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CoolCuddle-2 study: Embedding CoolCuddle into NICUs

Submission date
05/08/2022

Recruitment status
No longer recruiting

Registration date
30/08/2022

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Each year in the NHS, over 2000 babies with brain injury at birth need intensive care and cooling therapy for four days. During this time, parents cannot hold their babies in case it interferes with the cooling therapy. Not allowing cuddling during this important period can affect the bond between the parents and their baby. This can cause problems with breastfeeding, parent's mental health, and the baby's emotional and mental development. We have developed a safe way for parents to cuddle their babies during cooling therapy called CoolCuddle. This allows cooling treatment and intensive care to continue. CoolCuddle can help with breastfeeding, parent-baby bonding, parent mental health and may have other long-term benefits for parents and their new-born. We use a CoolCuddle standard procedure and a safety checklist that has allowed 27 cooled babies to be cuddled safely by their parents at two NHS hospitals. We have also made a training video for staff, and photos of how it works for parents.

Parents (including some who helped develop CoolCuddle) say that mothers and fathers would expect CoolCuddle during cooling. They agreed this study would lead to best practice in rolling out CoolCuddle nationally and avoid risk to babies. We have discussed details of the study and advisory group with parents.

The aim of this study is to find the best way to train and involve staff in using the CoolCuddle method in different intensive care units (NICUs) for newborn babies, by closely monitoring how it is introduced. We will also record baby safety measures and see how parents feel about the cuddles.

Who can participate?
Infants aged ≥35 weeks' gestation undergoing intensive care and cooling therapy for HIE, and their parents.

What does the study involve?
We will use our standard procedure and video to train staff at around 6 intensive care units for newborn babies. Staff at each unit will be interviewed every two months to see how well CoolCuddle is being used. Parents will be asked to fill in an online questionnaire, measuring depression, parent-baby bonding and breastfeeding when the baby is 1 and 8 weeks old. Some

parents will be interviewed to get their views on CoolCuddle. We will monitor the baby during the cuddles and record any effect on cooling or intensive care and how this is corrected. We will look at differences over time and between units to work out best practice.

What are the possible benefits and risks of participating?
The benefits of participating in the study include early physical and emotional contact between the parents and the babies who are undergoing cooling therapy for birth asphyxia which may help with establishing breastfeeding and potentially influence the long-term development of babies. Risks of participation may include disruption of the intensive care and cooling therapy. Any physical disruption of wires and catheters will be closely monitored and the chances of occurring will be reduced by following a standard procedure. Disruption occurring despite this will be immediately addressed by nurses and doctors and the new measures will be incorporated into the subsequent cuddles. Further, we will be monitoring the temperature, breathing, and heart function to ensure that these measures are stable during cuddle. Our previous study with CoolCuddle intervention did not show any measurable disruption to intensive care, cooling therapy, or adverse effects to babies or parents.

Where is the study run from?
University Hospitals Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From July 2022 to March 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
1. Dr Ela Chakkarapani, ela.chakkarapani@bristol.ac.uk
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
312535

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 312535, CH/2021/7268, CPMS 52790

Study information

Scientific Title
Process evaluation of embedding the CoolCuddle intervention into neonatal intensive care units.

Acronym
CoolCuddle2 Study

Study objectives
To assess the process of embedding the CoolCuddle intervention into standard care during cooling therapy for neonatal HIE in the NHS.
1. Track intervention implementation in 4 diverse tertiary NICUs using continuous monitoring with the NoMAD
Implementation measure based on NPT (www.normalizationprocess.org).
2. Examine barriers and facilitators for implementing CoolCuddle using NPT informed qualitative interviews
with neonatal staff and parents.
3. Evaluate cooling process and intensive care during cuddles, rates of postnatal depression,

parent-infant
bonding or attachment and breastfeeding at discharge and 8 weeks.
4. Examine safety issues associated with CoolCuddle and develop corrective actions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2022, North West-Greater Manchester West Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048384; gmwest.rec@hra.nhs.uk), ref: 22/NW/0141

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Neonatal hypoxic ischaemic encephalopathy (HIE)

Interventions
Process evaluation of implementing CoolCuddle intervention that allows parents to cuddle babies whilst undergoing therapeutic hypothermia and intensive care for neonatal hypoxic-ischaemic encephalopathy in different tertiary NICUs in the UK.

Intervention Type
Behavioural

Primary outcome(s)
1. Normalisation of the CoolCuddle intervention in 4 NICUs with a refined training package measured using the Normalisation MeAsure Development questionnaire (NoMAD) for each of the four domains of normalisation process theory (NPT) (coherence, cognitive participation, collective action, and reflexive monitoring) at up to 6 timepoints during implementation
2. Views of neonatal nurses and clinicians regarding barriers and facilitators of embedding CoolCuddle into routine practice measured using focus groups or staff interviews at the end of recruitment at each site
3. Views of parents on the integration of CoolCuddle into infant care practices at the four sites will be measured using telephone or virtual interviews after parents complete the questionnaires at 8 weeks
4. Stability and deliverability of CoolCuddle for the recruited infants in different NICUs measured using the following: (there is no timepoint here, it is the measure for the recruited infants or the recruitment period which will vary for each site)
4.1. Number and duration of cuddles throughout the NICU admission
4.2. Difference in mean core temperature, oxygen requirement, heart rate, and blood pressure between pre-cuddle, cuddle, and post-cuddle epochs
4.3. Safety issues and instigation of mitigating factors during the recruitment period
4.4. Frequency of stopping cuddles as per SOP and reasons for this (thermal control,

endotracheal tube, vascular or urinary catheter, EEG electrode dislodgement) during the recruitment period
4.5. Proportion of women breastfeeding, median Edinburgh Postnatal Depression Scale (EPDS) scores, the proportion at risk of depression (EPDS score ≥13), and Mother-to-Infant Bonding Scale (MIBS) scores at discharge and 8 weeks

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Infants, aged ≥35 weeks' gestation undergoing therapeutic hypothermia using a servo-controlled cooling machine and intensive care for Hypoxic Ischemic Encephalopathy (HIE), and their parents:

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
35 weeks

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Infants whose parents are not able to complete the consent form or questionnaires in English
2. Infants whose parents are aged <16 years

Date of first enrolment
01/08/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester

United Kingdom
M13 9WL

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham Womens Hospital
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Neonatal unit, Royal Victoria Infirmary
Newcastle upon Tyne
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NE1 4LP

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository managed by the University of Bristol Search and ublished as a supplement to the results publication

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/10/2024	21/10/2024	Yes	No
HRA research summary			28/06/2023	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes