Appendices

Appendix A: Reference list of studies included in integrative literature review

Amaliya, S., et al. (2017). "Comparison of Various Kangaroo Mother Care Carriers on Maternal Comfort: A Pilot Study." *Comprehensive Child and Adolescent Nursing* 40(sup1): 52-61.

Bigelow, A. E. and M. Power (2012). "The effect of mother–infant skin-to-skin contact on infants' response to the Still Face Task from newborn to three months of age." *Infant Behavior and Development* 35(2): 240-251.

Bigelow, A. E., et al. (2014). "Breastfeeding, skin-to-skin contact, and mother-infant interactions over infants' first three months." *Infant Mental Health Journal* 35(1): 51-62.

Chiu, S.-H., et al. (2005). "Newborn temperature during skin-to-skin breastfeeding in couples having breastfeeding difficulties." *Birth* 32(2): 115-121.

Dalbye, R., et al. (2011). "Mothers' experiences of skin-to-skin care of healthy full-term newborns – A phenomenology study." *Sexual & Reproductive HealthCare* 2(3): 107-111.

de Albuquerque, R. S., et al. (2016). "Newborns' temperature submitted to radiant heat and to the Top Maternal device at birth." *Revista Latino-Americana de Enfermagem* 24.

Gregson, S. and Blacker, J. (2011) Kangaroo care in pre-term or low birth weight babies in a postnatal ward. *British Journal of Midwifery*, 19(9), pp. 568-577.

Horst, J. (2017). "Effect of Multiple Skin-to-Skin Experiences on Exclusive Breastfeeding Rates." Available at: https://scholarworks.waldenu.edu/cgi/viewcontent.cgi?article=4715&context=dissertations

Owusu-Ansah, F., et al. (2019). "The effect of mother-infant skin-to-skin contact on Ghanaian infants' response to the Still Face Task: Comparison between Ghanaian and Canadian mother-infant dyads." *Infant Behavior & Development* 57: 101367.

Ramani, M., et al. (2018). "Kangaroo mother care for the prevention of neonatal hypothermia: a randomised controlled trial in term neonates." *Archives of Disease in Childhood* 103(5): 492-497.

Ruxer, D. J., et al. (2013). "The Impact of Increased Skin-to-Skin Contact on Breastfeeding Neonates on Exclusive Breastfeeding at 4 and 8 Weeks Postpartum." *Journal of Obstetric, Gynecologic & Neonatal Nursing* 42: S85-S86.

Svensson, K. E., et al. (2013). "Effects of mother-infant skin-to-skin contact on severe latch-on problems in older infants: a randomized trial." *International Breastfeeding Journal* 8(1): 1-1.

Thapa, K., et al. (2018). "Feasibility assessment of an ergonomic baby wrap for kangaroo mother care: A mixed methods study from Nepal." *PLOS ONE* 13(11): e0207206-e0207206.

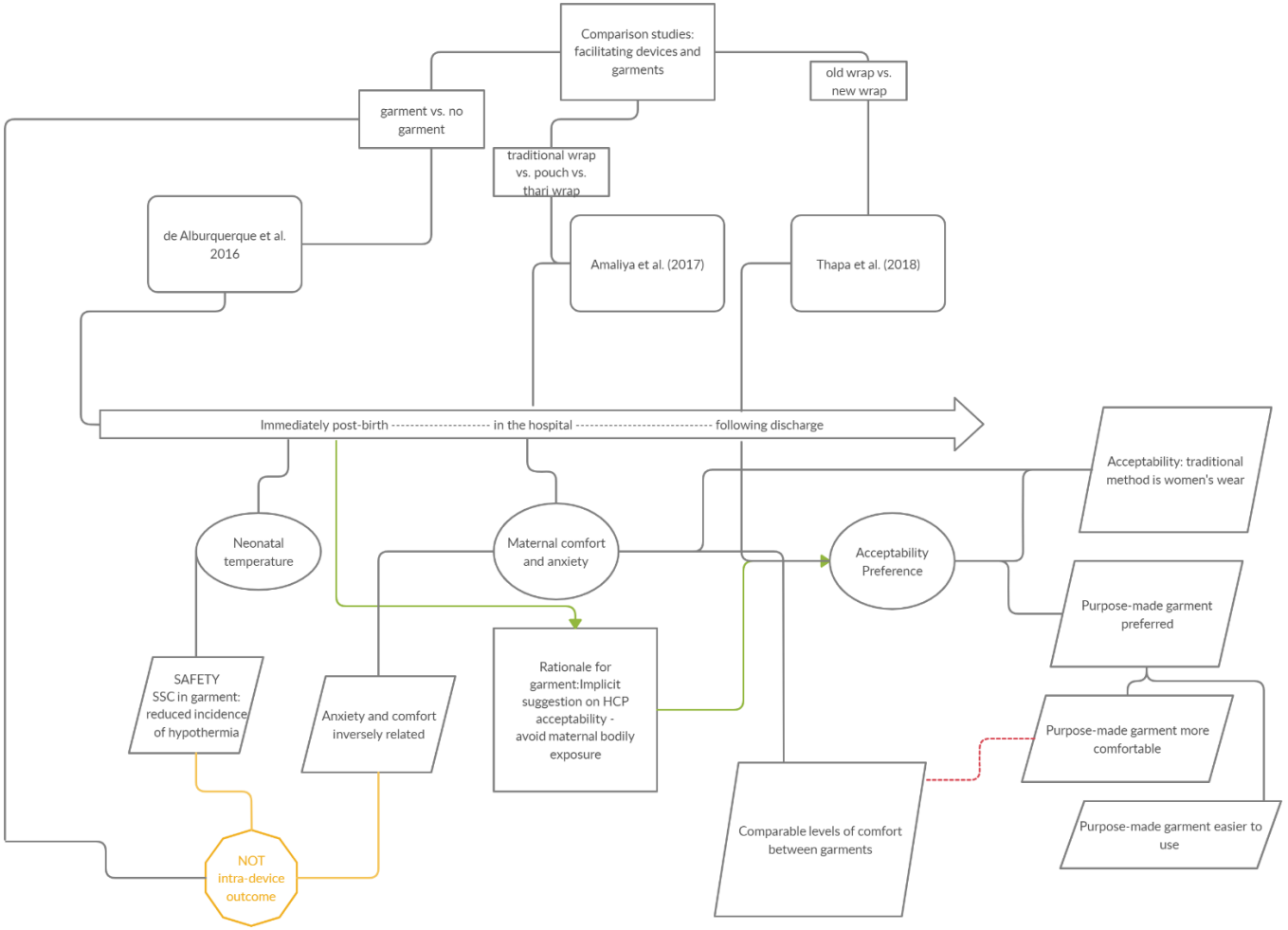
Appendix B: Data framework for mother-infant relational bonding

Study and outcomes	Study details	Applicable to/ Context	Data simplified	Data described
Dalbye et al. (2011) Mothers' experiences of skin-to-skin contact in the postnatal period	Use of lifeworld phenomenology – aims to describe and understand human (maternal) experience of skin-to-skin contact	Scandinavian mothers, mothers of healthy newborns, partnered mothers	The essence of the data: skin-to-skin contact nurtured a mutual affinity between the mother and infant. Use of SSC to allay the baby's cries resulted in positive feedback; energy and feelings of wellbeing were generated in the mother, and perceived in the baby. 3 meaningful clusters: 1) The surrounding's influence 2) Produces feelings of naturalness and wellbeing 3) The child signifies satisfaction	SSC is conceptualised by mothers as an instinctive, logical continuation of pregnancy. Mother-infant relational bonding increases through time spent SSC. SSC produces a positive experience of the postnatal period where mothers could provide the best possible care. The social and institutional surroundings positively influenced women to engage with SSC. Both maternal and infant satisfaction with SSC was perceived by the mothers, which increased mothers' perceptions of bonding between the dyad, and resulted in mother-infant affinity.

Bigelow and Power (2012) Response to the Still Face Task	Use of the Still Face Task – Suggestive of the infant's awareness and sensitivity towards its mother, and the infant's developing social expectations. Analysed through infant behaviour scoring.	Canadian mothers, mothers of healthy newborns, mothers with a high engagement in SSC, distal parenting practices	At 1 month: Infants receiving SSC: responded to the Still Face Task with vocalisations and attention. Demonstrated increased ability for social bidding (expecting and eliciting social behaviours from the mother) Infants not receiving SSC: responded to the Still Face Task with attention only. At 2 months: No difference between the groups.	Infants with and without SSC respond to their mothers' behaviour differently. Evidence of the development of a reciprocal relationship: the development of a reciprocal pattern of interaction between the mother and infant (shown through infant vocalisations) is accelerated when dyads engage in frequent SSC. Face to face time in distal parenting elicits infant vocalisations. Infants learn their own role in mother-infant interaction, and develop social expectations sooner.

Ansah et. al (2019)	Use of the Still Face Task – Suggestive of the infant's awareness and sensitivity towards its mother, and the infant's developing social expectations. Analysed through infant behaviour scoring.	Ghanaian mothers, mothers of healthy newborns, mothers with a high engagement in SSC, proximal parenting practices	At 6 weeks: Infants receiving SSC: responded to the Still Face Task with smiling and attention. Infants not receiving SSC: responded to the Still Face Task with attention. Comparative findings on acceleration of social behaviours between Canadian and Ghanaian infants, but exhibited differently.	Infants with and without SSC respond to their mothers' behaviour differently. Evidence of the development of a reciprocal relationship: the development of a reciprocal pattern of interaction between the mother and infant (shown through smiling) is accelerated when dyads engage in frequent SSC. Body contact in proximal parenting elicits smiling. Infants learn their own role in mother-infant interaction, and develop social expectations sooner.

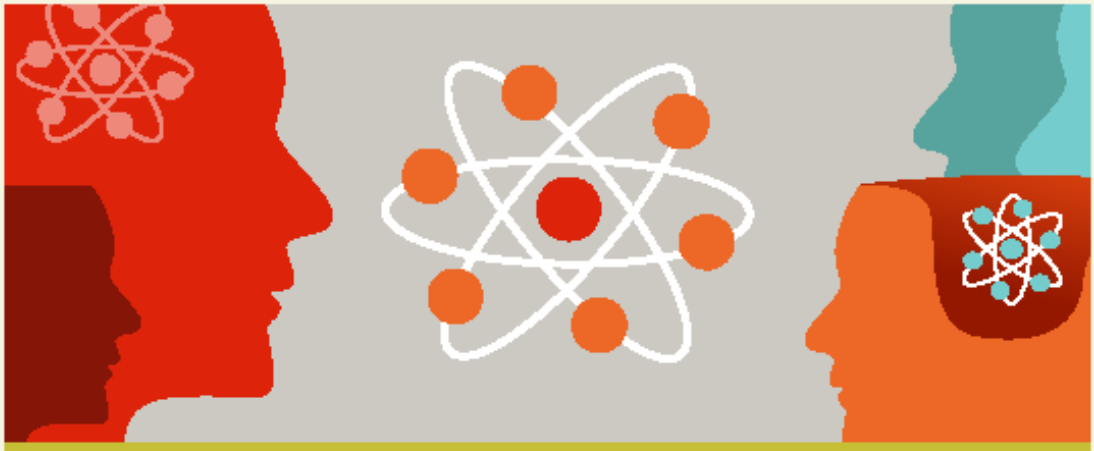
Appendix C: Mapping diagram for facilitating garments and devices



Appendix D: Bailey (2018) Applying Theory: How Salutogenesis can support a woman-centred approach to midwifery research

APPLYING THEORY:

HOW SALUTOGENESIS CAN SUPPORT A WOMAN-CENTRED APPROACH TO MIDWIFERY RESEARCH



Salutogenesis offers a theory to guide midwifery research that is congruent with the midwifery ethos of supporting normality and health. In contrast to the traditional medical model, midwifery research requires an underpinning theory that supports the concept of pregnancy and birth as a normal life event.

This article follows the application of salutogenesis through the research pathway, and uses the research topic of kangaroo mother care (KMC) to illustrate the use of salutogenesis in research.

By applying Antonovsky's theory of salutogenesis, midwives can design and carry out research that is woman-centred, and promotes health and wellbeing.

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INTRODUCTION

The medical model of care and research has dominated Western medicine and healthcare (Bryer and Sinclair 2011). It uses empirical evidence to seek generalisable findings based on risk, cure and pathology. Whilst this applies to the general population, it does not value the person as a human being (Cluett and Bluff 2006), which is paramount to woman-centred research and care.

When considering a research project, midwives may examine their own positionality as being 'with woman'; autonomous practitioners in physiological birth and health promotion (International Confederation of Midwives [ICM] 2017). Bryer and Sinclair (2011) assert that the individual and collective beliefs held by midwives influence the care that they provide.

When participating both in care and research, a theory of health, rather than disease, is needed to safeguard midwives' professional expertise, and continue to carve out midwifery research centred on women's health rather than risk or pathophysiology. Salutogenesis, meaning the origins of health, is a theory of health promotion (Antonovsky 1979). It offers an alternative theoretical perspective to the medical model of care and research that has manifested in obstetric-led, risk-centric care.

SALUTOGENESIS
AT A GLANCE:

EXPLORES THE 'ORIGINS OF HEALTH'

OFFERS AN EXTENSION TO PATHOGENESIS, 'ORIGINS OF DISEASE'

CONSIDERS HEALTH AND WELLBEING ALONG A CONTINUUM

ADDRESSES STRESSORS AND HOW WE RESPOND TO THEM

PROVIDES A USEFUL FRAMEWORK FOR HOLISTIC RESEARCH

CAN BE APPLIED TO MIDWIFERY RESEARCH AND PRACTICE

HEALTH AND RISK BASED MODELS IN MIDWIFERY

The philosophy of birth as a physiological event of health has been undermined by the technocratic paradigm of childbirth, which views the body as a machine that is fundamentally faulty, and at risk of disease (Davis-Floyd 1994). The technocratic paradigm can also be seen in infant feeding practices, where the physiology of lactation is mistrusted. In part, this may be due to an inability to quantify milk transfer, and simplify a breastfeeding dyad's reciprocal relationship.

The risk discourse in maternity care paints women and their babies as 'not yet patients' (Lauritzen and Sachs 2001), with screening for pathology throughout the childbearing continuum exacerbating a distrust for physiology (Walsh El-Nemer and Downe 2008). Crawford (2004) recognises that the ritual of risk makes us fear the unlikely, but become unconcerned with the truly dangerous. The pathology-orientated model of care has resulted in harms as well as benefits to women and their families; high caesarean section rates at over 15 per cent are positively correlated with *increased* maternal and neonatal mortality (Betrán et al 2007; Davis-Floyd 2008).

Stafford (2001) suggests that the development of a risk-centric environment negates professional autonomy, and is linked to institutional cultures of defensive practice, despite a 'no-blame culture' sought in risk management strategies (Walsh El-Nemer and Downe 2008)

Salutogenesis offers a theory of health promotion as an alternative to risk-centric research and practice, which may better support the midwife's endeavour to provide woman-centred, health focused care and research.

> Consider your last care episode with a woman: what proportion of that care centred on risk avoidance, and what proportion focused on health promotion? Decide whether the balance was proportionate.

KEY CONCEPTS OF SALUTOGENESIS

Antonovsky's theory of salutogenesis (1979; 1987) is a health orientation that views health as a continuum between total ill health and total health. In contrast to a pathogenic model, in which the absence of disease is the marker of health, Antonovsky viewed salutary – or health promoting – factors as the drivers that move people towards health. Antonovsky refuted the health-disease dichotomy and instead recognised people as complex organisms, all of which were capable of moving across the continuum.

Antonovsky (1979) was interested in what enabled good health in people following stressors in life. He identified general resistance resources (GRRs) (such as money, beliefs, and social support) which were used by people to combat stressors.

To explain how GRRs may work, Antonovsky developed the 'sense of coherence concept' (1979). One's sense of coherence (SOC) is dependent on three core tenets: an ability to understand the situation or life event; to find meaning in life's challenges; and utilisation of the available resources to move in a health-promoting direction towards quality of life. He theorised that people with a strong sense of coherence tended to have better mental and physical health (Antonovsky 1979).

