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A UK study exploring whether the BabblePlay app can support early vocalising in infants with Down syndrome

Submission date
09/01/2026

Recruitment status
Recruiting

Registration date
13/01/2026

Overall study status
Ongoing

Last Edited
12/01/2026

Condition category
Genetic Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Infants with Down syndrome are at increased risk of delays in speech and language development and typically produce fewer early vocalisations compared to typically developing infants. Early vocalisations (such as babbling) are an important foundation for later spoken language. Previous research suggests that early interventions which encourage these vocal behaviours may lead to improved later language outcomes.
BabblePlay is a novel, app-based intervention designed to encourage infants to vocalise by providing immediate, contingent, visual feedback. When the infant makes a vocal sound, the app responds with colourful, moving shapes on the screen; if the infant is quiet, the screen remains black. A pilot study demonstrated that infants vocalised at a higher rate while using BabblePlay over one week compared to using a mirror, suggesting that they were able to engage with and use the app. A feasibility study also found that the app was acceptable to families and could be used consistently for up to 6 weeks.
The current study aims to assess whether BabblePlay, when used for 6 weeks, leads to: 1) an increase in infant vocalisations outside of the context of app use (i.e. in every day life), 2) an increase in the amount of caregiver vocal input to their infants 3) an increase in infants' word production 11-months later

Who can participate?
Participants will be UK-based families with an infant who has a confirmed diagnosis of Down syndrome. Infants must be aged between 7 and 15 months at the point of randomisation. Infants also need to be from a monolingual, English-speaking household and have vision good enough to see shapes on a screen.

What does the study involve?
Participation in the study is fully remote, questionnaires are completed online and any required equipment is posted to families to be used at home.
After providing informed consent, eligible families complete baseline assessments. This includes online questionnaires about their child's health and demographic information, the Vineland-3 questionnaire, a short questionnaire on babble production and the UK Communicative

Development Inventory (UK-CDI). Families also complete a home audio recording of up to 15 hours.
Infants are then randomly allocated to one of two groups:
Intervention group: Infants use the BabblePlay app with their caregiver twice daily, 5 minutes per session, for 6 weeks. Control group: Infants continue with their usual practice for 6 weeks.
All families complete another 15-hour home audio recording immediately after the 6-week activity period and a final home audio recording 4 weeks later. Approximately 11 months after the 6-week activity period, caregivers will be asked to complete the UK-CDI again to assess their child's language comprehension and production.

What are the possible benefits and risks of participating?
Possible benefits:
The benefits of the BabblePlay app are not yet known. Infants in the intervention group may enjoy interacting with the app and practising vocal sounds. Families in both groups will contribute to research aimed at supporting early language development in infants with Down syndrome, which some families may find rewarding.
Possible risks:
There are minimal risks associated with participation. Some infants may not enjoy using the app or may become frustrated, if this occurs caregivers can stop or pause activities at any time. The intervention also involves brief screen exposure (approximately 5 minutes, twice a day for 6 weeks). This is not expected to have negative effects on children’s language or cognitive development.

Where is the study run from?
University of York, UK. All study procedures are conducted remotely, with participating families taking part from their own homes across the UK.

When is the study starting and how long is it expected to run for?
Recruitment and enrolment started in September 2025 and the study is expected to run until July 2027.

Who is funding the study?
The UK Research and Innovation Creating Opportunities, Improving Outcomes strategic theme and the Economic and Social Research Council.

Who is the main contact?
The Principle Investigator of the study, Professor Tamar Keren-Portnoy (tamar.keren-portnoy@york.ac.uk).

