Health Research Authority

Quantitative Protocol Development Tool

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study's progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you've used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

- **This protocol has regard for the HRA guidance and order of content; OR**
- **This protocol has regard for the HRA guidance; OR**
- **This protocol does not have regard to the HRA guidance and order of content**

SHORT TITLE/ACRONYM

FULL/LONG TITLE OF THE STUDY: From Womb to World: Creating Womb-Like Environments for Preterm Language Development

SHORT STUDY TITLE / ACRONYM: From Womb to World

PROTOCOL VERSION NUMBER AND DATE: 1.0 20th December 2025

RESEARCH REFERENCE NUMBERS

IRAS Number:	367689
SPONSORS Number:	TBC
FUNDERS Number:	TBC

SHORT TITLE/ACRONYM

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature:
.....

Date:
..20../.12../..25..

Name: (please print): Nayeli Gonzalez-Gomez

.....

LIST of CONTENTS

SHORT TITLE/ACRONYM

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Dr Nayeli Gonzalez-Gomez ngonzalez-gomez@brookes.ac.uk 01865 534148
Study Co-ordinator	Dr Shannon Kong p0088728@brookes.ac.uk
Sponsor	
Joint-sponsor(s)/co-sponsor(s)	Dr Zoe Davey Oxford Brookes University Jack Straw's Lane, Marston, Oxford OX3 0FL hls-sponsorship@brookes.ac.uk 01865 48 2697
Funder(s)	UKRI Economic and Social Research Council (ESRC) **esrcenquiries@esrc.ukri.org**

STUDY SUMMARY

It may be useful to include a brief synopsis of the study for quick reference. Complete information and, if required, add additional rows.

Study Title	From Womb to World: Creating Womb-Like Environments for Preterm Language Development
Internal ref. no. (or short title)	From Womb to World
Study Design	Other clinical trial to study a novel interventionLongitudinal study
Study Participants	Babies aged 0-12 months
Planned Size of Sample (if applicable)	150
Follow up duration (if applicable)	12 months
Planned Study Period	March 2026-August 2029
Research Question/Aim(s)	The main aim is to investigate whether exposure to a womb-like acoustic environment in NCU, including

	recordings of their parents, can improve language development in preterm infants later on.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)
UKRI Economic and Social Research Council (ESRC) **esrcenquiries@esrc.ukri.org**

ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor is Oxford Brookes University, which assumes overall responsibility for the initiation, management, and governance of the Womb-to-World project. As sponsor, the University ensures that the study is conducted in compliance with all relevant regulations, ethical standards, and institutional policies, including data protection and participant safety. The sponsor does not directly influence the scientific design, data analysis, or interpretation of results, but oversees that appropriate procedures and risk management strategies are in place.

The project is funded by the Economic and Social Research Council (ESRC). The funder's role is limited to providing financial support for the study and monitoring progress in line with grant conditions. The funder does not have authority over the study design, conduct, data analysis, interpretation of findings, or dissemination of results. The research team retains full independence in all scientific and publication decisions.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

This project is supported by an advisory group that includes clinical staff from Neonatal Care Units (consultant neonatologists, nurses, occupational therapists, and psychologists), parents of preterm infants, and charity partners (SSNAP and Speech and Language UK). This group acts as the Patient & Public Involvement (PPI) advisory group, providing guidance and feedback throughout the study.

Roles and Responsibilities of the PPI Group:

- Provide input on study design, participant information materials, and recruitment strategies to ensure acceptability and feasibility.

- Advise on approaches to reduce potential barriers to recruitment and improve engagement with families.
- Contribute to the development of public engagement resources and dissemination materials to ensure findings are understandable and relevant to families and the broader public.
- Offer lived experience and professional expertise to inform the interpretation of study findings.

Independence:
The PPI advisory group operates independently from the sponsor (Oxford Brookes University) and the ESRC funder. While they provide guidance and feedback, the final decisions regarding study design, conduct, data analysis, and dissemination rest with the Chief Investigator and research team.

KEY WORDS: Preterm infants, Early language development, Prosody acquisition, Neonatal Care Units, Womb-like auditory environment

STUDY FLOW CHART

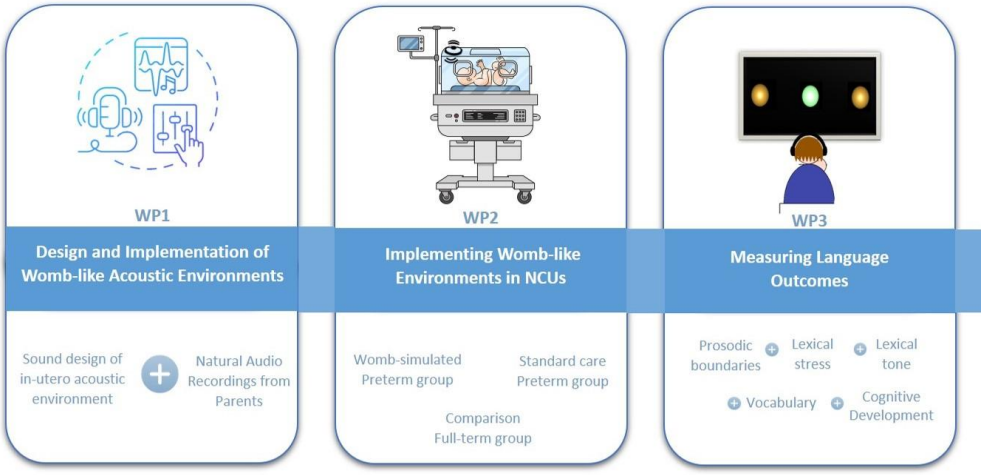


Fig. 1. Overview of the Project .

