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Do video materials help parents to support infant and toddler development?

Submission date
17/09/2024

Recruitment status
No longer recruiting

Registration date
19/09/2024

Overall study status
Completed

Last Edited
22/10/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This study aims to find out whether a smartphone-based service for parents can help them support their child's health and development. We would like to understand whether parents find the service useful, whether it helps them support their child and whether this benefits their child's health and development a year later.

Who can participate?
Parents with infants aged between 10-20 months on 17th September 2024 or toddlers aged between 28-38 months on 17th September 2024 are likely to be eligible to take part.

What does the study involve?
Families have been randomly assigned to one of two groups. Both groups will receive a text message three times a month with a link to an age-appropriate video with information about child development. In one group, caregivers will receive links to videos about supporting children's language development, using resources from BBC Education's Tiny Happy People service. In another group, caregivers will receive links to videos about supporting nutrition, dental and physical health from trusted public sites including NHS websites. In the first group, caregivers whose children are identified as potentially needing additional support will be given the option of a short series of video calls with a Speech and Language Therapist.
In order to test the value of the services, all participating caregivers will be asked to complete questionnaires and will be given the option to share a home video of play with their child. Participating families will also host researchers for a home visit at the end of the study, where age-appropriate language assessments will be completed during a visit lasting about 30 minutes.

What are the possible benefits and risks of participating?
Families in the first group may experience benefits to caregiver linguistic responsiveness and child language. Families in the second group may experience benefits to their child's physical development, particularly, diet and tooth brushing. All caregivers will receive £10 up to four times for completing the questionnaires, videos and the home visit. This equates to a possible total of £40 over the course of a year. Finally, families are likely to feel happy they supported research into how to support child health and development.
Regarding risks, the text-message services involve sending parents videos about how to support

child health and development via their phone. While all videos sent are open to the public, have been made for parents and checked by professionals, it is possible that some parents may feel concerned about their child's development or their own wellbeing after watching them or after being offered support from a speech and language therapist. Parents will have the opportunity to ask questions of a professional regarding the content of the videos. However, it is possible that the research team will not be able to address a parent's concern. In such instances, we will recommend contacting a GP.

Where is the study run from?
The University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
February 2024 to January 2026

Who is funding the study?
Nuffield Foundation (UK)

Who is the main contact?
Prof. Danielle Matthews, danielle.matthews@sheffield.ac.uk

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoS_181225

Study information

Scientific Title
Evaluating a text-message service that delivers BBC Education Tiny Happy People early language resources to families with infants and toddlers: a randomised controlled trial

Acronym
TiHP ToE (Tiny Happy People Infant and Toddler Evaluation)

Study objectives
Primary hypothesis:
The following hypothesis will be separately tested in the infancy and in the toddler group:
Child language (see measured variables section below for details of measurement) will be greater in the language intervention condition.

Secondary hypotheses:
The following hypotheses will be separately tested in the infancy and in the toddler group:
1. Caregiver responsiveness (measured using the PaRRiS rating scale. Levickis et al., 2020) will be greater in the language intervention condition.
2. Caregiver responsiveness (a binary variable derived from PaRRiS with >=4 coded as 1) will mediate any effect of the intervention on child language outcomes.

Further details on the analytic approach for the tests of efficacy and additional analyses have been registered with the Open Science Foundation (OSF): https://osf.io/crwt4

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/02/2024, University of Sheffield Department of Psychology Ethics Sub-committee (Department of Psychology, The University of Sheffield, ICOSS Building, 219 Portobello, Sheffield, S1 4DP, United Kingdom; +44 (0)114 222 6533; psy-ethics@sheffield.ac.uk), ref: 058667

Study design
Interventional blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Language development in early childhood (0 to 4 years) in socioeconomically diverse children, and linguistic responsiveness on the part of their caregivers

Interventions
This study is designed to evaluate a text-message service for parents that delivers BBC Education's Tiny Happy People video content (https://www.bbc.co.uk/tiny-happy-people) with the goal of promoting early language development. Families who indicate their child may need extra support will be offered contact with a speech and language therapist (SLT) via text message and phone/video call.

This smartphone-based digital service will be delivered to young children in two age groups, infants and toddlers and thus will be tested by two RCTs in parallel, one for each age group.

Randomisation will be conducted separately for each age group (infant and toddler) at the participant level. Participant assignment to two arms (language intervention and active control) will be performed using stratification based on groups created by crossing caregiver education (two levels – primary caregiver has a degree or not) and age at the start of the intervention (four bands spanning equal periods).

