

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

|                                        |                                                       |                                                                                                              |
|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>15/04/2021   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>19/04/2021 | <b>Overall study status</b><br>Completed              | <input checked="" type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>27/09/2024       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> 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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## Contact information

### Type(s)

Scientific

### Contact name

Dr Ilana Levene

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### Contact details

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## Additional identifiers

### Integrated Research Application System (IRAS)

291449

### Central Portfolio Management System (CPMS)

47567

## 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

**Primary study design**

Interventional

**Study design**

Randomized controlled trial with nested exploratory work

**Study type(s)**

Treatment

**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(s)**

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

### **Key secondary outcome(s)**

1. Proportion of participants expressing  $\geq 750$  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

### **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  $\geq 18$  years
4. Intends to express milk for  $\geq 14$  days
5. Access to a device that will play an MP3 file

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Total final enrolment**

**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**

United Kingdom

England

**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

**ROR**

## 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

### 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? |
|-----------------------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 04/03/2024   | 11/03/2024 | Yes            | No              |
| <a href="#">Results article</a>               |                               | 25/09/2024   | 27/09/2024 | Yes            | No              |
| <a href="#">Protocol article</a>              |                               | 29/07/2022   | 01/08/2022 | Yes            | No              |
| <a href="#">HRA research summary</a>          |                               |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Statistical Analysis Plan</a>     | version V1.0                  | 07/09/2022   | 15/06/2023 | No             | No              |
| <a href="#">Study website</a>                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |