ISRCTN94815142 https://doi.org/10.1186/ISRCTN94815142

From womb to world: creating womb-like environments for preterm language development

Submission date 03/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/02/2026	**Overall study status** Ongoing	
Last Edited 10/03/2026	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Babies who are born early (before 37 weeks) miss some of the important sounds they would normally hear in the womb—such as the rhythm and melody of their parents' voices. These early sound experiences help lay the foundations for language learning.

Preterm babies in Neonatal Care Units (NCUs) also hear far less speech and are exposed to more machine noise than babies in the womb. This may contribute to later language delays.

The From Womb to World study aims to find out whether recreating a safe, womb like sound environment—including filtered recordings of parents' voices—can support better early language and cognitive development in preterm babies. The study compares three groups:
-Preterm babies who hear the womb like sound environment
-Preterm babies who receive standard care
-Full term babies

Who can participate?
The study will involve 150 infants in total.
Preterm infants (two groups: one exposed to the womb-like environment and another group with standard care)
Babies born between 26–34 weeks who:
-Have no major brain injury
-Have no known hearing or vision problems
-Do not have developmental or language conditions
-Come from monolingual English-speaking families
Full term infants: Babies born at 37 weeks or later who meet the same health and family language criteria.

What does the study involve?
For families of preterm infants who are exposed to the womb-like environment:
1. Recordings of parents' voices: Parents who take part will create audio recordings to capture

their speech. These recordings are filtered to sound more like what a baby would hear in the womb. Babies will hear these filtered parental recordings and gentle womb like sounds while in the NCU.
For all participating infants:
As babies grow, families will be invited to four visits at the Oxford Brookes BabyLab—at around 7.5, 9, 10.5, and 12 months.
At each visit:
-Babies take part in short, infant-friendly language observations (about 5 minutes each) to measure how they listen to and process speech rhythm and sound patterns.
-Parents complete vocabulary questionnaires.
-At 7.5 and 12 months, babies also complete a standard cognitive development assessment.
Visits last about one hour with breaks as needed.

What are the possible benefits and risks of participating?
Benefits:
The study may provide preterm babies with extra, gentle sound stimulation that could support early language development.
Families may also appreciate contributing to research and gaining a better understanding of their baby's early progress.
Risks:
The study is low risk. Babies may become tired during the short, play based testing sessions, but these are closely monitored and will stop immediately if a baby becomes fussy or uncomfortable. The main inconvenience for parents is the time involved, such as completing brief questionnaires or making recordings.

Where is the study run from?
The Neonatal Care Unit at the participating NHS Trust (where preterm infants are identified and exposed to the womb-like sounds)
The Oxford Brookes University BabyLab (where language and development assessments take place)

When is the study starting and how long will it run?
The study is planned to run from March 2026 to August 2029.

Who is funding the study?
The research is funded by the UKRI Economic and Social Research Council (ESRC).
The sponsor (responsible for study governance) is Oxford Brookes University.

Who is the main contact?
Dr Nayeli Gonzalez Gomez, ngonzalez-gomez@brookes.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Nayeli Gonzalez- Gomez

ORCID ID
https://orcid.org/0000-0003-2012-8290

Contact details
Gipsy Lane
OXFORD
United Kingdom
OX3 0BP
+44 1865 534148
ngonzalez-gomez@brookes.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
367689

Central Portfolio Management System (CPMS)
73066

Study information

Scientific Title
From womb to world: creating womb-like environments for preterm language development

Study objectives
The goal is to investigate whether exposure to a womb-like acoustic environment including recordings of their parents in NCU, can improve language development in preterm infants later on.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Babies born preterm

Interventions
This study will explore whether providing a womb-like sound environment can support early language development in babies born prematurely.

Around 150 babies will take part in total:
50 preterm babies who experience a womb-like sound environment in the Neonatal Care Unit (NCU)
50 preterm babies who receive standard neonatal care
50 babies born full-term, who will act as a comparison group

All babies will be healthy, with no known hearing, vision, or major medical problems. Parents will be given full information and asked to provide written consent before taking part.

What will happen in the Neonatal Care Unit:
For families who agree to take part in the womb-like sound group, parents will be asked to make simple audio recordings of their everyday speech at home using a small, discreet recording device for four days. These recordings will then be carefully processed so that they sound similar to how speech is heard in the womb (softened and filtered). No identifiable raw recordings will be stored.