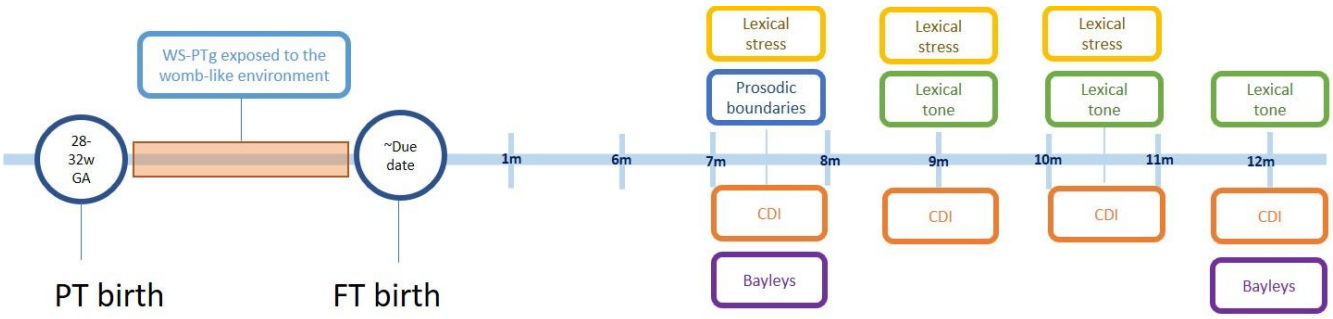


Fig. 2. Summary of testing points.

SHORT TITLE/ACRONYM

STUDY PROTOCOL

From Womb to World: Creating Womb-Like Environments for Preterm Language Development

1 BACKGROUND, RATIONALE and THEORETICAL FRAMEWORK

Premature birth, defined as delivery before 37 weeks of gestation, is a significant global health issue affecting millions of infants each year[1]. While advancements in neonatal care have increased the survival rates of preterm infants[2], premature infants continue to face unique challenges in their development. Numerous studies have shown that preterm birth increases the risk of cognitive deficits in the preschool and school years[3,4]. In terms of language, preterm children show poorer auditory discrimination and memory, reading difficulties, poor vocabulary, a specific delay in verbal processing and reasoning, less complex expressive language and lower receptive understanding than their matched controls[5–9]. Research by the PI has revealed that preterm birth affects, in particular, some aspects of early language development, specifically the acquisition of prosody—the rhythm and melody of speech—while having no significant impact on phonetics —speech sounds— or phonotactics —the rules governing sound combinations—[10,11]. This indicates a developmental delay in prosodic acquisition for preterm infants, consistent with other studies[12–14].

Importantly, hearing becomes functional around 25 weeks of gestation[15], allowing foetuses to perceive speech in the womb[16,17]. However, maternal tissues attenuate and filter out higher frequencies above 600–1000Hz[18], preserving speech melody and rhythm (prosody) while suppressing phonetic details, particularly consonants. As a result, prenatal auditory exposure primarily conveys prosodic information. Rhythmic sounds, like the mother's heartbeat, may act as a pacemaker, shaping early rhythm perception[19].

Evidence from animal models and simulations suggests that foetuses are exposed to a speech signal rich in prosodic features[20], further evidence has shown that foetuses can differentiate stimuli using prosodic cues[21,22]. There is evidence that this prenatal experience shapes infants' perceptual abilities. For instance, newborns are already sensitive to the prosodic grouping[23] and vocalic segments[24] of their native language. Furthermore, studies using EEG responses in newborns demonstrated that prenatal exposure to specific changes in vowels and pitch led to

the recognition of these postnatally[25]. Infants without such prenatal exposure only recognised vowel changes, suggesting that prenatal prosodic exposure is crucial for early language development.

The concept of 'prenatal prosodic bootstrapping'[26] proposes that foetuses' learning about speech prosody in the womb serves as an anchor for language learning after birth. This early exposure to prosody is, thus, crucial for laying the foundation for later language development[26–28]. Research has shown that prosody plays a central role in language acquisition, influencing various stages of language development. This includes the identification of a proto-lexicon[29], word segmentation[30], the storage and classification of words into categories such as lexical or functional[31], and even early morphosyntactic representations[32].

Preterm infants miss some or all essential prenatal prosodic exposure, potentially contributing to prosodic development delays[10,12–14]. Developmental theories[33] suggest that disruptions in typical brain development timing can have cascading effects. Early prosodic delays might, therefore, lead to later language deficits[34]. Language delay impacts school readiness, academic performance, and long-term health and social outcomes. While some children catch up, many experience lasting effects on literacy, quality of life, mental health, and career success well into adulthood[34].

Furthermore, preterm babies in Neonatal Care Units (NCUs) encounter other significant challenges, particularly a persistent lack of speech and auditory stimulation[35], compounded by continuous exposure to loud noises[36]. The NCU environment, dominated by the sounds of medical equipment and an absence of typical conversational interactions, deprives preterm infants of the rich auditory input crucial for their language development. Indeed, on average infants in NCUs are exposed to only 30 minutes of speech per day whereas foetuses experience nearly three hours of daily speech input[37].

Although, to our knowledge, no studies have directly examined the effects of auditory stimulation in NCUs on language development, evidence from other domains suggests potential benefits. For instance, preterm infants exposed to recordings of their mother's voice achieved full enteral feeding faster and exhibited significant heart rate improvements and auditory cortex plasticity compared to those receiving routine care[19,38,39].

2 RESEARCH QUESTION/AIM(S)

This project seeks to address these challenges by creating a personalized, womb-like acoustic environment for preterm infants in NCUs. The **goal** is to investigate whether exposure to a womb-like acoustic environment including recordings of their parents, can improve language development in preterm infants. The project will compare the language development of preterm infants exposed to this womb-simulated environment with those in standard neonatal care and full-term infants.

2.1 Objectives

- Design and implement a womb-like acoustic environment in the NCU using parental voice recordings and simulated sounds from the womb.
- Evaluate its effects on language development, including prosody, vocabulary acquisition, and cognitive development, comparing preterm infants exposed to the womb-like environment with those receiving standard care and full-term infants across their first year of life

2.2 Outcomes

- **Prosody perception and acquisition** – the ability to detect and process the rhythm and melody of speech, assessed through experiments.
- **Vocabulary comprehension and production** – assessed through parental report questionnaires.
- **Cognitive development** – measured using standardised developmental assessments.

Secondary outcomes include:

- **Feasibility and acceptability of the womb-like acoustic environment** – including parental and clinical staff feedback.

These outcomes will allow us to evaluate whether exposure to a womb-like auditory environment can support early language and cognitive development in preterm infants and provide evidence to inform future neonatal care practices.

3 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Design and Implementation of Womb-like Acoustic Environments

This WP involves comprehensive acoustic research to create a realistic womb-like auditory experience. Exposing infants to their mother's voice and the surrounding sounds involves three steps: recording, sound design and playback. Each step requires special care to accurately reproduce the sound environment the foetus experiences while ensuring safety, privacy, reliability and ease of implementation for the medical staff.