Antonovsky suggested that one's sense of coherence was formed largely as a result of experiences in childhood, and was unlikely to develop any further from when the individual reached adulthood (Antonovsky 1979). Downe and McCourt (2008) consider – conversely – that one's sense of coherence is open to constant change, and profound events such as childbirth may impact upon it.

Antonovsky's sense of coherence hypothesis has been widely tested with a range of research populations, including pregnant women. In their systematic review, Eriksson and Lindstrom (2005) found the SOC scale to be reliable, valid and appropriate to use across a multitude of populations, countries and languages.

Antonovsky (1996) recognised maternal and child health as an area where a health-promoting philosophy is evident. The application of the salutogenic model of health promotion challenges the risk-based pathology paradigm, and offers a theoretical basis to examine the multi-faceted factors of health that support normal physiological birth, feeding and nurturing in the postnatal period. Antonovsky (1996) suggested a symbiotic system in which disease prevention and cure are complemented by a drive to actively improve health.

KANGAROO MOTHER CARE (KMC)

Originally developed to alleviate the over-demand on incubators in low-resource settings, KMC reinstated the maternal chest as the habitat for small or premature babies. Medical research has since demonstrated a significant reduction in neonatal morbidity and mortality rates (Conde-Agudelo and Díaz-Rossello 2016). The act of caring for newborn babies on the maternal chest with close or near-continuous skin-to-skin contact is the evolutionary norm for humans (Moore et al 2016). Mother-infant skin-to-skin contact immediately after birth allows for neuro-programming; innate reflexes are exhibited, that allow the infant to move, familiarise themselves with the environment, and suckle (Moore et al 2016; Alberts 1994). Despite skin-to-skin contact and maternal-infant closeness facilitating normal maternal and neonatal physiology, Moore et al (2016) recognise that it has been constructed as the 'intervention', rather than the norm for both term and premature mother-infant dyads.

By adopting a salutogenic framework, KMC can be repositioned within the health continuum to promote normal growth, feeding, and extra-utero transition of all newborns, rather than solely as a disease prevention intervention.

Consider another 'anti-intervention': delayed (optimal) cord clamping. Identify another physiological process or event that is considered an intervention.

GENERATING RESEARCH QUESTIONS AND OUTCOMES

Antonovsky encourages the life orientation questionnaire to be used to test the theory itself (Antonovsky 1996). For example, how might birth affect a woman's sense of coherence? However, midwifery research using a salutogenic theory may use aspects of Antonovsky's theory to generate a research question that focuses on moving the research population towards health.

Avoid a focus on risk factors, disease incidence and morbidity and mortality. Instead, the midwife-researcher may consider which salutary factors (such as continuity of carer) could be important in moving women towards better health. Health-related outcomes may be more subtle and long term, such as parenting capacity or dyadic wellbeing (Downe and McCourt 2008).

KMC example

Rather than measuring morbidity and mortality as outcomes, health-promoting behaviours, such as breastfeeding and time spent in skin-to-skin contact, may be the outcomes of interest. Salutogenesis may position the mother's experiences of KMC as a life event that may affect her sense of coherence.

CHOOSING AND RECRUITING A STUDY POPULATION

Salutogenic theory applies population-wide, rather than to a segregation of a population based on a shared risk factor or pathology (Antonovsky 1996). Midwifery research studies may recruit a sample of healthy women or babies. A salutogenic approach to choosing a study population or setting may focus on areas of good practice, where normality is safeguarded, or birth outcomes are positive.

Antonovsky recognised the contribution one's socio-demographics may have on the ability to deal with life's stressors (Antonovsky 1996), such as the transition to motherhood. The cross-cultural validation of the theory supports its application to a diverse range of populations.

KMC example

A population of healthy, term babies and their mothers may be recruited, with the inclusion criteria focusing on health rather than on low birth weight and premature babies.

Identify a local area of good practice that works well to support women's choice. Jot down a few questions you could ask women using the service, in order to share some woman-centred best practice points with other clinical areas.

METHODOLOGY AND DATA

When designing a research method, a longitudinal design may be used to measure the impact an event has on the participants' sense of coherence. Ferguson et al (2016) used this to assess changes in the participants' sense of coherence before and after childbirth.

Similarly, a mixed-method design could collect data on a range of health outcomes, as the theory of salutogenesis recognises the breadth of salutary factors that move people towards health. Both qualitative and quantitative data can be collected and analysed with reference to salutogenesis.

Thomson and Dykes (2011) use Antonovsky's sense of coherence tenets to analyse women's experiences of infant feeding. Their experiences were understood through their own understanding of the life event (comprehensibility), the resources they used to manage the challenges faced in fulfilling their expectations (manageability), and the value they attributed to the challenge (meaningfulness).

KMC example

A mixed-method design may be used to collect quantitative data on markers of health, such as incidence of neonatal temperatures within the normal range, or the instigation and continuation of breastfeeding. Qualitative data from interviews or focus groups may explore women's experiences of nurturing their baby in skin-to-skin contact, the resources they use to overcome challenges in nurturing or feeding their babies, and the meaning they attribute to closeness and breastfeeding.

USING RESULTS TO INFORM FUTURE PRACTICE

Maternity services can strengthen women's sense of coherence through providing personalised care, considering the individual's own GRRs and own motivations for pursuing health promoting activities, such as breastfeeding. This may be through the implementation and evaluation of health promotion activities, such as breastfeeding support groups and birth preparation classes. Prior to and following any changes in care or practice, women's sense of coherence may be assessed using Antonovsky's sense of coherence questionnaires (Antonovsky 1987) to audit the effectiveness of the intervention, and continue to positively develop woman-centred care.

Apply the theory of salutogenesis to the last research study you read. How might it change the study's focus, outcomes and data?

> *"The medical model of care and research uses empirical evidence to seek generalisable findings based on risk, cure and pathology"*

Appendix E: research protocol

A Skin-to-Skin Contact (SSC) Facilitating Device used within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.

Version 24

October 2018

Short Title: Facilitating skin to skin contact in the postnatal period.

FAEC reference: Bailey/Nov/2016/RC/0640

Trial Sponsor: Birmingham City University

External Funding: None.

Study Personnel and Contact Details

Sponsor	Birmingham City University
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Chief Investigator	Roisin Bailey Birmingham City University Email: roisin.bailey@bcu.ac.uk Phone: 07563 230081
Study Site	Birmingham City University Faculty of Health, Education and Life Sciences Westbourne Road Edgbaston Birmingham B15 3TN And City Hospital Sandwell and West Birmingham NHS Trust Dudley Road Birmingham B18 7QH

Title	A Skin-to-Skin Contact (SSC) Facilitating Device used within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.
Short Title	Facilitating skin to skin contact in the postnatal period.
Chief Investigator	Roisin Bailey
Objectives	• To understand the mothers' perspective regarding the value of a SSC facilitating garment used both at home and within a clinical maternity setting. • To explore the SSC facilitating garment's effect on parent-infant bonding from the mothers' perspective. • To determine if a SSC facilitating garment affects breastfeeding initiation, continuation and exclusivity rates. • To determine the effect a SSC facilitating garment has on neonatal thermoregulation in comparison to SSC without a facilitating garment. • To understand how a SSC facilitating garment may be used by a mother-infant dyad, and for what purpose. • To explore midwives' views of the acceptability and clinical value of using a SSC facilitating garment in a clinical maternity setting.
Study Configuration	Single centre study.
Setting	City Hospital Birmingham, Birmingham City University, participants' homes.

Number of participants	Phase one mother infant dyads n=10 Phase two mother-infant dyads: n=184 Phase three midwives: maximum n=115
Eligibility Criteria	Mother-infant dyads: Women with vaginally born, healthy, term (37 – 42 completed weeks gestational age), singleton neonates weighing 2500g-4000g at birth. Midwives: Clinical midwives working part or full time on the birth centre or postnatal ward at City Hospital Birmingham, who have provided clinical care to the dyads participating in the study.
Description of Interventions	Phase one: 10 mother-infant dyads recruited to observe usage of the Snuby® and neonatal temperature taking under direct researcher supervision. Data collected by researcher with checklist to determine if written study information and data collection tools are appropriate for Phase two of trial. Phase two: 184 Mother-infant dyads randomized into an intervention and control group. Intervention group provided with Snuby®, a skin-to-skin contact facilitating garment (appendix 2). Control group receive no intervention, and continue with routine postnatal and neonatal care. Maternal participants recruited in the antenatal period complete an antenatal questionnaire detailing their intentions for skin-to-skin contact and infant feeding choices. Those recruited in the immediate postnatal period complete the questionnaire at enrolment. Follow-up questionnaires for all participants at 3 days or the day of discharge, whichever is sooner, then weekly until six weeks postnatal. Questionnaires include taking and recording two neonatal temperatures each time the dyad have skin-to-skin contact (facilitated or otherwise), frequency and duration of skin-to-skin contact using Snuby® or without, recording infant feeding practices,

	infant feeding support choices, neonatal behaviour and weight velocity. One-to-one semi-structured interview with the researcher at 6 weeks postnatal in the participant's home. To collect data on maternal experience of feeding and caring for the baby, and having skin to skin contact. Phase three: Questionnaire sent to all eligible midwives to collect data on experiences of using Snuby® as a skin-to-skin facilitation strategy in the inpatient setting. Option provided of attending one of two focus group for more in depth data about perceived value of implementation strategy.
Duration of Study	February 2017 – Phase one recruitment March 2017 – Phase one trial May 2017 – April 2019 Phase two recruitment and trial August 2019 – September 2019 Phase three recruitment and focus groups October 2019 – February 2020 Data analysis, interpretation and dissemination.
Outcome Measures	An understanding of the effect a skin-to-skin contact facilitating garment (Snuby®) has on mother-infant bonding, breastfeeding status, neonatal thermoregulation and perceived value at home and in a maternity inpatient setting.
Statistical Methods	Descriptive statistics.

Abbreviations and Terms

CI	Chief Investigator
GP	General Practice
ICF	Informed Consent Form
MISSC	Mother-Infant Skin to Skin Contact
NHS	National Health Service
NMC	Nursing and Midwifery Council
ONS	Office of National Statistics
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
REC	Research Ethics Committee
SIDS	Sudden Infant Death Syndrome
SSC	Skin to Skin Contact
Snuby®	The registered skin to skin facilitating device to be trialled
UK	United Kingdom
UNICEF	The United Nations' Children's' Emergency Fund

Table of Contents

Study Background and Rationale

Skin-to-skin contact (SSC) sits within the care package of Kangaroo Mother Care, which consists of plentiful and near-constant skin to skin contact, exclusive or near-exclusive breastfeeding and early discharge home from the clinical environment with appropriate clinical follow-up following transfer home (World Health Organisation (WHO) 2003). This care package was developed for low birth weight and preterm infants in countries with limited economic resources for medical equipment (WHO 2003). Following demonstrated neonatal health benefits, the area of research supporting Kangaroo Mother Care for stable, preterm infants is well established (Vesel et al 2015). However, this continues to be contradicted by low rates of implementation (Valsangkar 2015).

Synthesis of a range of high quality research has demonstrated that intermittent and continuous mother-infant skin to skin contact increases breastfeeding rates, and reduces rates of sepsis, hypothermia, and neonatal mortality (Conde-Agudelo and Díaz-Rossello 2014). A garment has been designed to safely hold the baby in a skin to skin position against its carer, and this research aims to find out if the effects of skin-to-skin contact are the same when the garment is used. Despite a strong evidence base surrounding the physiological benefits of skin-to-skin contact, there is little available conclusive research surrounding successful implementation strategies (Vesel et al 2015). This is especially apparent within a population of term, healthy infants, in spite of transferable physiological theory and recognized best practice standards (Royal College of Midwives 2012, UNICEF 2013). This research will fill a void in the field on a possible implementation strategy primarily aimed at healthy, term infants.

Implementation of a skin-to-skin contact facilitating device also has the potential to positively impact upon infant feeding practices, as SSC is acknowledged to affect rates of breastfeeding initiation and continuation (Robiquet et al 2016, Mahmood et al 2011). With only one percent of babies in the United Kingdom (UK) receiving exclusive breastmilk for six months as recommended by the World Health Organisation (Health and Social Care Information Centre 2012), there is a dearth of research into potential interventions or strategies, such as a skin-to-skin facilitating device, in order to address non-breastfeeding status as a fundamental barrier to health.

UNICEF, an international charity set up by the United Nations (UNICEF 2016a), now recognizes the role of relationship building and bonding as fundamental to healthy infant

feeding practices and child health (UNICEF 2013). Incorporated into their Baby Friendly Initiative to support breastfeeding and parent-infant relationships (UNICEF 2016b), skin-to-skin contact is used to facilitate bonding between parents and their infant whether breastfeeding or artificial formula feeding (UNICEF 2014). This widens the relevance and applicability of this research to all mother-infant dyads, whatever their choice of infant feeding practice.

Non-breastfeeding status, as well as neonatal temperature fluctuation, have been demonstrated within the research literature as identifiable risk factors for Sudden Infant Death Syndrome (SIDS) (Goldwater 2011). Although rates of SIDS have been generally decreasing since 2003, there has been a small rise in national rates in the most recently available data (Lullaby Trust 2015, ONS 2015). Although most regions in the UK demonstrate a reduction in SIDS rates in 2013, in comparison to 2003-2012 average figures, the West Midlands is one of three outliers showing no reduction in SIDS rates when compared to its last 9 year average (ONS 2015). The NHS Trust hosting the research has perinatal mortality rates more than 10% higher than NHS Trusts with similar numbers of birth per annum (MBRRACE-UK 2016). With 70% of SIDS cases occurring within the first 28 days of life (ONS 2015), the neonatal period is a crucial time to develop strategies to reduce SIDS occurrence. By researching the effects of the Snuby® on breastfeeding status and neonatal temperature regulation, skin-to-skin contact facilitation strategies may also contribute to a strategy to reduce SIDS rates locally, with wider application to national SIDS reduction rates.

Study Purpose and Objectives

Purpose:

The study's purpose is to explore the clinical and qualitative value of a SSC facilitating garment used within a mother-infant dyad in the first six weeks following birth. It aims to understand the value of a skin-to-skin facilitating device from triple perspectives of the mother, baby, and midwife, in order to create a holistic interpretation of the device's usage and effect. The study aims to explore the device's effect on bonding, breastfeeding and neonatal thermoregulation to fully inform its implementation in postnatal care.

Objectives:

- To understand the mothers' perspective regarding the value of a SSC facilitating device used both at home and within a clinical maternity setting.
- To explore the SSC facilitating device's effect on mother-infant bonding from the mothers' perspective.
- To determine if a SSC facilitating device affects breastfeeding initiation, continuation and exclusivity rates.
- To determine the effect a SSC facilitating device has on neonatal thermoregulation in comparison to SSC without a facilitating device.
- To understand how a SSC facilitating device may be used by a mother-infant dyad, and for what purpose.
- To explore midwives' views of the acceptability and clinical value of using a SSC facilitating device in a clinical maternity setting.

External Reviews

Reviews have been sought throughout and following the development of the research proposal. They reflect a breadth of perspectives including clinical risk management and guideline development, infant feeding, and maternity service user views. Feedback on the research proposal has led to clarifications and additions, resulting in this final version. The external reviews can be found attached electronically to the IRAS form.

Study Design

Study Design Overview

This proposed research will use a mixed method approach to explore both the physiological effects on the neonate, and holistic effects on the mother-infant dyad of a SSC facilitating device as an intervention in postnatal care. Phase one will act as a pilot study, to monitor the mother-infant dyad's ability to use the information sheet, neonatal axillary thermometers and data collection tool. The main study, phase two, will compare two randomized samples of healthy postnatal women with healthy, term, singleton neonates. An intervention and control group will be created using randomized sampling of a consenting maternity population within

an NHS Trust in the West Midlands to compare use of a SSC facilitating device as an intervention, and routine postnatal care as a control. Data will be collected on skin-to-skin contact intentions for those which are recruited antenatally. For those recruited in the immediate postnatal period, this data will be collected at study enrolment in the immediate postnatal period.

