

Information sheet

Please keep this information sheet and a signed copy of the participant information form for your records

You are invited to take part in a research study. Before you decide whether to participate it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully. If there is anything you do not understand, or if you want more information, please ask the researcher.

Title of study:

Estimating the cost effectiveness of the BabblePlay intervention for increasing vocalisations in infants with Down syndrome

Researchers:

Prof. Tamar Keren-Portnoy
Dr. Han-I Wang
Dr. Helena Daffern
Prof. Mona Kanaan
Dr. Kelly Burgoyne
Dr Laura Boundy
Ms. Sab Arshad

What is the research about?

This is an optional 'satellite-project', attached to the main study that you are taking part in, 'A Randomised Controlled Trial of the BabblePlay app intervention to encourage vocalising in infants with Down Syndrome'. We aim to assess the cost effectiveness of the BabblePlay intervention.

This is needed because if the app is found to be effective, we would want government and/or non-profit organisations, including the NHS, to adopt the app and recommend it to users. However, in order to do that, we must be able to demonstrate to those bodies that the app is cost effective, which means that its cost doesn't exceed its benefits.

'Cost' in this context means the burden that the intervention puts on the families and health system in terms of time and expenses. 'Benefits' are measured using standard scales that measure 'Quality of life'. These scales are very general and not focused on speech or language, but measure physical and mental health using standard questionnaires, with items that ask about breathing, feeding, movement, mood, etc.

The childhood questionnaires were created for a wide range of children, not specifically for children with Down syndrome. Although these questionnaires might not feel directly relevant to the BabblePlay intervention, this is the information that the NHS requires in order to decide whether to adopt an intervention.

For this purpose we are asking participants in the main study if they would agree to take part in this satellite project, so that such an assessment can be made based on the information that participants will give us at the start of their participation period as well as at the end.

Who is carrying out the research?

We are a group of researchers from the Universities of York and Manchester. The main researcher who will conduct this satellite study is Han-I Wang, who is a health economist at the University of York.

Who can participate?

Starting from early 2026 we are inviting all the families who are taking part in the main study and who have not yet been randomly allocated to a group, to take part in this satellite study. You do not have to consent to taking part in this satellite study in order to take part in the main study.

In order to take part in the satellite study, participating caregivers would need to have a baby with Down Syndrome who will be between ages 7 and 15 months when starting the study and who is growing up in an English speaking household. Your baby must also not be enrolled in another intervention-based research study that focuses on speech, language or communication (apart from the main study run by us). Finally, babies with severely limited vision will not be able to take part in the study, if they cannot see the shapes on the app screen.

What does the study involve?

Before you are randomised into one of the groups and after you have finished the first day-long recording as part of the main study, we will send you a short questionnaire to fill in, containing 3 sections:

1. A tickbox section about your baby's quality of life on the day in which you are filling the questionnaire (13 questions in total). You will tick boxes about whether your child has no problems, some problems, or a lot of problems in things such as moving around, eating and drinking, sleep quality and interacting with others, etc., as well as about your child's mood. There is currently no single questionnaire that covers the age range of the children in our main study, which is why we combine questions from two different questionnaires. You might find some questions difficult to choose a suitable response for. However, you will have the option of skipping questions. You will also have a space after every item to explain to us why you answered it as you did, if you want to do so. At the end of this section you will be asked to rank your child's health on a scale from 0 to 100.
2. A tickbox section about your own quality of life on the day on which you are filling the questionnaire (5 questions). The questionnaire asks you to score the items (mobility, self-care, anxiety, etc.) on a scale from 'no problems' to 'unable' or 'extreme'. Again, you can skip items you do not want to or cannot answer, and you will be able to explain your answers if

you want to. At the end of the section you will be asked to rank your own health on a scale from 0 to 100.

3. A section on how much you have used health services for your child in the previous 3 months

We will give you a deadline by which you will need to have completed these questionnaires. The deadline is when the randomisation will take place, so you will need to stick to the deadline in order to participate.

At the end of your participation in the main study, 11 months after the activity period, we will send you these same questionnaires to fill in again, to see how, if at all, your responses at the end are different from those at the start of the study.

We will pay you £10 in vouchers at each point, after you have completed the questionnaire for that point in time.

Do I have to take part?