Recordings. We will set up tools and equipment to record natural audio from the parents of each child. For the recording phase, the mother will be equipped with a discreet recording system for four days. This system, utilising 32-bit float technology, captures a wide dynamic range without the risk of saturation, allowing for a faithful reproduction of the auditory environment of each family. These initial recordings will provide a diverse array of daily soundscapes that can be randomised to avoid repetition.

Sound processing will involve applying a high-pass filter between 300-400Hz[40] to replicate the in-utero listening experience accurately. Measurements taken with ballistic gel and a hydrophone will ensure precise sound reproduction by capturing the acoustic response of the womb environment. Specific guidelines will be followed for different types of sounds[41]: mother's voice will increase in average by 5.2 dB; voices of other people will be attenuated by 2.1 dB for a man's voice and 3.2 dB for a woman's voice; external environment accentuation of 3.7 dB at 125 Hz and a gradual decrease up to a maximum of 10 dB at 4 kHz. Privacy will be ensured by applying destructive filtering to raw audio and securely storing processed data.

Secondary recordings: Following the initial recordings, mothers will be able to send additional audio messages to their child via email or a dedicated WhatsApp number. These recordings will be incorporated into the existing audio dataset and will undergo the same automated processing, filtering, anonymisation, and secure storage procedures as the original recordings. No raw audio from these secondary recordings will be listened to by researchers, and all raw files will be deleted immediately following processing.

Sound design. We will simulate in-utero sounds, including maternal heartbeat, respiration and other bodily functions. No suitable recordings of in-utero background sound exist. Therefore,

we will use film sound effects and sound design techniques, carefully respecting previous frequency and sound level measurements[42], as well as the timing of these events. This creates a realistic background sound environment for the infant. The final design will be mixed with the edited parent recordings.

Playback. During their NCU stay, infants transition from incubators to cots, and playback will be used in both. Both systems will prioritize safety, adaptability to medical needs, high-quality audio, and easy maintenance. Developed in close collaboration with NCU staff, they will ensure feasibility and acceptability.
It is crucial to emphasize that in addition to adhering to safety standards for the infant, we will pay special attention to sound levels and meet the standards previously suggested[42]. These levels will be meticulously studied, measured, and regularly checked using reference microphones to ensure they are safe and appropriate; emergency shut-off switches will be included for both systems.

After measuring the incubators' sound profile (resonance, frequency nodes, etc.), we will attach an external conduction speaker to the lid for spatial sound diffusion, avoiding intrusive equipment inside. For cots, externally positioned speakers behind the baby's head and acoustic panels will minimize sound leakage. The setup will be mounted on a mobile cart for easy handling. While complete sound isolation is impossible, the proximity of the sound source ensures it remains the dominant auditory input, creating a form of psychoacoustic isolation[43].

Our advisory group—including NCU staff (consultant neonatologists, nurses, occupational therapists, and psychologists), four parents of preterm children, and charity partners SSNAP and Speech and Language UK—has been involved since the project's inception. Their feedback has shaped the proposed approach and will continue to guide refinements before implementation.

Implementing Womb-like Environments in NCUs

Final outputs will be implemented and tested in incubators, initially without infants (as part of WP1). Once extensively tested, the system will be introduced to incubators with infants having parental consent.

Participants. A total of 150 infants will be tested, accounting for a 20% attrition rate due to multiple experiments (10%) and longitudinal design (10%). This ensures sufficient participants per group (WS-PTg, SC-PTg, CO-FTg) for statistical analyses (α=0.05, power=0.80, GPower 3.1). The estimate is based on effect sizes (d=0.59–0.80) from prior studies on early speech perception and language outcomes in preterm infants. Participants will include:

1) Womb-simulated PT group (WS-PTg): Forty healthy preterm infants meeting five primary criteria:
    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.

Infants eligible to participate in the WS-PTg will be identified by the NCU team as soon as possible after their arrival to the unit and parents of these infants will be approached by one of the neonatal nurses to ask if they would want to take part in the project. Families who have given consent will be approached by the research team and given the necessary equipment to do the audio recordings. Meanwhile, a general recording of infant-directed speech recorded by the research team will be used until parental recordings are available. Infants will be exposed to the recordings until they are discharged from the NCU or they reach their due date.

2) Standard care PT group (SC-PTg): Forty healthy preterm infants who meet the same criteria outlined above will be recruited using the same strategy. Infants assigned to the SC-PTg will, when possible, be those who have already been discharged from the NCU.

3) Comparison FT group (CO-FTg): Forty healthy full-term infants born at ≥37 weeks who also meet criteria 2–5 outlined above.

Recruitment of this group will be done via the Brookes BabyLab database (3500+ registered families). Infants in this group will be matched to the other groups based on gender and family SES (i.e., parental education, household income).

The incubator and cot systems will be equipped with computers that broadcast the womb-like acoustic environment developed in WP1. A marker process will facilitate the identification of elements within these recordings (e.g., specific speakers, singing…). These elements will be randomly distributed while preserving the original speech durations and times of day. A tracking system will record daily details of each child's exposure duration to:

1. The mother's speech.
2. The speech of the surroundings.
3. Moments without speech.
4. The total duration of sound broadcasting (in case the system is stopped).

Measuring Language Outcomes

WP3 includes three experiments on prosody development, one vocabulary measure, and one general cognitive development measure over five months.

Testing Intervals:

Infants will be tested at 7.5, 9, 10.5, and 12 months (see Fig. 2), as delays are detectable at these ages[10,44,45]. This longitudinal design will highlight pathways of early speech perception, crucial for studying atypical development.

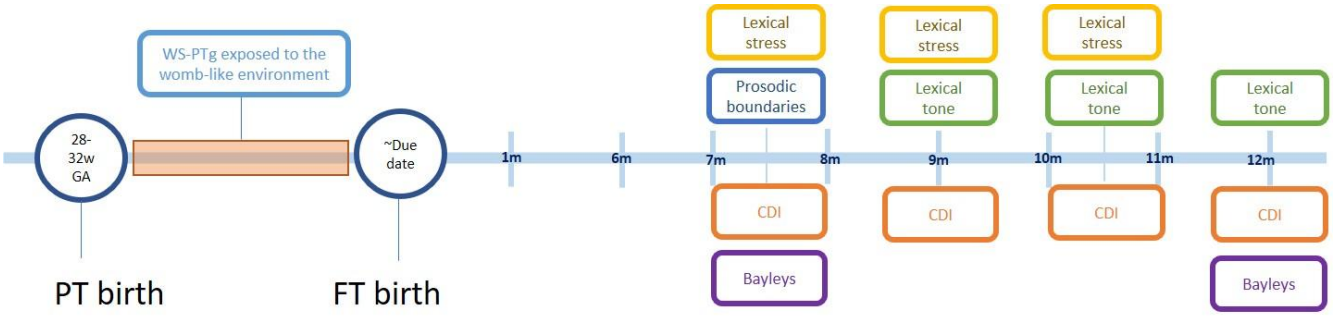


Fig. 2. Summary of testing points.

