

Department of Psychology, Social Work and Public Health
 Faculty of Health, Sciences and Technology
 Oxford Brookes University

Researcher: Dr Nayeli Gonzalez-Gomez,
 **Phone:** 01865 534148  **Email:** ngonzalez-gomez@brookes.ac.uk

PI sheet: Full-term Babies recruited through the Babylab database
From Womb to World

Dear parent or guardian,

We are running a new study at the Brookes Babylab to learn more about how babies begin to understand language. We would like to invite your child to take part.

Before you decide, it's important that you know why we are doing this research and what taking part would involve. Please take a moment to read the information below.

What is the purpose of the study?

We want to understand how babies begin learning language, both before and after they are born. Babies hear many sounds while they are in the womb — including the rhythm and melody of speech — and these early experiences may play a role in how language develops later on.

In this study, we are looking at how early sound experiences shape language development in both preterm and full-term babies. We are also exploring whether giving preterm babies a sound environment that is more similar to what they would have heard in the womb — including gentle sounds and their parents' voices — might support their early language learning.

Why have I been invited to participate?

You previously told us that you were interested in your child taking part in research at the Oxford Brookes Babylab. We are now running a study on early language development, and your child was born full term and fits the age group we are working with. We are also inviting families where English is the main language spoken at home.

Does my child have to take part?

No — taking part is completely your choice. If you decide to take part, you will keep this information sheet and be asked to sign a consent form. You can change your mind and withdraw your child from the study at any time, without giving a reason.

To take part, your baby should be developing typically and should not have any known visual or hearing difficulties at the time of the visit.

What will happen if my child takes part?

If you choose to take part, we will invite you and your baby to visit the BabyLab **four times** over **six months** (about once every six weeks). These visits help us track how your child's language skills develop over time.

	1 st Visit	2 nd Visit	3 rd Visit	4 th Visit
Your baby's age	7.5 months	9 months	10.5 months	12 months

The BabyLab is on the fourth floor of the Sinclair Building at the Oxford Brookes University Gipsy Lane campus in Headington. Your child will stay with you throughout the entire visit.

During each visit:

- Your baby will sit on your lap in front of a screen.
- They will see simple pictures and hear words while we record their attention using a small video camera.
- Each of these short observations lasts about 5 minutes, and your baby will do two of them per visit.
- During two of the visits, your baby will also take part in a standard, play-based developmental assessment to help us understand their general cognitive development.
- We will also ask you to complete some short questionnaires about your child's vocabulary and communication.

Although the tasks themselves are brief, we expect each visit to take around 1 hour in total.

Will I receive an incentive to participate in this study?

Yes. You will receive £80 in total, given as a £20 voucher at each visit. Your child will also receive a small toy or book at every visit. This is possible thanks to funding from the Economic and Social Research Council. Please note that not all our studies can offer financial support.

What will I have to do?

You will need to attend four scheduled visits to the BabyLab. We will arrange appointments at times that work best for you, and on-site parking is available.

We will also ask you to complete short online questionnaires to help us track your baby's vocabulary development.

What are the possible disadvantages and risks of taking part?

There are no known risks associated with this study. The main disadvantage is the time commitment, as you will need to attend four visits to the BabyLab and complete a few short online questionnaires between visits. If at any point your child shows signs of discomfort or becomes upset during the activities, the researcher will stop the session straight away.

What are the possible benefits of taking part?

Many parents enjoy learning more about how babies develop language and getting a closer look at how research with infants is carried out. While there may be no direct benefit to you or your child, we hope you will find the experience interesting and informative.

What if there is a problem?

If you have any concerns or are unhappy about any part of the study, please let us know. You can speak directly to the Principal Investigator, Dr Nayeli Gonzalez-Gomez, who will do her best to answer your questions and resolve the issue. Her contact details are listed at the top of this information sheet.

Will what I say in this study be kept confidential?

All information which is collected about you and your baby will be kept strictly confidential. Confidentiality, privacy, and anonymity will be ensured in the collection, storage, and publication of research materials (subject to legal limitations). All data will only be accessed by the research team. All data gathered will be identified by a code only and, therefore, used anonymously as group data. All data will be kept securely in Google Drive, for which the University has a security agreement. All data files will be encrypted and password-protected. Questionnaires and all identifying information will be kept in separate locked filing cabinets.

All data generated by the study will be retained following the University's policy on Academic Integrity. It will be kept securely in electronic form for a period of ten years after the completion of a research project. Anonymous data files will be used for academic archiving and stored using the UK Data Service. This helps other scientists learn from the study, but your identity will never be revealed.

What should I do if I want to take part?

If you would like to take part, please contact the Brookes BabyLab team to arrange your first visit. You can reach us by:  Phone: 01865 535285  Email: babylab@brookes.ac.uk

What will happen to the results of the research study?

In order to have a record of what happened during the observation, we will video record the session. This will only happen if you give your permission on the consent form. All data collected will be strictly confidential and stored anonymously and securely for a period of 10 years. During the session, we will ask you a few questions about you and your child (e.g., birth date, gender, hearing or language problems...). All information supplied will remain strictly confidential. It will not be possible to provide feedback on your child's results as the study is not designed to assess individual infants. However, a summary of the overall findings will be available for interested families via the project website (<http://psych.brookes.ac.uk/babylab/>). We also aim to publish our findings in scientific journals, but this may be two to three years from the end of the study.

How will we use information about you?

We will need to use information from you and your child for this research project.

This information will include:

Family Information:

- Name of caregiver
- Contact details of the parent or guardian (i.e., email)
- Languages heard/spoken at home
- Siblings
- Parents' educational attainment
- Household income
- History of Language Problems
- Postcode

Child's Information:

- Name
- Date of birth
- Gestational age
- Problems at birth
- Ear Infections
- Developmental disorders

We will also collect quantitative data about words that your child understands/says, your child's looking times and video recordings from three experiments on prosody, and scores from a developmental assessment.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Oxford Brookes University is the sponsor of this research. Oxford Brookes University is responsible for looking after your information. We will not share any of your personal information related to this research project with any other organisations. However, we will share anonymised information related to this research project with the following types of organisations:

- Universities
- NHS

We will keep all information about you safe and secure by:

- Treating all information about you and your baby as strictly confidential, in line with legal and ethical requirements.
- Ensuring confidentiality, privacy, and anonymity in the collection, storage, and publication of all research materials (subject to legal limitations).
- Restricting access to all data so that it can only be accessed by relevant members of the research team.
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International transfers

We may share or provide access to anonymised data about you outside the UK for research related purposes to:

- Analyse or re-analyse it.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Universities

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

We will keep your study data for a maximum of **10** years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study, using the UK Data Service.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- by asking one of the research team
- by sending an email to ngonzalez-gomez@brookes.ac.uk

Who is organising and funding the research?

I am conducting the research as a member of staff at the Department of Psychology at Oxford Brookes University. This study is funded by the Economic and Social Research Council (ESRC). All researchers, including students, have DBS (previously CRB) clearance.

Who has reviewed the study?

This study has been reviewed and approved by the research ethics committee at Oxford Brookes University and the NHS South Central –Hampshire B Ethics Committee. If you have any concerns about this, please contact the Chair of the Faculty REC at ethics@brookes.ac.uk

Contact for Further Information

If you want to discuss the research further, you can contact the Principal Investigator of this project: Dr Nayeli Gonzalez-Gomez, her contact details are listed at the top of this information sheet.

Thank you!

Dr Nayeli Gonzalez-Gomez

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Researcher: Dr Nayeli Gonzalez-Gomez,
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PI sheet: Preterm Babies Standard-Care recruited through the NCU team
From Womb to World

Dear parent or guardian,

We are running a new study at the Brookes Babylab to learn more about how babies begin to understand language. We would like to invite your child to take part.

Before you decide, it's important that you know why we are doing this research and what taking part would involve. Please take a moment to read the information below.

What is the purpose of the study?

We want to understand how babies begin learning language, both before and after they are born. Babies hear many sounds while they are in the womb — including the rhythm and melody of speech — and these early experiences may play a role in how language develops later on.

In this study, we are looking at how early sound experiences shape language development in both preterm and full-term babies. We are also exploring whether giving preterm babies a sound environment that is more similar to what they would have heard in the womb — including gentle sounds and their parents' voices — might support their early language learning.

Why have I been invited to participate?

We would like to invite your child to take part, because your baby was born between 27 and 34 weeks of pregnancy, and English is the main language spoken at home.

Does my child have to take part?

No — taking part is completely your choice. If you decide to take part, you will keep this information sheet and be asked to sign a consent form. You can change your mind and withdraw your child from the study at any time, without giving a reason.

To take part, your baby should be developing typically and should not have any known visual or hearing difficulties at the time of the visit.

What will happen if my child takes part?

If you choose to take part, we will invite you and your baby to visit the BabyLab **four times over six months** (about once every six weeks). These visits help us track how your child's language skills develop over time.

