University of BRISTOL

NIHR Advanced Fellowship (Anna Pease)

5 year Fellowship (start date 1st March 2021)

Work package 3: Co-production and Realist Evaluation study June 2023 – February 2025

The Baby Sleep Project Part 2

Supporting families with infants at risk of sudden unexpected death in infancy.

A protocol for co-production and realist evaluation of interventions to support safer infant sleep for families with infants at increased risk.

Research Reference Numbers

Short study title	**The Baby Sleep Project Part 2**
Protocol version number and date	**V3 07.02.2024**
Start Date	**01.06.2023**
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Version History	**Description of Change**
V1 25.07.2023	Required changes from ethics committee: Poverty – clarified that our target group will be eligible for extra support from health services. Detail on sample size added along with new figure 5 Detail on recruitment and recording consent added Non-English speaking participants included New document appendix T signposting to support for families included
V2 07.11.2023	New introductory cards for potential participants requiring substantial amendment and REC review. See page 25 and appendices U and V

Glossary and Abbreviations

Sudden Unexpected Death in Infancy (SUDI)	The death of a baby which was not anticipated as a significant possibility 24 hours before the death.
Sudden Infant Death Syndrome (SIDS)	"[T]he sudden unexpected death of an infant <1 year of age, with onset of the fatal episode apparently occurring during sleep, that remains unexplained after a thorough investigation, including performance of a complete

	autopsy and review of the circumstances of death and the clinical history" (Krous et al. 2004 (1)).
Back to Sleep Campaign	A national UK campaign to encourage parents to place their infants on the back for sleep.
Bed-sharing	Sharing an adult bed with a baby where both the baby and the adult are asleep.
Co-sleeping	Sharing any sleep surface (beds, sofas etc.) with a baby where both the baby and the adult are asleep.
Cot death	An older term for Sudden Infant Death Syndrome.
Prone sleep	Refers to an infant sleeping on the tummy.
Mortality (Rate per 1000 live births)	The number of babies who died for every 1000 live births. E.g. a rate of 0.3 means 3 babies in every 10,000 live births.
Sofa-sharing	Sharing a sofa with a baby where both the baby and the adult are asleep.
Supine sleep	Refers to an infant sleeping on the back.
Pre-term	The birth of a baby at fewer than 37 weeks' gestational age.
Low birth weight	Babies who are born weighing less than 2,500 grams (5 pounds, 8 ounces).
BNSSG	Bristol, North Somerset, South Gloucestershire
REC	Research Ethics Committee
ICB	Integrated Care Board

NFP or FNP	Nurse Family Partnership (USA) or Family Nurse Partnership (UK)
NICU	Neonatal Intensive Care Unit

Contents

KEY STUDY CONTACTS

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Funder(s)	NIHR Advanced Fellowship Ref: NIHR 300820
Key Protocol Contributors	Project Management Team: Prof Peter Blair Prof Jenny Ingram Prof Peter Fleming Dr Becky Lambert
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STUDY SUMMARY

Study Title	The Baby Sleep Project Part 2: co-production and realist evaluation of interventions to support safe infant sleep for those at increased risk
Internal ref. no. (or short title)	The Baby Sleep Project Part 2
Study Design	Co-production and Realist Evaluation methods engaging survey data, interviews, focus groups, photo voice and observations
Study Participants	Parents, caregivers, carers, partners, peers and wider family members of infants considered to be at increased risk of Sudden Unexpected Death in Infancy Health visitors, family nurse partnerships, neonatal nurses and midwives
Planned Size of Sample (if applicable)	40-50 health professionals 180 families
Whole Study Period	1st June 2023 – 28th February 2025
Research Aim(s)	Develop and evaluate an intervention, comprising a suite of resources, to increase the uptake of safer sleep advice in families with infants at increased risk of sudden unexpected death in infancy.

PLAIN LANGUAGE SUMMARY

Aim

Introduction

Every year in the UK, about 300 babies under a year die suddenly and unexpectedly, and most of these deaths remain unexplained. ‘Safer Sleep’ messages (e.g. Back is best) have worked for lots of families, but the deaths that now happen mostly occur within families experiencing poverty. Many of the deaths in these families could be prevented as they almost always have known, avoidable risks present, like sleeping on a sofa with a baby. We have developed some resources and tools for health professionals and families that we hope will help, but we need to test them to see how they work, for whom and under what circumstances.

What will we do?

Phase 1: Co-production

We will work together with families, relevant health professionals, commissioners and community based family support workers to refine and add to a suite of web based and print resources that can be used to support caregivers to follow safer sleep advice. Eligible family members will be responsible for the care of a baby aged one year or younger and will be eligible for extra support from their health services. We already have two resources in development: one is a risk assessment and safer sleep planning tool, and one is a milestones card for babies on neonatal units. We need to add to this suite of resources to support families with the ‘why’ and ‘how’ to follow safer sleep advice, in a way that makes it easier to follow. We will hold 4 workshops to do this, in locations accessible to all. Participants will be paid for their time.

Phase 2: Realist Evaluation

Realist research (using online questionnaires and interviews with health professionals and families) will be used to answer questions about the resources developed above. The evaluation will look at how they work, who they work for, why they work and in what context do they work. ‘Work’ means to describe the mechanism of the intervention, how it interacts with the context and the resources to produce changes in behaviour. For example, some health advice works by making people fearful for a particular outcome – someone might give up smoking because they are fearful of lung cancer. This fear is the mechanism, this is how telling people that smoking causes lung cancer can help them to quit. We have been investigating how people understand and act on advice about infant sleep and we have some ideas about the mechanisms we can try to use in our project. The realist evaluation will develop evidence-based theory about how the resources work or don’t work and why. We have already developed an initial programme theory from previous research.

What will happen to the results?

We will publish our findings in academic journals and talk about them at conferences. We will make sure the people who took part in the study hear about them first. We will use the results to make changes to the resources to make them work better. If they are shown to be useful, we will work with charities and the NHS to see how we can roll them out across the whole of the UK so that they can help as many people as possible, and hopefully save lives.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research (NIHR)	Advanced Fellowship overall award value £886,231

ROLE OF STUDY SPONSOR AND FUNDER

The University of Bristol is the sponsor for this study and has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University.

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

The University of Bristol's Public Liability insurance policy provides an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

The funder is the National Institute for Health and Care Research NIHR Advanced Fellowship award.

The Sponsor (University of Bristol) will have overall responsibility for the initiation and management of the study, but on a day-to-day basis this responsibility will be delegated to the chief investigator, and study management team. The funder (National Institute for Health and Care Research) will remotely monitor study progress against key targets by means of reports from the chief investigator and study management team. They will review and approve outputs (abstracts, conference presentations, academic papers and final report) from the study, but will not seek to influence the reporting of findings. In this regard, the views expressed in the outputs will be those of the author(s) and not necessarily those of the NHS, the National Institute for Health and Care Research or the Department of Health and Social Care.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Team

Members: Dr Anna Pease, Dr Becky Lambert, Prof Peter Blair, Prof Jenny Ingram, Prof Peter Fleming, Dr Michelle Farr.

The management team will meet at least monthly throughout the study keeping track of all aspects of the research including recruitment and data collection.

Professional Advisory Group

Members: Prof Karen Luyt, Prof Helen Ball, Jennifer Ward, Jeanine Young, Stephanie Lovell, Natasha Bradley, Bliss representative, iHV (institute of Health Visiting) representative, Katalin Bagi (ICB (integrated care board) representative).

The professional advisory group will meet twice yearly to provide overall supervision of the study on behalf of the NIHR and sponsor. The committee will concentrate on the progress of the study, protocol adherence, interpretation and dissemination of the findings.

Family Advisory Group - PPI

The family advisory group will provide ongoing patient and public (PPI) involvement throughout this study. The group comprises family members with young children we aim to meet with the group regularly to request their advice on: good ways to encourage parents/carers take part in surveys and interviews, participant information sheet wording, topics for interviews, interpretation of findings and dissemination to wider audiences. Group members will be supported by the inclusion of an induction into the role of advisory group member where we have agreed ‘safety ground rules’ for our meetings. UK Standards for Public Involvement, as recommended by the NIHR (2), will be used to provide support with voicing opinions, understanding research terms, signposting for emotional support and ensuring barriers to accessing meetings are broken down and that vouchers/payments for participation are paid promptly.

PROTOCOL CONTRIBUTORS

Chief Investigator: Dr A Pease

Study Management Team: Dr Becky Lambert, Dr Alice Keegan, Prof Peter Blair, Prof Jenny Ingram, Prof Peter Fleming

Professional Advisory Group

Family Advisory Group

KEY WORDS: SUDI, Sleep, infant care, risk factors, parenting, decision-making

Table 1: Gantt Chart with study milestones

Co-production of the intervention	March - May 23	June - August 23	Sept - Nov 23	Dec - Feb 24	March - May 24	June - August 24	Sept - Nov 24	Dec - Feb 25
Stakeholder Consultation								
Co-production workshops								
Prototyping								
Realist evaluation study								
Initial programme theory development								
Ethics application								
Recruitment of health teams								
Phase 1 pilot data collection								
Phase 2 Intervention delivery and data collection								
Analysis								
Refining programme theory								
Application of middle range theories								
Dissemination activities								

STUDY PROTOCOL

The Baby Sleep Project Part 2

A protocol for co-production and Realist Evaluation of an intervention to improve infant sleep safety and reduce sudden and unexpected deaths in infancy.

1 Background

Annually in the UK 300 infants die suddenly and unexpectedly (Sudden Unexpected Death in Infancy or (SUDI).(3) Of these deaths most (approx. 70%) remain unexplained following investigation, labelled Sudden Infant Death Syndrome (SIDS) or unascertained. The risk factor profiles between SIDS and explained SUDI are similar, suggesting inconsistent categorisation and that interventions could affect both.(4, 5) Every death profoundly affects family members, health professionals and wider society.(6, 7) While public health messages for safer sleep have worked in the general population, currently most deaths occur in families experiencing deprivation.(8, 9) Recent NCMD data also show a significantly larger proportion of unexplained deaths were of infants living in the most deprived neighbourhoods (42%) than those in the least deprived neighbourhoods (8%), which is a five-fold increase. Many deaths may be preventable as they involve known risks.(10) General advice given to parents is failing these families and there is little evidence of what might reduce the risks in often vulnerable families.(11)

Research into preventing unexpected infant deaths began with studies identifying three major risk factors: prone sleeping, overwrapping and exposure to cigarette smoke. These factors were combined and translated into advice for parents in the UK's 'Back To Sleep' campaign in the early 1990s.(12) While these messages remain a core part of SIDS risk reduction, the identification of further risk and protective factors is widely credited as responsible for the subsequent slower but steady fall in rates, from 0.52 per 1,000 live births in 2000 to 0.27 per 1,000 livebirths in 2017.(13) These subsequent risk factors include hazardous co-sleeping (including sofa sharing),(14) and infant head covering with bedclothes.(15) Subsequently identified protective factors include breastfeeding(16, 17) and room sharing.(18) The provision of this information to families when their babies are born, through health professionals and national campaigns, further reduced rates in the population of England & Wales to a low in 2019 of 0.29 per 1000 live births. Babies born to those in lower socioeconomic groups remain at disproportionately higher risk. In a review of child deaths from Wales in 2015, for 73% of babies that died in co-sleeping environments, this sleeping arrangement was not usual and was chosen for a specific reason that night, usually an unsettled baby.(19) An analysis of serious case reviews involving 27 unexpected infant deaths from 2011 – 2014 found unplanned final events in 12 (44%) cases, mostly involving unplanned co-sleeping and alcohol or drugs.(20) More recently, an analysis of deaths in 2020 found that 75% occurred with at least one known sleep environment risk factor present. (21)