Participants:

See WP2 for participant details.

Methods and Experiments:

Three experiments will investigate key aspects of prosody using the well-established head-turn preference and central fixation procedures (see Fig.3).

1. **Lexical Stress** – This experiment will explore infants' increasing ability to process native sounds, specifically their preference for the most frequent first-syllable stress (trochaic pattern). Infants will hear disyllabic words stressed on either the first syllable (e.g., "**gen**tle") or the second syllable (iambic pattern, e.g., "com**ply**").
2. **Lexical Tone** – This experiment examines infants' declining ability to process non-native sounds. Infants will be exposed to Cantonese tones instantiated on the syllable "chee" produced by a female native speaker with either the rising tone 25 (此 'this; thus'; 始 'start') or the middle level tone 33 (次 'next'; 刺 'thorn').
3. **Prosodic Boundaries** – This experiment will assess infants' sensitivity to sentence-level prosody, specifically prosodic boundaries. Infants will be presented with two versions of a sentence: one well-formed (e.g., "John doesn't know what rabbits eat. Leafy vegetables taste so good") and one ill-formed with unnatural phrase breaks (e.g., "what rabbits eat. Leafy vegetables taste"). Sensitivity to prosodic boundaries at 6 months has been linked to vocabulary development at 24 months[44], and this study will investigate whether this can predict vocabulary scores at 12 months in preterm infants.

SHORT TITLE/ACRONYM

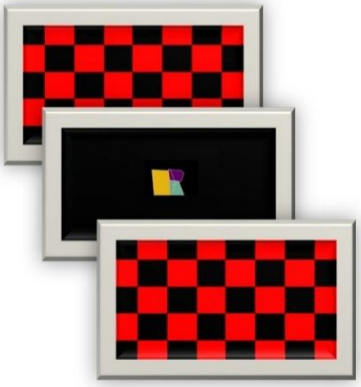
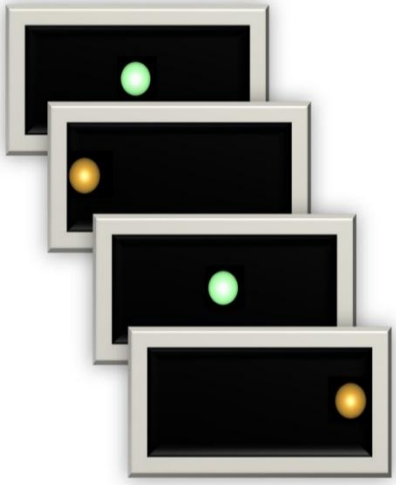
	Lexical Tone	Lexical Stress	Prosodic Boundaries
Method	Central Fixation Procedure (CFP)	Head-turn Preference Procedure (HPP)	
Visual Stimuli			
Auditory Stimuli	Two Cantonese lexical tone contrasts: Tone **25** vs 33 Instantiated on a CV syllable pronounced "chee"	192 disyllabic English words: • 96 with a weak-**strong** syllable accent • 96 with a **strong**-weak syllable accent	4 English sentences: 2 well-formed prosodic sentences 2 prosodically ill-formed sentences Two English passages
Familiarization Phase	30s Tone **25** or 33	4 music trials	2 versions of the same sequence: • One prosodically well-formed (**bold**) • One prosodically ill-formed (*italics*) John doesn't know what *rabbits eat.* ***Leafy vegetables*** **taste so good.** They don't cost much either.
Test Phase	8 trials: • 4 Alternating (i.e., **25** 33 **25** 33 … or 33 **25** 33 **25** …) •4 Non-Alternating (i.e., **25 25 25 25**… or 33 33 33 33…)	16 trials : • 8 weak-**strong** lists with 12 words each (e.g., com**ply**, be**fall**, de**part**…) • 8 **strong**-weak lists with 12 words each (e.g., **pli**ant, **falt**er, **com**et…)	2 passages: • One including the well-formed sentence. • The other including the ill-formed sequence.

Fig. 3.Summary of proposed methods.

Vocabulary: The Oxford Communicative Development Inventory (O-CDI), a parental questionnaire, will track infants' word comprehension and production at each time point.

Cognitive Development: The Bayley Scales will assess broader cognitive development at 7.5, and 12 months.

Experiment Duration: Each experiment will last approximately 5 minutes, with each visit lasting around one hour to allow parents time to complete the O-CDI and provide infants with breaks between experiments to minimise fatigue.

Predictions: Based on previous findings[10,12–14] Preterm groups are expected to show delayed acquisition of these properties compared to the full-term group. If, as predicted, the delay stems from a lack of prenatal prosody exposure, the delay will appear in the Standard-Care-group but not in the Womb-Simulated-group.

Analyses: Data on looking times, vocabulary, and cognitive development will be collected and compared across the three study groups. Analyses will be conducted using linear mixed-effects models, which are particularly suitable for handling missing data in longitudinal studies with repeated measurements.

Analyses will be conducted using R and the lme4 package to fit linear mixed-effects models. Fixed effects will include Group (womb-simulated preterm, standard-care preterm, full-term), Age (7.5, 9, 10.5, 12 months), and Stimulus Type (e.g., alternating vs. non-alternating). Participants and stimuli will be included as random effects. Model selection will follow a stepwise comparison approach, retaining the model with the lowest BIC and a significant log-likelihood ratio test. A typical model will take the form:

lmer(TotalLook~Group*Age*StimType+(Age|SubjectID)+(1|Stimulus)).

P-values will be derived from F-values using the Satterthwaite approximation. Planned comparisons will use orthogonal contrasts. While SES, gestational age, and birth weight will not be included in the primary models, their effects will be explored in secondary analyses. All analyses will be pre-registered and conducted in line with open science practices.