Follow-up questionnaires and data collection sheets postnatally recording infant feeding choices and support, skin-to-skin contact practices, and neonatal behaviour and weight change in the first six weeks postnatal. This quantitative data will be complemented by a 'thoughts' section on the questionnaires, facilitating participating mothers to share their views on skin-to-skin contact weekly. The chief investigator will facilitate a semi-structured interview, seeking participant views on skin-to-skin contact's impact on infant feeding, mother-infant bonding, and its perceived value to the mother-infant dyad.

Phase three involves collecting data from the clinical midwives that have worked with the intervention group participants using the Snuby® in the inpatient setting to evaluate the Snuby®'s value as a facilitation strategy in comparison to conventionally facilitated skin-to-skin contact. This data will come from an electronic questionnaire, and focus group conversations. The research is necessary to determine the holistic value of such an intervention on neonatal health markers and dyadic bonding and wellbeing, as well as its value in inpatient and community postnatal care.

Study Design

The research will use a mixed methods approach in order to provide qualitative and quantitative perspectives on the skin-to-skin facilitating device. Mixed methods will facilitate data collection that explores the holistic effects of the skin-to-skin device in keeping with midwifery's philosophy of holistic care (International Confederation of Midwives 2014). A mixed method approach bridges the dichotomy of positivistic stance within the natural sciences and the various qualitative paradigms within social sciences (Bowling 2002), much like midwifery intersects the bio-medical and social health model (Cluett and Bluff 2000).

Pragmatism best facilitates the most appropriate choice of methods by prioritizing the research question, and the most pragmatic techniques to answer it (Doyle et al 2009). This research requires data regarding measurable health outcomes such as thermoregulation as

well as qualitative perspective on subjective experiences of the health intervention. Therefore, it is necessary to work within a methodological paradigm that recognizes the importance of answering the research question, rather than unnecessary focus on epistemological stance (Bowling 2002).

The research consists of three phases, which will be undertaken consecutively, each addressing different research outcomes. Phase one consists of the pilot study; direct researcher observation of the facilitating device being used by mother-infant dyads.

Phase two involves randomizing the consenting participants into an intervention and control arm, and using the Snuby® as the intervention. Phase two will collect data on infant feeding choices, skin-to-skin contact frequency and duration, neonatal temperature, behaviour, and weight. Following the six week study, a semi-structured interview will be coordinated by the chief investigator in the participant's home, to collect data on maternal experience of feeding, bonding and skin to skin contact.

Phase three consists of collecting the clinical midwives' perspective by using a questionnaire to record their views on the Snuby®'s use in the inpatient setting, and a follow-up focus group for more in depth exploration into the Snuby®'s perceived clinical value.

The pilot study and main research study will take place within an NHS Trust in the West Midlands area. The West Midlands locality has a higher than national average SIDS rate (ONS 2015), making it ideal to trial a healthcare intervention which may positively affect risk factors for SIDS, such as neonatal temperature fluctuation and non-breastfeeding status (Goldwater 2011). The local demographic holds a 'super diverse' population, largely representative of the different social and ethnic variation throughout the United Kingdom (Birmingham City Council 2013). By using a sample of this population, the results will have greater applicability within a wider national context, and better represent the population of the United Kingdom.

Phase One

The pilot study will involve trialling the Snuby® at the pilot participant's home with the chief investigator present. The CI will provide a safe usage sheet for the SSC facilitating device, a data collection sheet, a temperature taking 'how-to' sheet, and an electronic axilla thermometer.

The CI will observe the participant using the device and taking and recording the baby's temperature before usage and 30 minutes into usage of the device. Any initial temperatures suggesting a fever (temperature exceeding 37.5°C) will be excluded from the study as this may suggest an unwell baby. As the CI will be present, this will be explained to the mother prior at the consenting stage, and then discussed again following measuring the temperature. In this case, the mother will be informed to contact a health care professional via NHS 111 and will be excluded from the study. Should the initial temperature be within normal parameters (36.5°C – 37.5°C), the infant will be eligible for usage of the device. The second temperature will be recorded after 30 minutes in the device. Details on actions regarding temperatures inside and outside of normal parameters can be found on the pilot study and main study information sheet.

The CI will use a checklist to record whether the participant used the device as instructed, took the temperature correctly, and used the data collection sheet correctly. This will act as a validator for the information and how-to sheets prior to phase two of the study where participants will use the device unobserved by the CI. Any verbal feedback regarding usage of the device will be documented in the CI's field notes with the participant's consent, and simple word repetition analysis applied to identify any issues or adjustments required of the device, information sheets or data collection tool prior to phase two of the study. Should the Snuby®, data collection tools or user guidance require any amendment, necessary ethics re-approval will be sought by the university and NHS Research Ethics Committee (REC) following the minor or major amendment process as applicable.

Following usage of the device, the CI will take the data collection tool back to the secure office at Birmingham City University. The data will be stored in a locked assigned cabinet prior to and following analysis.

Phase Two

Once recruited, with their informed consent, the participants will be randomized to either the intervention or control group using computer-generated random number allocation inside sealed opaque envelopes. This will avoid selection bias and reduce the potential effect of confounding variables (Bowling 2002). There is no possibility for participant blinding, as the intervention group will be issued with the Snuby®. Each participant will be allocated an identifying number with which the data they generate will be matched to. There is no possibility for researcher blinding as the chief investigator will be having weekly telephone conversations with phase II participants as interim data analysis measures to identify any issues with the Snuby®. To conduct the qualitative aspect of the study, there will be no researcher or participant blinding due to the open nature of semi-structured interviews conducted to investigate the perceived value of the SSC facilitating device.

Questionnaires

Once randomized, a closed-question questionnaire will be used to collect data on skin-to-skin contact intentions, as well as comparable characteristics such as self-defined socio economic standing, maternal age, ethnicity and parity. Follow-up questionnaires will be used at three days or day of discharge from hospital care (whichever sooner), one week, and then weekly intervals until six weeks postnatal to record infant feeding choices and time spent skin to skin for both the intervention and control group.

These questionnaires will be individually dated for each participant to maximize the ease of data collection. The questionnaires will be used to collect data on infant feeding choices and support, and skin-to-skin contact and neonatal weights as recorded in the Child Health Record. This will maintain adherence to the exclusion criteria of neonatal weight below 2500g, exceeding 6000g or dropping two growth centile throughout the six week duration.

On each weekly questionnaire, there is a small free text box for participants to note down their general thoughts on conducting skin-to-skin contact that week. This provides the opportunity for qualitative feedback in relation to each week of the postnatal period. The box aims to hold around 50-70 words of hand-written text.

Following completion of the weekly questionnaire booklet over the six weeks, participants will return their questionnaires to the researcher when they visit to conduct the semi-structured interview

Each participating dyad will be contacted via telephone on a weekly basis for the six weeks of their involvement of the trial. This is to provide the opportunity to answer any questions regarding ongoing usage of the Snuby® or conventionally facilitated skin-to-skin contact, and verbally confirm ongoing participation. Regular contact with participants from a consistent member of research staff, in this case the CI, has been found to significantly reduce post randomization attrition rates in intervention based research (Karlson and Rapoff 2008). The telephone calls will be structured through a topic sheet, including incidence of temperatures outside of the normal range, baby weight outside of study parameters, health concerns of mother or baby that are outside of study parameters, and any concerns completing the data collection sheets. This acts as a weekly interim risk assessment for safe continuation in the study.

The chief investigator will also keep a record of any temperature fluctuations outside of the normal range through weekly telephone conversations. This ensures any concerns with neonatal temperature fluctuation will be recognized in order to re-examine the ethical issue of continuing the study should either the intervention or control group demonstrate a significantly stronger positive or negative outcome. Should this be the case, the academic supervisor of the chief investigator will be contacted within 24 hours to review the raw data and seek input from Research Ethics Committee at Birmingham City University.

The researcher will make a maximum of three attempts per participant in one week for a weekly telephone conversation, and will document their preferred time (morning, afternoon, evening) to be contacted once consented for the study. A log of these attempted and completed phone calls will be recorded in Microsoft Excel, password protected on private work computer.

Temperature Charts

Skin-to-skin contact is already used as a first choice approach in stabilizing neonatal temperatures within clinical maternity settings, which is confirmed by neonatal axilla temperature monitoring by staff (NHS Trust Withheld 2015). Participants will be trained on

how to collect neonatal axilla temperatures safely and simply by the use of the how-to sheet used in phase one and phase two of the study, as well as being provided with the normal parameters for neonatal wellbeing and appropriate actions for abnormal neonatal temperatures in the same data collection pack.

Neonatal axilla temperatures will be recorded when commencing skin-to-skin contact and following 30 minutes of skin to skin contact with or without the use of the Snuby® garment. The temperature will be taken by the parents with an electronic axilla thermometer, resulting in minimal invasiveness on the neonate. Such details on temperature parameters are included on the information sheets provided to all participants at the beginning of the study. These include signposting to NHS 111 telephone service and medical help should the baby have a temperature over 37.5°C. Should the initial temperature be within normal parameters (36.5°C – 37.5°C), the infant will be eligible for usage of the device. The second temperature will be recorded after 30 minutes to ascertain any differences in Snuby® facilitated and conventionally facilitated skin-to-skin contact on neonatal thermoregulation. The participants will also be informed verbally prior to commencing active participation and in writing that they should contact their community midwife or doctor with any health concerns, including hyperthermia or hypothermia. Appendix 1 flowchart demonstrates all potential neonatal temperature outcomes, and a clear pathway to be followed.

Semi-structured interviews

Once the six week period is completed, phase II participants will be invited to participate in a semi-structured interview to collect qualitative data on their experience of skin to skin contact. A list of topics will be used by the chief investigator to structure the interview, which will be slightly different for the intervention and control group participants to adequately reflect their experiences with or without the Snuby® device. For the intervention groups, the topic guide will include: Snuby®'s ease of use, its perceived value, its effect on bonding, its effect on breastfeeding, comparison to conventionally facilitated skin-to-skin contact, and other views. For the control groups, the topic guide will include: ease of skin-to-skin contact, perceived value of SSC, effect on breastfeeding, effect on bonding, and other views. The themes of manageability, comprehensibility, and meaningfulness (Antonovsky 1979) will be explored in the interviews.

Prior to commencing the interview, participants will be informed about maintaining privacy and confidentiality: theirs or their baby's names will not be used at all in the research publication or dissemination to protect their identities, their comments will instead be attributed to pseudonyms. The chief investigator will explain that not everything said will be published, and will explain the research's dissemination strategy (see page 26).

These interviews will be electronically audio recorded and transcribed following verbal and written consent on the informed consent form (ICF). Thematic analysis will be used to analyse the raw data, supporting by NVIVO software (QSR International 2016).

These interviews will take place at the participant's home. Interviews will be scheduled for a mutually convenient time and date. Participants will have the option to withdraw prior to or during the interview process.

For phase III of the study, a questionnaire will be sent to all eligible midwives that have worked with the Snuby® device on the co-located or standalone birth centre, labour ward and postnatal ward. This online questionnaire will be hosted by Bristol Online Survey, also used to facilitate data analysis. The link for the online questionnaire will be emailed to the eligible midwives' NHS email addresses. This questionnaire includes accepting or declining further participation in a focus group. Those that answer 'yes' for further participation will be contacted via the CI to invite them to participate in a focus group. Focus groups will be conducted within the NHS maternity unit. Informed consent will be sought and documented via the informed consent form signed on attendance of the focus group, prior to participation. The questionnaire and focus group combined will provide an additional perspective on the value of the Snuby® when compared to conventionally facilitated skin-to-skin contact. A list of topics will be used by the chief investigator to prompt discussion on: ease of use, perceived clinical value, and ease of implementation of a skin-to-skin facilitation strategy in the hospital environment.

The qualitative data from the postnatal participants and from the midwives will then be triangulated to provide a rounded account of the Snuby®'s value in a variety of settings from differing but relevant perspectives.

Study Management

Supervision

Regular monthly supervision meetings will be held between the chief investigator (CI) and their first academic supervisor to monitor progress in recruitment, data collection, data analysis and dissemination. Additionally, joint academic supervisions between the CI, and their first and second academic supervisors will be held bi-monthly to monitor overall progress. Additional meetings will be scheduled as required, either by the CI, or their academic supervisors.

The CI will meet with their Supervisor of Midwives at the NHS Trust in which the study is being held prior to recruitment, and then at six month intervals through the study to ensure continued compliance with NMC guidance and provide an opportunity to reflect on and address any professional or ethical issues arising through the study. Due to uncertainty regarding the role of midwifery supervision, this plan is on the proviso that midwifery supervision remains comparable to the form it is currently operating in.

Data Collection and Storage

All data collection material, including ICF, codes, electronic recordings and transcripts, when not in use, will be stored in a locked cabinet in a locked office at Birmingham City University City South Campus. Access to this data will only be available to the CI and her academic supervisors.

Electronic recordings will be transcribed as soon as practically possible, then the recordings will be destroyed. Consent for transcription and destroying of recordings will be documented on the ICF. Electronic recordings will be stored on a private computer, which is password protected until transcription.

Phase I data collection will take place at times mutually convenient to the CI and pilot participant at the participant's own home. The CI will operate under the NHS Trust's Lone Working Policy (NHS Trust Withheld), and use her electronic work calendar to notify her academic supervisor of her home visits, including date, time, and expected duration of visit. These addresses are already accessible to the community midwifery team who will be providing the usual community postnatal care in this period, therefore personal data will not

need to be shared further. The academic supervisor will be able to contact the NHS trust should they have any concerns about the chief investigator's safety.

Data collection for phase three of the study will take place between 7:30 – 20:00 at the NHS hospital site. These hours are selected to cover the day shift period, where facilities to conduct the focus group will be available. Data storage between the NHS hospital site and the University will be in a securely fastened bag labelled with 'private and confidential' and return details to Birmingham City University. The bad will be transported in a locked car immediately after its collection, in order to be stored as detailed above.

Study Duration

February-March 2017	Phase one recruitment of pilot participants (n=10) at 36-38 weeks gestation.
March-April 2017	Phase one trial of pilot participants that birth >2 weeks following consideration of participation and birth between 38-42 weeks.
April 2017- May 2017	Phase I preliminary data analysis. Phase two recruitment (n=184) and trial.
May 2017 – April 2019	Phase two recruitment is ongoing throughout this period whilst the data collection is taking place due to the nature of the window of consent in terms of pregnancy gestation.
May 2019 – August 2019	Phase II preliminary data analysis.
August 2019 – September 2019	Phase three recruitment (n=115) and data collection.

October 2019 – February 2020	Data analysis, interpretation and dissemination of findings.
February 2020	End of study.

Selection and Withdrawal of Participants

Selection

Recruitment of participants will take place at Children's Centres and General Practice (GP) surgeries within the catchment area of the NHS hospital. Posters will be circulated in the GP surgeries, Children's Centres, antenatal ward, co-located and standalone birth centres and antenatal clinic of the NHS Trust.

A small sample of pregnant women will be recruited for the phase I study through dissemination of the study by community midwives in the Trust. Following initial risk assessment of the device at Birmingham City University, phase I will provide an opportunity for formative feedback from the participant population as to any necessary alterations to the guidance provided on safe usage of the device and the data collection sheets.

Ten phase I participants will be recruited through their existing community midwife appointments at 36-38 weeks gestation. Community midwives will provide the PIS with written information on the study regarding the study's aims and objectives, method, consent process, data collection and storage procedures, as well as the CI's contact details for any questions, queries or concerns. Should the potential participants be interested, their contact details will be passed to the CI with informed consent, and the potential participants will be contacted via phone to further discuss the study and answer any questions they may have. Should the potential participants wish to continue in the study, they will be provided with the CI's work research mobile number to contact the CI once they have given birth and have been discharged from the inpatient setting.