Currently, midwives and health visitors deliver safer sleep advice. They generally aim to increase parent knowledge of SUDI risk and protective factors. This model has worked well for some but can fail those starting from a disadvantage with multiple risk factors present at birth. Our previous work with health professionals suggests they would welcome a new approach for use with families with infants considered to be at increased risk.(22-24)

Several studies have investigated the interpretation and application of safer sleep advice by families with infants at increased risk of SIDS. From previous work done by our team,(23) mothers were sceptical of didactic messages, wanting to understand how or why the messages work but felt no-

one could explain this. In 2020, members of our team were commissioned by the National Safeguarding Panel Practice Review into SUDI to conduct a systematic review of the literature into interventions to prevent SUDI in families with children at increased risk of abuse or neglect. (25) This work included a systematic review and thematic synthesis of qualitative research investigating decision-making for the infant sleep environment in families with children considered to be at risk of SUDI. (26) This review highlighted the influence of peers and family in decisions, and a lack of studies which included their practices, knowledge and sources of information. The review also recommended investigating ways of improving discussions about the risk of SIDS in families where the risks are higher. In a study by Clarke in 2016(27) mothers described competing needs for sleep duration over safety, leading to unplanned risk situations. Similarly, our own previous research, mothers described ignoring the advice in favour of coping with their own sleep deprivation or unplanned living arrangements.(28) Increased likelihood of risky infant sleep environments due to disruption to routine is also seen in epidemiological data. Unaccustomed sleeping environments are consistently seen to increase risk, where they are measured.(19, 29, 30) While social *deprivation* is easily measured and correlates with increased risks for a range of diseases and outcomes, the mechanism by which social *disruption* mediates this relationship remains unclear. The development of new theory-based tools and resources is now paramount to bringing down death rates in those with infants most at risk. We have good data on which babies are more at risk, and good evidence of several principles that can be actioned into a set of resources by families and health professionals to improve the credibility of advice, make safer sleep the priority during times of disruption, and empower families with information and support to impact their decision making and their own needs for sleep.

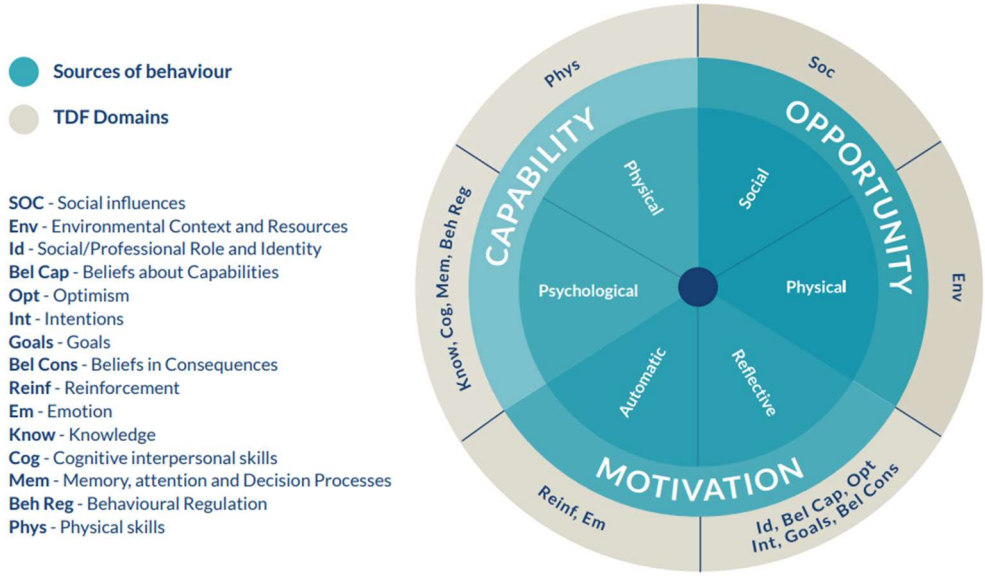
2 Theoretical basis

2.1 COM-B and TDF

The COM-B is a behaviour change model which describes how capability and opportunity interact with motivation, to influence behaviour.(31) Capability describes the psychological and physical capacity to engage in a behaviour. Opportunity describes the external factors that influence behaviour, and motivation can be defined as reflective or automatic brain processes that influence behaviour. The Theoretical Domains Framework (TDF) was developed as an integrative framework of behavioural change theories and provides a more detailed explanation of the COM-B model.(32) Capability is constructed of: knowledge, skills, memory, attention and decision processes, and behavioural regulation. Opportunity is constructed of: social influences and environmental context and resources. Motivation is constructed of: beliefs about capabilities, beliefs about consequences, intentions, social/professional role and identity, goals, optimism, reinforcement and emotion.(33) Figure 1 shows how the COM-B and TDF relate to each other. Recent work has used the COM-B model and TDF Framework to map interventions to increase the uptake of safer sleep advice, in families with infants at increased risk of SIDS finding that advice-giving interventions are most often used, but that there may be potential for incorporating motivational factors into intervention design to be more successful for this group. Another analysis mapped a qualitative meta-synthesis of decision-making for safer sleep in higher risk families to both COM-B and TDF again.(34) This analysis elicited findings relevant to motivational factors including previous parenting experiences, beliefs about ‘fate’, using alternative strategies which were more convenient and understanding how the messages protect their infants. The COM-B will be used as the basis for a ‘middle range theory’

which can be used to extract the transferable parts of the baby sleep project programme theory, in order to make it applicable in more settings and potentially, to a wider range of topics outside safer infant sleep.

Figure 1: The three components of the COM-B model and the corresponding TDF domains, taken from Michie, Atkins and West, 2014. (32)



2.2 Realist Evaluation

Realist evaluation is essentially a theory-based approach to evaluation, first introduced by Pawson and Tilley in 1997.(35) Realist philosophy sits between positivist and constructionist views, asserting that reality exists outside of us, but that it is filtered through social constructs such as culture, identity, gender and social systems. This means that efforts to learn about the world are possible, but that these efforts will only increase our understanding of how the world works via the human brain, and that universal truths remain largely unknowable. For programme evaluations, this means that the impact of programmes on outcomes exists, but this may be difficult to identify as mechanisms are rarely 'seen'. Mechanisms are often the cognitions and subsequent decisions by those influenced by the programme or intervention. For our purposes, mechanisms refer to decision making of parents and caregivers about how and where their babies will sleep. We are fortunate that a body of research exists for us to draw on, to provide evidence of the cognitions and prerequisites that can support (or hinder) parents and caregivers to follow safer sleep advice. Pawson and Tilley describe mechanisms as the 'casual powers' of programmes and differentiate between causation and attribution.(36) Causation describes how programmes bring about change, and attribution describes how changes or outcome can be assigned to specific parts of programmes.(37)

Realist evaluation is a theory-led approach to evaluation rather than a prescriptive set of methods. The initial programme theory should inform the choice of methods for data collection and analysis.

Realist Evaluation considers what works, for whom, under what circumstances, recognising that nothing works the same way for everyone. Where randomised controlled trials deal in overall effects on target populations, they do so without explaining sources of variation between people. Applying them to complex interventions with rare outcomes introduces issues including attrition, non-blinding,

social desirability bias and other problems with self-reported outcome measures. Realist evaluations have been applied successfully to other interventions and can inform the conditions needed for the implementation of similar interventions.(38) They do this via 'middle range theories' which indicate domains that could be generalised to other settings, thus providing useful insights into maintaining intervention effectiveness where contexts change. (E.g. apples increase vit C but if no apples, can use oranges – vit C is the mechanism, fruit availability is the context, fruit provision is the intervention).(39)

2.3 Development of the Initial Program Theory

Several sources of data were used to develop the initial programme theory, describing the functions of the intervention with a focus on causal mechanisms and outcomes. The theory should include the how and the why of how the intervention delivers on the outcomes described. The sources of data include: 1) qualitative interviews with families with infants at risk, 2) a survey of infant care practices, 3) a synthesis of qualitative literature on decision making for the infant sleep environment, 4) a COM-B mapping of this qualitative synthesis, 5) a systematic review of interventions to increase uptake of safer sleep advice, 6) a COM-B analysis of this systematic review.

Each source of data was used to develop configurations describing the context (C) of our intervention, potential mechanisms (M), and subsequent outcomes (O). Initial 'C-M-O' configuration statements were used to inform the initial theory.

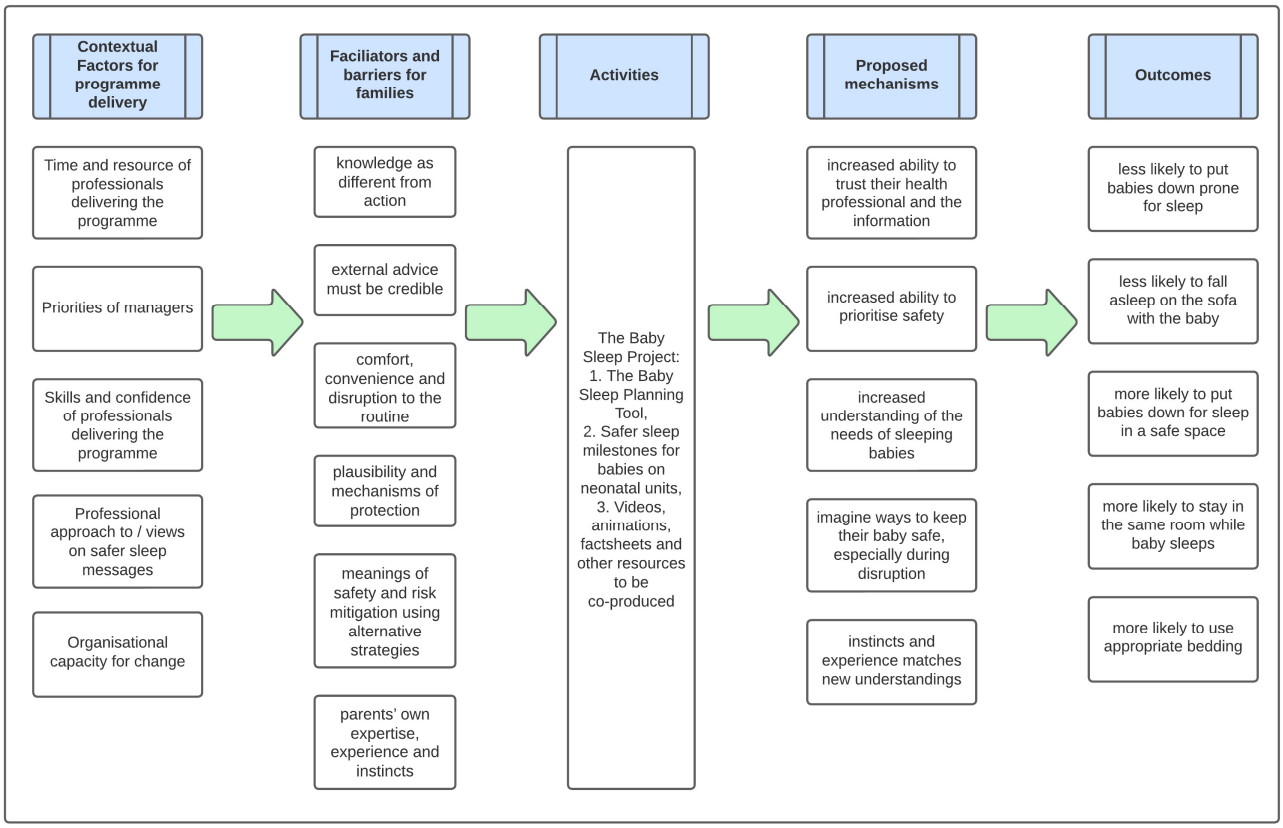
2.3.1 Initial CMO configurations:

Where health professionals value the importance of conversations about safer sleep and are willing to deliver the tools in a non-judgemental, curious way, (CONTEXT) providing caregivers with information about their baby's individual risk and the opportunity to plan for safety will increase their ability to prioritise safety especially during busy nights and imagine ways to provide a safer environment for their baby (MECHANISM), thus reducing their risks for SIDS by making sure their baby sleeps in a safe environment (OUTCOME).