Data will be summarised using descriptive statistics and visualised with graphs to illustrate group differences and developmental trajectories. Demographic matching of full-term infants will further strengthen causal inference by reducing potential confounding factors.

Dissemination Activities: Co-designed resources such as infographics, videos, animations, and a website will target families and practitioners. Workshops for families, practitioners, and

policymakers will share results and gather feedback. Evidence syntheses, policy briefings, and press releases will accompany publications, including an article for *The Conversation*.

All materials and code will be shared in high-impact journals and open-access repositories to promote reproducibility. Findings will be presented at international conferences (e.g., WILD28, IASCL27).

4 STUDY SETTING

Study sites and design
This is a **single-centre study** conducted at two closely linked settings within the same research infrastructure:

1. The **Neonatal Care Unit (NCU)** at the host NHS Trust.
2. The **Oxford Brookes University BabyLab (Centre for Psychological Research)**.

Together, these settings allow recruitment, exposure to the study environment, and developmental assessment to be carried out in a way that is appropriate, safe, and aligned with the research aims.

Access to participants

- **Preterm infants** are identified and initially approached within the NCU by members of the clinical care team (research nurses). Families who express interest are then approached by the research team to provide full study information and obtain informed consent.
- **Full-term infants**, and potentially preterm infants receiving standard care, are identified through the Oxford Brookes BabyLab participant database. Families registered in the database are contacted when their child reaches the appropriate age and are provided with full study information before deciding whether to participate.

Activities at each site

- **Neonatal Care Unit**:
    - Identification of eligible preterm infants by the clinical team.
    - Initial approach to families by research nurses.
    - Exposure to the study sound environment for participating infants during their NCU stay.
    - No additional clinical procedures beyond standard care.
- **Oxford Brookes BabyLab**:
    - Longitudinal behavioural testing of infants at multiple time points.
    - Parent-completed questionnaires assessing language and development.
    - Video monitoring during testing sessions for attention and safety purposes only.

Appropriateness of the research setting
The NCU is essential for addressing the research question, as it is the environment in which preterm infants experience altered auditory input compared to the womb. The BabyLab provides a controlled, infant-friendly setting with well-established methodologies for measuring early language and cognitive development. Together, these settings allow the research aims to be addressed comprehensively across early development.

Site-specific requirements

- Close collaboration with NCU clinical staff to ensure that all procedures are compatible with routine neonatal care.
- Secure storage facilities for consent forms and data within restricted-access areas.
- Access to quiet, infant-appropriate testing spaces within the BabyLab.

Types of activity across sites

- **NCU**: Identification, initial approach, parental recording procedures, and exposure during hospital stay.
- **BabyLab**: Recruitment via database, developmental testing, questionnaire administration, and follow-up.

This integrated study setting ensures that the research can be conducted safely, ethically, and in a way that directly addresses the study's aims.

5 SAMPLE AND RECRUITMENT

5.1 Eligibility and Inclusion Criteria

Preterm 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 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.

5.1.1 Exclusion criteria

Preterm infants

- Infants will be excluded from the study if they meet any of the following criteria:
- Born before 26 weeks' gestation or after 34 weeks' gestation.
- Evidence of major brain injury or neurological damage, including but not limited to periventricular leukomalacia or intraventricular haemorrhage.
- Known or suspected hearing impairment or visual impairment.
- Presence of diagnosed genetic, neurological, developmental, or language disorders, or a known family history of developmental or language disorders that may affect language development.
- Infants from bilingual or multilingual households, or where English is not the primary language spoken to the infant at home.
- 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 infants

- Infants will be excluded from the study if they meet any of the following criteria:
- Born before 37 weeks' gestation.
- Evidence of major brain injury or neurological damage, including but not limited to periventricular leukomalacia or intraventricular haemorrhage.
- Known or suspected hearing impairment or visual impairment.
- Presence of diagnosed genetic, neurological, developmental, or language disorders, or a known family history of developmental or language disorders that may affect language development.
- Infants from bilingual or multilingual households, or where English is not the primary language spoken to the infant at home.
- Any medical condition or clinical concern identified by the clinical or research team.

5.2 Sampling

5.2.1 Size of sample

The study will include a total of **150 infants**, accounting for an estimated **20% attrition rate** due to the longitudinal nature of the research (10%) and participation in multiple experimental tasks (10%). This sample size ensures sufficient statistical power for comparisons across the three study groups.

The final sample will comprise:

- Preterm infants exposed to a womb-like auditory environment.
- Preterm infants receiving standard neonatal care.
- Full-term comparison infants.

Sample size calculations were informed by prior research on early speech perception and language development in preterm infants, which report medium to large effect sizes (d = 0.59–0.80). Power calculations ($\alpha = 0.05$, power = 0.80) conducted using G*Power (version 3.1) indicate that this sample size is adequate to detect meaningful group differences in language and cognitive outcomes. This sampling strategy directly addresses the study's aim of identifying whether early auditory experience influences language development trajectories.

5.2.2 Sampling technique

A purposive sampling strategy will be used.

- Preterm infants will be identified through the Neonatal Care Unit by the clinical care team based on clearly defined eligibility criteria. This approach ensures that participants meet specific gestational, medical, and family language background requirements relevant to the research question.
- Full-term infants will be recruited through the Oxford Brookes BabyLab participant database, which includes families who have previously expressed interest in taking part in developmental research. Infants will be selected to match the preterm groups on key demographic variables such as age, gender, and socioeconomic background.

This sampling approach is justified by the study's developmental and theoretical framework, which requires carefully defined comparison groups to isolate the effects of early auditory experience on language development. Random sampling is neither feasible nor appropriate in this context, as the study focuses on specific infant populations with well-defined characteristics.

5.3 Recruitment

Eligible preterm infants will be identified by members of the direct clinical care team within participating NCUs through routine review of medical records. A research nurse will make the initial approach to families to assess interest in participation. Families who express interest will then be approached by a trained postgraduate research assistant at a suitable time to provide full study information and seek informed consent.

Full-term infants, and potentially preterm infants receiving standard care, will be recruited via the Oxford Brookes BabyLab database. Families registered in the database have previously consented to be contacted about research opportunities. Eligible families will be contacted when their child reaches the appropriate age and will be provided with full study information before deciding whether to take part.