When the phase I participants contact the CI following the birth, the CI will take a history of the obstetric, birth and neonatal outcomes, including mode of birth, weight of baby and any ill health to assess the participating dyad's eligibility for the pilot study. The CI will

then attend the eligible participants' home within the initial six week postnatal period at a mutually convenient time and date.

For phase II, participants will be recruited via their existing community midwife appointments in local G.P. surgeries and SureStart Children's Centres, as well as within the maternity unit of the NHS Trust. Women eligible for participation will be provided with written information regarding the study's aims and objectives, method including randomization, consent, data collection and storage procedures, as well as CI's contact details for any questions, queries or concerns. Women will also be recruited on the postnatal wards and birth centre at the hosting NHS Trust by the CI. For those recruited through their community midwife, community midwives will gain permission to pass the potential participants' contact details to the CI, who will contact the potential participants via phone to further discuss the study and consent process. Women will have a minimum of 24 hours to consider participation. There is no maximum consideration time, as long as the woman remains within the eligibility criteria for the study. Women may wish to take more than 24 hours to consider, or a consenting appointment may require more than 24 hours to schedule.

Following any adaptations made after the pilot trial, participants will be recruited from the NHS Trust as detailed above. Statistical support from an external mathematician (Harry Reynolds at University of Oxford) has been sought by the chief investigator. Recruitment of 184 participants will occur, randomized into two equal groups. This sample size is based on meta-analysis of breastfeeding rates with a similar intervention and control procedure (Conde-Agudelo and Díaz-Rossello 2016). By working alongside community midwives within the Trust, recruitment will continue until the desired sample size is reached.

Phase III of the study will involve recruiting midwives working in the inpatient setting for a focus group. This stage of the research will occur after the mother-infant dyad data collection so the midwives have been exposed to the intervention prior to gathering their feedback. The focus group will be held in the hospital setting so as to maximize ease of access to the focus group, and to ensure least disruption to the midwives pattern of work.

Inclusion and Exclusion Criteria

The sampling for both the pilot study and main study will include pregnant women aged 16 years old or over, with or without a partner, with a singleton pregnancy expected to have a term birth, and healthy neonatal and maternal outcomes. Women aged 16 or 17 years old will be eligible to participate should they be able to understand the purpose, benefits and risks associated with participation, as well as what participation involves, and how to withdraw from the study, should they wish to. Their understanding will be assessed by the chief investigator at the time of consent using a Gillick competency framework, and through ongoing weekly conversations during participation. Women in this age group are included to address the under-representation of young women in research (Frew et al 2014), and create an inclusive sample of pregnant women across traditional barriers of age and socio-economic status. The Mental Capacity Act (2005) will also be used by the chief investigator to assess all participants' ability to understand and process information, and give their ongoing consent to participate in the study.

Maternity participants aged under 16 years of age are excluded from this study as their disclosure of sexual relations around the pregnancy conception presents a significant safeguarding issue for the researcher to address. This disclosure also has the potential to negatively affect the researcher-participant dynamic, and limit the participant's capacity to give their consent when particularly vulnerable to coercion.

Women will be recruited throughout the pregnancy and immediate postnatal period. This will exclude women with multiple pregnancies, significant morbidities where they may not be expected to be well enough to care for their baby after birth, or any women who labour and birth prematurely, before 37 completed weeks of gestational age. Women with a body mass index of 18-30 inclusive at their booking appointment will be eligible to ensure comfortable fit of the Snuby® garment. Pregnancies with expected fetal anomalies, or neonatal diagnosis of morbidities where the neonate will require care deviating from the routine postnatal and neonatal care guidelines used within the NHS Trust's postnatal ward will not be eligible for participation.

Following birth, participating dyads will be re-evaluated with further criteria, excluding those who have not had a vaginal birth to ensure comfort and ease using the device. Babies with a birth weight below 2500g will be excluded due to the design and measurements of the device to ensure safe usage. The device is designed to accommodate babies up to 6000g, which includes 95% of infants at six weeks of age (World Health Organisation 2004). Should neonates drop two centiles on their customized child health record charts ('red books'), they will no longer be eligible for continuing participation in the study. Neonates receiving intravenous antibiotics or phototherapy will not be eligible for participation, as these interventions may confound data collected on neonatal thermoregulation. These criterion create a population of healthy, term neonates whose results can be used with the greatest population applicability. Due to the data collection method, women will be required to have basic literacy in English in order to participate with the study. Potential participants will be informed of all of this criteria prior to consenting to the research, so they understand the dynamic nature of their consent due to the unpredictable nature of pregnancy and birth.

Participant Withdrawal

On the PIS and ICF, participants will be informed that they are free to withdraw at any time without the need to provide any explanation, and that this will not affect the care they receive or are entitled to, nor will it affect NHS staff's employment rights. Participants will also be made aware on the ICF that any data they provide may not be able to be withdrawn or erased from data analysis due to the nature of anonymizing data, particularly in transcription of raw data from focus groups, and may still be used in final analysis. However, if they have not yet partaken in the focus group, the participant's consent will be sought to use the existing data they have supplied. This will be documented on the 'participant withdrawal' form. Should they decline existing data usage, the existing data will be erased as per their wishes. The participant withdrawal form will be filed alongside the initial informed consent form.

Informed Consent

The participants will also be informed about the dynamic nature of consent, and their ability to withdraw from the research at any time without necessary explanation or affecting their health care provision. Once verbal consent is initially gained, the participant will be sent two

copies of the consent form via post with a self-addressed envelope to return one copy to the CI, and keep the second copy for their reference. These will also be signed by the CI to demonstrate the participant's ability to give informed consent has been assessed and deemed satisfactory. Alternatively, the CI will meet with the mother at her next maternity appointment to discuss the study in person then gain informed consent if the mother wishes to participate.

There will be a minimum period of twenty four hours consideration period prior to providing written consent for the study to promote maternal autonomy and ensure consent is fully informed. The CI will work within the Mental Capacity Act (2005) and local Trust guidelines to ensure that each participant has the ability to give their consent to participate. This assessment of ability to consent will be dynamic and ongoing throughout the research, as opposed to a one-off event (Dimond 2014). The chief investigator has completed Good Clinical Practice training e-module, and is completing the face-to-face workshop prior to recruitment to ensure competence in research practice. The consideration period of 24 hours is a minimum time period, therefore women may take longer to consider if they wish, as long as long as they remain in the eligibility criteria.

Participants will also be informed should an amendment be made to the study regimen, and an amended consent form will be issued to ensure their informed consent is gained to continue participating in the study.

Should a participant lose the capacity to consent, their participation in the study will cease immediately. Existing data will be erased as they may be unable to consent to its use. The CI will contact the relevant lead healthcare professional within 24 hours to inform them of a change in capacity which may have immediate effect on healthcare provision.

Data Access and Follow Up of Participants

The chief investigator will have access to participant maternity records through an electronic login issued with a Research Passport by the NHS Trust. Access to electronic patient maternity records is password protected, with a mandatory password change six weekly.

Consent to access electronic patient maternity records is reflected in the informed consent forms for phase I and II of the study. The informed consent forms are designed to provide accurate information on what information the researcher will be accessing, and why.

Electronic maternity records will not be accessed in order to recruit participants. Access will only be used by the researcher to confirm eligibility following consent to review electronic records.

The researcher will continue to confirm participant eligibility for the study by accessing particular information in the electronic maternity records. Antenatally, this will involve screening for child protection concerns relevant to this pregnancy, and accessing the midwifery risk assessments to assess eligibility.

The researcher will access the electronic records, as entitled through the research passport at the NHS Trust, at 40, 41 and then 42 weeks of pregnancy, prior to contacting the participant, if they have not yet informed the researcher of their birth. Prior access to the records will allow the researcher to identify any adverse and unexpected pregnancy outcomes, such as a stillbirth or neonatal death, avoiding re-traumatizing the participant.

Should such an event be identified by the researcher, the participant will be removed from the study, and any antenatal data collected will be destroyed and not used in the research.

If the records state that the participant has given birth vaginally with a healthy infant, and continues to meet the inclusion criteria, the researcher will then contact the participant to enquire whether they wish to continue in the research study. A maximum of one follow up telephone call will be made the day after, if the researcher does not get an answer on the first call.

If the researcher cannot communicate with the participant after the two attempts, they will be removed from the study unless they contact the researcher.

Researcher Considerations

As the chief investigator is a registered midwife, and a PhD researcher, there has been significant consideration into the ethical and professional issues relating to this dual role. As a qualified health professional, the CI has a professional duty to report and escalate safeguarding concerns (Department for Children, Schools and Families 2010). When working with the mother-infant dyads, the CI may be exposed to cases involving mistreatment, abuse or neglect of the infant participating, or a sibling or vulnerable family member. Although the CI is not

providing clinical care for the participating dyad or wider family, safeguarding concerns will be reported back to the family's allocated community midwife, general practitioner or health visitor (dependent on care episode) and the lead safeguarding midwife within 24 hours, with supporting documentation provided as requested by the health professional referred to. Should these safeguarding concerns require any further action, the CI will contact the lead safeguarding midwife and her named Supervisor of Midwives for support and guidance. Participating mother-infant dyads will be made aware of the CI's duty to report safeguarding concerns through the PIS, and will consent to this via the ICF.

The CI also has a duty of care to women as part of her midwifery registration. The Nursing and Midwifery Council (NMC) recognize that a midwife must adhere to the professional code of conduct whether working clinically or in midwifery disciplines such as research (NMC 2015). As a researcher, the CI will not be equipped to work clinically with the participating dyads by means of access to necessary medicines and technology. Therefore, should the CI recognize a complication or case requiring medical review or clinical intervention that has not already been acted upon, she will contact the relevant healthcare professional should the participant be unable to do so. For example, the CI will signpost the participant to her community midwife, general practitioner, breastfeeding support worker etcetera, but if the participant is too unwell to access this support, the CI will contact the relevant professional for her to ensure timely and appropriate care is received (NMC 2015), and provide emergency care within her means as required by the NMC (2015).

Health promotion is a significant aspect of a midwife's role, aiming to reduce health inequalities, improve population health and maximize the wellbeing of families (Department of Health 2005). The midwife has a professional duty to promote positive behavioural changes and actions, such as skin to skin contact and breastfeeding, as stipulated through national care pathways (NICE 2015). The midwife's promotion of breastfeeding and skin-to-skin contact (NICE 2015) may sit at odds with the researcher not promoting one infant feeding or neonatal care choice over another to avoid bias in the study. This will be addressed by all women receiving usual health promotion from their community midwives, inclusive of the benefits of skin-to-skin contact and breastfeeding. This allows the CI to conduct the study with neutrality, in the knowledge that participants have all received the

same health promotion information for them to make informed decision on their participation in the research, and infant feeding and neonatal care choices.

Research is integral to the development of evidence based care (Titler 2008), as required by the Nursing and Midwifery Council (2015). Such research is valued in midwifery as its contribution to safe and effective care has been demonstrated to improve maternal and neonatal health outcomes (Department of Health 2010). However, when recruiting participants for the study, the researcher must remain neutral to decisions to decline or withdraw from the research study, despite knowing that participant attrition rates may negatively affect the validity of research outcomes (Barry 2005). To bridge this dichotomy of stances, the CI acknowledges their own positive stance to research participation, but acts under the ethical notions of autonomy and choice, central to both research and midwifery (Ledward 2011, Ghooi 2011). This values the potential participant's decision to determine their own care pathway, with or without participating in research, and recognizes that individual decision are personal, complex, and do not need justification for validity.

Finally, there is potential for the CI to have an unwarranted bias towards the perceived success or implementation of the Snuby device, which could create a conflict of interest or bias the research method, data collection, analysis or dissemination of the research outcomes. To address this, the CI has had minimal input in the development of the device, and has no financial involvement in the potential success of the Snuby® device. The CI neither owns rights to the Snuby®, nor has any involvement in potential implementation following the research study.

Outcomes and Statistics

Data captured through this research will contribute to many aspects of research surrounding neonatal physiology and carer-infant holistic wellbeing. Firstly, the Snuby® user will self-report how often and for how long the Snuby® is in use using a data collection chart provided to them. Quantitative data will be collected in the form of neonatal temperature measurements prior to using the Snuby® or commencing unfacilitated skin-to-skin contact and 30 minutes in to skin-to-skin contact. The temperature readings collected by the mothers will provide comparable data sets for neonates receiving conventionally facilitated skin-to-skin contact and Snuby® facilitated skin-to-skin contact. To promote participant autonomy, each mother-infant

dyad may choose to conduct skin-to-skin contact at different frequencies and for different durations in the six week postnatal period. Therefore quantities of neonatal temperature measurements are impossible to forecast. However, when conducting conversations with women who have given birth in the past year as part of Patient and Public Involvement (PPI), estimates were gathered of using the device approximately twice per week. This would result in twelve paired temperature ranges per participant over the six week postnatal period.

The data will then demonstrate what, if any, effect the device has on neonatal thermoregulation, and contribute to a valuable evidence base for practitioner use and hospital policy implementation regarding best practice for neonatal thermoregulation.

Data will also be collected regarding the mother's experience of parenting whilst using the Snuby®. Semi-structured interviews following the six week trial period will provide qualitative data on ease of usage, comfort, and perceived value relating to bonding, infant feeding and any other feedback felt necessary from the study participants. This data will give a preliminary insight into the device's holistic value, and its strength or weakness as a tool to be implemented.

This service user perspective will contribute significantly to a neglected area of research within midwifery – a woman-centred perspective of healthcare interventions, valuing the woman's lived experience surrounding the intervention, as well as the quantifiable outcomes of the intervention itself.

Following transcription from the electronic recordings, data will be reviewed. Notes will be taken as the CI identifies initial themes in the qualitative data. Data will be reviewed by the CI's academic supervisors to ensure accuracy, and corroborate findings. The data will then be coded and grouped into themes. These themes will be compared, and analysed using computer software. A written interpretation of these findings will be produced, as well as visual display techniques on NVivo software (QRS International 2016) to explore the significance and frequency of key themes.

Methodological triangulation (Denzin 1978) will increase validity of the research findings, as the multiple methods of qualitative data collection from the maternity and midwife focus groups will be collated into more generalizable findings on user experience of the intervention. This will be through qualitative coding (Bowling 2002) as detailed above.

Between-approach triangulation (Cluett and Bluff 2000) will then combine the quantitative and qualitative aspects of the research to formulate applicable knowledge to guide possible implementation or adaption of the device within and outside of a clinical maternity setting. Convergence coding matrix (Farmer et al 2006) will be used to explore the connections between the types of data and collate findings into a more cohesive, holistic interpretation. Such triangulation will provide a route to understand the health care intervention in its full complexity (Mertens and Hesse-Biber 2012), in keeping with the pragmatic methodological underpinnings of addressing the research aim firstly, and midwifery's position at the holistic social, medical and psychological intersect of wellbeing (International Confederation of Midwives 2014).

Ethical Considerations:

Category C proposal (Birmingham City University 2015)

Involving practicing midwives within NHS clinical research

Nursing and Midwifery Council (Midwives) Rules Order of Council 2004 requires all clinical trials involving practicing midwives within the NHS to undertake a Research Ethics Committee (REC) for ethical approval.

Using participants who are unable to consent/ children

The intended research includes newborn infants as participants, who are unable to consent or assent. Therefore, their primary care giver (most often their mother) will give informed consent for the parent-infant dyad. There are no anticipated harmful effects of the research, and potential lifelong implications for better health outcomes and relationship bonding if within the intervention group. However, potential risks have been identified and considered in the drafting of the research proposal.

Should the Snuby® be used by somebody other than the participating dyad, there is a risk that the user will not adhere to the safe usage information, and put the neonate at risk of

falling, smothering and overheating. This could occur if the infant is not positioned facing the mother or on its side, or the Snuby® is used when not supine, semi-recumbent or sitting position. To minimize this risk, the importance of safe usage principles will be outlined when the participant consents to the study, with written information for the participant to retain, and key safety principles revisited intermittently through the weekly telephone conversations between the CI and participants.