Where managers prioritise the need for time and resources to be directed to those families with more vulnerable infants (CONTEXT) building relationships via continuous, partnership-based approaches will allow families to trust and believe in the safer sleep messages presented to them (MECHANISM), increasing the likelihood that they will develop good habits from the start of a baby's life by following safer sleep advice for every sleep (OUTCOME).

When professionals understand the mechanisms of protection of safer sleep and possess the skills and confidence to present the tools and resources to families with infants at risk (CONTEXT), supporting caregivers to understand the physiological needs of their sleeping baby and how safer sleep advice protects them, will influence their own instincts and expertise as parents or caregivers, allowing them to feel confident about how to protect their baby during sleep and empowered to make decisions about where and how their baby will sleep (MECHANISM), resulting in babies sleeping in safer environments, especially in situations where the routine is disrupted (OUTCOME).

Figure 2: Visual representation of the initial programme theory for the baby sleep project:



3 Phase One: Co-production of the Intervention

3.1 The intervention

The intervention comprises a suite of web based resources for health professionals and families about infant sleep. The co-production phase will be used to add resources to this 'toolbox', but we have already developed two resources which are described below.

The Baby Sleep Planner

The baby sleep planner is a web-based tool which uses an algorithm to calculate an individual baby's risk for SIDS, and provides a planning tool for families to plan for a safe sleep environment, especially during times where the normal routine is disrupted. The tool was developed as part of an NIHR RfPB grant (NIHR202230) via a co-design process, with associated process evaluation. The tool allows for the sleep plan to be downloaded as an image to the user's phone for sharing with wider friends and family. The tool was popular with health professionals and caregivers, with evidence of potential for impact from our evaluation.

Safer sleep milestones card for babies on neonatal units

Babies who spend time on neonatal units are sometimes cared for in ways that don't fit the national safer sleep advice. Families told us that it could be confusing to be told to change their infant's sleep environment once home and would have appreciated knowing why, and having this modelled while their baby was still on the unit. The safer sleep milestones card uses five milestones that can be expected to be reached while the baby is on the unit and each one can be ticked off as they apply.

The card was developed as part of this fellowship and via a collaboration with University Hospitals of Leicester NHS Trust, Stork, The Lullaby Trust and Bliss. A co-design process was followed engaging caregivers of infants who had spent time on neonatal units and unit staff, consultants and the homecare team.

3.2 Engagement

We will invite family members via local children's centres in the Bristol, North Somerset & South Gloucestershire region to take part in the co-production study. We will aim to include young parents/caregivers, parents/caregivers whose infant spent time on a neonatal unit, and parents/caregivers with social worker involvement, or living in supported accommodation. We will also invite health visitors, midwives, neonatal nurses and specialist family nurses to take part, along with the family members they support, if that is preferred. We will investigate the possibility of pairs of support workers and family members to attend, where people may feel more comfortable attending with someone they already know. We will involve health professionals and commissioners who are not at the workshops, separately, to keep number small and maintain a safe and inclusive environment for the families involved. Co-production does not involve the collection of research data, so no formal consent process is required, however we will seek views from the members of the co-production team on a signed copy of the project aims and involvement for each person.

3.3 Co-production workshops and a focus group

Aim

- Use co-design principles to develop intervention resources and training to increase uptake of safer sleep advice for families with infants at increased risk of SUDI.

The co-production workshops will bring together families with infants at increased risk of SUDI, health professionals, and researchers to design and produce resources to support families to follow safer sleep advice. The family members will be invited to take part via their health professional. Co-production is where 'citizens can play an active role in producing public goods and services of consequence to them'.(40) Participants will not be required to provide informed consent for these workshops as they do not constitute research.

The workshops will engage the five principles of co-production, provided in the NIHR's 'Guidance on co-producing a research project', (2) (see Table 2).

Photovoice

Photovoice is a visual research methodology which is founded in community-based participation. As a methodology it is intended to balance power relationships between participants (co-investigators) and researchers, allowing the experiences of the co-investigators to take prominence in the process. Photovoice is often used as a method to initiate social change and as a way to engage stakeholders and policy makers.

Participatory arts-based research, such as photovoice can have positive effects on those involved, resulting in empowerment, improved mental health and greater social inclusion (Hacking et al. 2008;

in participatory research methods book[1]). As a visual research method, co-investigators are not required to have significant communication or education levels in order to participate in the process.

The photovoice process involves providing individuals with a prompt and inviting them to take photographs or contribute images that relate to that prompt. Participants are then invited to a group session where they create 'poster narratives', selecting photographs and including audio or written narrative(s), explaining the relevance of that visual image for them in relation to the prompt. Co-investigators can then be invited to participate in facilitator-guided in-depth interviews or focus group discussions to share narratives and engage with others having similar experiences.

Focus Group

Following the fourth workshop we will invite willing participants to gather their feedback regarding the co-production experience. This will constitute research and we will use an information sheet (Appendix B) and informed consent form (Appendix C). The focus group will allow for reflection on the coproduction process, providing rich data from participants that can be summarised and reported on in the peer reviewed publication from this work.

Table 2:

Principles for co-production:

1. **Sharing of power** – the research is jointly owned and people work together to achieve a joint understanding
2. **Including all perspectives and skills** – make sure the research team includes all those who can make a contribution
3. **Respecting and valuing the knowledge of all those working together on the research** – everyone is of equal importance
4. **Reciprocity** – everybody benefits from working together
5. **Building and maintaining relationships** – an emphasis on relationships is key to sharing power.

While these principles were developed to apply to the co-production of research project, we are applying them here to support the co-production of a health intervention. Enacting these principles will involve setting up the workshops in a space familiar to health professionals and families such as a local children's centre. We will use our first workshop to establish our purpose and set some ground rules together, using the principles listed above in order to create an environment where all voices can be heard and respected. Agreeing a joint understanding and clarifying roles and responsibilities will be a key part of this initial workshop in an attempt to establish a more equal share of power. We will provide opportunities for communication between workshops so that people can continue to contribute in ways that suit them. For example, attendees will be asked for their preference regarding communication: those who cannot attend in-person may be sent a summary via email and invited to participate online, and, other attendees may feel more comfortable sharing their thoughts via email or other forms of communication (messenger apps, for example), in

individual conversations rather than within a group. We will decide together how to value all members of the group, and will provide options for financial remuneration as well as other types of reciprocity, for example letters of reference. We will make sure there is time each time we meet to clarify how we have understood our roles and responsibilities, and provide summaries of our discussions and decisions for all members.

We will organise four workshops and a research focus group, as follows:

Workshop 1

- Purpose, roles and ground rules/safety
- Generating ideas through our own experiences
- Photovoice activity preparation for the following workshop. Ensure participants have a phone with a camera (or supply one) and ask them to take photos before the next workshop of moments/scenarios/objects which are significant in their opinion in relation to their baby's sleep. These photos will be used as a discussion tool in the following workshop.

Workshop 2

- Discussing Photovoice photos and connecting ideas back to our purpose
- Deciding on content to be co-created
- Planning for who will do what by when

Workshop 3

- Review initial content and discuss how it could work
- Generate refinements and decide on those items
- Planning for who will do what by when

Workshop 4

- Final 'reveal' of completed resources
- Ideas generating for how to test out the resources to see if they work
- Keeping in touch as a virtual group

Focus group (research)

- Reflect on the codesign process via a research focus group
- Explore perspectives and views on the coproduction process

4 Phase Two: Realist Evaluation study

4.1 Research Aim

Following the four co-production workshops, the study will enter its second phase. Our aim for this phase is to evaluate an intervention, comprising a suite of resources, to increase the uptake of safer sleep advice in families with infants at increased risk of sudden unexpected death in infancy.

Research Questions

1. How, why, for whom, to what extent and in what circumstances do targeted infant safe sleep resources (the baby sleep project resources) improve the uptake of safer sleep advice?
    a. What are the mechanisms by which the baby sleep project resources work to improve the uptake of safer sleep advice?
    b. What are the important contexts which determine whether the different mechanisms of the new resources work to improve the uptake of safer sleep advice?
    c. In what circumstances are the baby sleep project resources likely to be effective?

4.2 Objectives

- Investigate barriers and facilitators to using the resources with families using CMO informed interviews with 3 groups of health professionals.
- Examine how families respond to the resources using CMO informed interviews with participating caregivers.
- Track parental self-efficacy using the Tool to measure Parenting Self-Efficacy (TOPSE) (38)
- Track adherence to infant safer sleep advice using self-reported sleep diaries
- Track intervention implementation using the NoMAD Implementation measure based on NPT(www.normalizationprocess.org).(41)

4.3 Outcomes

- Prototype intervention with associated training materials.
- Interview and focus group analyses used to refine and validate programme theory about what works, for whom, in what circumstances.
- Data on parental self-efficacy and sleep environment.
- Data on intervention implementation using Nomad questionnaires.

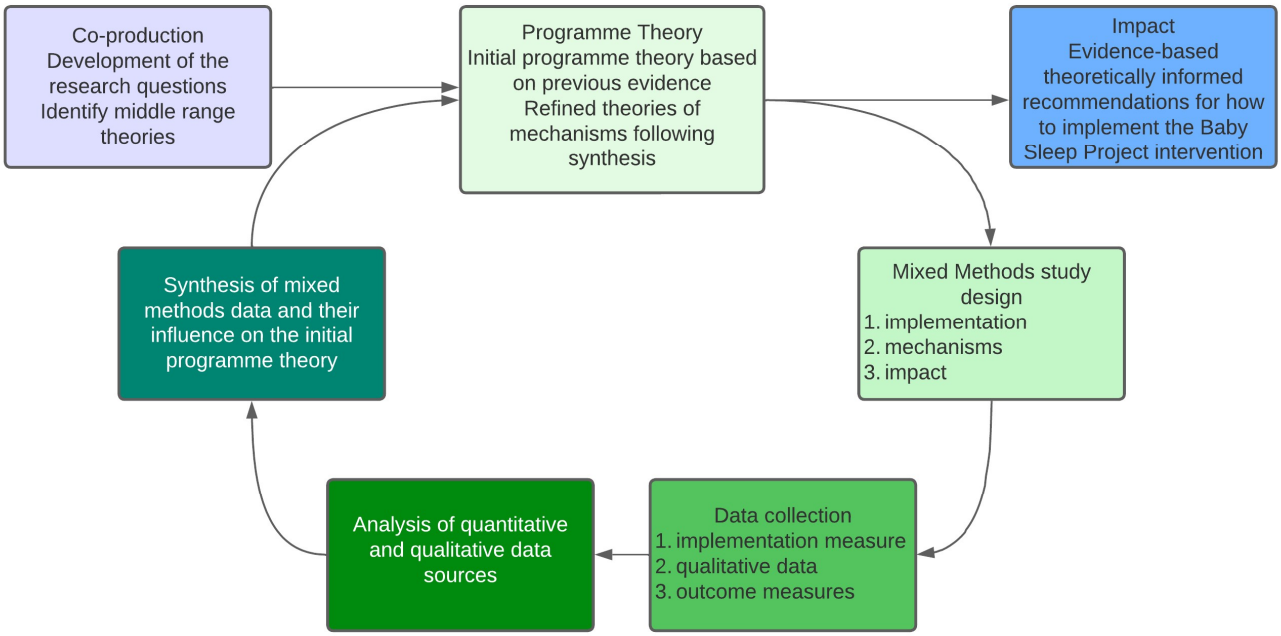
5 Methods

5.1 Phase Two – Realist Evaluation

5.1.1 Design

The Realist evaluation study is a mixed methods research project using quantitative surveys, qualitative interviews, and focus groups. There will be a three month baseline phase to collect baseline data with no intervention period, to refine data collection methods. Figure 3 shows the realist research cycle we will engage.