Posters and flyers inviting families to join the Babylab Participant Database will be displayed across the hospital (e.g. maternity wards, lifts). The postgraduate research assistant will also spend some time in the ultrasound unit, where women/partners are waiting for their scans and talk about the study. At this point, parents will receive a flyer and interested parents will be asked to complete an expression of interest card to join the BabyLab Participant Database.

All recruitment procedures are designed to minimise burden, respect confidentiality, and ensure that participation is entirely voluntary.

5.3.1 Sample identification

Preterm infants (womb-like environment group)
Eligible preterm infants will be identified within participating Neonatal Care Units (NCUs). Identification will be carried out exclusively by members of the infant's direct clinical care team (e.g. neonatal research nurses or clinical staff), who will have legitimate access to medical records as part of their routine clinical role. The clinical team will screen infants against the study inclusion and exclusion criteria using existing medical records. No member of the research team will access identifiable medical records prior to consent.

For families identified as potentially eligible, the initial approach will be made by a neonatal research nurse or another appropriate member of the clinical care team. This first contact will be limited to providing brief, non-coercive information about the study and asking whether the family would be interested in hearing more. Families who express interest will then be referred to the research team. At a later, suitable time, a postgraduate research assistant from the project team will provide full study information and seek informed consent.

Preterm infants (standard care group)
The clinical care team will identify and approach families with babies who meet the eligibility criteria. They will provide brief verbal information about the study and distribute a written invitation letter and participant information leaflet. Families who are interested in learning more will be invited to complete an expression-of-interest card. These cards will be stored securely in a locked collection box at the nurse station. The research team will collect the cards regularly and follow up with families at a suitable time to provide full study details and seek informed consent.

Full-term infants and potential standard-care preterm participants recruited outside NCUs
Full-term infants, and potentially some preterm infants in the standard-care group, will be identified through the Oxford Brookes BabyLab participant database. This database consists of families who have proactively registered their interest in taking part in developmental research and have provided consent to be contacted about future studies.

Recruitment to the BabyLab database occurs via general publicity, including leaflets, posters, and the BabyLab website. These materials advertise participation in BabyLab research broadly rather than a specific study. Eligible families are contacted by email when their child reaches the appropriate age and are then provided with full written and verbal information about the study before any consent is sought.

The researcher will also spend some time in the ultrasound unit where women/partners are waiting for their scans and talk about the study. At this point, parents will receive a flyer and interested parents will be asked to complete an expression of interest card to join the BabyLab Participant Database.

Publicity and resources

Publicity materials (posters and leaflets) may be used to support recruitment to the BabyLab database and, where appropriate, to raise awareness of research opportunities for families of preterm infants. A study-specific poster will be developed for preterm populations.

Confidentiality and data access
Prior to consent, identifiable personal information and medical records will only be accessed by the infant's direct clinical care team. The research team will only receive contact details and participant-provided data after families have given informed consent. No Patient Identification Centres (PICs) will be used beyond the participating NCUs.

Payments and expenses
Participants will receive a voucher and a small token of appreciation for taking part. At each visit to the BabyLab, infants will receive a small toy or book. To compensate for parents' time and travel expenses, families will receive a £20 voucher per visit. These incentives are intended to offset expenses and time commitment and are not contingent on completion of all study visits.

5.3.2 Consent

Informed consent will be obtained prior to participants undertaking any activities that are specifically for the purposes of this study.

For preterm infants, the identification of potentially eligible families will be carried out by members of the infant's direct clinical care team within the Newborn Care Services. Given that parents of preterm infants may be in a particularly stressful situation, the initial approach will be made sensitively by a clinical or research nurse who is known to the unit. Families will be provided with brief verbal information about the study and asked whether they would be interested in hearing more. No research activities will take place at this stage.

Families who express interest will then be approached by a trained postgraduate research assistant or a member of the research team at a time deemed appropriate by the clinical team and the parents. The researcher will provide the approved written Participant Information Sheet and explain the purpose, procedures, potential risks and burdens, and potential benefits of the study in clear, non-technical language. Parents will be given the opportunity to ask questions and sufficient time to consider their participation before making a decision. Written informed consent will be obtained from a person with parental responsibility before any study-specific procedures begin.

For full-term infants recruited via the Brookes BabyLab database, families will be contacted by email with full written information about the study, including the Participant Information Sheet and consent materials. Families will be able to take as much time as they wish to review the information and ask questions by email or telephone before deciding whether to participate. Written informed consent will be obtained prior to any testing visit.

Consent discussions will be conducted by members of the research team who are knowledgeable about the study and trained in ethical research practice. Consent will be treated as an ongoing process, and parents will be reminded that participation is entirely voluntary and that they are free to

withdraw their child from the study at any time without giving a reason and without any impact on their child's clinical care or relationship with the hospital or university.

As participants are infants, consent will be obtained from parents or legal guardians with parental responsibility. The research does not seek assent from children, as they are below an age at which they can meaningfully provide informed consent. Capacity to consent will therefore rest solely with the parent or legal guardian, and researchers will ensure that consent is freely given, informed, and not influenced by perceived pressure from clinical or research staff.

All consent procedures and documentation will comply with REC approval, local regulatory requirements, and relevant legal and ethical guidelines.

6 ETHICAL AND REGULATORY CONSIDERATIONS

This study has been designed in accordance with the principles of the UK Policy Framework for Health and Social Care Research, the Declaration of Helsinki, the General Data Protection Regulation (GDPR), and relevant Health Research Authority (HRA) guidance. The research methods are non-invasive, pose minimal risk, and are appropriate for the vulnerable population involved. The study aims to maximise potential benefits while minimising any risks or burdens to participants and their families.

Informed Consent

Caregivers will be fully informed about the nature, purpose, procedures, and expected duration of the study through an approved written participant information sheet. This will be supplemented by verbal explanation from a trained member of the research team, with opportunities to ask questions and seek clarification. Written informed consent will be obtained from a person with parental responsibility before any research-specific activities take place.

Consent will be sought in a manner that recognises the emotional demands placed on families, particularly those with infants in neonatal care. Parents will be given sufficient time to consider participation, and consent will be treated as an ongoing process rather than a single event.

Voluntary Participation and Right to Withdraw

Participation is entirely voluntary and free from coercion. Caregivers will be informed that they may withdraw their child from the study at any time, without providing a reason and without any impact on their child's care. If withdrawal occurs, no further data will be collected. Where requested, all data collected up to that point will be destroyed and not used in analyses.

