ISRCTN17491849 https://doi.org/10.1186/ISRCTN17491849

Do video materials help parents to support toddler development?

Submission date
29/11/2023

Recruitment status
No longer recruiting

Registration date
30/11/2023

Overall study status
Completed

Last Edited
23/01/2025

Condition category
Other

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

Plain English summary of protocol
Background and study aims
The current study will evaluate a smartphone service for parents using video materials from BBC Education's Tiny Happy People initiative (https://www.bbc.co.uk/tiny-happy-people). The service seeks to reduce the risk of children having delayed language when they start primary school. This risk is known to be greater for children experiencing relative socio-economic disadvantage. BBC Education have created videos for parents and other caregivers with information about child development, tips and activities as well as other content of interest. The current study will test a service that delivers the video materials to parents of toddlers by text message, with additional support in the form of video calls with a Speech and Language Therapist where parents suggest this may be needed. This service follows on from a similar service offered to parents when their children were babies. This study will test 1) whether parents opt to continue receiving the service having previously received it when their children were babies, and whether parents stay in the study to completion, 2) whether it is feasible to deliver the improved text message service to caregivers, 3) whether it is feasible to deliver the new video-call component of the service, 4) whether parents find the toddler-wave service acceptable, and 5) whether it is feasible to evaluate the outcomes of the service. If the intervention is found to be feasible to implement and evaluate, and a sufficient number of participants participate, the researchers will evaluate its effectiveness by analysing measures of child language and caregiver linguistic responsiveness to test whether there are any benefits due to receiving the service.

Who can participate?
For this pilot and feasibility study, only participants from the earlier evaluation are eligible to participate. At the start of this study, children will be between the ages of 30 and 36 months.

What does the study involve?
Families have been randomly assigned to one of two groups. In both groups, they will receive a text message three times a month with a link to an age-appropriate video with information about child development. In the Intervention group, caregivers will receive links to videos about supporting children's language development, using resources from BBC Education's Tiny Happy People service. In the control group, caregivers will receive links to videos about supporting other areas of child development, such as nutrition and dental health. In the intervention 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. All participating caregivers will be asked to complete a questionnaire and share a home video when their child is 3 ½ years old in order to test for any impacts on a) caregiver confidence b) caregiver-child interaction and c) child language. Participating families will also host researchers for a home visit, where two language assessments will be completed during a visit lasting about 30 minutes.

What are the possible benefits and risks of participating?
Families in the intervention condition may experience benefits to caregiver responsiveness and child language. Families in the control condition may experience benefits to their child's physical development (e.g., more regular tooth brushing). All caregivers will receive £10 for the questionnaire they complete and £10 for the home video they record and send in (at outcome). They will receive a further £10 for the home visit. This equates to a possible total of £30 over the course of a year.
Regarding risks, it is possible that some parents may feel concerned about their child's language or physical development, or their own wellbeing, as a result of watching the videos, completing the measures or being offered additional support from an SLT. The researchers will limit risk by using video materials that have been quality controlled, using measures that have been used before with families and developing protocols with input from parent focus groups. Before beginning this wave of the study, parents will be provided with an information sheet stating that the staff answering text messages are not clinicians and that they should speak to their GP should they have any concerns regarding their own wellbeing or their child's development. Once study participation has begun, the family-facing team will ensure caregivers feel able to flag concerns and are listened to.

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

When is the study starting and how long is it expected to run for?
August 2023 to July 2024

Who is funding the study?
University of Sheffield (UK)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
182244

Study information

Scientific Title
Evaluating a service delivering BBC Education Tiny Happy People resources to families with toddlers: a pilot and feasibility study

Acronym
TiHP ToP (Tiny Happy People Toddler Pilot)

Study objectives
The aim of this study is to test the feasibility, acceptability and efficacy of a digital service delivering BBC Education's Tiny Happy People video materials to parents via text messages (with extra support via video calls where appropriate) in order to support language development prior to school entry. This study builds on a prior evaluation with a cohort of 435 families who took part in an evaluation of video materials during an infancy phase. Over 300 families have volunteered to continue receiving the service so that the researchers can evaluate materials and improve delivery methods during a toddler phase.