Figure 3: Realist research cycle



5.1.2 Sites

To be confirmed. We have had interest from:

HCRG Care Group - health visiting and family nurse partnership services in Bristol and North East Somerset, Swindon, Wiltshire, Essex and Lancaster

University Hospitals of Leicester NHS Trust – neonatal service

University Hospitals Bristol and Weston NHS Foundation Trust – neonatal service

We intend to include 9 health professional teams in total: three health visiting teams, three neonatal team and three family nurse partnership teams.

5.1.3 Participants

5.1.3.1 Inclusion criteria

- Health Professionals working in deprived areas or who caseload with more vulnerable families (FNP and neonatal nurses)
- Parents/caregivers of infants either still pregnant or with infants under 2 weeks old at the time of recruitment, receiving services from recruited health professional teams

5.1.3.2 Exclusion criteria

Individuals under 16 years of age, anyone who lacks cognitive capacity to consent.

5.1.4 Sampling

Quantitative

1. Nomad questionnaires – 3 timepoints, completed by each health professional who is using the intervention.

2. Parental self-efficacy measures when baby is approx. 4 weeks and approx. 8 weeks old.
3. Infant sleep diaries when baby is approx. 4 weeks and approx. 8 weeks old.

Qualitative

1. Health professional interviews
2. Family member interviews

5.1.5 Sampling technique

We will purposively sample all eligible families receiving support from participating health professional teams to take part in the study.

Purposive sampling will be used to recruit both health professionals and family members to interviews. We will aim to interview a purposive sample of health professionals using the resources, varying on professional role and site. Family members will be sampled using a matrix to provide a range of views which will include variation on infant risk status.

5.1.6 Recruitment

5.1.6.1 Sample identification

Approach

We will approach teams of health visitors, neonatal nurses, midwives and specialist nurses (family nurse partnerships) working with families experiencing the effects of living in deprivation, or who are eligible for extra support from those services and invite them to take part in our evaluation. These health professionals will be given an information sheet by the research team about the study with information about taking part (Appendix D).

Baseline data collection

Health professionals who agree to take part will be asked to approach eligible family members to ask for consent to be contacted by the study team. Health professionals will show eligible family members the introductory video, or the introductory text (Appendices G & H) **and** provide them with a study details postcard (Appendices U & V), inviting them to take part in the study. They will also give participant information sheets to eligible family members (Appendices E & F), containing an invitation to an interview, with contact details (email, messenger and phone number) to contact the research team if they would like to take part. For family members with literacy difficulties or where they don't speak English, this information sheet can be read with support from the health professional, Language Line, or another family member, if appropriate. We will ask health professionals to promote the study with families at the first point of contact, in the antenatal period or shortly after admission to a neonatal unit. We will ask them to pass on an information sheet and video link and the research team contact details. Health professionals will be asked to record that they have passed details to the study team in the family member's medical notes. Families who contact the research team, or give permission for their contact details to be shared by their health professional, will be contacted by a member of the team, giving the family time to think about participation, ask questions, and go through full informed consent.

Health professional training

Following baseline data collection, we will invite health professionals to a 1-hour training session in the intervention. Health professionals will be given full access to the new resources, and training materials,

with online support from the study team, and via a named Baby Sleep Project Champion at each of the three sites.

Intervention activities

We will encourage health professionals to use the new resources primarily with families who are eligible for extra support. This will be different for different teams, and for some it will be all of their clientele, for example family nurse partnership nurses. Families can see and use the resources without taking part in the study. We will ask health professionals to approach all family members who have seen or used the resources, to ask for consent to be contacted by the study team.

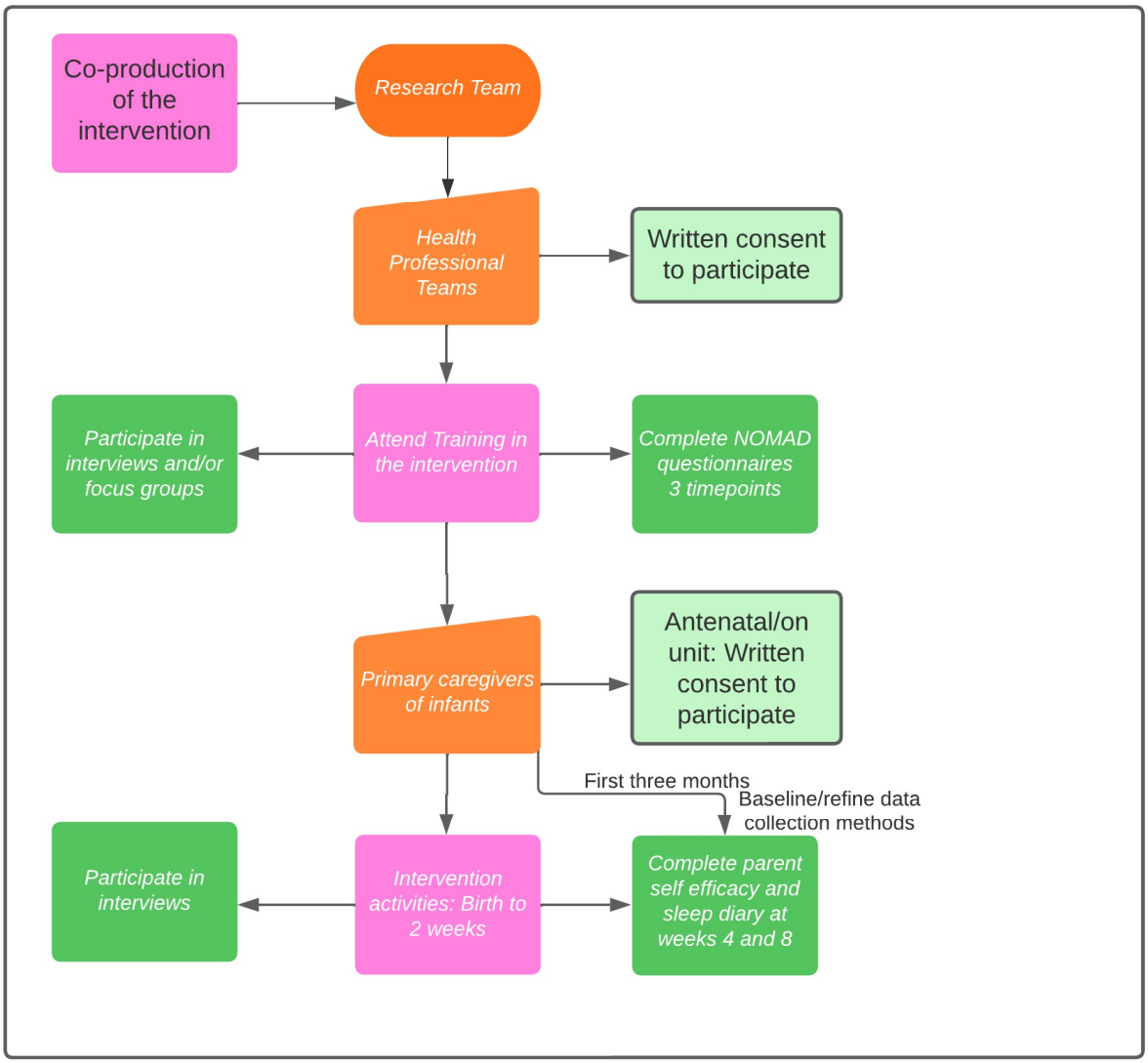
Health professionals research activities

We will ask all health professionals who take part in the study to complete NOMAD questionnaires at three time points, and ask a subset to take part in an interview or focus group.

Families research activities

We will invite families who give consent to take part, to complete online surveys when their babies are 4 weeks old and again when they are 8 weeks old. We will also invite a subset to take part in an interview. Figure 4 shows the intervention and research activities for health professionals and families taking part in the study.

Figure 4: flowchart of evaluation study



5.1.6.2 Consent

Consent to take part in the study will be obtained by members of the research team from both health professionals and parents/caregivers.

The consent form will be online (via Jisc) or on paper (Appendices I & J).

All users who access the intervention will be asked for their consent for their data to be used within the study in order to improve the resources for other families. A consent statement will be displayed on the landing page before accessing the resources.

5.1.6.3 Participants

We will recruit teams of health professionals in each site who either work in a deprived area, or case load with more vulnerable families, for example family nurse partnerships who only work with mothers under 20, or teams of neonatal nurses.

All those receiving services from one of our recruited health professional teams will be eligible to take part in the study, provided they meet the eligibility criteria.