The active control text-message service will deliver content about healthy eating, dental care and other aspects of health using video resources also available to the public, e.g, via the NHS.

Families in all groups will receive four texts per month - three delivering video content and one summary text. They will receive texts for 8 months.

The intervention and baseline data collection will be conducted remotely via smartphone and outcome data will be conducted remotely and with home visits.

Intervention Type
Behavioural

Primary outcome(s)
Child language. Confirmatory factor analysis will be used to derive a composite measure of language ability for each age group from the following measures:
Infant group (three variables):
1. Real word repetition measured using the Early Repetition Battery (PSRep Real-Word scale) subscale at study completion, which will be 9-12 months after baseline when children are aged 19-33 months old
2. Expressive vocabulary measured using the Early Language Identification Measure - Word List score at study completion, which will be 9-12 months after baseline when children are aged 19-33 months old
3. Receptive vocabulary measured using the receptive vocabulary subscale from Preschool Language Scales – 5th Edition (PLS-5) at study completion, which will be 9-12 months after baseline when children are aged 19-33 months old

Toddler group (six variables):
1. Language ability measured using the Language Screen score on all four subscales at study completion, which will be 9-12 months after baseline when children are aged 37-51 months old
2. Word and sentence repetition ability measured using the Early Repetition Battery on two subscales (real-word PSREP and full-sentence SIT) at study completion, which will be 9-12 months after baseline when children are aged 37-51 months old

Key secondary outcome(s))
Parent linguistic responsiveness measured using the Parental Responsiveness Rating Scale (PaRRiS) at study completion, which will be 9-12 months after baseline when children in the infant group are aged 19-33 months old and children in the toddler group are aged 37-51 months old

Completion date
31/01/2026

Eligibility

Key inclusion criteria
In order to be invited to take part, the child must meet the following criteria:
1. Age:
1.1. Infant group, date of birth between 1st February 2023 - 18th November 2023 (i.e.,10-20 months on 17th September)
1.2. Toddler group, date of birth between 3rd August 2021 - 15th May 2022 (i.e. 28-38 months on 17th September)
2. Birth weight must not be below 2.5 kg (5 lb 8 oz)
3. Must not have been born more than 3 weeks premature (full term is 37-42 weeks - anything 36+6 or earlier is preterm)

4. Child hears English spoken in the home at least 50% of the time
5. Postcode must have an Index of Multiple Deprivation (IMD) of 1-5 or country equivalent
6. Must not have any known significant disability themselves, or on the part of their parent, that would significantly affect language development (decided before randomisation)

Families must have access to the internet and a device to watch videos (via smartphone, tablet or computer/laptop).

In order to be offered follow-up calls with an SLT, families must meet one of the following criteria:
1. Baseline score on the communication subset of the ASQ that falls within the grey (monitoring zone, 1-2 SD from mean) or black zone (at risk, 2+ SD from mean)
2. PaRRiS score below 3 (if volunteering to send home video)

Participant type(s)
Healthy volunteer, Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 months

Upper age limit
38 months

Sex
All

Total final enrolment
803

Key exclusion criteria
Current key exclusion criteria as of 22/10/2025:
1. Infant had a condition known to affect child language development at the point of recruitment
2. Child did not hear English at home more than 50% of the time
3. Child premature or low birth weight
4. Family IMD 6 or above

NB. Children may receive a diagnosis of a medical condition after the study starts and they will remain in the study even if this is the case.

Previous key exclusion criteria:
1. Caregiver or infant had a condition known to affect child language development at the point of recruitment
2. Child did not hear English at home more than 50% of the time
3. Child premature or low birth weight
4. Family IMD 6 or above

NB. Children may receive a diagnosis of a medical condition after the study starts and they will remain in the study even if this is the case.

Date of first enrolment
15/07/2024

Date of final enrolment
07/09/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University of Sheffield
Western Bank
Sheffield
United Kingdom
S10 2TN

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Charity

Funder Name
Nuffield Foundation

Alternative Name(s)
NuffieldFound

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
1. Stored in a publicly available repository (anonymised data)
2. Stored in a non-publicly available repository (video data with parent permission)

IPD sharing plan summary
Stored in publicly available repository, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	31/05/2024	17/09/2024	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol (other)			17/09/2024	No	No
Statistical Analysis Plan			17/09/2024	No	No