For the evaluation of the feasibility and acceptability of this toddler phase, it is hypothesised that:

Service delivery will be feasible. Sufficient families will engage with the service. Specifically:
1. Most caregivers will remain opted in to the service for the 6 months the toddler phase is offered (retention percentage set at 75%; see study protocol).
2. Most caregivers will click through to 25% of video content links per month on average (percentage set at 75%; see study protocol). [PRIMARY OUTCOME MEASURE 1 - please see "Primary Outcome Measure" section]
3. Most caregivers offered 1-1 video calls will attend the majority of calls booked (average attendance rate set at 75%; see study protocol). [PRIMARY OUTCOME MEASURE 2 - please see "Primary Outcome Measure" section]
4. Most caregivers will feel they have the Capabilities, Opportunities, and Motivations to engage with the intervention text messages (average rating above 6/10 on a measure adapted from Keyworth et al. 2020).
5. Speech and Language Therapists will be able to deliver the 1-1 video calls with high fidelity to protocol (an average score of at least 4 out of 5 on the summed presence of five 'Quality of Interaction' characteristics: engagement, demeanour, listening skills, attentiveness, accuracy; see study protocol).
6. Text messaging researchers will respond to parents' text messages promptly and with a high quality of interaction (as measured by mean time to respond to texts and a Quality of Interaction score recorded for each researcher based on a randomly selected 30 text exchanges with a parent. An average score of at least 3 out of 4 on the summed presence of four relevant 'Quality of Interaction' characteristics: engagement, demeanour, listening skills, accuracy).

Service evaluation will be feasible. Specifically:
1. Most caregivers will respond to questionnaires collecting outcome measures (75% percentage return rate).
2. Some caregivers will share home videos via their phone as part of the collection of outcome measures (percentage set at 25%; see study protocol).
3. Most invited caregivers will agree to book a home visit for a researcher to collect child language measures in person, and will be present when the home visits take place (percentage set at 75%; see study protocol).
4. It will be possible to collect data using the Early Repetition Battery (ERB; Seeff-Gabriel, Chiat & Roy, 2008) and the Language Screen (West et al., 2022; https://www.languagescreen.com/) in homes with 3 ½ year olds (75% of children tested will be able to complete each measure).

The text message and video-call elements of the proposed service and the methods of evaluating the service will be acceptable to parents. On the basis of questionnaire data, it is hypothesised that:
1. Caregivers will find the text messaging service acceptable (on each of the 7 dimensions of the Sekhon framework there will be positive acceptability ratings i.e., an average rating of 5 or above). No areas for improvement are noted in free text comments.
2. Caregivers will find the 1-1 video calls acceptable (on each of the 7 dimensions of the Sekhon framework there will be positive acceptability ratings i.e., an average rating of 5 or above). No areas for improvement are noted in free text comments.
3. Speech and Language Therapists will find the 1-1 video calls acceptable (on each of the 7 dimensions of the Sekhon framework there will be positive acceptability ratings i.e., an average rating of 5 or above). No areas for improvement are noted in free text comments.
4. Caregivers will find the mode of evaluation acceptable (>75% of participants would recommend taking part in a similar study to a friend).

In addition to the above acceptability measures the researchers will collect the following related measures and expect the THP service not to diminish self-efficacy or exacerbate mental health difficulties (although the researchers note the absence of baseline measures):
1. The service will not diminish caregiver self-efficacy (group comparison on participant self-ratings, bespoke questionnaire).
2. The service will not exacerbate caregiver mental health difficulties (group comparison on Kessler 6 measure).

NB. The researchers will qualitatively analyse focus group data to aid interpretation of findings.

If retention is sufficient to allow statistical analysis, the researchers will run tests of the efficacy of the service in promoting child language development. Primary outcome measures will focus on overall caregiver linguistic responsiveness and child language ability (a composite measure). Secondary outcome measures will include specific parent strategies, parent report of child pragmatics and preliteracy, child toothbrushing frequency (promoted in the active control condition) and caregiver well-being. In this case, it is hypothesised for the primary outcome measures that:
1. The service will promote caregiver linguistic responsiveness (group comparison using the PaRRiS rating scale).
2. The service will promote child language (group comparison using the composite child language score; see Section 17 below).

For secondary outcome measures, it is hypothesised that:
1. The service will promote caregivers' specific responsiveness strategies (group comparison on the frequency of individual strategies).