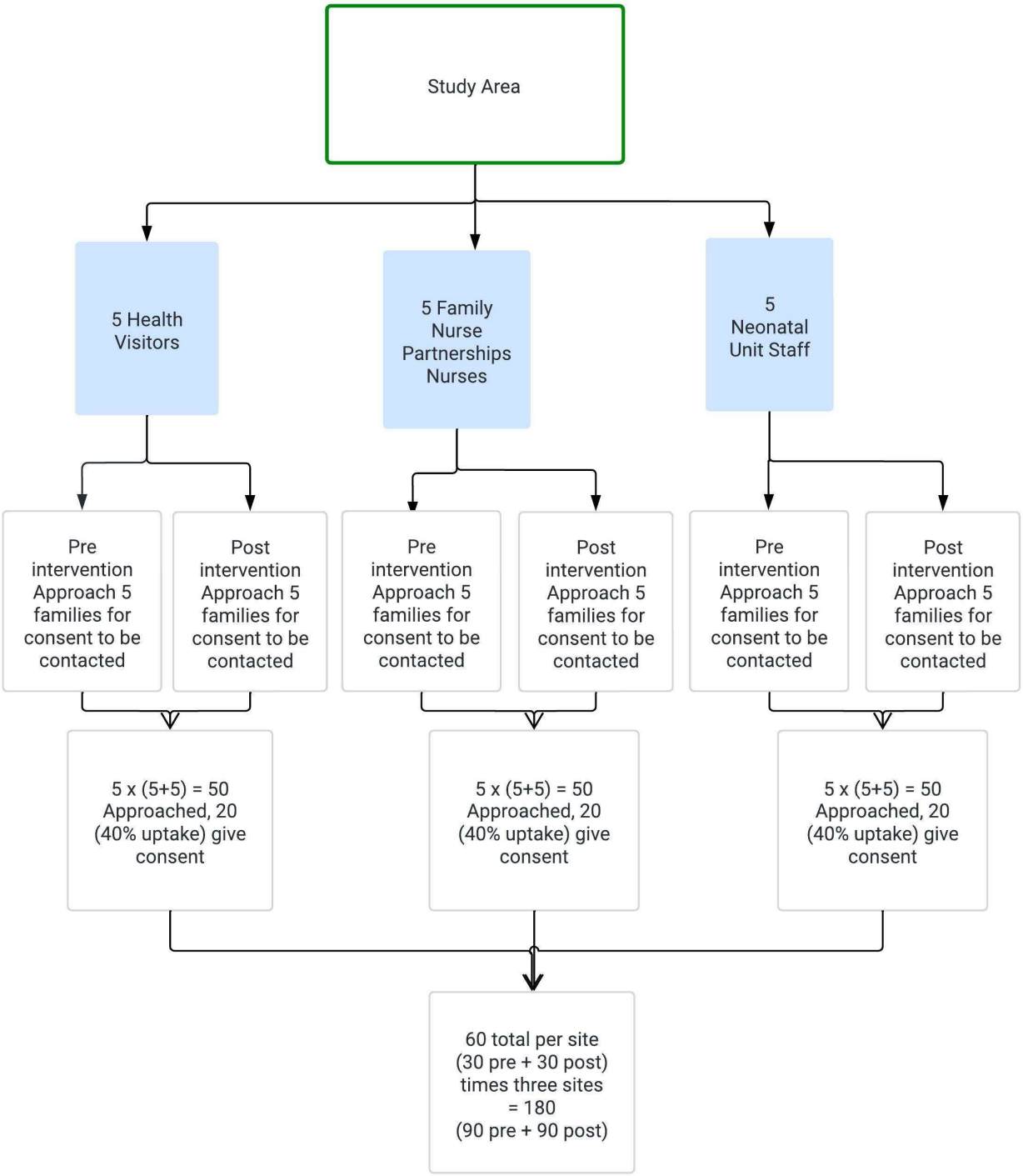
5.1.6.4 Sample size

Sample sizes are based on what is pragmatic and feasible within the study timeframe. We will aim to recruit enough families to provide a signal upon which to base a future power calculation on for a full trial or implementation study. We will aim to sign up 3 study sites in different regions in England. We will approach Integrated Care Boards for details of health visiting teams, family nurse partnerships units, neonatal units and midwifery units. We will aim to recruit 3 teams per area (9 teams total), with approximately 5 health professionals per team (28 approx. 45 health professionals total). Each region will have 3 health professional champions (1 per team) and a clinical principal investigator.

We will aim to recruit between 40-50 health professionals in total, depending on the size of the team.

We will ask health professionals to approach 5 families each before the intervention training (asking for consent to be contacted by the research team), and 5 each afterwards, assuming a 40% sign up rate of approximately 4 families per health professional in total. At this rate, we should be able to recruit 90 families before and 90 families after the intervention, total number of families approximately N=180. Figure 5 shows the sample size per site.

Figure 5: Sample size per study area (site)



5.1.6.5 Withdrawal or discontinuation from the study

Participants will have the right to withdraw from the study at any stage prior to the analysis stage. They will be given the option to withdraw all their data, or to discontinue but allow data already collected to be used.

5.1.7 Data collection

Nomad questionnaires

We will ask each recruited health professional to complete Nomad questionnaires at three timepoints following the start of the intervention period, beginning after they have used the intervention with at least 2 families (approximately 4 weeks after attending the training), then at 8 week and then at 12 weeks following the training. The Nomad questionnaires will be used to assess implementation across each of the four domains of Normalisation Process Theory (coherence, cognitive participation, collective action and reflexive monitoring). A copy of the Nomad questionnaire is included in Appendix K.

Health professional interviews and focus groups

We will invite all health professionals using the intervention to take part in an individual interview. The interviews will take place 8-12 weeks after the implementation of the intervention to give them time to have had some experience with it with several families. Topic guides (Appendix L) will be informed by our CMO configurations and initial programme theory.

Parental self-efficacy measures and sleep diaries

We will ask parents/caregivers to complete online self-efficacy measures and sleep diaries. We will also collect background data on: maternal age, parity, smoking during pregnancy, NICU admission, baby's sex, birthweight, partner support and partner smoking status. For the first three months we will not introduce the intervention to provide a period of testing the data collection methods are feasible and reasonable to request from families. We will make any necessary changes before beginning the intervention period. This will also allow us to compare self-efficacy and sleep outcomes before and after the intervention has been introduced.

The TOPSE (0-6 months) parental self-efficacy measure will be used to measure parental self-efficacy at 3-4 weeks after birth and 8-10 weeks after birth.

The sleep diary will ask about usual infant sleep location/position and sleep location/position last night. Our outcome measures will be prevalence of non-supine sleeping positions and hazardous co-sleeping (co-sleeping with an infant on a sofa, or in a bed with an adult who has consumed alcohol, smokes, has taken drugs that may make them drowsy, or with an infant that was born before 37 weeks gestation or under 2500g birthweight.) See Appendix M for a copy of the sleep diary questionnaires at 4 and 8 weeks. (Appendix M includes the TOPSE parental self-efficacy measure).

Parent/caregiver interviews

Following the completion of the self-efficacy measures and sleep diaries at 8 weeks, parents/caregivers in the intervention group will be invited to a semi structured interview. The topic guide (Appendix N) will be informed by our CMO configurations and initial programme theory. We are investigating the use of PhotoVoice (42, 43) for the parent/caregiver interviews, to encourage participants to take up to 6 images of what 'infant safe sleep' means to them over 7 consecutive days and also complete a logbook documenting each photograph. These photos will be discussed in the semi-structured interview to obtain insights into participants' experiences with the baby sleep project resources and their impact on their decision making for infant sleep.

5.1.8 End of the study

The study will end for health professionals when they have completed Nomad questionnaires at three timepoints, and for a sub group, completed a telephone interview or taken part in a focus

group. The study will end for parents/caregivers when they have completed their online sleep and self-efficacy measures, and for a sub group, when they have completed a telephone interview.

5.1.9 Analysis

Quantitative data will be analysed using STATA to compare responses before and after the intervention is introduced, and differences in changes in scores between 4 and 8 weeks. We will also compare subgroups of responses based on lower (<115) and higher (115+) risk scores, using our recently developed risk scoring algorithm (publication in preparation). Qualitative interview recordings will be transcribed and analysed using NVivo, looking for outcome patterns to identify context-mechanisms-outcome configurations. Nomad questionnaires will present the trajectory of each domain across both timepoints to see changes on each of the four domains. Any transfer of recordings or transcripts will be done using the University of Bristol's Facility for the Upload of Large Files (FLUFF), which is a secure method of transfer, sending a specific link to download files rather than attach them to emails.

5.1.10 Refining programme theory and applying middle range theories

As per the realist research cycle (figure 3), alongside the synthesis of the findings, we will refine the initial programme theory via modifications to our CMO configurations. We will use evidence collected via the evaluation to make these changes, producing up to date evidence based programme logic and mapping this to the COM-B and TDF model. We will also write up the intervention with consideration for the TIDieR guidance. (44)

5.1.11 Incentives to participate in the study

Coproduction team members will be offered a £20 voucher for attending each workshop and the focus group.

Parents/caregivers who complete the online measures at both timepoints will be offered a £10 voucher. Those who also take part in an interview will be offered a £20 voucher to thank them for their participation.

6 STUDY SETTING

- Co-production workshops will be held in community based facilities in Bristol such as children's centres or family hubs if these are open by the time we start the study.
- The intervention will be delivered predominantly at home visits in the first few days after the baby is born, and on neonatal units.
- Quantitative study measures will be online, or via phone depending on participant preference
- Qualitative interviews and focus groups will be via telephone, online or in person if within reasonable travelling distance for the research team.

7 ETHICAL AND REGULATORY CONSIDERATIONS

7.1 Assessment and management of risk

The main ethical issue with this study is sensitivity around discussing sudden and unexpected death in infancy. We are aware that parents may have had direct or indirect experience of a baby dying. We do not presume anything about the emotional states of people who have lost a baby, and eligible individuals are free to take part if they wish to do so. Our team have many years of experience of discussing sensitive topics with families. We are highly skilled in setting up safety at the start of the interview, are able to listen without judgement, know when to allow participants to keep talking and when to suggest a different topic or signpost to support. When upset is seen during an interview we will use a checklist (Appendix O) to make sure that we take the right steps, document the event thoroughly and follow up or report where required. Each family member who takes part in an interview will be sent a copy of a list of support organisations they can contact for advice about safer sleep for babies and for support with mental wellbeing during parenthood (Appendix T). This will be emailed by the research team, and a paper copy offered to be sent in the post.

Another ethical issue is safeguarding of babies and children. It is unlikely, but possible that the interviews may reveal issues of safeguarding for infants, children and young people. We are committed to protecting the health and well-being of infants, children and young people. Any issues will be reported in line with statutory guidance. If necessary, relevant organizations will be consulted, including the NSPCC or local children's care services. We would make a formal referral when required to a statutory child protection agency or the police. This is in line with statutory requirements that apply to all professionals, whether or not they are involved in research. The CI has recently completed two safeguarding training courses: Introduction to Safeguarding Children and Safeguarding Children in Practice both run by The Independent Safeguarding Service. Our safeguarding referral policy is shown in Appendix P.

Risks to the research team will be managed by adherence to the University's "Health and safety guidance for research undertaken in the community" policy document, found here: https://www.bristol.ac.uk/safety/media/gn/research-comm-gn.pdf Researchers conducting any home interviews will use a 'check in, check out' policy with another member of the research team. Specific protocols for what to do if a researcher does not make contact following a home interview will include contacting the police, and always notifying another member of the team the exact address, name of individuals and time expected to finish.

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service NHS REC, the Health Research Authority, for the study protocol, information sheets, consent forms, and interview topic guides.

For NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.

- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any participants can be enrolled into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. This will include R&D approvals from all study sites, via the HRA approvals application.

For any amendments to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with study sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

The CI will submit any amendments to the protocol to: NHS R&D dept and NHS REC contact. Amendments will be documented in Appendix Q.

Guidance on the categorisation of amendments for studies involving the NHS will be sought via the HRA website. http://www.hra.nhs.uk/resources/after-you-apply/amendments/

7.3 Peer review

The study has been reviewed by a panel of experts as part of the funding application, as an Advanced NIHR Fellowship Award. An executive summary of the comments relating to this study and how they have been addressed has been prepared (Appendix R).

7.4 Patient & Public Involvement

Background PPI

Through attendance at parent groups and regular events specifically for families with support workers, parents suggested we investigate how partners and other caregivers interact with safe sleep advice and consider how a future intervention would engage them. Comments from parents at these groups and events highlight how much pressure is often on mothers as primary carers to keep to ‘safety rules’ and suggest that involving partners, peers and family members who are both influential in sharing advice and looking after the baby would support any future efforts to decrease risks. Parents also told us that resources they can use need to be online and preferably not in an app. We have continuously sought parent views on our study methodology via attendance at groups run via our local children’s centre, and through our network of local health visiting teams.

Ongoing PPI through the Baby Sleep Project Family Advisory Group

The Family Advisory Group have met to discuss this protocol in its draft form and we have asked them specific questions around recruitment and data collection. The group consists of fifteen parents with young babies. The group meets with a quorum of two at any meeting and email communication supplements each meeting. The group have so far made valuable contributions to the development

of the baby sleep planner and the safer sleep for neonatal babies resources. The group also suggested ways to maximise recruitment of other family members, including having a range of incentives to offer and reminders to those who agree to be contacted. These suggestions have been incorporated into the current protocol. The group will continue to meet at least quarterly throughout the research and make further contributions to all aspects of the research, including interpretations and dissemination of the findings.

7.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol:

- Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Confidentiality of all information will be maintained throughout the study process and all data will be handled in accordance with the recommendations of the Caldicott Committee, the requirements of the Data Protection Act 2018, General Data Protection Regulation, Human Rights Act and Section 60 of the 2001 Health and Social Care Act.

Interviews and questionnaires will only collect non-identifiable information and given a study ID to link quantitative and qualitative responses for the purposes of analysis only.

Contact details for those who indicate they would like to be sent a copy of the results of the study will be saved separately from all study data, unlinked by ID, only used for sending results and deleted following results being sent out.

