

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

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
03/02/2026	Not yet recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
06/02/2026	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
06/02/2026	Neonatal Diseases	<input checked="" type="checkbox"/> Record updated in last year

## 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](mailto: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

## 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  $\geq 26$  and  $\leq 34$  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  $\geq 37$  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**

**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)**

Economic and Social Research Council (ESRC), 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?
<a href="#">Participant information sheet</a>	version 1		03/02/2026	No	Yes
<a href="#">Participant information sheet</a>	Graphic version version 1		03/02/2026	No	Yes
<a href="#">Protocol file</a>	version 2	20/12/2025	03/02/2026	No	No