	1 st Visit	2 nd Visit	3 rd Visit	4 th Visit
Your baby's age	7.5 months	9 months	10.5 months	12 months

The BabyLab is on the fourth floor of the Sinclair Building at the Oxford Brookes University Gipsy Lane campus in Headington. Your child will stay with you throughout the entire visit.

During each visit:

- Your baby will sit on your lap in front of a screen.
- They will see simple pictures and hear words while we record their attention using a small video camera.

- Each of these short observations lasts about 5 minutes, and your baby will do two of them per visit.
- During two of the visits, your baby will also take part in a standard, play-based developmental assessment to help us understand their general cognitive development.
- We will also ask you to complete some short questionnaires about your child's vocabulary and communication.

Although the tasks themselves are brief, we expect each visit to take around 1 hour in total.

Will I receive any incentives?

Yes. You will receive £80 in total, given as a £20 voucher at each visit. Your child will also receive a small toy or book at every visit. This is possible thanks to funding from the Economic and Social Research Council. Please note that not all our studies can offer financial support.

What will I have to do?

You will need to attend four scheduled visits to the BabyLab. We will arrange appointments at times that work best for you, and on-site parking is available.

We will also ask you to complete short online questionnaires to help us track your baby's vocabulary development.

What are the possible disadvantages and risks of taking part?

There are no known risks associated with this study. The main disadvantage is the time commitment, as you will need to attend four visits to the BabyLab and complete a few short online questionnaires between visits. If at any point your child shows signs of discomfort or becomes upset during the activities, the researcher will stop the session straight away.

What are the possible benefits of taking part?

Many parents enjoy learning more about how babies develop language and getting a closer look at how research with infants is carried out. While there may be no direct benefit to you or your child, we hope you will find the experience interesting and informative.

What if there is a problem?

If you have any concerns or are unhappy about any part of the study, please let us know. You can speak directly to the Principal Investigator, Dr Nayeli Gonzalez-Gomez, who will do her best to answer your questions and resolve the issue. Her contact details are listed at the top of this information sheet.

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What should I do if I want to take part?

If you would like to take part, please complete the expression of interest card or contact the Brookes BabyLab team. You can reach us by:  Phone: 01865 535285  Email: babylab@brookes.ac.uk

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Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of **10** years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

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Who is organising and funding the research?

I am conducting the research as a member of staff at the Department of Psychology at Oxford Brookes University. This study is funded by the Economic and Social Research Council (ESRC). All researchers, including students, have DBS (previously CRB) clearance.

Who has reviewed the study?

This study has been reviewed and approved by the research ethics committee at Oxford Brookes University and the NHS South Central –Hampshire B Ethics Committee. If you have any concerns about this, please contact the Chair of the Faculty REC at ethics@brookes.ac.uk

Contact for Further Information

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Thank you!

Dr Nayeli Gonzalez-Gomez

Department of Psychology, Social Work and Public Health
Faculty of Health, Sciences and Technology
Oxford Brookes University

Researcher: Dr Nayeli Gonzalez-Gomez,
 **Phone:** 01865 534148  **Email:** ngonzalez-gomez@brookes.ac.uk

PI sheet: Preterm Babies Womb-Like Environment recruited through the NCU team
From Womb to World

Dear parent or guardian,

We are running a new study at the Brookes Babylab to learn more about how babies begin to understand language. We would like to invite your child to take part.

Before you decide, it's important that you know why we are doing this research and what taking part would involve. Please take a moment to read the information below.

What is the purpose of the study?

We want to understand how babies begin learning language, both before and after they are born. Babies hear many sounds while they are in the womb — including the rhythm and melody of speech — and these early experiences may play a role in how language develops later on.

In this study, we are looking at how early sound experiences shape language development in both preterm and full-term babies. We are also exploring whether giving preterm babies a sound environment that is more similar to what they would have heard in the womb — including gentle sounds and their parents' voices — might support their early language learning.

Why have I been invited to participate?

We would like to invite your child to take part, because your baby was born between 27 and 34 weeks of pregnancy, and English is the main language spoken at home.

Does my child have to take part?

No — taking part is completely your choice. If you decide to take part, you will keep this information sheet and be asked to sign a consent form. You can change your mind and withdraw your child from the study at any time, without giving a reason.

To take part, your baby should be developing typically and should not have any known visual or hearing difficulties at the time of the visit.

What will happen if my child takes part?

At home: For four days, you'll wear a small, discreet audio recorder while doing your normal activities. It will capture voices, music, and everyday sounds—similar to what babies hear in the womb.

Privacy: We never listen to the recordings. They will be filtered to keep mostly the rhythm and melody (removing most of the consonant information) and then securely stored. The originals will be immediately deleted. You can pause, stop or remove the recorder at any time.