Willing prospective interview participant's contact details will be saved in electronic form at the time of agreeing to be contacted about an interview and only used for this purpose.

Qualitative interviews will be transcribed verbatim with all personal identifiers removed and replaced with non-identifiable objects, eg. 'Jane' replaced with '[name]'.

Any manual data (e.g. any paper consent forms) will be kept in a locked filing cabinet, with access restricted to appropriate University of Bristol researchers. Electronic questionnaire responses will be stored online on Jisc Online Surveys which is fully compliant with all UK data protection laws and meets UK accessibility requirements. Study data will be downloaded and all personal details removed and stored separately. Electronic data resulting from the online survey will be stored on password-protected computers, only accessible to University of Bristol researchers involved in this study. All reporting of quantitative and qualitative data in presentations, reports and academic papers will be in the form of pseudoanonymised data (i.e personally identifiable information fields will be replaced by one or more artificial identifiers, or pseudonyms). A Data Security and Privacy Notice will be available in full (Appendix S) on the study website www.babysleepresearch.co.uk . A shorter version is available on the participant information sheet(s) (Appendices D, E & F).

The data custodian for the University of Bristol is Mr Henry Stuart: Information Governance Manager

Email: Henry.Stuart@bristol.ac.uk
Phone: (0117) 394 1824 (Internal: 41824)

An anonymised research dataset will be stored indefinitely in line with a project specific University of Bristol data management plan.

7.7 Indemnity

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University. The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from overall management of the research by the University of Bristol.

7.8 Access to the final study dataset

The CI, senior research associate and members of the study management team will have access to the final study dataset as required for robust data entry, cleaning, checking and analysis. Secondary analysis of data will be possible and the interview consent form includes this option. Full dataset access by anyone outside of the study team for use in other research will be strictly limited to those with valid research proposals subject to full research ethics committee approvals, and the study team reserves the right to object to inappropriate uses of the data if this arises. The data will be uploaded to https://data.bris.ac.uk/data/ as per our institution's data sharing policy.

8 DISSEMINATION POLICY

8.1 Dissemination policy

The data arising from the study will be owned by the University of Bristol. Upon completion of the study, a full study report will be prepared along with two papers for publication: one detailing the results from the survey and one with the findings from the qualitative interviews.

All qualitative sampling, data collection, analysis and reporting will comply with the COREQ guidance for qualitative research.(45)

All publications and outputs from this study are subject to the conditions of dissemination provided by the funder, the NIHR and are stipulated in detail, here: *https://www.nihr.ac.uk/documents/nihr-research-outputs-and-publications-guidance/12250*

We will aim to disseminate the findings via peer reviewed publication in relevant academic journals within 12 months of the end of the study.

Participants will be notified of the findings of the study, if they have explicitly asked for the study team to send them. This will be done with a confidential newsletter with a plain English summary of the overall findings, with links to open access publications.

8.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will include the study management team and any members of the PPI group who wish to be named, or acknowledged as a group. Order for authorship will be decided by all those eligible with regard for the International Committee of Medical Journal Editors authorship criteria.

9 REFERENCES

1. Krous HF, Beckwith JB, Byard RW, Rognum TO, Bajanowski T, Corey T, et al. Sudden infant death syndrome and unclassified sudden infant deaths: a definitional and diagnostic approach. Pediatrics. 2004;114(1):234-8.
2. Coldham T, Group I. Guidance on co-producing a research project. INVOLVE. https://www. invo. org. uk/wpcontent/uploads/2019/04 …; 2018.
3. Office for National Statistics. Child and infant mortality in England and Wales: 2017. 2019.
4. Platt MW, Blair PS, Fleming PJ, Smith IJ, Cole TJ, Leach CEA, et al. A clinical comparison of SIDS and explained sudden infant deaths: how healthy and how normal? Archives of disease in childhood. 2000;82(2):98-106.
5. Fleming P, Pease A, Ingram J, Sidebotham P, Cohen MC, Coombs RC, et al. Quality of investigations into unexpected deaths of infants and young children in England after implementation of national child death review procedures in 2008: a retrospective assessment. Archives of disease in childhood. 2019.
6. Friedman GR, Franciosi RA, Drake RM. The effects of observed sudden infant death syndrome (SIDS) on hospital staff. Pediatrics. 1979;64(4):538-40.
7. Garstang J, Griffiths F, Sidebotham P. What do bereaved parents want from professionals after the sudden death of their child: a systematic review of the literature. BMC pediatrics. 2014;14:269.
8. Pickett KE, Luo Y, Lauderdale DS. Widening social inequalities in risk for sudden infant death syndrome. American journal of public health. 2005;95(11):1976-81.
9. Blair PS, Sidebotham P, Berry PJ, Evans M, Fleming PJ, Blair PS, et al. Major epidemiological changes in sudden infant death syndrome: a 20-year population-based study in the UK. Lancet. 2006;367 North American Edition(9507):314-9.
10. Garstang J, Ellis C, Griffiths F, Sidebotham P. Unintentional asphyxia, SIDS, and medically explained deaths: a descriptive study of outcomes of child death review (CDR) investigations following sudden unexpected death in infancy. Forensic science, medicine, and pathology. 2016;12(4):407-15.
11. Sidebotham P, Bates F, Ellis C, Lyus L. Preventive Strategies for Sudden Infant Death Syndrome. In: Duncan JR, Byard RW, editors. SIDS Sudden Infant and Early Childhood Death: The Past, the Present and the Future. Adelaide (AU): University of Adelaide Press; 2018.
12. Fleming P, Blair P, Bacon C, Berry J. Sudden Unexpected Deaths in Infancy: The CESDI-SUDI Studies, 1993-1996: Stationery Office Books; 2000. 172 p.
13. Office for National Statistics. Unexplained deaths in infancy, England and Wales: 2017. 2019.
14. Blair PS, Sidebotham P, Evason-Coombe C, Edmonds M, Heckstall-Smith EM, Fleming P. Hazardous cosleeping environments and risk factors amenable to change: case-control study of SIDS in south west England. Bmj. 2009;339:b3666.
15. Mitchell EA, Thompson JM, Becroft DM, Bajanowski T, Brinkmann B, Happe A, et al. Head covering and the risk for SIDS: findings from the New Zealand and German SIDS case-control studies. Pediatrics. 2008;121(6):e1478-e83.
16. Thompson JM, Tanabe K, Moon RY, Mitchell EA, McGarvey C, Tappin D, et al. Duration of breastfeeding and risk of SIDS: an individual participant data meta-analysis. Pediatrics. 2017;140(5):e20171324.
17. Vennemann M, Bajanowski T, Brinkmann B, Jorch G, Yücesan K, Sauerland C, et al. Does breastfeeding reduce the risk of sudden infant death syndrome? Pediatrics. 2009;123(3):e406-e10.
18. Blair PS, Sidebotham P, Pease A, Fleming PJ. Bed-sharing in the absence of hazardous circumstances: is there a risk of sudden infant death syndrome? An analysis from two case-control studies conducted in the UK. PloS one. 2014;9(9):e107799.
19. Davis P, Price L, Heatman B, Bailey L, John N, Rolfe K. Sudden Unexpected Death in Infancy: A Collaborative Thematic Review 2010–2012: Child Death Review Programme and All Wales Perinatal Survey. Public Health Wales NHS Trust. 2015.
20. Garstang JJ, Sidebotham P. Qualitative analysis of serious case reviews into unexpected infant deaths. Archives of disease in childhood. 2019;104(1):30-6.
21. Williams T, Sleap V, Pease A, Fleming P, Blair PS, Stoianova S, et al. Sudden and Unexpected Deaths in Infancy and Childhood: National Child Mortality Database Programme Thematic Report. National Child Mortality Database, ; 2022.

22. Pease A, Blair PS, Ingram J, Fleming P. Conversations with families about reducing the risk of sudden infant death syndrome. Journal of Health Visiting. 2019;7(5):226-31.
23. Pease A, Ingram J, Blair PS, Fleming PJ. Factors influencing maternal decision-making for the infant sleep environment in families at higher risk of SIDS: a qualitative study. BMJ paediatrics open. 2017;1(1):e000133.
24. Pease AS, Blair PS, Ingram J, Fleming PJ. Mothers' knowledge and attitudes to sudden infant death syndrome risk reduction messages: results from a UK survey. Archives of disease in childhood. 2018;103(1):33-8.
25. National Child Safeguarding Practice Review Panel. Out of routine: a review of sudden unexpected death in infancy (SUDI) in families where the children are considered at risk of significant harm. Crown copyright. ; 2020.
26. Pease A, Garstang JJ, Ellis C, Watson D, Ingram J, Cabral C, et al. Decision-making for the infant sleep environment among families with children considered to be at risk of sudden unexpected death in infancy: a systematic review and qualitative metasynthesis. BMJ paediatrics open. 2021;5(1).
27. Clarke J. Velcro babies: A Qualitative Study Exploring Maternal Motivations in the Night-time Care of Infants: University of Otago; 2016.
28. Pease A, Ingram J, Blair PS, Fleming PJ. Factors influencing maternal decision-making for the infant sleep environment in families at higher risk of SIDS: A qualitative study. BMJ Paediatrics Open. 2017;1.
29. Cote A, Gerez T, Brouillette RT, Laplante S. Circumstances leading to a change to prone sleeping in sudden infant death syndrome victims. Pediatrics. 2000;106(6):E86.
30. McGarvey C, McDonnell M, Chong A, O'Regan M, Matthews T. Factors relating to the infant's last sleep environment in sudden infant death syndrome in the Republic of Ireland. Archives of disease in childhood. 2003;88(12):1058-64.
31. Michie S, Van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implementation science. 2011;6(1):42.
32. Michie S, Atkins L, West R. The behaviour change wheel: a guide to designing interventions: Silverback Publishing; 2014.
33. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implementation science. 2017;12(1):1-18.
34. Shiells K, Barrett S, Cann H, McGovern R, Pease A, Woodman J, et al. Promoting safer sleeping for babies in high-risk groups in England. NIHR Policy Research Unit Children and Families, University College London; 2023.
35. Pawson R, Tilley N. An introduction to scientific realist evaluation. Evaluation for the 21st century: A handbook. 1997;1997:405-18.
36. Westhorp G. Understanding mechanisms in realist evaluation and research. Doing realist research: SAGE Publications Ltd; 2018. p. 41-58.
37. Bonell C, Warren E, Melendez-Torres G. Methodological reflections on using qualitative research to explore the causal mechanisms of complex health interventions. Evaluation. 2022;28(2):166-81.
38. Duncan C, Weich S, Fenton S-J, Twigg L, Moon G, Madan J, et al. A realist approach to the evaluation of complex mental health interventions. The British Journal of Psychiatry. 2018;213(2):451-3.
39. Westhorp G. Realist impact evaluation: an introduction. London: Overseas Development Institute. 2014:1-12.
40. Ostrom E. Crossing the great divide: coproduction, synergy, and development. World development. 1996;24(6):1073-87.
41. Rapley T, Girling M, Mair FS, Murray E, Treweek S, McColl E, et al. Improving the normalization of complex interventions: part 1-development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC Medical Research Methodology. 2018;18(1):1-17.
42. Rose T, Sharpe TL, Shdaimah C, DeTablan D. Exploring coping among urban youth through photovoice. Qualitative Social Work. 2018;17(6):795-813.

43. Wang C, Burris MA. Photovoice: Concept, methodology, and use for participatory needs assessment. Health education & behavior. 1997;24(3):369-87.
44. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. Bmj. 2014;348.
45. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007;19(6):349-57.