2. The service will promote child pragmatic and pre-literacy skills (group comparison on CELF-P2 questionnaire).
3. The active control text service will promote the frequency of tooth brushing (group comparison on participant self-ratings, bespoke questionnaire).

Further details on the analytic approach for the tests of efficacy can be found in a further Open Science Foundation (OSF) preregistration: https://osf.io/csqnk/

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/09/2023, University of Sheffield Department of Psychology Ethics 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: 056540

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 (2.5 to 4 years) in socioeconomically diverse children, and linguistic responsiveness on the part of their caregivers

Interventions
This study is designed to evaluate a digital service for parents based around BBC Education's Tiny Happy People video content (see: https://www.bbc.co.uk/tiny-happy-people). This service has been designed to operate over three waves - infancy, toddlerhood and preschool and this study is focused on the toddler wave. Participants for this study are drawn from a prior, completed RCT testing the efficacy of the infancy phase of the service (infants aged 6-24 months). The current pilot will test the toddler phase. If willing, the same families will be retained to participate in this phase, staying in the same condition they were originally allocated to a language intervention or an active control. All families taking part in this original ‘infancy phase’ evaluation were eligible for and invited to the current ‘toddler phase’ study. The design is as follows:

Study Design Study Type: Interventional
Primary Purpose: Basic Science Study
Model: Parallel Assignment
Number of Arms: 2

Masking: Quadruple (Participant, Caregiver, Investigator, Outcomes Assessor) Text messages are sent blind to condition. SLT support is only given to one condition so no chance for bias.

Allocation: Randomized

All participants were recruited prior to randomisation with parallel assignment using computer-generated random numbers. Poststratification based on 24 groups was created by crossing caregiver education (two levels - higher and lower), ASQ (two levels - higher and lower), sex (two levels - M/F) and age (six levels - 5, 6, 7, 8, 9 or 10 months at the start of intervention). The random sequence of values (0 or 1) was generated by Colin Bannard (University of Manchester). The allocation of values to conditions (intervention or control) was decided separately by Tom Stafford (University of Sheffield, external to the project), by coin flip, in the presence of Kiera Solaiman (University of Sheffield, project manager) such that Colin Bannard remained blind to participant allocation to conditions. This took place on 06/09/2021.

Arms and Interventions
Arm 1: Experimental: BBC Tiny Happy People intervention
Assigned Behavioural Intervention: Parents are sent links each month directing them to BBC Tiny Happy People content via SMS text message. This content is aimed at supporting language development. Parents will be asked to watch the video content and incorporate it into their parenting practices. The original 'infancy phase' intervention started when infants were aged 4-10 months and concluded when they were 24 months. This 'toddler phase' intervention will continue (but with new developmentally appropriate video links) now children are 30 to 36 months and complete when they are 36 to 42 months. It will follow the same format as the infancy phase with the addition of optional video calls with a Speech and Language Therapist for children who are at higher risk of language delay based on data shared by parents.

Arm 2: Active Comparator: Physical health control intervention.
Assigned Behavioural Intervention: Similar to the experimental condition, parents have been sent links each month via SMS text message. These links directed them to publicly available web content with tips to promote the healthy development of their baby, focusing on things such as healthy eating, physical activities, and dental care. The original 'infancy phase' intervention started when infants were aged 4-10 months and concluded when they were 24 months. This 'toddler phase' intervention will follow the same format (but with new developmentally appropriate video links) now children are 30 to 36 months and complete when they are 36 to 42 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Engagement with the text message component of the intervention, measured by the percentage of links texted to participants that were clicked on by participants between November 2023 and May 2024.
2. Engagement with the higher intensity video-call component of the intervention, measured by the percentage of scheduled sessions attended by caregivers, recorded by research team members during the implementation period between November 2023 and May 2024.