Skin-to-skin contact may affect a neonate's temperature, for example mother-infant skin-to-skin contact (MISSC) is used to correct mild neonatal hypothermia in some NHS Trusts (NHS Trust Withheld 2015). However, as the Snuby® has not been researched yet, its effect on neonatal temperature regulation in comparison to conventionally-facilitated SSC is unknown. To minimize the risk of any harm occurring through overheating in the Snuby® or losing excessive heat, neonatal axilla temperature monitoring will be conducted by the mother prior to and after 30 minutes of MISSC. A flowchart has been developed to identify abnormal neonatal temperatures, and inform parents in the home setting of an appropriate pathway for correction of neonatal temperature and medical assistance via NHS 111 or presenting at a walk in centre or hospital (see appendix 1).

There is also a risk of mothers partaking in unsafe sleeping practices linked to Sudden Infant Death Syndrome (SIDS) with the baby in the Snuby® should they fall asleep in an armchair or sofa. However, there is no rationale or evidence to suggest use of a facilitating device is more unsafe than having the baby held in the mother's arms. On the contrary, the baby may be less at risk of slipping down the side of armchairs or sofas if supported in a device. In addition to this, all participants will receive standard information from their community midwives on reducing the risk of SIDS as part of usual postnatal care. Participants will also be advised via their study information sheet that they should not use the Snuby® if they feel especially sleepy, have been drinking alcohol, smoking, or taking medication which makes them sleepy.

Working within the NHS

Care provision and standards will be completely unaltered should a potential participant decline or withdraw their consent for the research at any point. This will be made explicit several times in the consenting and research process to ensure ongoing, active

consent. All people involved within the research will be fully authorized to work within a research capacity within NHS trusts.

Enhanced disclosure certificates from the Disclosure Barring Service have been obtained with Research Passports at the NHS trust to ensure participant safety and security. The CI already has an employment contract at the Trust including an enhanced disclosure certificate, and is qualified to work with infants.

Diminishing parenting choice and capacity

In order to avoid diminishing the choices of new parents with random allocation, all pregnant women are educated regarding the benefits of skin to skin contact and how to facilitate this with no equipment necessary. This education takes place both within the community midwife setting in pregnancy and immediately after birth. This ensures all women whether participating in the intervention, control group, or not at all have access to skin to skin contact with their newborn and fully understand the benefits. Parents have the opportunity to opt out of the research at any point should they wish to without their care being affected.

Protecting patient anonymity and confidentiality

All data will be stored appropriately using password-protect safeguards. All data will be stored in keeping with the Data Protection Act (1998). Participants will be made aware of how and where their data will be stored, and what they should do should they want their data erased or withdrawn at any point. Participant and participating dyad identification numbers will be allocated at the consenting process. This avoids any unnecessary use of personal identifiable details on data collection tools. The record of identifiable details linked to identification numbers will be kept electronically, and password protected, accessible only by the chief investigator.

Device safety

The device will be trialled in phase I with the chief investigator overseeing usage to ensure absolute safety and identify any problems needing rectifying before the device is trialled on study participants without direct supervision. Primary carers will be educated about key components of safe usage including baby positioning and temperature monitoring,

temperature parameters, and how and when to seek help should they feel the baby was unwell, even if unrelated to trial.

The Snuby® will be allocated one per eligible dyad. For Phase I dyads, the Snuby® will be collected in immediately after the episode of data collection. For Phase II dyads, the Snuby® will be collected in following the six week postnatal period. The Snuby® can be machine washed and reused by the dyad during this time. It is the responsibility of the researcher to collect in all Snubies® once the data collection episode is completed. The used Snubies® will be stored in carrier bags marked with the participating dyad's ID number in secure premises with the research documentation at Birmingham City University. The Snubies® will not be disposed of until data analysis has been completed to identify any anomalies, adverse outcomes or trends which may concern the manufacturing process.

Researcher- Participant Power Dynamic

To address the potential hierarchical power dynamic between participant and researcher, and possibility of implicit coercion to participate, informed consent will be seen as a dynamic process which can be withdrawn at any time. The participants will be informed that they can contact their midwife, who is unconnected from the trial and impartial to the trial outcome, with any concerns. The CI is female, which negates a gender power dynamic, and is experienced working with women within a healthcare environment.

Following the focus groups, participants will be offered the opportunity to self-identify their own key themes that have emerged from the topic prompts. This respondent validation (Torrance 2012) will both improve the validity of the research, and help address the researcher-participant power dynamic.

Audit and Quality Assurance

Insurance and Indemnity

Research Passports in the NHS Trust will be sought for the chief investigator, which will entitle the researcher to indemnity insurance issued under the cover of HSG 96(48), as required by the Nursing and Midwifery Council (2016). There is no specific compensation procedure for the study, but participants may access existing NHS complaints procedures.

Study Conduct

Various aspects of the study will be available for audit through the NHS Trust's Research and Development Department, and through the sponsor. This may include certificates of staff training, written permission, retention of essential documents, adherence to policy and procedures, and the accountability of study materials.

Study Data

Data may be monitored by a designated nominee of the sponsor. This may include data confirming participant consent, data storage and transfer, source data verification, and local quality control checks and procedures. Study data and evidence of monitoring and systems audits will be made available for inspection by a research ethics committee as required.

Record Retention and Archiving

In accordance with Birmingham City University's Research Code of Conduct, the CI will maintain all records and documents regarding the conduct of the study. These will be retained for at least 5 years or longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the CI on behalf of the Sponsor shall be finally archived at secure archive facilities at Birmingham City University. This archive shall include all study databases and associated metadata encryption codes.

Discontinuation of the Trial by the Sponsor

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

Statement of Confidentiality

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

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

Publication and Dissemination

Participants will be informed that the research will be disseminated to the participants once published, both through access to an electronic copy of a summary of the written thesis and through an private informal presentation and discussion group, both of which are entirely optional to receive or participate in.

The study will be presented as a thesis for a PhD from Birmingham City University. Elements related to the study, such as ethical considerations or components of the literature review may be published in paper or electronic open access journals throughout the study's duration. Publications into journals may also follow publication of the thesis.

At no point in the publication or dissemination will participants be identifiable in writing or verbally.

Patient and Public Involvement

Student midwives at Birmingham City University have contributed feedback to the research proposal, for which they are kindly thanked. Two members of the public who have received maternity care within the last year have also contributed their thoughts in the development of the research proposal and design of the Snuby® device. Midwifery lecturers at Birmingham City University and midwives at Birmingham Women's Hospital have provided professional critique of the research proposal including the research method.

Study Finances

The doctorate is fully funded by Birmingham City University, including course fees. No additional external funding has been received, but applications for funding to cover research expenses such as axilla thermometers will be sought from external grants, trusts and charities. This will not involve companies who promote breastmilk substitutes in adherence with the International Code of Marketing of Breast-Milk Substitutes (WHO 1981).

Participant Stipends and Payments

Participants will receive no incentives or financial stipends to participate in this research study.

Reference List

Antonovsky, A. (1979) Health, Stress, and Coping. San Francisco: Jossey Bass.

Barry, A. (2005) How Attrition Impacts the Internal and External Validity of Longitudinal Research. *The Journal of School Health* 75 (7) Pp. 267-70.

Birmingham City University (2015) *Guidance for Ethical Approval for Research Activity*. Available at: https://icity.bcu.ac.uk/Content/Document/RESEARCH-Ethics-Guidance [Accessed on: 05.05.16]

Birmingham City University (2016) Faculty Academic Ethics Committee: Participant Information Leaflets and Consent Forms - Supporting guidance for researchers and supervisors. Birmingham: Birmingham City University.

Bowling, A. (2002) *Research Methods in Health: Investigating Health and Health Services*. 2nd edn. Berkshire: Open University Press.

Cluett, E. R. and Bluff, R. (eds) (2000) *Principles and Practice of Research in Midwifery.* London: Balliere Tindall.

Conde-Agudelo, A. and Díaz-Rossello, J.L. (2014) *Kangaroo mother care to reduce morbidity and mortality in low birthweight infants*. Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD002771. DOI: 10.1002/14651858.CD002771.pub3

Data Protection Act (1998) London: The Stationery Office.

Denzin, N.K. (1978) *The Research Act: A Theoretical Introduction to Sociological Methods*. New York: McGraw-Hill.

Department of Children, Schools and Families (2010) *Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children*. (pdf) Available at: http://webarchive.nationalarchives.gov.uk/20130401151715/https://www.education.gov.uk/publications/eorderingdownload/00305-2010dom-en-v3.pdf [Accessed: 11.08.16]

Department of Health (2010) *Midwifery 2020: Delivering Expectations*. (pdf) Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216029/dh_119470.pdf [Accessed: 11.08.16]

Dimond, B. (2014) *Legal Aspects of Consent*. 2nd edn. London: Quay Books Provision.

Doyle, L., Brady, A.M., and Byrne, G. (2009) An Overview of Mixed Methods Research. *Journal of Research in Nursing.* 14 (2) Pp. 175-185

Farmer, T., Robinson, K., Elliott, S.J. and Eyles, J. (2006) Developing and implementing a triangulation protocol for qualitative health research. *Qualitative Health Research.* 16 Pp 377-394.

Goldwater, P. (2011) A perspective on SIDS pathogenesis. The hypotheses: plausibility and evidence. *BMC Medicine* 9 (64) DOI: 10.1186/1741-7015-9-64

Ghooi, R. (2011) The Nuremberg Code: A Critique. *Perspectives in Clinical Research*. 2 (2) Pp 72-76.

Health and Social Care Information Centre (HSCIC) (2012) *Infant Feeding Survey 2010*. Available through: http://www.hscic.gov.uk/article/2021/Website-Search?productid=9569&q=infant+feeding+survey&sort=Relevance&size=10&page=1&area=both#top [Accessed on: 04.05.16]

Kangaroo Mother Care (2012) *What is KMC?* Available at: http://www.kangaroomothercare.com/what-kmc-is.aspx [Accessed on: 17/03/16]

Karlson, C. and Rapoff, M. (2008) Attrition in Randomized Controlled Trials for Pediatric Chronic Conditions. *Journal of Pediatric Psychology.* 34 (7) Pp.782-793.

International Confederation of Midwives (2014) *Philosophy and Model of Midwifery Care*. [pdf] Available at: http://www.internationalmidwives.org/who-we-are/vision-mission/ [Accessed on: 04.05.16]

Ledward, A. (2011) Informed Consent: Ethical Issues for Midwife Research. *Evidence Based Midwifery.* Available at: https://www.rcm.org.uk/learning-and-career/learning-and-research/ebm-articles/informed-consent-ethical-issues-for-midwife [Accessed: 11.08.16]

Lidz, C., Meisel, A., Zerubavel, E. and Carter, M. (1984) Informed Consent: A Study of Decision making in Psychiatry. Available at: http://works.bepress.com/charles_lidz/81/

Lullaby Trust (2015) *Statistics on SIDS*. Available at: http://www.lullabytrust.org.uk/statistics [Accessed on 01/08/16]

Mahmood, I., Jamal, M., and Khan, N. (2011) Effect of mother-infant early skin-to-skin contact on breastfeeding status: a randomized controlled trial. *Journal of the College of Physicians and Surgeons – Pakistan.* 21 (10) Pp 601-605.

Manktelow, B.N., Smith, L.K., Seaton, S.E., Hyman-Taylor, P., Kurinczuk, J.J., Field, D.J., Smith, P.W., Draper, E.S., on behalf of the MBRRACE-UK Collaboration. (2016) *MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2014*. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester.

Metaconnects (2016) *Focus Groups as a Research Method: Hear From a Variety of Voices, Explore New Ideas, Gain Clarity and Draw Conclusions.* Available at: http://metaconnects.org/focus-conduct [Accessed: 10.08.16]

Mertens, D. and Hesse-Biber, S. (2012) Triangulation and Mixed Methods Research: Provocative Positions. *Journal of Mixed Methods Research.* 6 (2) Pp 75-79.

National Institute of Health and Care Excellence (NICE) (2015) *Intrapartum Care: Quality Standard*. London: NICE.

NHS Litigation Authority (n.d.) *NHS Indemnity.* (pdf) Available at: http://www.nhsla.com/claims/Documents/NHS%20Indemnity.pdf [Accessed: 10.08.16]

NHS Trust Withheld (2015) *Care of the Newborn*. Location Withheld: Trust Withheld.

Nursing and Midwifery Council (Midwives) Rules Order of Council (2004) c. 8. London: The Stationery Office.

Nursing and Midwifery Council (NMC) (2015) *The Code: Professional Standards of Practice and Behaviour for Nurses and Midwives*. London: NMC.

Nursing and Midwifery Council (2016) *Professional indemnity arrangement.* Available at: https://www.nmc.org.uk/registration/staying-on-the-register/professional-indemnity-arrangement/?_t_id=1B2M2Y8AsgTpgAmY7PhCfg%3d%3d&_t_q=indemnity+insurance&_t_tags=language%3aen%2csiteid%3ad6891695-0234-463b-bf74-1bfb02644b38&_t_ip=193.60.130.207&_t_hit.id=NMC_Web_Models_Pages_ContentPage/_9e531083-e411-40d8-931d-07511e909056_en-GB&_t_hit.pos=2 [Accessed: 10.08.16]

Office of National Statistics (2015) *Unexplained Deaths in Infancy , England and Wales*: *2013*. Available at:http://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/unexplaineddeathsininfancyenglandandwales/2015-08-19 [Accessed: 01/08/16]

QRS International (2016) *NVIVO software*. Available at: http://www.qsrinternational.com/product [Accessed on: 05.05.16]

Robiquet, P., Zamiara, P,, Rakza, T., Deruelle, P., Mestdagh, B., Blondel, G., Turck, D. and Subtil, D. (2016) Observation of Skin-to-Skin Contact and Analysis of Factors Linked to Failure to Breastfeed Within 2 Hours After Birth. *Breastfeeding Medicine* 11 Pp 126-132.

Royal College of Midwives (2012) *Evidence Based Guidelines for Midwifery-Led Care in Labour: Immediate Care of the Newborn.* [pdf] London: Royal College of Midwives. Available at: https://www.rcm.org.uk/clinical-practice-and-guidance/evidence-based-guidelines [Accessed on: 04.05.16]

Titler, M. (2008) *The Evidence for Evidence-Based Practice Implementation.* In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US) Chapter 7. Available at: http://www.ncbi.nlm.nih.gov/books/NBK2659/ [Accessed: 11.08.16]

Torrance, H. (2012) Triangulation, respondent validation, and democratic participation in mixed methods research. *Journal of Mixed Methods Research*. 6 (2) Pp 111-123.

UNICEF (2013) *The evidence and rationale for the UNICEF UK Baby Friendly Initiative standards. Standard Two.* London: UNICEF.

UNICEF (2014) *Building a Happy Baby*. (pdf) Available at: http://www.unicef.org.uk/Documents/Baby_Friendly/Leaflets/building_a_happy_baby.pdf [Accessed: 01/08/16]

UNICEF (2016a) Our History. Available at: http://www.unicef.org.uk/UNICEFs-Work/Our-history/ [Accessed: 03/08/16]

UNICEF (2016b) *What is the Baby Friendly Initiative?* Available at: http://www.unicef.org.uk/BabyFriendly/About-Baby-Friendly/What-is-the-Baby-Friendly-Initiative/ [Accessed: 01/08/16]

Valsangkar, B. (2015) *Accelerating Scale-up of Kangaroo Mother Care—What's Next for the KMC Acceleration Partnership?* Global Maternal Newborn Health Conference 2015. Available through: https://www.globalmnh2015.org/portfolio/accelerating-scale-up-of-kangaroo-mother-care-whats-next-for-the-kmc-acceleration-partnership/ [Accessed on: 04/05/16]

Vesel, L., Bergh, A.M., Kerber, K., Vasangar, B., Mazia, G., Moxon, S.G., Blencowe, H., Darmstadt, G., De Graft Johnson, J., Dickson, K., Ruiz Pelaez, J.G., Ritter Von Zylander, S., and Lawn, J. (2015) Kangaroo mother care: a multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy & Childbirth*. 15 (2) doi: 10.1186/1471-2393-15-S2-S5

Villalon H.U. and Alvarez P.C. (1993) Short term effects of early skin-to-skin contact (kangaroo care) on breastfeeding in healthy full-term newborns [Efecto a corto plazo del contacto precoz piel a piel sobre la lactancia materna en recien nacidos de termino sanos]. Revista Chilena de Pediatria 64 (2) Pp 124–8.