Contact information

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Principal investigator, Scientific, Public

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Additional identifiers

Open Science Framework (OSF) registration DOI
10.17605/OSF.IO/DWVP8

Study information

Scientific Title
A UK-based Randomised Controlled Trial of the BabblePlay app intervention to encourage vocalising in infants with Down syndrome

Study objectives
The current study will compare whether an intervention group, who will receive the BabblePlay intervention for 6 weeks, will show an increase, relative to a “usual care” control group, in:
1. Infant vocalisations outside the context of playing with the app:
1.1. Immediately after the 6-week Activity Period
2. 4 weeks later
2. The amount of caregiver speech addressed to the infants:
2.1. Immediately after the 6-week Activity Period
2.2. 4 weeks later
3. Infant lexicon size 11 months after the end of the 6-week Activity Period

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/07/2025, Language and Linguistic Science Ethics Committee (University of York Heslington, York, YO10 5DD, United Kingdom; N/A; linguistics-ethics@york.ac.uk), ref: DSD 21-07-2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Down syndrome

Interventions
The study is a two-arm, parallel-group, individually Randomised Controlled Trial (RCT) designed to evaluate the effectiveness of the BabblePlay app in supporting early vocal development in infants with Down syndrome. BabblePlay is a novel, app-based intervention that responds to infant vocalisations by producing colourful, moving shapes on a screen. The intervention is caregiver-led and will be delivered by the caregiver at home.

Participants will be randomly assigned in a 1:1 ratio to one of two study arms using block randomisation with random block sizes. Randomisation will be stratified by chronological and developmental age, the latter determined by scores on the Vineland-3. The randomisation code will be generated using the statistical software STATA (version 18 or later).
In the case of twins or multiple births where more than one infant has Down syndrome, infants will be randomised as a unit and allocated to the same study arm. If allocated to the intervention group, all infants in the unit will receive the BabblePlay intervention. However, only one infant will be randomly selected to be included in the main analysis sample.

Participants will be randomly assigned to one of two groups:
1. Intervention group - caregivers will be sent an iPad with the BabblePlay app on, and will be instructed to use the app with their child for two 5-minute sessions a day over a 6-week activity period.
2. Control group (usual care) - families will receive no additional intervention during the 6-week activity period and will continue with any standard care that they usually receive.
The control group will not be given access to the BabblePlay app at any stage of the trial. This design allows for comparison of the long-term effects of the intervention to standard care.

Allocation concealment will be implemented by sealed, opaque envelopes labelled with an ID number on the outside and containing the group allocation inside. Someone independent to the research team will randomly assign A or B to the intervention and prepare the envelopes

accordingly. Group allocation will not be masked from participants or the researchers running the study. However, allocation will be concealed from the statistician responsible for the primary analyses.

Intervention Type
Behavioural

Primary outcome(s)
1. Rate of infant vocalisations measured using automatic analysis of home audio recordings by Automatic LInguistic Unit Count Estimator (ALICE) software at immediately after the 6-week Activity period

Key secondary outcome(s))
1. Quantity of caregiver speech measured using automatic analysis of home audio recordings by Automatic LInguistic Unit Count Estimator (ALICE) software at immediately after the 6-week Activity period and 4 weeks later

2. Rate of infant vocalisations measured using automatic analysis of home audio recordings by Automatic LInguistic Unit Count Estimator (ALICE) software at 4 weeks after the 6-week Activity period

3. Quantity of words produced and comprehended by the infants measured using UK-Communicative Development Inventory (parent-report questionnaire to assess infant comprehension and production) at 11 months after 6-week Activity period

Completion date
31/07/2027

Eligibility

Key inclusion criteria
1. The infant has a diagnosis of Down syndrome
2. The infant is aged between 7 and 15 months at the point of randomisation
3. The infant is growing up in a monolingual English-speaking household, or is exposed to less than 10% of another language, based on caregiver report
4. The infant has eyesight good enough to view shapes on an iPad screen (based on caregiver report)
5. Twins (triplets/quadruplets/….) are eligible to participate
6. The family is based in the UK
7. The infant is not taking part in another speech, language or communication intervention research study

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 months

Upper age limit
15 months

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Infant does not meet the diagnosis, age, language exposure, or residency requirements listed above
2. Infant has visual difficulties that would prevent them from seeing shapes on the iPad screen
3. Infant is currently participating in another speech, language, or communication intervention research study

Date of first enrolment
24/09/2025

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of York
Heslington
York
England
YO10 5DD

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available