You do not have to take part in the study. If you decide to take part, we will give you this information sheet to keep and ask you to sign an electronic participant information form (this is the consent form). If you decide to take part you will still be free to withdraw without giving a reason, before the end of the study (31 July 2027). If you withdraw from the study, we will destroy your data and will not use it in any way. Your decision whether to take part in this satellite study on cost-effectiveness or not will not affect your continuing to take part in the main study.

What are the possible risks of taking part?

The only risk involved in taking part is that thinking of past hospitalisations or other health-related events might cause you some distress. However, if that is the case, you are always free to skip some questions, or to withdraw from the satellite study, if you want to. This will not affect your continued participation in the main study.

Are there any benefits to participating?

You will contribute to research on language interventions for children with Down syndrome. You will also help us in our efforts to make the app widely available to other babies with Down syndrome, if at the end of the main study we will find out that BabblePlay is effective in making children use their voices more.

Will I know the results?

Once all the data has been collected and analysed, we will send a newsletter by email with the findings from the study to parents involved in studies in the York BabyLab. We will not discuss findings regarding any specific child, but only group results.

On what basis will you process my data?

Under the General Data Protection Regulation (GDPR), the University has to identify a legal basis for processing personal data and, where appropriate, an additional condition for processing special category data.

In line with our charter which states that we advance learning and knowledge by teaching and research, the University processes personal data for research purposes under Article 6 (1) (e) of the GDPR:

Processing is necessary for the performance of a task carried out in the public interest

Special category data is processed under Article 9 (2) (j):

Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes

Research will only be undertaken where ethical approval has been obtained, where there is a clear public interest and where appropriate safeguards have been put in place to protect data.

In line with ethical expectations and in order to comply with common law duty of confidentiality, we will seek your consent to participate where appropriate. This consent will not, however, be our legal basis for processing your data under the GDPR.

How will you use my data?

Data will be processed for the purposes outlined in this notice.

The data you provide will be used alongside the data of other participants to analyse if the intervention is considered cost effective and to plan future research if appropriate. Your data will be stored securely in the University of York.

Will you share my data with 3rd parties?

No. Data will be accessible to the project team at York only.

Anonymised data may be reused by the research team or other third parties for secondary research purposes. In this case, we have agreed to give anonymised data to one of the bodies that is developing the quality of life questionnaires, as the questionnaire is still under development, and these anonymised responses will help in the testing of the questionnaire.

How will you keep my data secure and store it?

The University has put in place appropriate technical and organisational measures to protect your personal data and/or special category data. Information will be treated confidentially and shared on a need-to-know basis only. The University is committed to the principle of data protection by design and default and will collect the minimum amount of data necessary for the project. In addition, we will anonymise or pseudonymise data wherever possible.

Your data will be stored securely on the University of York cloud storage solution (Google Drive). This means that data can be located at any of Google's globally spread data centres. The University has data protection compliant arrangements in

place with this provider. For further information see our [IT Service Google Privacy Policy here](#).

Will I be identified in any research outputs?

No real names will be used in any presentations or publications.

How long will you keep my data?

Data will be retained for 10 years.

This is in line with legal requirements or where there is a business need. Retention timeframes will be determined in line with [the University's Records Retention Schedule Section 9.4](#), which states that research data should be kept confidentially for a minimum of 10 years after the completion of the project.

What rights do I have in relation to my data?

Under the GDPR, you have a general right of access to your data, a right to rectification, erasure, restriction, objection or portability. You also have a right to withdrawal. Please note, not all rights apply where data is processed purely for research purposes. For further information see [this page on Individual Rights](#).

Questions or concerns

If you have any questions about this participant information sheet or concerns about how your data is being processed, in the first instance, please contact Tamar Keren-Portnoy, Department of Language and Linguistic Science, University of York, Heslington, York, YO10 5DD. tel: (01904 323614), email: tkp502@york.ac.uk. If you are still dissatisfied, please contact the University's Data Protection Officer at dataprotection@york.ac.uk.

Right to complain

If you are unhappy with the way in which the University has handled your personal data, we ask that you contact us first, to enable us to try to resolve matters. If you remain unhappy, you have a right to complain to the Information Commissioner's Office. For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns.

*This study has been reviewed and approved by the Departmental Ethics Committee of the Department of Language and Linguistic Science at the University of York. If you have any questions regarding this, you can contact the chair of the L&LS Ethics Committee (**email:** linguistics-ethics@york.ac.uk).*

Contact details:

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If you are interested in taking part, please click on the link below to indicate that you understand the study and are interested in taking part in it:

[Link for agreeing to take part in the research](#)