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The baby sleep project: evaluation of support for families to follow safer sleep advice.

Submission date	**Recruitment status**	[X] Prospectively registered
06/02/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/04/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

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.

Who can participate?

The study will recruit health professionals (neonatal staff, health visitors and family nurse partnership nurses) and families with new babies.

What does the study involve?

The health professionals will get some training in how to use the new resources and start to use them with families. They will fill out some questionnaires about usingthe new resources and we will interview some of them to find out how the new resources have been embedded into their work practices. We will ask families to complete questionnaires about their baby's sleeping habits and how they feel about being a parent. We will ask some parents who have not seen the new resources and some who have seen the new resources and look for any differences in their responses. We will also invite some of the parents to be interviewed by us to find out more about their experiences with the resources and what may have changed for them as a result of using them. We will use all of this information to develop our theory about how these new resources work, including working out where and when they work best, and what the underlying mechanisms might be for any changes we see as a result of using them.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part, although we will say thank you for caregivers time by offering them a shopping voucher for taking part. There are no risks to taking part as using the resources will not replace any standard care or information that families receive.

Where is the study run from?
The study is led by a team of researchers based at the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
June 2023 to March 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Anna Pease, a.pease@bristol.ac.uk

Study website
http://www.babysleepresearch.co.uk/

Contact information

Type(s)
Scientific

Contact name
Dr Anna Pease

Contact details
Level D
St Micheals Hospital
Southwell St
Bristol
United Kingdom
BS2 8EG
+44 117 342 5144
a.pease@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329961

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58215, NIHR300820, IRAS 329961

Study information

Scientific Title

Supporting families with infants at risk of sudden unexpected death in infancy: co-production and realist evaluation of intervention to support safer infant sleep for families with infants at increased risk.

Acronym
The Baby Sleep Project Part 2

Study objectives
When the baby sleep project resources are integrated into conversations with families about safer sleep (context), families will be more likely to implement safer sleep advice (outcome) because they understand the risks to their own infant, understand how safer sleep works to protect their baby and have made a plan for safety during times when the routine is disrupted (mechanisms).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/12/2023, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol , BS1 6PN, United Kingdom; +44 207 104 8184; frenchay.rec@hra.nhs.uk), ref: 23/SW/0119

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Home, Internet/virtual, Telephone

Study type(s)
Other

Participant information sheet
https://babysleepresearch.co.uk/baby-sleep-project/

Health condition(s) or problem(s) studied
Supporting families with infants at risk of sudden unexpected death in infancy

Interventions
A realist evaluation study involving before and after mixed methods data collection as follows:
1. Pre-intervention baseline data collection from families completing surveys at approximately 4 and 8 weeks after the birth of the baby
2. Training for health professionals using the baby sleep project resources
3. Post-intervention follow-up data collection from families completing surveys at approximately 4 and 8 weeks after the birth of the baby
4. Post-intervention Nomad questionnaires for health professionals

5. Qualitative interviews will take place when quantitative surveys have been completed with health professionals and family members

Intervention Type
Behavioural

Primary outcome measure
Safer sleep adherence is measured using infant sleep diaries at 4 weeks and 8 weeks post birth

Secondary outcome measures
Current secondary outcome measures:
1. Parental self-efficacy is measured using the 13-item two-factor Uppsala Parental Self-Efficacy about Infant Sleep Instrument (UPPSEISI) at 4 weeks and 8 weeks post birth
2. Implementation processes are measured using the 23-item Nomad questionnaires at baseline, 2 months and 4 months

Previous secondary outcome measures:
1. Parental self-efficacy is measured using the TOPSE-baby questionnaire at 4 weeks and 8 weeks post birth
2. Implementation processes are measured using the 23-item Nomad questionnaires at baseline, 2 months and 4 months

Overall study start date
01/06/2023

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Health professionals (teams of health visitors, neonatal nurses, midwives and specialist nurses (family nurse partnerships) working with families experiencing poverty.
2. Parents/caregivers of infants, either still pregnant or with infants under 2 weeks old, receiving services from recruited health professional teams, can take part in the evaluation.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 220; UK Sample Size: 220

Key exclusion criteria
1. Individuals under 16 years of age
2. Anyone who lacks cognitive capacity to consent
3. Anyone unable to complete an interview in English

Date of first enrolment
01/04/2024

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
St Michaels Hospital
Southwell Street
Bristol
United Kingdom
BS2 8EG

Study participating centre
Wirral Community Nmp
St. Catherines Health Centre
Church Road
Birkenhead
United Kingdom
CH42 0LQ

Study participating centre

HCRG Care group
The Heath Business Park
Runcorn
United Kingdom
WA7 4QX

Study participating centre
Bath and North East Somerset Community Health and Care Services
St. Martins Hospital
Clara Cross Lane
Bath
United Kingdom
BA2 5RP

Study participating centre
Essex Child and Family Wellbeing Service
3rd Floor Endeavour House
Coopers End Road
Stansted
United Kingdom
CM24 1SJ

Study participating centre
Wiltshire Childrens Services
1 Brook Lane
Holt
Trowbridge
United Kingdom
BA14 6RL

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House, Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

+44 1173940177
research-governance@bristol.ac.uk

Sponsor type
University/education

Website
http://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Publication and dissemination plan
The results of this study will be shared with other health staff and parents by reports in medical and health journals, newsletters, and talking about the results at conferences.

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The data will be made available on the University of Bristol Research Data Repository (https://data.bris.ac.uk/data/). Access will only be granted to researchers with appropriate ethical approval. Consent for this will be obtained from participants. All data will be anonymised. Data will be available by the end of January 2026 indefinitely.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	07/02/2024	09/02/2024	No	No
Protocol file	version 5	21/02/2024	09/04/2024	No	No