10 APPENDICES

A: Research Team CVs

B: Coproduction team focus group information sheet

C: Consent form for focus group

D: Information sheet for health professionals' interviews

E. Parent/caregiver information sheet (Baseline Group)

F: Parent/caregiver information sheet (Intervention Group)

G: Introductory invitation text and video (Baseline group)

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M: Baby Sleep Project Parent Questionnaires sleep diary and TOPSE

N: Topic Guide for family member interviews

O: Distress Protocol and checklist

P: Safeguarding Procedure

Q: Amendment History

R: Peer Review information

S: Data security and privacy notice

T: Signposting to support for families

U: Study Details Postcard – pre-intervention

V: Study Details Postcard – post-intervention

A: Research Team CVs

Chief Investigator

Full Name	Dr Anna Pease	**Title**	Research Fellow
Department	Bristol Medical School	**Institution**	University of Bristol
ORCID iD	0000-0002-3472-1047	**Phone No.**	+44 7414664623
Address	1-5 Whiteladies Road Bristol	**Country**	United Kingdom
Postal Code	BS8 1NU	**Web Page**	

Qualification	Subject	Institution	From	To
PhD	Factors influencing infant care practices in the infant sleep environment amongst families at high risk of SIDS.	University of Bristol	December 2012	July 2016
MSc	Health Psychology	Queen Margaret University, Edinburgh	September 2004	November 2005
MA	Applied Psychology	Heriot-Watt University	September 1998	July 2001

Publications
Pease, A., Garstang, J. J., Ellis, C., Watson, D., Ingram, J., Cabral, C., Blair, P. S., & Fleming, P. J. (2021). Decision-making for the infant sleep environment among families with children considered to be at risk of sudden unexpected death in infancy: a systematic review and qualitative metasynthesis. *BMJ Paediatrics Open*, *5*(1), [e000983]. https://doi.org/10.1136/bmjpo-2020-000983
Garstang, J., Watson, D., Pease, A., Ellis, C., Blair, P. S., & Fleming, P. (2021). Improving engagement with services to prevent Sudden Unexpected Death in Infancy (SUDI) in families with children at risk of significant harm: a systematic review of evidence. *Child: Care, Health and Development*, *47*(5), 713-731. https://doi.org/10.1111/cch.12875
Fleming P, Pease A, Ingram J, Sidebotham P, Cohen MC, Coombs RC, Ewer AK, Ward Platt M, Fox J, Marshall D, Lewis A, Evason-Coombe C, Blair P. Quality of investigations into unexpected deaths of infants and young children in England after implementation of national child death review procedures in 2008: a retrospective assessment. Arch Dis Child. 2020 Mar;105(3):270-275.
Blair PS, Rubens D, Pease A, Mellers D, Ingram J, Ewer AK, Cohen MC, Sidebotham P, Ward Platt M, Coombs R, Davis A, Hall A, Fleming P.Sudden infant death syndrome (SIDS) and the routine otoacoustic emission infant hearing screening test: an epidemiological retrospective case-control study. BMJ Open. 2019 Jul 18;9(7):e03002.
Baddock SA, Purnell MT, Blair PS, Pease AS, Elder DE, Galland BC. The influence of bed-sharing on infant physiology, breastfeeding and behaviour: A systematic review. Sleep Med Rev. 2019 Feb;43:106-117.
Blair PS, Pease A, Bates F, Ball H, Thompson JMD, Hauck FR, Moon R, McEntire B, Shatz A, Cohen M, Salm Ward TC, Fleming P. Concerns about the promotion of a cardboard baby box as a place for infants to sleep. BMJ. 2018 Oct 17;363:k4243.
Pease, A., Blair, P., Ingram, J., & Fleming, P. (2018). Mothers' knowledge and attitudes to sudden infant death syndrome risk reduction messages: results from a UK survey. *Archives of Disease in Childhood*, *103*(1), 33-38. https://doi.org/10.1136/archdischild-2017-312927
Pease, A., Ingram, J., Blair, P., & Fleming, P. (2017). Factors influencing maternal decision-making for the infant sleep environment in families at higher risk of SIDS: a qualitative study. *BMJ Paediatrics Open* , *1*(1), [e000133]. https://doi.org/10.1136/bmjpo-2017-000133

Fleming, P., Blair, P., & Pease, A. (2017). Why or how does the prone sleep position increase the risk of unexpected and unexplained infant death? *Archives of Disease in Childhood: Fetal and Neonatal Edition*. https://doi.org/10.1136/archdischild-2017-313331
Pease, A., Fleming, P., Hauck, F. R., Moon, R. Y., Horne, R. S. C., L'hoir, M. P., Ponsonby, A-L., & Blair, P. (2016). Swaddling and the Risk of Sudden Infant Death Syndrome: A Meta-analysis. *Pediatrics*, *137*(6), [e20153275]. https://doi.org/10.1542/peds.2015-3275

Grants					
Start Date	**Duration**	**Amount**	**Source**	**Title**	**Role of Applicant**
01/03/2021	36 months	£678,923	NIHR Advanced Fellowship	Preventable infant deaths: Improving uptake of safe sleep messages in high-risk families	Chief Investigator
01/10/2019	6 months	£24,357	National Child Safeguarding Practice Review Panel, Department for Education	Literature review into Sudden Unexpected Death of Infants (SUDI) in families where children are considered to be at risk.	Co-Chief Investigator
01/07/2019	9 months	£2,000	Bioethics, Biolaw & Biosociety Research Strand of the Elizabeth Blackwell Institute.	Human Milk: Bodies, Boundaries and Barriers.	Co-applicant
01/01/2018	24 months	£ 186,864	Bristol North Somerset South Gloucestershire NHS Clinical Commissioning Group	Developing an intervention to improve infant safety and wellbeing.	Chief Investigator
01/02/2016	18 months	£152,549	The Lullaby Trust	Newborn Hearing Feasibility Study and the Risk of Unexpected Infant Death.	Co-applicant
01/12/2012	36 months	£ 61,438	The Lullaby Trust	PhD award: Factors influencing infant care practices in the infant sleep environment amongst families at high risk of SIDS.	PhD Candidate

Study Co-ordinator
Full Name Dr Becky Lambert, nee Ali
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Qualification	Subject	Institution	From	To
PhD	What works? Individuals' experiences and knowledge of suicide prevention interventions in Aotearoa/ New Zealand	University of Auckland	Oct 2015	May 2019
MSc	Social Work Research	University of Bristol	Sept 2013	Sept 2014
BA	Social Policy	University of Kent	Sept 2004	June 2007

Publications
Papadaki, A., **Ali, B**., Willis, P., Cameron, A. et al. (2023). *The Service, I Could Not Do without It: A Qualitative Study Exploring the Significance of Meals on Wheels among Service Users and People Who Refer Them to the Service.* Health & Social Care in the Community. doi: https://doi.org/10.1155/2023/6054895.
Denford, S., Towler, L., **Ali, B.,** Treneman-Evans, G., Bloomer, R., Peto, T., Young, B., & Yardley, L. (2022). *Feasibility and acceptability of daily testing at school as an alternative to self-isolation following close contact with a confirmed case of COVID-19: A qualitative analysis.* BMC Public Health 22, 742. doi: https://doi.org/10.1186/s12889-022-13204-x
Ali, B., Staniforth, B., & Adamson, C. (2021). *Reflecting on lived experience: Suicide prevention and the importance of social work in mental health.* Aotearoa New Zealand Social Work, 33(2), 6-18. doi: https://doi.org/10.11157/anzswj-vol33iss2id861
Papadaki, A., **Ali, B**., Willis, P., Cameron, A. et al. (2021). *'It's not just about the dinner; it's about everything else that we do': A qualitative study exploring how Meals on Wheels meet the needs of self-isolating adults during COVID-19.* Health and Social Care in the Community. doi: https://doi.org/10.1111/hsc.13634
Willis, P., Lloyd, L., Bezzina, A., & **Ali, B**. (2021). *Online advice to carers: an updated review of local authority websites in England.* NIHR School for Social Care Research - Commissioned Report
Ali, B. (2019). *What works? Individuals' Experiences and Knowledge of Suicide Prevention Interventions in Aotearoa/New Zealand* (PhD thesis). University of Auckland, ResearchSpace

Project Management Team

Full Name	Prof Peter Blair	**Title**	Professor of Epidemiology & Statistics
Department	Bristol Medical School	**Institution**	University of Bristol
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Address	1-5 Whiteladies Road Bristol	**Country**	United Kingdom
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Qualification	Subject	Institution	From	To
PhD	Assessing the changing risk factors associated with Sudden Infant Death Syndrome (SIDS)	University of Bristol	November 1994	July 1998
MSc	Medical Statistics & Information Technology	University of Leicester	September 1991	September 1992
BSc (Hons)	Applicable Mathematics	Manchester Polytechnic	September 1985	September 1990

Publications
Fleming P, Pease A, Ingram J, Sidebotham P, Cohen MC, Coombs RC, Ewer AK, Ward Platt M, Fox J, Marshall D, Lewis A, Evason-Coombe C, **Blair P**. Quality of investigations into unexpected deaths of infants and young children in England after implementation of national child death review procedures in 2008: a retrospective assessment. Arch Dis Child. 2020 Mar;105(3):270-275.
Blair PS, Ball HL, McKenna JJ, Feldman-Winter L, Marinelli KA, Bartick MC; Academy of Breastfeeding Medicine.Bedsharing and Breastfeeding: The Academy of Breastfeeding Medicine Protocol #6, Revision 2019. Breastfeed Med. 2020 Jan;15(1):5-16.
Blair PS, Rubens D, Pease A, Mellers D, Ingram J, Ewer AK, Cohen MC, Sidebotham P, Ward Platt M, Coombs R, Davis A, Hall A, Fleming P.Sudden infant death syndrome (SIDS) and the routine otoacoustic emission infant hearing screening test: an epidemiological retrospective case-control study. BMJ Open. 2019 Jul 18;9(7):e03002.
Baddock SA, Purnell MT**, Blair PS**, Pease AS, Elder DE, Galland BC. The influence of bed-sharing on infant physiology, breastfeeding and behaviour: A systematic review. Sleep Med Rev. 2019 Feb;43:106-117.
Blair PS, Pease A, Bates F, Ball H, Thompson JMD, Hauck FR, Moon R, McEntire B, Shatz A, Cohen M, Salm Ward TC, Fleming P. Concerns about the promotion of a cardboard baby box as a place for infants to sleep. BMJ. 2018 Oct 17;363:k4243.
Luyt K, Jary S, Lea C, Young GJ, Odd D, Miller H, Kmita G, Williams C, **Blair PS**, Fernández AM, Hollingworth W, Morgan M, Smith-Collins A, Thai NJ, Walker-Cox S, Aquilina K, Pople I, Whitelaw A. Ten-year follow-up of a randomised trial of drainage, irrigation and fibrinolytic therapy (DRIFT) in infants with post-haemorrhagic ventricular dilatation. Health Technol Assess. 2019 Feb;23(4):1-116.