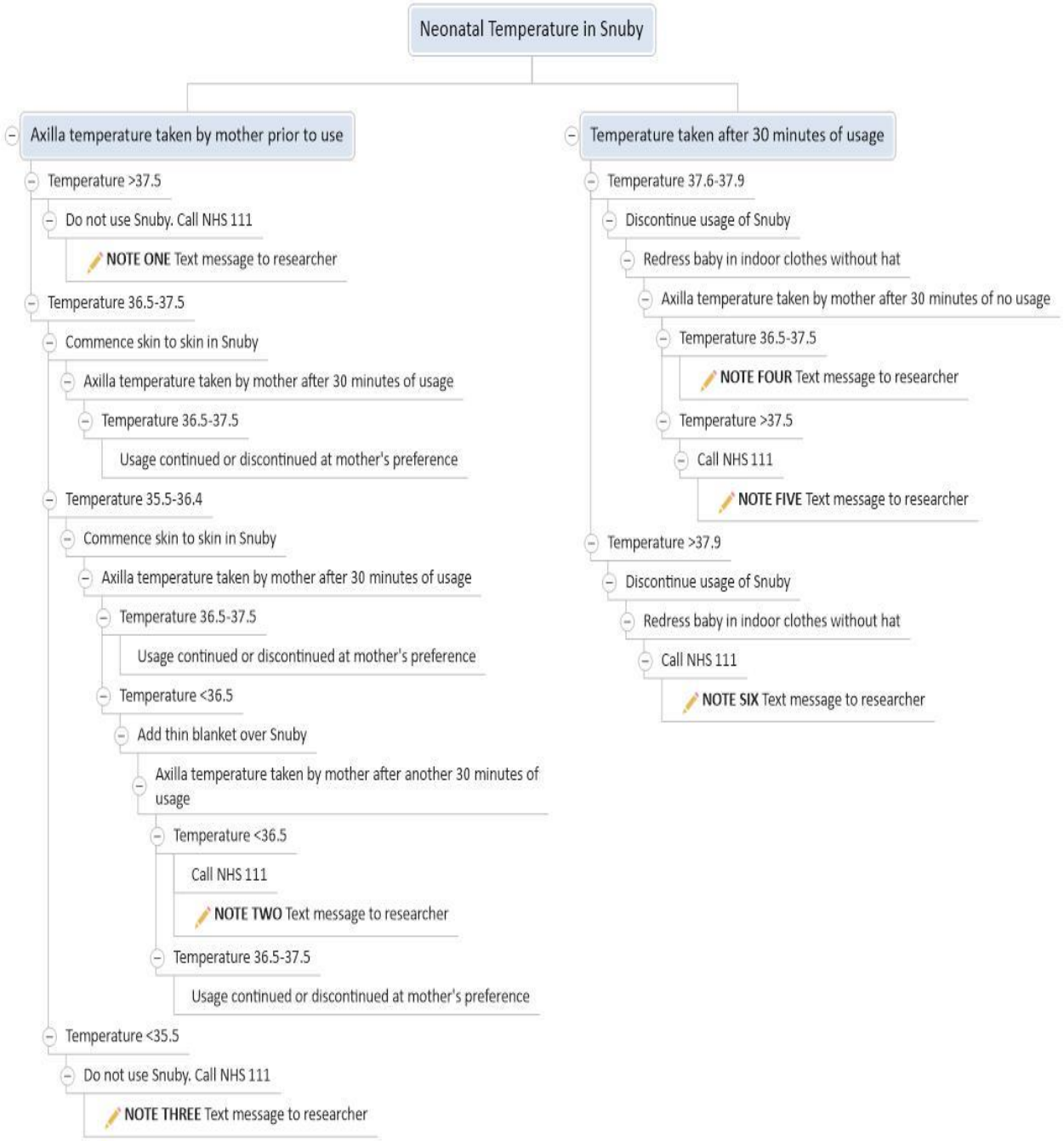
World Health Organisation (WHO) (2003) *Kangaroo Mother Care: A Practical Guide*. France: World Health Organisation.

World Health Organisation (WHO) (1981) *International Code of Marketing of Breast-Milk Substitutes.* Available at: http://who.int/nutrition/publications/infantfeeding/9241541601/en/ [Accessed: 11.08.16]

World Health Organisation (WHO) (2004) *The WHO Multicentre Growth Reference Study (MGRS): Rationale, planning, and implementation.* Available at: http://www.who.int/childgrowth/mgrs/fnu/en/ [Accessed: 10.08.16]

World Health Organisation (WHO) (1997) Thermal Protection of the Newborn: A Practical Guide. Available at: http://www.who.int/maternal_child_adolescent/documents/ws42097th/en/ [Accessed on 05.05.16]

Appendix 1


Neonatal Temperature in Snuby
Axilla temperature taken by mother prior to use
Temperature >37.5
Do not use Snuby. Call NHS 111
NOTE ONE Text message to researcher
Temperature 36.5-37.5
Commence skin to skin in Snuby
Axilla temperature taken by mother after 30 minutes of usage
Temperature 36.5-37.5
Usage continued or discontinued at mother's preference
Temperature 35.5-36.4
Commence skin to skin in Snuby
Axilla temperature taken by mother after 30 minutes of usage
Temperature 36.5-37.5
Usage continued or discontinued at mother's preference
Temperature <36.5
Add thin blanket over Snuby
Axilla temperature taken by mother after another 30 minutes of usage
Temperature <36.5
Call NHS 111
NOTE TWO Text message to researcher
Temperature 36.5-37.5
Usage continued or discontinued at mother's preference
Temperature <35.5
Do not use Snuby. Call NHS 111
NOTE THREE Text message to researcher
Temperature taken after 30 minutes of usage
Temperature 37.6-37.9
Discontinue usage of Snuby
Redress baby in indoor clothes without hat
Axilla temperature taken by mother after 30 minutes of no usage
Temperature 36.5-37.5
NOTE FOUR Text message to researcher
Temperature >37.5
Call NHS 111
NOTE FIVE Text message to researcher
Temperature >37.9
Discontinue usage of Snuby
Redress baby in indoor clothes without hat
Call NHS 111
NOTE SIX Text message to researcher

Appendix 1 continued

Note one

Applicable to both intervention and control group:

CI to contact participant within 48 hours of text message via telephone. CI to discuss medical input from NHS 111 or any other services. If baby is unwell (requiring medication, inpatient care, ongoing treatment or monitoring), the dyad are excluded from the study. CI explains this to the mother. If following medical review (NHS 111 +/- medical review in person) baby is deemed well, dyad may continue in the study. Flowchart begins again from the top. If temperature exceeds 37.5°C on two separate occasions, dyad excluded from study.

Note two

Applicable to both intervention and control group:

CI to contact participant via telephone within 48 hours of text message. CI to discuss medical input from NHS 111 or any other services. If baby is unwell (requiring medication, inpatient care, ongoing treatment or monitoring), the dyad are excluded from the study. CI explains this to the mother. If following medical review (NHS 111 +/- medical review in person) baby is deemed well, dyad may continue in the study.

Specific to Snuby® usage:

CI reviews usage instructions of Snuby, clarifies: baby just in nappy, inside home or hospital environment, blanket over the top if mother feels cool. If CI deems participant to understand, they continue in the study. If baby temperature falls below 36.5°C twice on two separate occasions, dyad excluded from study.

Note three

Applicable to both intervention and control group:

CI to contact participant via telephone within 48 hours of text message. CI to discuss medical input from NHS 111 or any other services. If baby is unwell (requiring medication, inpatient care, ongoing treatment or monitoring), the dyad are excluded from the study. CI explains this to the mother. If following medical review (NHS 111 +/- medical review in person) baby is deemed well, dyad may continue in the study. If baby temperature falls below 35.5°C on two separate occasions, dyad excluded from study.

Note four

Specific to Snuby® usage:

Appendix 1 continued

CI to contact participant within 24 hours of receiving text message.

CI logs as adverse event and notifies academic supervisor within 24 hours of receiving text message. If baby's temperature exceeds 37.5°C on two separate occasions following a normal temperature prior to usage:

1) Dyad excluded from study

2) Academic supervisors notified

3) Study protocol reviewed

Note five

Specific to Snuby® usage:

CI to contact participant within 24 hours of text message.

CI logs adverse event and notifies chief investigator within 24 hours of text message.

Applicable to both intervention and control group:

CI to discuss medical input from NHS 111 or any other services. If baby is unwell (requiring medication, inpatient care, ongoing treatment or monitoring), the dyad are excluded from the study. CI explains this to the mother. If following medical review (NHS 111 +/- medical review in person) baby is deemed well, dyad may continue in the study. Flowchart begins again from the top. If temperature exceeds 37.5°C twice on two separate occasions, dyad excluded from study.

Note six

Specific to Snuby® usage:

CI contacts participant within 24 hours of text message.

CI records serious adverse event.

CI notifies chief academic supervisor and research sponsor within 24 hours of text message.

Research protocol reviewed, suspension of trial considered with sponsor.

Applicable to both intervention and control group:

Participating dyad removed from study.

Appendix 2

The Snuby®

This skin-to-skin contact facilitating garment has been developed by textile design student Jade Ming with technical expertise from Birmingham City University Textile Lecturer Sheila Griffiths following commission by Dr. Helen McIntyre (Principle Investigator). The intellectual property of the device has been signed to Birmingham City University. Snuby® is in the process of registration, patent pending GB1609249.6.

The University is responsible for the commissioning, design and manufacture of the garment. The chief investigator will be responsible for supplying the garment to eligible participants. Following each of the first two phases of the study, the CI will collect in the Snuby® garment from the participants, and store each individual Snuby® in bags labelled with the participating dyad's ID number alongside raw data collection materials.

Appendix F: Temperature and behaviour chart

Recording your baby's temperature and behaviour Participating dyad ID:

Please complete a row of this chart each time you have skin-to-skin contact with your baby, or use the Snuby®.

Date (dd/mm/yy)	Time period M:Morning A:Afternoon E: Evening N: Night-time	Using the Snuby? Y: Yes N: No	Temperature before skin-to-skin contact (SSC) (°C)	Baby's behaviour before SSC 1=Unsettled 2= Settled 3= Hungry 4= Asleep	Temperature after 30 minutes of SSC (°C)	Baby's behaviour after 30 minutes of SSC 1=Unsettled 2= Settled 3= Hungry 4= Asleep	Duration of SSC (minutes)	Your position 1= lay down 2= leant back 3= sat up	Your overall feeling after the SSC 1= very frustrated 2=unsettled 3=settled 4=relaxed
Example 01/01/16	M	N	36.6	1	36.5	4	40	3	3

Appendix G: Pilot study checklist

Researcher checklist: Phase I

Participating dyad ID: Date:

Phase I participant actions	Tick/cross
Did the participant raise any concerns with the 'how to take an axilla temperature' guide?	
Did the participant position the thermometer correctly?	
Did the participant record the temperature correctly?	
Was the initial temperature in normal parameters (36.5-37.5°C) to use the Snuby?	
Could the participant relate her baby's behaviour to one of the options on the chart?	
Did the participant position her baby in accordance with the 'dos and don'ts' information sheet?	
Did the baby fit securely in the garment?	
Could the participant take the second temperature whilst using the garment?	
Did the participant complete the chart columns correctly?	
Did the participant adopt and maintain an appropriate position to use the garment, as on the 'dos and don'ts' sheet?	
Was the neonatal temperature within normal parameters (36.5-37.5°C) after 30 minutes in the garment?	

Appendix H: Bailey et al. (2017) Piloting Kangaroo Mother Care in the Community: dyadic responses to a novel innovation facilitating skin-to-skin contact. MIDIRS Midwifery Digest 27(4) pp. 518-522.

Neonatal & Infancy

Piloting kangaroo mother care in the community: dyadic responses to a novel innovation facilitating skin-to-skin contact

Roisin Bailey, Helen McIntyre, Merryl Harvey

ORIGINAL

Introduction

Skin-to-skin contact between a mother and her baby may first occur straight, or soon after birth, where the naked baby is dried and placed prone on the mother's bare chest. The maternal chest is regarded as the ideal evolutionary habitat for the fulfilment of the baby's immediate and long-term biological needs through its own neurodevelopment, such as the establishment of feeding (Moore *et al* 2016).

Kangaroo mother care (KMC) was developed in Bogotá, Colombia in 1979 (Rey & Martínez 1983). It consists of a care package that incorporates early, continuous, or prolonged mother-baby skin-to-skin contact, ideally with exclusive breastfeeding, and early discharge from the hospital unit, with appropriate neonatal follow-up (World Health Organization 2003). This care package was designed in response to inadequate incubator facilities for low birth weight babies which, once stable, required support only to feed and grow (World Health Organization 2003).

A systematic review of trials using KMC demonstrated a reduction in neonatal morbidity and mortality rates in low birth weight and premature babies when compared to babies receiving incubator care (Conde-Agudelo & Díaz-Rossello 2016). Meta-analysis of neonatal outcomes for preterm and full-term babies being cared for in KMC demonstrated a reduction in the incidence of neonatal sepsis, hypothermia and hyperthermia, hypoglycaemia, and hospital readmission — concluding that implementation strategies were necessary to facilitate KMC across the neonatal population (Boundy *et al* 2016).

Breastfeeding behaviour also differs between babies receiving KMC and those receiving swaddling or cot care. Mother-baby skin-to-skin contact following birth results in increased effectiveness of the first breastfeed (Moore *et al* 2016), and is associated with an increase in breastfeeding exclusivity up to six months postpartum (Vaidya *et al* 2005).

Despite rigorous data on safety and neonatal health benefits, implementation of KMC within high-income settings has remained low (Engmann *et al* 2013). UNICEF's Baby Friendly Initiative standards advocate maintaining close proximity between the mother and baby, and skin-to-skin contact from birth, and throughout the postnatal period (UNICEF UK Baby Friendly Initiative 2012). However, routine separation of mothers and babies immediately following birth has occurred widely in industrialised nations since the 20th century, with babies being dressed and wrapped, and cared for in a crib or nursery (Moore *et al* 2016). Further separation of the mother-baby dyad may result from obstetric or neonatal medical interventions, such as maternal caesarean section, or admission to a neonatal special care unit.

Specific to the UK, extremely low breastfeeding rates, coupled with discouragement of mother-baby bed-sharing, based on the association between co-sleeping and sudden infant death syndrome (National Institute for Health and Care Excellence (NICE) 2006, The Lullaby Trust 2017), may also contribute to the separation of the baby from the evolutionary habitat of the maternal chest.

A novel innovation

A novel health innovation has been designed to facilitate dyad-led KMC in the context of a population of healthy mothers, and their healthy, term babies. This aims to counteract the routine separation of the dyad on a non-medical basis both in acute settings, and within the community. It constitutes a specially-designed soft, cotton top with an in-built pouch to support the baby against the mother's chest. This can be used at home or within the hospital or birth centre, and as frequently, or for as long as, the mother wishes.

The garment was commissioned by Dr Helen McIntyre, Senior Midwifery Lecturer at Birmingham City University, and has been developed as part of a joint enterprise between the midwifery and fashion departments. The garment is currently pending patenting, prior to further production.

This pilot study is part of a larger PhD research project, and opens a growing research focus with Birmingham City University, investigating the effects of a facilitation strategy of KMC on maternal and neonatal health and well-being.

Ethics

The research proposal was presented to both the Health, Education and Life Sciences Faculty Academic Ethics Committee at Birmingham City University, and the Health Research Authority. Favourable ethical opinion was gained from both committees.

Aims

The research project aims to explore what impact the facilitation of skin-to-skin contact may have on skin-to-skin contact uptake and duration, infant feeding practices, maternal-infant interaction and bonding, and maternal experience of using the innovation as part of motherhood.

