ISRCTN16356650 https://doi.org/10.1186/ISRCTN16356650

Does listening to a guided relaxation recording increase the amount of breastmilk that mothers can express when their babies are born very early?

Submission date
15/04/2021

Recruitment status
No longer recruiting

Registration date
19/04/2021

Overall study status
Completed

Last Edited
27/09/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Babies who are born early (prematurely) are more likely to have serious health problems, which can affect them for the rest of their lives. Being born early is also the most common cause of death for newborns in the UK. Giving breastmilk to premature babies prevents serious gut illnesses, infections, and eye problems, and builds babies' brains for their long-term development. However, it can be hard for mothers who give birth early to express enough breastmilk for their baby. This study will investigate if listening to a guided relaxation and visualisation recording increases the amount of milk mothers can express in the first three weeks after birth. The study also aims to find whether the recording will help more mothers to exclusively breastfeed for up to four months after the baby's due date. The study team will also look at whether mothers listening to the recording feel less anxious or distressed and other aspects of how they express milk.

Who can participate?
Women who have given birth to a single baby or twins when they were less than 7 months pregnant.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Half of the mothers will be allocated to listen to a guided relaxation and visualisation recording while expressing milk, on top of normal care, and the other half the mothers will receive normal care only. The recording will talk the mother through relaxing their muscles, deep breathing, picturing their baby, and imagining their milk flowing. Participants will be asked to listen to the recording frequently while expressing milk.

What are the possible benefits and risks of participating?
Taking part in research can give people a sense of satisfaction, and may provide a source of distraction.

Paying close attention to how much milk they are expressing might make people anxious. Weighing milk and answering questionnaires takes time.

Where is the study run from?
The National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) at the University of Oxford (UK). It will take place in the neonatal intensive care units of two NHS Trusts in England.

When is the study starting and how long is it expected to run for?
From May 2021 to January 2023

Who is funding the study?
The National Institute of Health Research (UK)

Who is the main contact?
Dr Ilana Levene
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Study website
https://www.npeu.ox.ac.uk/express

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

291449

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47567, IRAS 291449

Study information

Scientific Title
Does a guided relaxation audio track increase yield of expressed milk in mothers of very preterm infants? EXpressing in PREmaturity - Simple interventionS (EXPRESS): A randomised controlled trial and nested exploratory work

Acronym
EXPRESS

Study objectives
In mothers of babies born at less than 32 weeks of pregnancy, does the use of a guided relaxation and visualisation audio track compared to standard care, improve expressed milk volume, proportion human milk feeding, and maternal mental health?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2021, London - Bloomsbury REC (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ; +44 (0)207 104 8196; bloomsbury.rec@hra.nhs.uk), REC ref: 21/LO/0279

Study design
Randomized controlled trial with nested exploratory work

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.npeu.ox.ac.uk/express/parents

Health condition(s) or problem(s) studied

Insufficient volume of expressed milk and breastfeeding duration in mothers of very premature infants

Interventions
Once the participant has given informed consent (which can only happen after birth), they will be trained on how to use a pocket accurate scale to weigh their expressed milk and their competence assessed. They will be randomised to the intervention or control group. Participants will be randomised using a computerised permuted block randomisation method, stratified for gestational age, centre, and multiple birth.

Participants in the intervention group will be given a link to an MP3 file of a guided relaxation and visualisation recording for expressing milk, modified for mothers of very preterm babies. They are asked to listen to the recording while expressing milk several times a day for 21 days.

Participants in the control group will receive standard care only.

Intervention Type
Behavioural

Primary outcome measure
Expressed milk volume measured using by weighing the output each time the participant expresses milk in a 24 h period at 4, 14, and 21 days

Secondary outcome measures
1. Proportion of participants expressing ≥750 g milk in 24 h (the target set by UNICEF Baby Friendly Initiative UK) measured by weighing the output each time the participant expresses milk in a 24 h period at 4, 14, and 21 days
2. Expressing efficiency measured by calculating the average weight of milk expressed per min from each participant weighing their output in a 24 h period, and reporting the length of time they spent expressing, at day 21
3. Anxiety measured using the Spielberger State Trait Anxiety Index, 6 question format (STAI-6) at 21 days
4. Stress reaction score measured using the Post-traumatic stress Check List for DSM-5 (PCL-5) at 21 days
5. Proportion exclusive human milk feeding measured by maternal report at 36 weeks post-menstrual age and 18 weeks after the estimated date of delivery (4 months corrected age)
6. Proportion with any human milk feeding measured by maternal report at 36 weeks post-menstrual age

Overall study start date
01/01/2021

Completion date
20/01/2023

Eligibility

Key inclusion criteria
1. Mother of 1 or 2 live infants who are:
1.1. Born between 23+0 and 31+6 weeks gestation

1.2. Inpatient on a recruiting neonatal unit at the time of consent
1.3. Aged <4 days of age at the time of enrolment
2. Willing and able to give informed consent for participation in the study
3. Aged ≥18 years
4. Intends to express milk for ≥14 days
5. Access to a device that will play an MP3 file

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 132; UK Sample Size: 132

Total final enrolment
132

Key exclusion criteria
1. No dating scan antenatally
2. Triplet or higher-order pregnancy with >2 live-born infants

Date of first enrolment
02/08/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington

Oxford
United Kingdom
OX3 9DU

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office
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Boundary Brook House
Churchill Drive
Headington
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United Kingdom
OX3 7GB
+44 (0)1865 289885
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name
National Institute for Health 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

Results and Publications

Publication and dissemination plan
Planned publication in a specialist peer-reviewed journal. Planned dissemination to parents on neonatal units via production of postcards to attach to breast pumps in collaboration with Best Beginnings charity. The study protocol will be available at https://www.npeu.ox.ac.uk/express/clinicians.

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Director of the NPEU, currently Prof Jenny Kurinczuk (jenny.kurinczuk@ndph.ox.ac.uk) according to the NPEU data sharing policy. Requests for data sharing that meet the criteria will be considered by the NPEU data sharing committee as appropriate. The criteria are: to ensure the integrity of any data that it releases to the public (e.g. resolving data quality issues); and to allow a reasonable period of exclusivity - a minimum of five years after database lock. The composition of the committee will be Unit Director; Senior Statistician; Head of IT and Information Security; the original principal investigator (PI) if available; and others as appropriate. The committee will assure themselves that the research proposal is scientifically sound, the protocol has been peer-reviewed, there is adequate funding for the work, and there are appropriate ethics approvals in place or in progress. The committee will require evidence that the likely commitment of NPEU staff has been realistically assessed and will normally expect funding to be available to cover any NPEU costs in making data available and providing ongoing support. The committee must also assure itself that releasing the data can be justified within the scope of the original participant consent where applicable.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version V1.0	29/07/2022	01/08/2022	Yes	No
Statistical Analysis Plan		07/09/2022	15/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		04/03/2024	11/03/2024	Yes	No
Results article		25/09/2024	27/09/2024	Yes	No