Risks, Burdens, and Safeguards

The research procedures involve brief behavioural tasks, parental questionnaires, and audio/video recordings used solely for monitoring infant attention and task engagement. These procedures pose no physical risk and are comparable to activities infants experience in everyday interactions.

Given the vulnerability of preterm infants and the emotional strain experienced by parents in Neonatal Care Units (NCUs), particular care will be taken to minimise distress. Initial approaches to families of preterm infants will be made only by trained research nurses who are part of the clinical care environment, ensuring that families are approached sensitively and at appropriate times. Testing sessions will be paused or terminated immediately if an infant shows signs of distress or fatigue.

All members of the research team involved in direct contact with infants will hold valid DBS clearance and will be trained in infant testing procedures. The Principal Investigator has over seventeen years of experience conducting infant research and will oversee all procedures.

Confidentiality and Data Protection

All personal data will be handled in accordance with GDPR and the Data Protection Act. Identifiable information (e.g., consent forms and demographic questionnaires) will be stored securely and separately from research data. Research datasets will be pseudonymised using participant ID codes.

Audio recordings provided by parents will undergo destructive filtering to remove identifying content not required for the study. Raw audio files will be deleted once processing is complete. Video recordings of infants will be used only for monitoring task engagement and will not be used for dissemination or shared outside the research team.

No identifiable data will be included in publications, presentations, or public reports. Only fully anonymised, group-level data will be disseminated.

Data Archiving and Open Research

In line with open research practices, fully anonymised datasets will be archived at the end of the project and made publicly available via an approved data repository (e.g., the UK Data Service).

Participant information sheets will clearly state this intention. Archived data will contain no personal identifiers and will be used exclusively for academic research purposes.

Dignity and Respect for Participants

All research activities are designed to uphold the dignity, privacy, and welfare of infants and their families. Sessions will be scheduled flexibly to accommodate families' needs, with frequent breaks and a parent present at all times. The study does not interfere with routine clinical care, and all procedures have been developed in close consultation with neonatal clinicians and parent advisors to ensure acceptability and appropriateness.

6.1 Assessment and management of risk

Risk Analysis:

The study involves non-invasive testing of infants, audio recording of parental speech, and exposure to a womb-like auditory environment in the NCU or cot. The primary risks for participants are:

Infant distress during experimental tasks or exposure to the auditory environment, which could manifest as fussiness, crying, or temporary discomfort.

Parental distress, particularly for parents of preterm infants, due to the stressful context of having a child in a Neonatal Care Unit (NCU).

Data privacy risks, such as breaches of confidentiality or accidental disclosure of personal or sensitive information.

Auditory exposure risks: The womb-like auditory environment will be carefully controlled for volume, frequency, and duration according to neonatal safety standards, minimizing the risk of overstimulation or hearing damage. Emergency stop mechanisms are included in the system.

Risk Management:

Infant distress: Testing sessions are brief (approximately 5 minutes per experimental task, total visit about 1 hour), with breaks built in. Infants' responses will be continuously monitored, and testing or auditory exposure will be paused or stopped if distress is observed. NCU staff will support health and safety throughout.

Auditory environment safety: Sound levels are calibrated to meet neonatal safety guidelines and regularly monitored with reference microphones. No invasive equipment is used, and speakers are externally positioned to avoid intrusion.

Parental distress: Parents are initially approached only by the NCU research nurse to ensure a sensitive introduction. Full written and verbal information is provided, and participation is voluntary. Parents can withdraw their infant at any time.

Data confidentiality: All audio, video, and questionnaire data are pseudonymised or anonymised. Access is limited to authorised research staff, and all data are stored securely on password-protected systems.

Safeguarding and Harm Reporting:

Potential harm to participants: If a researcher becomes aware of safeguarding concerns (e.g., suspected abuse or neglect), the issue will be immediately reported to the NCU safeguarding lead and, if necessary, to local authority children's services.

Potential harm to others: Any disclosure of intention to harm others will also be reported through safeguarding procedures.

Staff training: All research staff will receive safeguarding training and be familiar with escalation procedures.

6.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service NHS REC for the study protocol, informed consent forms and other relevant documents, e.g. advertisements.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the

study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) need to be notified about substantial amendments in case the amendment affects their opinion of the study.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

In all instances the protocol should describe:

- *The* process for making amendments.
- Who will be responsible for the decision to amend the protocol and for deciding whether an amendment is substantial or non-substantial?
- How substantive changes will be communicated to relevant stakeholders (e.g., REC, R&D, regulatory agencies).
- How the *amendment history will be tracked to identify the most recent protocol version.*

7.3 Peer review

This study protocol has undergone multiple levels of peer review to ensure scientific quality, methodological rigor, and clinical appropriateness:

- **Internal review:** The protocol was first reviewed extensively within the project team and the Advisory Group, which includes NCU staff, parents of preterm infants, and relevant charity partners. Feedback from these stakeholders informed study design, feasibility, and acceptability.
- **Host institution review:** Two independent reviewers from the host institution, external to the project team, evaluated the protocol to assess study design, methodology, and ethical considerations.
- **Funder review:** The Economic and Social Research Council (ESRC) conducted a rigorous peer review as part of the funding application process. Three independent external experts provided detailed feedback on the scientific and methodological aspects, which was subsequently evaluated by the ESRC panel. The project was approved for funding following this process, confirming its scientific validity and appropriateness.

These steps meet the standards for high-quality peer review: reviewers are independent, expert in the relevant disciplines, and the review process is proportionate to the study's size and complexity.

7.4 Patient & Public Involvement

Patients, parents, healthcare professionals, and members of the public have been actively involved in this research from its earliest stages and will continue to be involved throughout the project.

Design of the research:
An advisory group was established at the outset of the project. This group includes neonatal care staff (consultant neonatologists, neonatal nurses, occupational therapists, and psychologists), four parents of children born preterm, and representatives from the charities SSNAP (Supporting Sick Newborns and their Parents) and Speech and Language UK. Their feedback has shaped the research questions, study design, and proposed procedures, ensuring they are acceptable, realistic, and relevant to families' experiences in Neonatal Care Units (NCUs). Parents highlighted the emotional challenges of being separated from their babies and emphasised that hearing their parents' voices could provide reassurance and comfort during NCU stays.