A pilot study was designed to trial the garment with a minimum of ten healthy mother-infant dyads, receiving routine postnatal and neonatal care in the community. The pilot study aimed to investigate the garment's effect on neonatal thermoregulation, maternal-infant feeding and responsiveness, and the maternal perception of wearing and using the garment. This constituted a preliminary safety and efficacy evaluation of the garment to guide subsequent design and methodology changes necessary for a larger trial.

Methodology

Recruitment

The mixed method design of the pilot study gathered quantitative and qualitative data on safety, efficacy and experience of using the garment to facilitate kangaroo care. Direct observation of the mother-infant dyads using the garment at home was used to collect data on the dyad's behaviour whilst having skin-to-skin contact. This direct observation occurred on a single occasion, lasting between forty minutes to two hours, as led by the maternal participant.

A table was completed by the maternal participants, documenting neonatal axilla temperature readings and a multiple-choice neonatal behavioural state ranking, recorded before and thirty minutes into the skin-to-skin episode. In addition to participant-led data collection, verbatim comments elicited spontaneously, or through direct questions related to the design, fit, and appearance of the garment, were transcribed, and researcher field notes documenting maternal vocal tone and body language, and signs of mother-infant reciprocal bonding and feeding were recorded contemporaneously.

A checklist was used as an audit tool to assess the safe positioning and fit of the garment, completion of the data collection sheet, and adherence to the study documentation detailing safe usage and correct thermometer use. The checklist was completed by the researcher at the end of the home visit.

The methodology was designed to be woman-centred, with the data collection taking place at the mother's home, and the mother instigating and discontinuing the data collection episode, as well as assessing and recording her baby's temperature and behaviour.

Setting

Pregnant and postnatal women were recruited across three months in the inpatient and outpatient settings of an NHS trust in England facilitating around 6000 births per year. Participants were recruited from antenatal and postnatal wards, parent craft classes, and antenatal and community clinics. Data collection visits took place in the participants' homes across the locality. Several visits took place during unusually high seasonal temperatures, averaging 20–30 degrees Celsius.

Sample recruitment

The sample of women all met inclusion criteria of a singleton pregnancy, with spontaneous or induced labour on or after 37 weeks' gestation, resulting in a vaginal birth. Maternal participants had booked their pregnancy at a specific NHS trust in England, and had basic spoken English as a first or additional language. Participants were recruited antenatally, irrespective of pregnancy-risk status that did not affect the exclusion criteria.

Maternal exclusion criteria were: aged less than 16 years old, multiple pregnancy, a caesarean birth, current high-dependency care, and significant child protection concerns. Maternal participants were diverse in ethnicity, nationality, age and parity. Nine of the 11 participants' postcodes generated an Index of Multiple Deprivation score (National Perinatal Epidemiology Unit 2017); the remaining two postcodes produced no results. Eight of the nine scores were within the 5th centile of most deprived, and one was in the 3rd centile.

The sample of infants all met inclusion criteria of a birth weight >/2500g, born at or after 37 completed gestational weeks, aged from newborn to six weeks old. Infants requiring transitional, special or intensive care at the time of data collection were excluded from the study.

Inclusion and exclusion criteria were applied antenatally following an expression of interest in the study, and repeated postnatally following birth, prior to consenting to participate. Demographic, medical, obstetric, and neonatal details were reviewed from the participant's maternity notes to ensure eligibility criteria were met, with prior consent.

Participants had a minimum of two weeks to consider participation after receiving a participant information sheet. Of the 18 women who expressed interest antenatally, and remained eligible for participation, 11 chose to participate in the study.

Instruments and equipment

Neonatal axilla temperatures were monitored using Omron EcoBasic axilla thermometers, issued by the researcher to each participating dyad. Garments were issued to each participating dyad based on maternal pre-pregnancy clothing size. Garments were returned to the researcher immediately following data collection until preliminary pilot data analysis and quality control testing demonstrated no issues with quality or design. Following this, participants that remained in the six week postnatal period could opt to have the garment back. No cost was incurred by the participants for study equipment or participation.

Outcome measures

Axilla temperatures were recorded to one decimal place as displayed on the thermometers. Temperatures within the range of 36.5–37.5 degrees Celsius were regarded as normal (Wyllie *et al* 2015). The same researcher recorded field notes with each dyad, including on infant feeding. This constituted whether the infant had a breast or bottle feed, infant feeding cues and maternal responsiveness, and the infant's positioning for the feed, recorded as longitudinal, oblique, or transverse in relation to the maternal spine (Colson 2005). Infant feeding cues and maternal responsiveness were assessed using Cadwell's breastfeeding assessment (2007) and themes from the Responsiveness to Child Feeding Cues Scale (Hodges *et al* 2013), which applied to neonates.

An 11 point checklist was completed by the researcher to audit compliance to safe usage instructions, completion of the data collection sheets, and axilla temperatures within normal parameters (Wyllie *et al* 2015). Checklists scoring 11/11 were the outcome measure for safe usage of the garment and appropriate documentation.

Recruitment and retention

The target for recruitment was met and exceeded, with one additional participating dyad. Recruitment took place over three months, with one third of the thirty-three women recruited antenatally proceeding to study enrolment. A fifty per cent attrition rate was forecast, which was exceeded, with a recruitment to enrolment attrition rate of 66%.

Results

Safety checklist

All audit checklists scored a maximum of 11/11, demonstrating participant adherence to the study design and safety information.

Neonatal temperature and behaviour changes with the garment

The eleven participating dyads collected data on the neonate's behaviour and temperature before, and during, skin-to-skin contact. The second range of temperatures were taken 30 minutes after the commencement of skin-to-skin contact, apart from dyads 1 and 7, where the second temperature was taken at 15 minutes, prior to maternal-led discontinuation of the skin-to-skin episode.

Neonatal axilla temperature

The mean temperature difference of the neonates before and during skin-to-skin contact was 0.0 degrees Celsius, with the mode average of temperature differences -0.1 degrees Celsius. These temperature fluctuations lack clinical or statistical significance in this study. There were no incidences of hypothermia or hyperthermia during participation; the garment maintained normothermic temperatures in all 11 neonates.

Neonatal behaviour

The most commonly identified neonatal behaviour prior to commencing skin-to-skin contact was 'hungry' (6/11 neonates). Of these six, all went on to breastfeed in skin-to-skin contact.

Table 1. Dyad demographic details.

Dyad subject	Maternal age (years)	Parity	Ethnicity and nationality	Gestation at birth (week+day)	Birth type	Neonatal age (days)	Neonatal birth weight (grams)
1	29	3	5	42+2	SVB	20	3050
2	26	2	5	39+6	SVB	9	3240
3	39	1	1	39+4	NBF	5	3320
4	23	2	6	42+2	SVB	12	3840
5	26	1	4	40+4	SVB	4	3300
6	35	3	7	38+3	SVB	6	2900
7	30	2	2	38+4	SVB	14	4000
8	30	1	6	41+6	VEN	7	3160
9	24	1	2	40+5	SVB	10	3320
10	27	2	5	37+5	SVB	11	2500
11	32	2	1	41+0	SVB	9	4300

Ethnicity key: 1 White British, 2 White European, 3 Irish Traveller/Roma, 4 Black British, 5 Black African/Caribbean, 6 British Asian – Indian subcontinent, 7 Asian – Indian subcontinent, 8 Asian – other, 9 Mixed ethnicity.

Birth type key: SVB Spontaneous vaginal birth, NBF Neville Barnes forceps assisted birth, VEN Ventouse assisted birth.

Table 2. Neonatal temperature and behaviour during garment facilitated skin-to-skin contact (SSC).

Neonate	Feeding practice	Temperature before SSC (°C)	Temperature during SSC (°C)	Temperature difference (°C)	Behaviour before SSC	Behaviour after SSC	Duration of SSC (minutes)
1	BF	36.7	36.8	+0.1	3	4	15
2	BF	37.1	37.0	-0.1	3	2	40
3	FF	36.5	36.6	+0.1	2	4	60
4	MF	36.7	36.9	+0.2	3	4	45
5	BF	37.0	36.9	-0.1	3	2, 4	40
6	BF	36.9	36.8	-0.1	3	4	40
7	MF	36.9	36.8	-0.1	3	2	15
8	FF	36.8	36.7	-0.1	4	2	37
9	MF	36.9	36.7	-0.1	4	4	43
10	BF	36.6	36.6	0	1	4	30
11	FF	36.6	36.8	+0.2	4	4	40

Feeding key: BF Breastfeeding exclusively, or with the addition of expressed breast milk supplementation, MF Mixed feeding including breastfeeding and formula feeding, with or without expressed breast milk supplementation, FF Formula feeding exclusively.
Neonatal behaviour key: 1 Unsettled, 2 Settled, 3 Hungry, 4 Asleep.

Maternal reactions to their perception of a hungry baby were similar across all six dyads, with breastfeeding initiated by all of the dyads within the first 30 minutes of skin-to-skin contact.

None of the mothers identified that skin-to-skin contact had led to their baby being unsettled. Two mothers, who had moved from breastfeeding to formula feeding, voiced their concern prior to skin-to-skin contact that having skin-to-skin contact may unsettle the baby by encouraging rooting at the breast. However, both reported the behaviour as settled or asleep during skin-to-skin contact, with one of the mothers giving a formula feed part way through.

Infant feeding cues and maternal responsiveness

Feeding cues were observed in eight of 11 dyads. These were increased activity (n=5), head bobbing (n=8), rooting (n=3), and fussing (n=2).

Although six babies were described by their mothers as 'hungry' prior to skin-to-skin contact, eight went on to exhibit feeding cues when in skin-to-skin contact.

Of the eight exhibiting feeding cues, all eight mothers responded by instigating or facilitating a feed, in seven instances, a breastfeed, and in one instance, a formula feed. Of the two neonates who displayed feeding cues and were mixed feeding, both were breastfed rather than formula fed during the skin-to-skin contact.

Maternal responses to feeding cues included verbal cooing and smiling (n=4), stroking of the baby's back and head (n=2), and facilitating the move to the nipple (n=7). Other maternal behaviour noted following feeding cues were: facilitating a change of the baby's position (n=5), reclining their position (n=4), gazing or reciprocal eye contact (n=4), and laughter (n=1).

Dyadic interaction was heightened following commencement of skin-to-skin contact. Four of the 11 mothers expressed their perception of how the baby was feeling. Two mothers spontaneously reported that their baby *'loved it'*, one mother reported that her baby *'really liked it'*, and one mother asked her baby *'What're you thinking about? Are you happy?'* All 11 mothers increased verbalisations to their babies on commencement of skin-to-skin contact, including use of rhetorical questions, and infant-directed speech.

Maternal experience using the garment

Maternal participants remarked positively on the design, fit, and appearance of the garment. Simple word repetition identified 'safe', 'secure', and 'comfortable' as the most frequently used descriptors of the garment.

None of the participants reported a negative experience; however, one participant discontinued skin-to-skin contact as she felt too hot.

Discussion

In the 11 episodes of trialling the innovation, no adverse outcomes occurred; there was no deterioration perceived in neonatal behaviour, no clinically significant fluctuations in neonatal temperature, and no unsafe positioning of the infant in the garment pouch. Pilot findings suggest the design maintains neonatal temperatures in a thermo-neutral range, with no clinically significant fluctuations in temperature.

Further research is required with an adequately powered sample size to compare neonatal temperature fluctuation in the garment to that in conventionally facilitated skin-to-skin contact. A mixed method, randomised, controlled trial is planned, involving the recruitment of a larger sample of mother-infant dyads meeting the same inclusion and exclusion criteria. Recruitment for the randomised controlled trial will take place at the same NHS trust in England, targeting an ethnically diverse and socio-economically disadvantaged urban population.

The unanticipated use of the garment to support a breastfeed in skin-to-skin contact has emerged from the pilot observations, as mothers used and adapted the garment to support their preferred positioning for breastfeeding. Further research is

needed to understand the garment's potential role in breastfeeding uptake, continuation, and exclusivity, in order to guide breastfeeding support practices.

Positive maternal experiences conveyed in this pilot study warrant further exploration of the mother's voice in providing KMC. Experiences of using skin-to-skin contact at home in the postnatal period will be explored in small focus groups, providing woman-centred data to guide facilitation strategies to support ongoing skin-to-skin contact.

This pilot study supports further exploration into the potential effect skin-to-skin facilitation may have on neonatal thermoregulation, breastfeeding, dyadic bonding, and the mother's experience of caring for her baby through the postnatal period.

Roisin Bailey, Registered Midwife, PhD student, and Assistant Lecturer in Midwifery, Birmingham City University.

Dr Helen McIntyre, DHSci, Registered Midwife, Senior Lecturer in Midwifery, Birmingham City University.

Dr Merryl Harvey, PhD, Professor of Nursing and Family Health, Birmingham City University.

References

Boundy EO, Dastjerdi R, Spiegelman D *et al* (2016). Kangaroo mother care and neonatal outcomes: a meta-analysis. *Pediatrics* 137(1).

Cadwell K (2007). Latching-on and suckling of the healthy term neonate: breastfeeding assessment. *Journal of Midwifery and Women's Health* 52(6):638-42.

Colson S (2005). Maternal breastfeeding positions: have we got it right? (2). *Practising Midwife* 8(11):29-32.

Conde-Agudelo A, Díaz-Rossello JL (2016). Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *The Cochrane Database of Systematic Reviews*, Issue 8.

Engmann C, Wall S, Darmstadt G *et al* (2013). Consensus on kangaroo mother care acceleration. *Lancet* 382(9907):e26-7.

Hodges EA, Johnson SL, Hughes SO *et al* (2013). Development of the responsiveness to child feeding cues scale. *Appetite* 65:210-19.

Moore ER, Bergman N, Anderson GC *et al* (2016). Early skin-to-skin contact for mothers and their healthy newborn infants. *The Cochrane Database of Systematic Reviews*, Issue 11.

National Institute for Health and Care Excellence (2006). *Postnatal care up to 8 weeks after birth*. London: NICE.

National Perinatal Epidemiology Unit (2017). *IMD tool*. University of Oxford. https://tools.npeu.ox.ac.uk/imd/ [Accessed 23 August 2017].

Rey E, Martínez H (1983). *Manejo racional del niño prematuro*. Bogotá: Curso de Medicina Fetal, Universidad Nacional.

The Lullaby Trust (2017). *Co-sleeping with your baby*. https://www.lullabytrust.org.uk/safer-sleep-advice/co-sleeping/ [Accessed 18 August 2017].

UNICEF UK Baby Friendly Initiative (2012). *Guide to the Baby Friendly Initiative standards*. London: UNICEF UK.

Vaidya K, Sharma A, Dhungel S (2005). Effect of early mother-baby close contact over the duration of exclusive breastfeeding. *Nepal Medical College Journal* 7(2):138-40.

World Health Organization (2003). *Kangaroo mother care: a practical guide*. Geneva: WHO.

Wyllie J, Bruinenberg J, Roehr *et al* (2015). European Resuscitation Council Guidelines for Resuscitation 2015: Section 7. Resuscitation and support of transition of babies at birth. *Resuscitation* 95:249-63.

Bailey R, McIntyre H, Harvey M. MIDIRS Midwifery Digest, vol 27, no 4, December 2017, pp 518-522.

Appendix I: Recruitment flyer

BIRMINGHAM CITY UNIVERSITY
SANDWELL AND WEST BIRMINGHAM NHS TRUST

BONDING WITH YOUR BABY

Supporting mums and babies to have skin to skin contact

WE'RE LOOKING FOR MUMS AND THEIR BABIES TO TRY OUT A NEW TOP TO WEAR... TOGETHER!

The Snuby® top supports you and your baby to cuddle, feed, and relax whilst having skin to skin contact.
It's **free** to try out at home once your baby arrives. We want to know if it works for you.