Key secondary outcome(s))
Feasibility of service delivery:
1. Engagement with service measured by the number of participants opting to withdraw from the study by participants between November 2023 and May 2024
2. Fidelity of Speech and Language Therapists' implementation of 1-1 video call sessions measured by the Quality of Interaction measure of Wickersham et al. (2011) between November 2023 and May 2024

Feasibility of service evaluation:
3. Response to outcome questionnaires measured by the number of participants returning questionnaires between May 2024 and July 2024
4. Response to request to share home videos via smartphones (to allow outcome measurement of interaction and child language) measured by the number of participants sharing a video between May 2024 and July 2024
5. Response to request to book a home visit (for a researcher to collect child language outcome measures in person) as measured by the number of participants returning making an appointment between June 2024 and July 2024
6. Presence for home visit (for a researcher to collect child language measures in person) as measured by the number of participants at home for outcome data collection appointment between June 2024 and July 2024
7. Feasibility of collecting data using the ERB and the Language Screen in homes with 3 ½ year olds as measured by the number of participants for whom data could be collected between June 2024 and July 2024

Acceptability and fidelity of delivery:
8. Acceptability of the text message component of the intervention to caregivers measured using a questionnaire based on the Sekhon et al. (2017) framework in May 2024
9. Acceptability of the high-intensity video-call component of the intervention to caregivers measured using a questionnaire based on the Sekhon framework in May 2024
10. Acceptability of the high-intensity video-call component of the intervention to SLT(s) delivering the language intervention measured using a questionnaire based on the Sekhon framework and by interview in May 2024
11. Fidelity to the text message component of the intervention measured using the Quality of Interaction measure of Wickersham et al. (2011) in May 2024

NB. The researchers will also qualitatively analyse focus group data to aid the interpretation of findings.

If the study finds that the intervention is feasible following the primary outcome measures 1 and 2, and secondary outcome measures 1 to 11, further analyses focusing on the intervention efficacy will be conducted. For more details, including a full statistical analysis plan, please see the accompanying Open Science Foundation pre-registration (https://osf.io/csqnk/).

The two primary efficacy analyses of interest (as the planned primary outcome measures in the potential full trial) are:
12. Caregiver responsiveness measured using the Parental Responsiveness Rating Scale (PaRRiS) in June 2024 and July 2024
13. Child language measured using a composite score of child language ability measured using a combination of the ERB, the Language Screen, and naturalistic measures (word tokens, word types and Mean Length of Utterance), in June 2024 and July 2024

The secondary efficacy analyses are:
14. Specific caregiver responsive strategies measured using an existing reliable coding scheme (see https://osf.io/preprints/psyarxiv/4h36e) in May 2024
15. Child Pragmatics and Pre-literacy measured using the Clinical Evaluation of Language Fundamentals - Preschool 2 questionnaire (CELF-P2) in May 2024
16. Caregiver self-efficacy measured using a bespoke questionnaire in May 2024
17. Caregiver mental health measured using the Kessler 6 questionnaire (Kessler 6) in May 2024

18. Caregiver Capabilities, Opportunities, and Motivations measured using a survey created by Keyworth et al. (2020) in May 2024
19. Dental health and diet outcomes measured using a bespoke questionnaire in May 2024

Completion date
31/07/2024

Eligibility

Key inclusion criteria
Participants are included in this toddler-wave evaluation if they were part of the prior infancy-wave evaluation. The inclusion criteria for the original infancy-wave evaluation were as follows:

1. Infants must be no younger than 4 months
2. Infants must be no older than 10 months
3. Infants must be full-term
4. Infants must have a healthy birth weight
5. Families must be raising their child as a monolingual English speaker (at least 80% of the language they hear in the home is English)
6. Families must have a postcode in deciles 1-5 of the Office of National Statistics Index of Multiple Deprivation
7. Families must have access to the internet and a device to watch videos (via smartphone)
8. Participants (caregivers, infants) could be any sex/gender

Inclusion criteria for this feasibility study:
9. Families must have taken part in the previous phase of the RCT

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 months

Upper age limit
36 months

Sex
All

Total final enrolment
304

Key exclusion criteria

1. Neither caregiver nor infant had a condition known to affect child language development at the point of recruitment to the infancy-wave evaluation.

NB. Since joining the study when infants were 4-10 months, children may since have been diagnosed with a developmental condition and families will remain in this phase of the study even if this is the case.

Date of first enrolment
10/10/2023

Date of final enrolment
30/10/2023

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University of Sheffield
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Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
University/education

Funder Name
University of Sheffield

Alternative Name(s)
sheffielduni, University of Sheffield UK, theuniversityofsheffield, University of Sheffield in United Kingdom, University of Sheffield, UK, The University of Sheffield, Sheffield University

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Danielle Matthews (danielle.matthews@sheffield.ac.uk). Consent from participants was required and obtained. Please see the study protocol for details.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)			30/11/2023	No	No