Grants					
Start Date	**Duration**	**Amount**	**Source**	**Title**	**Role of Applicant**
01/09/2019	18 months	£148.82	NIHR (RfPB)	"CoolCuddle" study. Do parents cuddling babies undergoing cooling therapy for hypoxicischaemic encephalopathy (HIE) affect the cooling process or intensive care? Refinement and evaluation of an intervention protocol	Co-applicant
01/03/2018	49 months	£950,000	NIHR (HTA)	A multi-faceted intervention to improve management of antibiotics for CHIldren presenting to primary care with acute COugh: The CHICO RCT.	Chief Investigator
01/09/2017	30 months	£579,631	SPCR	TEST (Trial of Eczema allergy Screening Tests) feasibility RCT with economic evaluation and nested qualitative study	Co-applicant
01/04/2017	36 months	£1,999,913	NIHR (Global Health Research Group)	Nepal research Injury unit	Co-applicant
01/07/2016	18 months	£152.549	Charity (Lullaby Trust)	Oto-Acousting Signals In SIDS (OASIS) Feasibility observational study	Co-PI
01/09/2015	15 months	£527,571	NIHR (Public Health)	Plan-A: Interventions to Maintain or Increase Physical Activity in Adolescents. Sebire S (PI) Centre for Exercise Nutrition and Health Sciences UoB.	Co-applicant

Full Name	Prof Jennifer Ingram	**Title**	Senior Research Fellow
Department	Bristol Medical School	**Institution**	University of Bristol
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Country	UK		
Postal Code	BS8 1NU		

Qualification	Subject	Institution	From	To
BSc	Zoology	University of Southampton		
PhD	Psychology	University of Bristol		

Publications
Ingram J, Johnson D, O'Mahen HA, Law R, Culpin I. et al. (3) 'Asking for help': a qualitative interview study exploring Interpersonal Counselling (IPC) compared to low-intensity cognitive behavioural therapy (CBT) for women with depression during pregnancy. *BMC Pregnancy & Childbirth* 2021; 21:765 doi.org/10.1186/s12884-021-04247-w
Odd D, Okano S, **Ingram J,** Blair PS, Billietop A, Fleming PJ, et al. (2) Physiological responses to cuddling babies with hypoxic–ischaemic encephalopathy during therapeutic hypothermia: an observational study. *BMJ Paediatrics Open* 2021; 5:e001280. doi:10.1136/bmjpo-2021-001280.
A Pease, J Garstang, C Ellis, D Watson, **J Ingram**, C Cabral, PS Blair, PJ Fleming. Decision-making for the infant sleep environment amongst families with children considered to be at risk from Sudden Unexpected Death in Infancy: A systematic review and qualitative meta-synthesis. *BMJ Paediatrics Open* 2021; 5:e000983.
G Thomson, **J Ingram**, JL Clarke, D Johnson, H Trickey, SU Dombrowski, et al.(3) Exploring the use and experience of an infant feeding genogram to facilitate an assets-based approach to support infant feeding. *BMC Pregnancy & Childbirth*, 2020, 20:569
Clarke J, **Ingram J**, Johnson D, Thomson G, Trickey H, Dombrowski SU, et al.(7) An assets-based intervention before and after birth to improve breastfeeding initiation and continuation: the ABA feasibility RCT. *Public Health Res* 2020;8(7)
Ingram JC, Thomson G, Johnson D, Clarke J, Trickey HJ, Hoddinott P, et al.(2) Women's and peer supporters' experiences of an assets-based peer support intervention for increasing breastfeeding initiation and continuation: a qualitative study. *Health Expect*ations. 2020;23.
Ingram J, Copeland M, Johnson D, Emond A. The development and evaluation of a picture tongue assessment tool for tongue-tie in breastfed babies (TABBY). *BMC International Breastfeeding Journal.* 2019;14, 31. doi: 10.1186/s13006-019-0224-y
Kandiyali R, Hawton A, Cabral C, Mytton J, Shilling V, Morris C, **Ingram J**. Working with Patients and Members of the Public: Informing Health Economics in Child Health Research. *PharmacoEconomics – Open*. 2018.
Pease A, **Ingram J,** Blair P, Fleming P. Factors influencing maternal decision-making for the infant sleep environment in families at higher risk of SIDS: a qualitative study. *BMJ Paediatrics Open*,2017; 1
Ingram J, Redshaw M, Manns S, Beasant L, Johnson D, Fleming P, Pontin D. "Giving us hope": Parent and neonatal staff views and expectations of a planned family -centred discharge process (Train-to-Home). *Health Expectations*.2016.

Grants					
Start Date	**Duration**	**Amount**	**Source**	**Title**	**Role of Applicant**
May 2022	15mth	£147,853.	NIHR RfPB	Process evaluation of embedding the CoolCuddle intervention into neonatal intensive care units. (CoolCuddle 2)	Co-PI
Sept 2021	15 mth	£144,678	NIHR RfPB	Baby Sleep Tool: Preventing Sudden Unexpected Deaths in Infancy: an assessment and planning tool for families at increased risk	Co-I
Jan 2021	16 mth	£145,017	NIHR RfPB	FLASH: Implementation of flash glucose monitoring in four paediatric diabetes clinics – before and after study to produce real world evidence of patient benefit.	Co-PI
Jan 2021	9 mth	£19,757	Southmead Hosp Charity	CoCCo: Covid-19 Clinician's Cohort qualitative study. Assessing the needs and treatment preferences of frontline clinicians to improve understanding of the psychological impact of the COVID-19 pandemic on frontline staff in order to adapt currently effective interventions	Co-I
Oct 2020	39 mth	£1,787,790	NIHR Public Health Research Programme	ABA-feed: Effectiveness and cost-effectiveness of Assets-based feeding help before and after birth for improving breastfeeding initiation and continuation.	Co-I
Sept 2019	18 mth	£148,412	NIHR RfPB	CoolCuddle: Do parents cuddling babies undergoing cooling therapy for hypoxic-ischaemic encephalopathy (HIE) affect the cooling process or intensive care? Refinement and evaluation of an intervention protocol.	

Full Name Peter John Fleming **Title** Professor
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Qualification	Subject	Institution	From	To
MB ChB	Medicine	Bristol University	1967	1972
PhD	Physiology	Bristol University	1990	1993
FRCP	Adult Medicine	Royal College of Physicians, London		1988
FRCP (c)	Paediatrics	Royal College of Physicians, Canada		1981
FRCPCH	Paediatrics	Royal College of Paediatrics and Child Health		1996

Publications
Catherine Ellis, Anna Pease, Joanna Garstang, Debbie Watson, Peter S Blair, and **Peter J Fleming**. Interventions to improve safer sleep practices in families with children considered to be at increased risk of sudden unexpected death in infancy: A systematic review. *Frontiers in Pediatrics* 2022. DOI: 10.3389/ped 2021.778186 (Published online January 3rd 2022).
Ifigeneia Mavranezouli, Jo Varley-Campbell, Sarah Stockton, Jennifer Francis, Clare Macdonald, Sunita Sharma, **Peter Fleming**, Elizabeth Punter, Charlotte Barry, Maija Kallioinen, Nina Khazaezadeh,David Jewell .The cost-effectiveness of antenatal and postnatal education and support interventions for women aimed at promoting breastfeeding in the UK. *BMC Public Health 2022 22*:153. https://doi.org/10.1186/s12889-021-12446-5
David Odd, Satomi Okano, Jenny Ingram, Pete S Blair, Amiel Billetop, **Peter Fleming**, Marianne Thoresen. Physiological responses to cuddling babies with hypoxic-ischaemic encephalopathy during therapeutic hypothermia: an observational study. *BMJ Paediatrics* Open [in press] 2022.
David Odd, Sylvia Stoianova, Tom Williams, **Peter Fleming**, Karen Luyt. Child Mortality in England During the First Year of the COVID-19 Pandemic*. Archives of Disease in Childhood 2021*. Epub ahead of Print [07.12.2021] doi:10.1136/archdischild-2021-323370
David Odd, Sylvia Stoianova, Tom Williams, Vicky Sleap, Peter Blair, **Peter Fleming**, Ingrid Wolfe, Karen Luyt *Child mortality in England during the COVID-19 pandemic*. Arch Dis Child. 2021. doi:10.1136/archdischild-2020-320899 [published online 21.6.2021]
Garstang, J., Watson, D., Pease, A., Ellis, C., Blair, P. S., & **Fleming, P.** Improving engagement with services to prevent Sudden Unexpected Death in Infancy (SUDI) in families with children at risk of significant harm: A systematic review of evidence. *Child: Care, Health and Development, 2021; 47*:713- 731. https://doi.org/10.1111/cch. 12875
Anna Pease, Joanna J Garstang, Catherine Ellis, Debbie Watson, Jenny Ingram, Christie Cabral, Peter S Blair **Peter J Fleming.** *Decision-making for the infant sleep environment among families with children considered to be at risk of sudden unexpected death in infancy: a systematic review and qualitative metasynthesis*. BMJ Paediatrics Open 2021; doi:10.1136/bmjpo-2020-000983
A. Pease, J. Garstang, C. Ellis, D. Watson, P. S. Blair, **P. J. Fleming** (2020). *Systematic literature review report for the National Child Safeguarding Practice Review into the sudden unexpected death of infants (SUDI) in families where the children are considered to be at risk of significant harm*.
Pauline Heslop, Elena Baker-Glenn, **Peter Fleming**, Marian Knight, Marisa Mason, Pauline Turnbull, Clare Wade. The impact of the National Clinical Outcome Review Programmes in England: a review of the evidence. *Clinical Medicine 2020;20*:e52-58
Peter Fleming, Anna Pease, Jenny Ingram, Peter Sidebotham, Marta C Cohen, Robert Coombs, Andrew K. Ewer, Martin Ward Platt, John Fox, David Marshall, Anne Lewis, Peter S Blair. Quality of investigations into unexpected deaths of infants and young children in England after implementation of National Child Death Review Procedures in 2008: a retrospective assessment. *Arch. Dis Childhood 2020;105*: 270-275 [DOI: 10.1136/archdischild-2019-317420] (Epub ahead of print. 28.09.2019).

Blair PS. Pease A, Ingram J**, Fleming PJ** *Sudden Infant Death Syndrome (SIDS) and the routine otoacoustic emission infant hearing screening test: an epidemiological retrospective case-control study.* BMJ Open 2019;9:e030026. doi:10.1136/bmjopen-2019-030026

Grants					
Start Date	**Duration**	**Amount**	**Source**	**Title**	**Role of Applicant**
01/09/21	15 months	£144,616	NIHR (RfPB)	Preventing Sudden Unexpected Deaths in Infancy: an assessment and planning tool for families at increased risk.	Co-applicant
2019 -	2021	£24,389	Dept for Education	Systematic Literature Review for the National Child Safeguarding Practice Review into the Sudden Unexpected Death of Infants (SUDI) in families where the children are considered to be at risk of significant harm.	Principal Investigator
2019 -	2021	£50,000	Above and Beyond: Charitable Trust of University Hospitals Bristol	Pilot Study for a National Registry of Unexpected Deaths in Childhood.	Principal Investigator
2018 -	2021	£1,900,000	NHS England. (Healthcare Quality Improvement Partnership)	Extension to the National Learning disability mortality review programme grant.	Co-Applicant
2018-	2023	£2,200,000	NHS England (Healthcare Quality Improvement Partnership)	National Child Mortality Database	Co-Applicant
2015 -	2018	£2,300,000	NHS England. (Healthcare Quality Improvement Partnership)	National Learning Disability M Mortality Review Programme.	Co-Applicant

B: Family members focus group information sheet
See attached documents

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E. Family member information sheet (Baseline Group)
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See attached documents

M: Baby Sleep Project Parent Questionnaires sleep diary and TOPSE

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N: Topic Guide for family member interviews

See attached documents

O: Distress Protocol and checklist

See attached documents

P: Safeguarding Procedure

See attached documents

Q: Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
Am 1 Non Sub 2023 - 4362	1	20.12.23	AP	Addition of new sites: UHBW NHS Foundation Trust UHLeicester NHS Trust
Am 2 Substantial 2023 - 4362	2	07.02.24	AP	Copies of new materials calling attention of potential participants to the research. REC review required.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

R: Peer Review information

See attached documents

S: Data security and privacy notice
See attached documents

T: Signposting to support for families
See attached documents

U: Study Details Postcard – pre-intervention
See attached documents

V: Study Details Postcard – post-intervention
See attached documents