Management of the research:
Members of the advisory group will continue to provide ongoing input during the project, advising on feasibility, communication with families, and practical issues arising in the NCU. Neonatal staff ensure that procedures align with routine clinical care and do not place additional burden on families or healthcare teams.

Undertaking the research:
Parents and carers will be involved through the recording of parental voices and feedback on the acceptability of study procedures. Advice from SSNAP and Speech and Language UK will support sensitive engagement with families during this period.

Analysis of results:
The advisory group, including parent representatives, will be invited to comment on the interpretation of findings, helping ensure that outcomes are understood in ways that reflect families' lived experiences.

Dissemination of findings:
Public and patient involvement will be central to dissemination. Parents and charity partners will help co-develop accessible resources, public engagement activities, and summaries of findings. WP4 specifically focuses on raising public awareness of the challenges faced by preterm infants, with input from the Parent Advisory Group to maximise reach and impact.

7.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 regarding the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

Collection and coding of data: Personal information from participants will be collected via consent forms and demographic questionnaires. Each participant will be assigned a unique identifier, and identifiable information will be stored separately from research data. Audio and video recordings of infants during tasks will be pseudo-anonymised using the same identifier.

Secure storage: Identifiable information will be stored in a locked cabinet within a restricted-access area of the Babylab. Electronic files will be stored on encrypted, password-protected folders on University computers. Linking codes between identifiers and personal data will be kept separately from research data to maintain confidentiality.

Access control: Access to personal data will be limited to the research team directly involved in participant management and data analysis. No medical data will be accessed by the research team; only data provided directly by participants through questionnaires or recordings will be used.

Data transmission: When data are shared with co-investigators or for analysis, only pseudo-anonymised datasets will be transmitted via secure, encrypted channels.

Data retention: Identifiable data will be retained for over three years for participants who consent to be contacted for future studies, in line with Brookes BabyLab policy. Consent forms and demographic sheets will be stored securely for 10 years in accordance with University regulations. Fully anonymised datasets will be archived and made publicly available at the end of the project.

Data custodian: The Principal Investigator will act as the data custodian, ensuring compliance with data protection regulations, overseeing secure storage, and managing access to the datasets.

7.7 Indemnity

Aim: to fully describe indemnity arrangements for the study

The following areas should be addressed in the protocol:

1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?
2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?
3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research? Note that if the study involves sites that are not covered by the NHS indemnity

scheme (e.g. GP surgeries in primary care) these investigators/collaborators will need to ensure that their activity on the study is covered under their own professional indemnity.

4. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?
5. If equipment is to be provided to site(s) for the purposes of the study, the protocol should describe what arrangements will be made for insurance and/ or indemnity to meet the potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment)

NB Usually the responsibility for sections 1&2 lie with the sponsor, section 3 with the participating site and section 4 with the sponsor. Section 4 is not mandatory and should be assessed in relation to the inherent risks of the study; however, it may be a condition of REC favourable opinion to have these arrangements in place.

7.8 Access to the final study dataset

Access to the full study dataset will be restricted to the research team at the Brookes BabyLab during the study period for the purposes of management, analysis, and oversight. This includes the Principal Investigator, research assistants, and co-investigators. Only pseudo-anonymised data will be used internally.

After completion of the study and pre-registered analyses, the fully anonymised dataset will be made publicly available for other researchers in line with open research practices. Any future secondary analyses using the dataset will be conducted only with anonymised data and in accordance with participants' consent.

No external individuals, including clinical staff, will have access to identifiable participant data. Individual site investigators outside the core research team will not have independent access to the dataset during the study to ensure confidentiality and prevent premature disclosure of results.

8 DISSEMINIATION POLICY

8.1 Dissemination policy

Data Ownership and Intellectual Property: Dr Gonzalez-Gomez and Oxford Brookes University (OBU) will jointly own the copyright and intellectual property rights to the data generated by this study. Dr Gonzalez-Gomez retains the right to freely use all data for academic purposes.

Final Study Report: Upon completion of the study, the data will be analysed, tabulated, and a Final Study Report prepared.

Access to Study Report: The full study report will be made publicly available via the Brookes BabyLab website and other open access platforms where appropriate.

Publication Rights: The Principal Investigator and designated co-investigators will have rights to publish study findings. All publications will acknowledge the funding body (ESRC) and supporting partners (e.g., SSNAP, Speech and Language UK). The funder has reviewed the study protocol but does not control interpretation of data or final publications.

Participant Notification: Participants will be informed of study outcomes through:

- A summary on the Brookes BabyLab website.
- Direct emails to participants.
- Verbal information during ongoing engagement activities, as described in the participant information sheet.

Data Sharing: Fully anonymised participant-level datasets and statistical code will be made publicly available following completion of pre-registered analyses, in line with open research practices.

Timeframes and Review: No specific time limits restrict investigators from publication after the Final Study Report, but publications will respect academic standards and ensure anonymisation. Any publications will be reviewed internally to ensure confidentiality and compliance with data protection and ethical standards.

8.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship Guidelines: Authorship on all publications arising from this study will follow the CRediT (Contributor Roles Taxonomy) framework.

Eligibility for Named Authorship: Individuals who meet the following criteria will be granted authorship:

- Substantial contributions to the conception or design of the study; or acquisition, analysis, or interpretation of data.
- Drafting or critically revising the work for important intellectual content.
- Final approval of the version to be published.
- Agreement to be accountable for all aspects of the work, ensuring accuracy and integrity.

Contributor Roles: Specific roles will be attributed according to the CRediT framework (e.g., Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft, Writing – Review & Editing). This ensures transparency and appropriate recognition of each contributor’s work.

Professional Writers: No professional writers will be employed for manuscript preparation; all writing will be conducted by study investigators and collaborators who have contributed substantively to the work.

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10. APPENDICIES

10.1 Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

10.2 Appendix 2 – Schedule of Procedures (Example)

Procedures		Visits (insert visit numbers as appropriate)						
	Identification	Screening	Recordings	Womb-like exposure	7.5m	9m	10.5m	12m
1. Identification and initial approach to families	x							
2. Informed consent		x						
3. Audio recording of parental speech (womb-like acoustic environment exposed group only)			x					
4. Exposure to womb-like acoustic environment (womb-like acoustic environment exposed group only)				x				
5. Language and developmental assessments					x	x	x	x
6. Parent questionnaires (vocabulary measures and demographics)					x	x	x	x
7. Cognitive development assessment					x			x

10.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.