

Economic evaluation of the BabblePlay app intervention to support early vocalising in infants with Down syndrome

Submission date 20/04/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/04/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 27/04/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Infants with Down syndrome often experience delays in speech and language development. BabblePlay is an app designed to encourage these infants to make more sounds (vocalise) by responding with colourful shapes on a screen when they speak. While the main BabblePlay trial (<https://www.isrctn.com/ISRCTN12366576>) is testing whether the app improves language skills, it is also important to know if it is a good use of limited healthcare budgets. Hence, this study is an "economic evaluation" running alongside that main trial. The study goal is to determine if BabblePlay provides "value for money" for the NHS and social services compared to the usual care families receive. It will look at whether the costs of the intervention are justified by improvements in the children's health-related quality of life.

Who can participate?

Participants are families already enrolled in the BabblePlay clinical trial (ISRCTN12366576). These are UK-based families with an infant (aged 7–15 months) who has a diagnosis of Down syndrome and lives in a monolingual English-speaking household, has eyesight good enough to see shapes on a screen, and is not enrolled in another speech, language or communication intervention study.

What does the study involve?

This research is all done remotely. Caregivers will be asked to complete online questionnaires (including both tailored resource use and quality of life questionnaires) at two time points: at the start (baseline) and 11 months after the initial activity period.

- Tailored resource use questionnaire: Caregivers will report on their child's use of health and social care services (such as speech therapy or GP visits) to help us calculate total costs.
- Quality of Life (QoL) questionnaires: Caregivers will complete two specific surveys (the IQI designed for infants under 1 year and the EQ-TIPS designed for children aged 1–3) to measure their child's wellbeing and development.

By combining information on costs and quality of life, we can determine the "cost-effectiveness" of the app.

What are the possible benefits and risks of participating?

Possible benefits: There are no direct clinical benefits to participating in this specific economic sub-study. However, the results will help the NHS and policymakers decide whether to fund and provide BabblePlay to other families in the UK.

Possible risks: There are no physical risks. The only "burden" is the small amount of extra time required for caregivers to complete the online questionnaires.

Where is the study run from?

The University of York, UK.

When is the study starting and how long is it expected to run for?

February 2026 to December 2026.

Who is funding the study?

The University of York, UK.

Who is the main contact?

Prof Tamar Keren-Portnoy, tamar.keren-portnoy@york.ac.uk

Contact information

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Public, Scientific, Principal investigator

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Study information

Scientific Title

Economic evaluation of the BabblePlay app intervention to support early vocalising in infants with Down syndrome: a cost-utility analysis alongside a randomised controlled trial

Study objectives

The primary aim of this economic evaluation is to assess the cost-effectiveness of the BabblePlay intervention compared to usual care for infants with Down syndrome. To achieve this, the study has the following specific objectives:

- To estimate the total costs from a National Health Service (NHS) and Personal Social Services (PSS) perspective, including intervention delivery costs and healthcare resource use.
- To measure health-related quality of life (HRQoL) using infant-specific instruments (IQI and EQ-TIPS) and calculate Quality-Adjusted Life Years (QALYs) using the area under the curve (AUC) approach.
- To calculate the incremental cost-effectiveness ratio (ICER) and compare it against the NICE willingness-to-pay threshold to determine the app's cost-effectiveness.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 02/02/2026, Language and Linguistic Science Ethics Committee (University of York, Heslington, York, YO10 5DD, United Kingdom; -; linguistics-ethics@york.ac.uk), ref: Keren-Portnoy_120126_Staff

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 intervention being evaluated is BabblePlay app, a novel, tablet-based behavioural intervention designed to support early vocal development in infants with Down syndrome. The intervention uses a contingent reinforcement model, where the app provides immediate, moving, and colourful visual feedback on an iPad screen in response to infant vocalisations. If the infant remains quiet, the screen remains black, encouraging the child to engage in vocal play to trigger the visual stimuli.

The intervention is delivered in the home environment and is caregiver-led. Families allocated to the intervention arm are provided with an iPad pre-loaded with the BabblePlay app and instructed to facilitate two 5-minute sessions per day over a 6-week activity period. Caregivers will receive instructions on using the BabblePlay app. Adherence will be monitored using app usage data recorded automatically by the device.

Participants are allocated to the intervention or usual care group in a 1:1 ratio using block randomisation with variable block sizes, stratified by chronological and developmental age (Vineland-3). The randomisation sequence is generated using Stata (version 18 or later), and allocation is implemented using sealed, opaque envelopes prepared by an independent individual not involved in the research team. Allocation is not masked from participants or intervention providers, but outcome analysis is conducted blind to group allocation.

The intervention will be compared with usual care, defined as the standard health and social care services typically available to families of infants with Down syndrome. Families in the control arm will not have access to the BabblePlay app during the trial period.

Intervention Type

Behavioural

Primary outcome(s)

1. Incremental cost-effectiveness ratio (ICER) measured using a cost-utility analysis, based on quality-adjusted life years (QALYs) derived from the IQI proxy questionnaire, and resource use measured using caregiver-reported resource use questionnaires, at baseline and 11 months post-activity

Key secondary outcome(s)

1. Mean total costs per infant measured using data collected on the intervention costs combined with caregiver-reported resource use (e.g. speech and language and GP visits), at baseline and 11 months post-activity

2. Mean QALYs per infant measured using the "area under the curve" approach based on utility scores derived from the IQI proxy questionnaire at baseline and 11 months post-activity

Completion date

07/12/2027

Eligibility

Key inclusion criteria

Same as the BabblePlay RCT:

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

Same as the BabblePlay RCT:

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 in another speech, language, or communication intervention research study

Date of first enrolment

26/02/2026

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

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**

University of York

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			27/04/2026	No	No
Participant information sheet		01/01/2026	27/04/2026	No	Yes