Meanwhile, a general recording of infant-directed speech produced by the research team will be used until parental recordings are available. While the baby is in the NCU, these sounds will be played at safe, carefully monitored levels through external speakers placed outside the incubator or cot. No equipment will be placed inside the baby's bed space. The sound system can be stopped at any time if needed, and it will never interfere with medical care. Babies will be exposed to the sounds until they leave the NCU or reach their due date.

Babies in the standard care group will not receive any additional sounds beyond usual NCU care.

What will happen after discharge:
All babies will be followed over their first year of life. They will be invited to take part in four short research visits at the Brookes BabyLab at 7.5, 9, 10.5, and 12 months of age.

At each visit:
Babies will take part in short listening tasks (about 5 minutes each), where their looking or listening responses to speech sounds are measured while they sit on their parent's lap.
Parents will complete a short questionnaire about their child's understanding and use of words.
Babies' general development will be assessed at two time points using age-appropriate play-based tasks.
Each visit will last about one hour, with regular breaks to ensure babies remain comfortable and relaxed.

Intervention Type
Behavioural

Primary outcome(s)

1. Lexical stress sensitivity measured using Head-turn Preference Procedure at 7.5, 9, 10.5 months of age

2. Prosodic boundaries sensitivity measured using Head-turn Preference Procedure at 7.5 months of age

3. Lexical Tone sensitivity measured using Central Fixation Procedure at 9, 10.5, 12 months of age

4. Bayley scores measured using Bayley questionnaire at 7.5, 12 months of age

5. Vocabulary scores measured using Communicative Development Inventory at 7.5, 9, 10.5, 12 months of age

Key secondary outcome(s))

Completion date
30/09/2029

Eligibility

Key inclusion criteria
Preterm Infant Group:
1. Gestational age ≥26 and ≤34 weeks.
2. Absence of major cerebral damage (e.g., periventricular leukomalacia, intra-ventricular haemorrhage…).
3. No indication of visual or hearing impairment.
4. No family risks of developmental or language disorders.
5. From monolingual English-speaking families.

Full-term Infant Group:
1. Gestational age ≥37 weeks.
2. Absence of major cerebral damage (e.g., periventricular leukomalacia, intra-ventricular haemorrhage…).
3. No indication of visual or hearing impairment.
4. No family risks of developmental or language disorders.
5. From monolingual English-speaking families.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
0 weeks

Upper age limit
13 months

Sex

All

Total final enrolment
0

Key exclusion criteria
Preterm Infant Group
1. Born before 26 weeks' gestation or after 34 weeks' gestation.
2. Evidence of major brain injury or neurological damage, including but not limited to periventricular leukomalacia or intraventricular haemorrhage.
3. Known or suspected hearing impairment or visual impairment.
4. Presence of diagnosed genetic, neurological, developmental, or language disorders, or a known family history of developmental or language disorders that may affect language development.
5. Infants from bilingual or multilingual households, or where English is not the primary language spoken to the infant at home.
6. Medical instability or clinical concerns identified by the neonatal care team that would make participation inappropriate or place additional burden on the infant or family.

Full-term Infant Group
1. Born before 37 weeks' gestation.
2. Evidence of major brain injury or neurological damage, including but not limited to periventricular leukomalacia or intraventricular haemorrhage.
3. Known or suspected hearing impairment or visual impairment.
4. Presence of diagnosed genetic, neurological, developmental, or language disorders, or a known family history of developmental or language disorders that may affect language development.
5. Infants from bilingual or multilingual households, or where English is not the primary language spoken to the infant at home.
6. Any medical condition or clinical concern identified by the clinical or research team.

Date of first enrolment
01/03/2026

Date of final enrolment
01/01/2029

Locations

Countries of recruitment
United Kingdom

England

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

Oxford
England
OX3 9DU

Study participating centre
Oxford Brookes University
Gipsy Lane
Oxford
England
OX3 0BP

Sponsor information

Organisation
Oxford Brookes University

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type

Funder Name
Economic and Social Research Council

Alternative Name(s)
Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1		03/02/2026	No	Yes
Participant information sheet	Graphic version version 1		03/02/2026	No	Yes
Protocol file	version 2	20/12/2025	03/02/2026	No	No