Text 'top' and your name to 07563 230081 for more info

@MIDWIFEPHD

Appendix J: Interview topic guide

Focus Group – Intervention Group

Topic list

- **How was using the Snuby©?**
  - Easy or difficult?
  - A chore or enjoyable?
- **What made you choose to use the Snuby© at a particular time or day?**
- **Did the Snuby© have any effect on bonding with your baby?**
  - How did you feel when you were using it?
  - Did it have a different effect when your baby was new-born or bigger?
- **What about feeding your baby?**
  - Did you use it whilst feeding?
  - Breast or bottle feeding?
  - Did it help or hinder the feeding?
- **Any issues identified with using the Snuby©?** What could we do to resolve these?
- **How was it compared to skin-to-skin contact without a Snuby©?**
- **Do you think it is worthwhile to own once you've had a baby?**
  - Why?
  - How so?
- **Would you choose to use a Snuby© again?**
  - Why?
- **Anything else you feel is important?**

Facilitating skin to skin contact in the postnatal period V2 28/09/16
Intervention group prompt sheet- focus group.

Appendix K: Health Research Authority Approval Letter

NHS
Health Research Authority

Ms Roisin Bailey
PhD Student, Registered Midwife
Birmingham City University
Ravensbury 216, Westbourne Road
Edgbaston, Birmingham
B15 3TN

Email: hra.approval@nhs.net

21 February 2017

Dear Ms Bailey,

Letter of HRA Approval

Study title:	**A Skin-to-Skin Contact (SSC) Facilitating Device Used Within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.**
IRAS project ID:	**209469**
REC reference:	**17/WM/0033**
Sponsor	**Birmingham City University**

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Appendix L: Participant information sheet

Sandwell & West Birmingham Hospitals NHS
NHS Trust

Phase II Participant Information Sheet

A Skin-to-Skin Contact (SSC) Facilitating Device used within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.

I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or would like more information. Take time to decide whether or not to take part.

The Snuby®

A new device has been developed by Birmingham City University called a Snuby®.

The Snuby® is a soft fabric top for new mothers to wear which supports their baby in having skin-to-skin contact against the mother's chest. It can be used for breast and bottle feeding, and cuddling and relaxing with baby.

It is designed to be used in the hospital and in your home for the first six weeks of your baby's life.

Skin-to-skin contact refers to the baby's skin against the mother's skin. This happens when a baby is placed on its mother's chest. Babies are either nude or wearing a nappy so their bare chest and tummy is against their mother's skin. Some babies will breastfeed or bottle feed in a skin-to-skin position with their mothers, or just be cuddled there. Babies can have skin-to-skin contact with anybody, but this study is focussing on mother-baby skin-to-skin contact. Skin-to-skin contact can help soothe and settle your baby, help you and your baby bond, and keep your baby warm.

What is the purpose of the study?

The study's focus is skin-to-skin contact between mothers and their babies. The study will look at what effect skin-to-skin contact has on babies' temperatures, breast and formula feeding, and mother-baby bonding. The study will compare mothers and babies using the Snuby® garment to mothers and babies having skin-to-skin contact without the garment in the hospital and at home. The study will also collect the views of mothers and midwives on skin-to-skin contact, and bonding.

There are three parts to the study:

The first part involves a small number of participants trialling the Snuby® at home with the researcher observing.

The second part involves a larger number of participants completing questionnaires and recording their babies' temperatures in the first six weeks after birth. After six weeks, the researcher will ask for your feedback on how you found feeding and caring for your baby. Half of these participants use the Snuby®, and the other half have skin-to-skin contact without the Snuby®.

The third part involves midwives completing a questionnaire and attending a focus group.

You are invited for the *second part* of the study. The information below is all about the second part of the study.

Why have I been invited?

You have been invited because your midwife has assessed you and you are expected to have a normal vaginal birth and a healthy baby. This study is inviting healthy women aged 16 and over with healthy pregnancies to participate. This includes women of all ethnicities and nationalities planning to have their baby at City Hospital or at Halcyon birth centre in Sandwell and West Birmingham NHS Trust.

Do I have to take part?

Taking part is totally voluntary, you do not have to take part if you don't want to. It is up to you to decide. If you decide not to take part, or to withdraw from the study, the standard of care you receive from the hospital will not be affected in any way. You may withdraw from the study at any time without providing a reason. If you do wish to take part, we will provide a consent form for you to read and sign to ensure you fully understand the study and your rights.

What happens if I choose to take part in the study?

You will have a minimum of twenty four hours to think about whether you'd like to take part once you've read this information.

If you decide to take part, you will be put in one of two groups. One group will be given the Snuby® garment to use with their baby. The other group will *not* receive the Snuby® garment. A computer programme will decide which group you will be in, which the researcher cannot change. This process is called randomization. The researcher will explain whether you will get the Snuby to use, or

whether you will have skin-to-skin contact with your baby in the usual way. This is by using a blanket or item of clothing to drape over you and your baby when you have skin-to-skin contact.

You will call the researcher once you have given birth. The researcher will ensure you and your baby are suitable for this particular study. The researcher will access you electronic maternity records at the end of your pregnancy, and when you call them following the birth. This is to review the type of birth you have, your baby's weight, and any health or social concerns.

Your electronic records will not be used for any purpose outside of the research study. If you have any questions about access to your hospital records, please contact the researcher. Details can be found at the end of this document.

Once the researcher has confirmed with you over the telephone that you and your baby are safe to take part, you can continue in the research study. Women who have a vaginal birth, and healthy baby, are able to take part. The researcher will visit you and your baby either in the hospital or at home, to enrol you in the study.

The research will last for between two and four months. In this time you will complete one questionnaire in pregnancy, and then weekly questionnaires after you have given birth. You will also record your baby's temperature each time you have skin-to-skin contact.

Each questionnaire takes approximately 10 minutes to complete, and it takes approximately 3 minutes to take and write down your baby's temperature. This is the same whether you are using the Snuby® or not.

Over the six weeks, the researcher will call you once a week, at a preferred time for you. They will ask similar questions each week to answer any questions you may have, to check you and baby are still suitable to continue in the study, and monitor the baby's temperature readings from that week. This phone call will take approximately 10 minutes each week.

Once your baby reaches six weeks of age, the researcher will visit your house to collect the questionnaires, and ask you some questions about how you found feeding and caring for your baby. The researcher will record the conversation on an audio recorder (no video), so your views can be written down at a later date. If you were using a Snuby®, it will be collected by the researcher at this visit.

Yours and your baby's name will never be used when the researcher writes up the study, so readers will not be able to identify you. All the information you provide on questionnaires and in the interview will be stored securely on a password-protected computer if electronic, or in a locked cabinet in a locked office if on paper. All data will be kept in accordance with General Data Protection Regulations (2016).

Expenses and Payments

You will not be paid for your participation in the study. You will be provided with an electronic thermometer for your baby, which you may keep. No expenses are anticipated whilst participating in this study.

What will I have to do?

You will have to complete eight questionnaires, which will be collected by the researcher from you. One questionnaire is completed towards the end of your pregnancy, or soon after your baby is born. The researcher will provide this for you. The other seven questionnaires are attached together. You complete one on the day you are discharged from hospital after giving birth, one when your baby is seven days old, and the rest weekly until your baby reaches 6 weeks of age. All the questionnaires are labelled so you know when to complete them.

You are also asked to take and write down your baby's temperature and behaviour before you have skin-to-skin contact, and after 30 minutes of skin-to-skin contact. This is the same for the Snuby® group, and the group without the Snuby®. You will also record how long you had skin-to-skin contact for, what position you were in, and how you found it. This information is all entered into a simple, short chart to make it quick and easy for you to complete.

The researcher will provide you with information on the normal temperatures for babies in writing before the study starts. If your baby is too hot or too cold, you are asked to follow the specific instructions given to you about requesting medical help and the use of the Snuby®.

You will also be asked to have a brief conversation on the telephone with the researcher each week. The researcher will call you at a preferred time and day. Details of this conversation can be found in the 'what happens if I choose to take part in the study?' section. The conversation will last approximately 10 minutes.

When the researcher comes to collect your questionnaires, you will have the opportunity to provide feedback on how you found feeding and caring for your baby. The researcher will ask you some questions to gather your views. The conversation will be recorded on an audio recorder, and written down by the researcher.

What are the possible disadvantages or risks of taking part?

There is a chance you will not be in the group that you would have preferred. This may cause disappointment. There are two groups so the results can be compared. The reason that you or the researcher cannot choose which group you go in is to make sure the participants are spread fairly and evenly between the two groups.

The Snuby® is designed to be used when you are sat down, leant back or lay down. If the Snuby® is used when you are moving around, or not as directed, there is a risk your baby could slip out. To avoid this, the Snuby® must be used only by the mother, and only as shown on the sheet provided.

There is a chance that your baby may become too hot or too cold in the Snuby®, or when having skin-to-skin contact. This is why you are asked to monitor the temperature before skin-to-skin contact, and then after 30 minutes of skin-to-skin contact, with or without the Snuby®. Instructions have been provided on what to do if your baby is too hot or too cold, including who to contact.

Certain sleeping practices have been linked to Sudden Infant Death Syndrome, where babies die suddenly and the reason is unknown. It is important to avoid falling asleep with your baby on top of you, particularly on a sofa or armchair. This includes if you are using a Snuby®, if you are not using a

Snuby® whilst having skin-to-skin contact, and if you are just cuddling your baby whilst dressed. Do not use the Snuby® if you feel very tired.

What are the possible benefits of taking part?

You may find participating in the study enjoyable. By participating in the study, you are contributing to valuable research to help develop good care for mothers and babies.

We cannot promise the study will help you, but the information we get from the study may help us to understand the best ways to support mothers and babies in the first six weeks after birth.

The data you provide may also help us find ways to better support bonding and feeding choices in the maternity wards.

If you are allocated to the Snuby® group, you will have the opportunity to trial the new Snuby® garment.

What if there is a problem?

If you have a concern about any aspect of this study, you can contact the researcher Roisin Bailey on 07563 230081, or her supervisor Dr. Helen McIntyre on 0116 229 7354.

If you would rather speak to somebody external to the study, or wish to make a formal complaint, you can contact Julie Quick, Insurance Lead at Birmingham City University at julie.quick@bcu.ac.uk or on 0121 331 7080.

Birmingham City University provide study indemnity insurance as the study sponsor. There is no specific compensation procedure for the study, but participants may access existing NHS complaints procedures.

Will my participation in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

At the stage of consenting for the research, you will have an ID number given to you. This will then be used instead of your name to protect your identity.

All the procedures for handling, storing, processing and destroying data are in keeping with the Caldicott principles and General Data Protection Regulations (2016).

This includes safe storage of completed questionnaires and your informed consent form within locked drawers in a locked premises, only available to the researcher and your community midwife. Your community midwife will collect the questionnaire you complete at the end of pregnancy in a locked drawer in her locked office until it is collected by the researcher. It will then be transported in a secured bag, labelled with a 'return to' address and 'private and confidential', in a private car

straight back to the researcher's office within University premises. Here it will be locked in a secure drawer, in a locked office.

All electronic data will be encrypted on a password-protected personal work computer. The researcher will be the only person able to access the list of participant names linked to their ID numbers.

The data will not be used in any further studies. The data will only be accessible by the chief investigator, academic supervisors and designated University employees for monitoring and auditing purposes. Records and documents will be retained for a minimum of seven years, as required by the University.

Your general practitioner (G.P.) will not be notified of your involvement in the study.

If the researcher has any safeguarding concerns, that you or your baby may be at significant risk, they have a duty to notify the appropriate healthcare professional, including Birmingham/Sandwell Children's Services. Safeguarding concerns do not require your consent to share important information to keep you or your baby safe. Wherever possible, you will be involved in these decisions.

What will happen if I don't continue in the study?

You are free to withdraw at any time. You need to notify the researcher (contact details at the end of this document) so they can remove you from the study. If you withdraw from the study, we will ask you if we can keep the data you have provided up until this point. If you choose, we can erase the data you have given us.

You have a right to information to make a decision about taking part, and a right to the data you provide being kept securely and kept anonymous as per the General Data Protection Regulations (2016). You also have a right to withdraw at any time without it affecting your health care.

What will happen to the results of the study?

The results will be published in a PhD thesis, and presented at various conferences. The thesis and conference proceedings, as well as any journal articles will be available to the general public, as well as healthcare professionals.

You will be invited to a discussion group about the study's results, and have access to an electronic summary of the thesis. Both of these are entirely optional, and not a necessary part of participation in the study.

Who is organising the research?

The research is sponsored by Birmingham City University.

Further Information and Contact Details:

For general study information:

Chief Investigator: Roisin Bailey

Roisin.Bailey@nhs.net / Roisin.Bailey@bcu.ac.uk

07563 230081

Principle Investigator: Dr Helen McIntyre

Helen.mcintyre@leicester.ac.uk

+44(0) 116 229 7354

For information on skin-to-skin contact:

Skin to Skin Contact National Quality Standard Available at:
https://www.nice.org.uk/guidance/qs105/chapter/quality-statement-7-skin-to-skin-contact

For complaints:

Julie Quick, Insurance Lead at Birmingham City University at julie.quick@bcu.ac.uk or on 0121 331 7080

PALS - Phone: 0121 507 5836, 10am – 4pm, Monday – Friday. (Please leave a message if the line is engaged or if you are calling outside office hours.) Email: swb-tr.pals@nhs.net.

If you wish to participate, the researcher will provide you with an informed consent form.

Appendix M: Informed consent form

Sandwell & West Birmingham Hospitals NHS
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Consent Form – Research Study Phase II

Research:

A Skin-to-Skin Contact (SSC) Facilitating Device used within a Mother-Infant Dyad: Exploring its Acceptability, Usage and Effect on Health Outcomes in the Postnatal Period.

Aim: This study aims to explore the effect of a skin-to-skin contact facilitating garment used by women and their babies. This includes its effect on babies' temperature stability, breast and formula feeding, and mother and baby bonding. This part of the study will form two groups of healthy mothers with their babies. One group will receive the Snuby® garment, and the other group will not. Both groups will record how much skin-to-skin contact they have with their babies, their babies' temperatures before and during skin-to-skin contact, their babies' weight and behaviour, their breast or bottle feeding choices, and their views on skin-to-skin contact. The researcher will compare these two groups to see if the Snuby® garment makes a difference.

You are invited to take part in this part of the study. Participation is entirely voluntary, and you can withdraw at any time.

Researcher: Roisin Bailey

	Please initial each box below to show your agreement.
I confirm that I have been given and read the participant information sheet, and that I fully understand it.	
I have been given the opportunity to ask questions regarding the research, and that I have been given satisfactory answers.	
I confirm that my consent is given totally voluntarily.	
I understand my consent can be withdrawn at any time without the need for justification.	
I understand that I will be randomised to one of two groups.	
I understand that there is equal chance of being in the comparison group and not trialling the Snuby®, and equal chance I will be in the group trialling the Snuby®.	
I understand withdrawing from the research study will not affect my clinical care in the maternity services in any way.	

Sandwell & West Birmingham Hospitals NHS
NHS Trust

I understand the data I supply will be treated as confidential and anonymised.	
I understand that this research will be published in a thesis, and may be published in journals, conferences and in other academic writing made available to the general public.	
I agree to the use of direct quotes from myself being anonymised and included in the research and following publications.	
I agree to the data I provide being stored as per the Data Protection Act (1998), and kept for a minimum of five years as per University policy.	
If I attend the focus group, I agree to respect other participant's privacy by not discussing any other participant's involvement outside of the focus group.	
I understand that if I choose to withdraw following the focus group, the researcher cannot remove the data I have provided as it is not personally identifiable on the audio recording.	
I understand that if the researcher has significant concerns about the safety and wellbeing of myself, or a member of my family, she will share this information with the appropriate safeguarding agencies. I understand that this may be done without my consent if the researcher is unable to safely discuss these concerns.	
I understand that if I am given a Snuby® as part of the research, I cannot share it with other friends or family, and I will make sure it is only used by me and my baby.	
I agree to take part in the above study.	

Researcher: Signed: **Print Name:** **Date:**

Participant: Signed: **Print Name:** **Date:**

One copy to participant, one copy to be stored securely with researcher.