In hospital: We will mix these filtered recordings with gentle womb-like sounds (heartbeat, breathing) and play them to your baby in the NCU using safe external speakers. While your recording is being prepared, we'll use a standard recording, so your baby receives stimulation as soon as possible.

Follow-up visits: To see if this helps early language development, we'll invite you and your baby to visit the BabyLab four times over six months (about once every six weeks). The first visit will take place when your baby is about 7 months old.

	1 st Visit	2 nd Visit	3 rd Visit	4 th Visit
Your baby's age	7.5 months	9 months	10.5 months	12 months

The BabyLab is on the fourth floor of the Sinclair Building at the Oxford Brookes University Gipsy Lane campus in Headington. Your child will stay with you throughout the entire visit.

During each visit:

- Your baby will sit on your lap in front of a screen.
- They will see simple pictures and hear words while we record their attention using a small video camera.
- Each of these short observations lasts about 5 minutes, and your baby will do two of them per visit.
- During two of the visits, your baby will also take part in a standard, play-based developmental assessment to help us understand their general cognitive development.
- We will also ask you to complete some short questionnaires about your child's vocabulary and communication.

Although the tasks themselves are brief, we expect each visit to take around 1 hour in total.

Will I receive any incentives?

Yes. You will receive £80 in total, given as a £20 voucher at each visit to the BabyLab. Your child will also receive a small toy or book at every visit. This is possible thanks to funding from the Economic and Social Research Council. Please note that not all our studies can offer financial support.

What will I have to do?

You will need to attend four scheduled visits to the BabyLab. We will arrange appointments at times that work best for you, and on-site parking is available.

We will also ask you to complete short online questionnaires to help us track your baby's vocabulary development.

What are the possible disadvantages and risks of taking part?

There are no known risks associated with this study.

For parents, the main disadvantage is the time commitment. This includes attending four visits to the BabyLab, wearing an audio recorder for four full days, and completing a small number of short online questionnaires. Wearing the recorder may feel mildly inconvenient at times, and you may choose to pause the recording whenever you wish.

There are no anticipated risks for your child. If at any point your child shows signs of discomfort or becomes upset during the activities, the researcher will stop the session straight away.

What are the possible benefits of taking part?

Many parents enjoy learning more about how babies develop language and getting a closer look at how research with infants is carried out. While there may be no direct benefit to you or your child, we hope you will find the experience interesting and informative.

What if there is a problem?

If you have any concerns or are unhappy about any part of the study, please let us know. You can speak directly to the Principal Investigator, Dr Nayeli Gonzalez-Gomez, who will do her best to answer your questions and resolve the issue. Her contact details are listed at the top of this information sheet.

Will what I say in this study be kept confidential?

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What should I do if I want to take part?

If you would like to take part, please let the clinical team know. They will arrange for the research team to contact you to explain the study in more detail and answer any questions you may have.

What will happen to the results of the research study?

In order to have a record of what happened during the observation, we will video record the session. This will only happen if you give your permission on the consent form. All data collected will be strictly confidential and stored anonymously and securely for a period of 10 years. During the session, we will ask you a few questions about you and your child (e.g., birth date, gender, hearing or language problems...). All information supplied will remain strictly confidential. It will not be possible to provide feedback on your child's results as the study is not designed to assess individual infants. However, a summary of the overall findings will be available for interested families via the project website (<http://psych.brookes.ac.uk/babylab/>). We also aim to publish our findings in scientific journals, but this may be two to three years from the end of the study.

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We will also collect quantitative data about words that your child understands/says, your child's looking times and video recordings from three experiments on prosody, and scores from a developmental assessment.

You will also be invited to provide audio recordings.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study. We will keep your study data for a maximum of **10** years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study, using the UK Data Service.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- by asking one of the research team
- by sending an email to ngonzalez-gomez@brookes.ac.uk

Who is organising and funding the research?

I am conducting the research as a member of staff at the Department of Psychology at Oxford Brookes University. This study is funded by the Economic and Social Research Council (ESRC). All researchers, including students, have DBS (previously CRB) clearance.

Who has reviewed the study?

This study has been reviewed and approved by the research ethics committee at Oxford Brookes University and the NHS South Central –Hampshire B Ethics Committee. If you have any concerns about this, please contact the Chair of the Faculty REC at ethics@brookes.ac.uk

Contact for Further Information

If you want to discuss the research further, you can contact the Principal Investigator of this project: Dr Nayeli Gonzalez-Gomez, her contact details are listed at the top of this information sheet.

Thank you!

Dr Nayeli Gonzalez-Gomez