ISRCTN62346103 https://doi.org/10.1186/ISRCTN62346103

Evaluation of Early Talk Boost Efficacy Trial

Submission date
19/09/2023

Recruitment status
Stopped

Registration date
05/10/2023

Overall study status
Stopped

Last Edited
21/10/2024

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 way children talk and communicate can affect how well they do in school and later on in their jobs. In the UK, about 85,000 to 90,000 children aged 2 to 6 get help from speech and language therapists every year. Children from families with less money are more than twice as likely to have trouble with speaking and understanding words compared to children from richer families. This difference in language skills probably plays a part in the gap in how well children do in school early on and later. But here's the thing: most of the help with speech and language problems happens after children are already referred for therapy. Children who have only a bit of trouble with language often don't get enough help. Plus, COVID-19 has made the gap in language skills even bigger for children from poorer families.

So, now more than ever, we need programs to help children who have some language problems but don't need therapy. Early Talk Boost is one such program. It's for 3-4-year-olds who are a bit behind in their talking and understanding words. Speech and language experts, along with an experienced nursery teacher, designed it based on what we know works best for language development in young children. Speech and Language UK, which used to be called I CAN, runs this program.

Because there's a gap between research and practice when it comes to language programs for 3-4-year-olds, the EEF is funding a study to see how well Early Talk Boost works. This study will give us more evidence on what helps children in this age group, especially those who need help with language. They're going to use a Randomized Controlled Trial, which means they'll compare children who do the program with children who don't. They want to see if Early Talk Boost makes these 3-4-year-olds better at talking and understanding words.

But it's not just about numbers. They're also going to look at how well the program is put into practice. They want to know if people are doing it the way it's supposed to be done and if everyone involved is on board. They'll also check if other things, like government policies, affect how well the program works. They'll talk to the teachers, children, and parents to learn more about their experiences with the program. They'll also chat with the people who run the program to get their insights.

In summary, the study aims to check if Early Talk Boost really helps children with their language skills and to understand how and why it works or doesn't work.

Who can participate?
Children can take part if:
• 3-4 years old who may be behind with talking and understanding words.
• Has to be signed up for at least 2 terms.
• Should be able to attend the sessions at least 3 times a week.
• 3 years old and no more than 4.5 years old at the end of the intervention. Only children with birth date between 1 December 2019 and 1 Oct 2020 will be included e.g., the oldest children will just turn 4 on 1 Dec 2023 (and won't be 4.5 until end May of that year so will have finished the intervention by then). And the youngest children will be born on 1 October 2020 and will just turn 3 on 1 Oct 2023 (allows for baselines from 1 Oct 2023).

Children can't take part if they have:
• SEND concerns - have significant SEND which would prevent them from accessing the assessment and/or would be distressed through completing the assessment and taking part in the intervention.
• Diagnosed conditions e.g., Down's Syndrome, complex learning needs.

What does the study involve?
Children will undergo a WellComm screening test and only children who meet the cut-off (i.e. amber and the top end of red ratings for their age) will be selected into the study. Once the screening has been completed and children have been selected into the study, a baseline measure of the primary outcome (a brief early language assessment) will be conducted for all selected children. Following this, half of the settings will be randomised to receive the intervention and the other half of the settings will be randomised to be the control group. Therefore, as part of the evaluation, only the selected children in the intervention settings will receive Early Talk Boost.

Overall, all children selected in the study will be asked to complete the brief early language assessment before the intervention starts and again after the intervention ends. At the end of the study, practitioners will also be asked to complete a questionnaire about children's attention and communication.

The Early Talk Boost programme starts with training for Early Years practitioners, which includes four main topics. These are:
• typical speech, language and communication development;
• things that can potentially go wrong and what impact that has on children's learning and behaviour;
• which children will receive the most benefit from the intervention and how to use the Tracker to identify them and track their progress;
• planning and running the Early Talk Boost sessions, along with using the manual and accompanying resources, as well as involving parents (i.e. parent workshops and using the Jake and Tizzy book to support the home learning environment).

The training develops practitioners (1) ability to understand the Early Talk Boost activities and how to support children's language, (2) understanding of how to identify children who will benefit from Early Talk Boost and monitor their progress, and (3) understanding of working with parents to support their child's talking and understanding words. Two practitioners per setting are invited to take part in the training, which allows for continuity in the settings in case of staff changes and supports the practitioners in establishing Early Talk Boost as part of the daily nursery routine and sharing of good practice. Only one practitioner is required to run the intervention sessions.

What are the possible benefits and risks of participating?
Nurseries taking part in the programme will receive an Early Talk Boost Intervention pack which normally costs £550 and training and support, all of which is fully funded. Control settings will receive the same fully funded training and support in the academic year 2024/2025. In recognition that there are costs associated with undertaking and implementing professional development, additional funding has been made available by the EEF to reimburse nurseries for approximately 50% their staff's time/cover cost to attend training, by providing settings with £60 per practitioner who completes the professional development activities, for up to two staff members. In addition, settings will receive £400 in the evaluation year (2023/2024) to assist in parental recruitment and completion of evaluation measures (surveys, setting visits, child language assessments). This will be divided into £150 for baseline (i.e., Spring 2024) and £250 on completion of endline (by Aug/Sept 2024).

We do not anticipate any potential risks. Parents/guardians are able to withdraw their children from the study at any time.

Where is the study run from?
The evaluation is being carried out by the Institute for Employment Studies (IES) in England. The Early Talk Boost programme is designed and delivered by Speech and Language UK.

When is the study starting and how long is it expected to run for?
January 2023 to April 2025

Who is funding the study?
Education Endowment Foundation (UK)

Who is the main contact?
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Public

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Additional identifiers

Protocol serial number
6279G

Study information

Scientific Title
Does the Early Talk Boost programme, delivered along existing practice in Early Years settings, lead to improved communication and language outcomes for 3-4 year-old children who are behind their peers in talking and understanding words?

Acronym
ETB

Study objectives
The primary research questions include:
RQ 1) What is the difference in expressive language ability measured by the Preschool Language Scale 5 Expressive Communication subscale, between children in intervention settings receiving Early Talk Boost and children in waitlist control settings receiving business as usual, after controlling for the baseline measure of outcome?

RQ 2) What is the difference in attention and social communication measured by the FOCUS-34, between children in intervention settings receiving Early Talk Boost and children in waitlist control settings receiving business as usual?

The secondary research questions will explore heterogenous effects by various sub-groups:
RQ3) Early Years Pupil Premium (EYPP) eligibility: EYPP, non-EYPP
a. Does the impact of the Early Talk Boost programme on expressive language vary by the EYPP eligibility status of the children?
b. Does the impact of the Early Talk Boost programme on attention and social communication vary by the EYPP eligibility status of the children?
c. Does Early Talk Boost programme have a significant impact on the expressive language of EYPP children? (We have not powered the study for this, but we will explore)
d. Does Early Talk Boost programme have a significant impact on the attention and social communication of EYPP children? (We have not powered the study for this, but we will explore)

RQ4) Setting type: Private, voluntary, and independent (PVI); Maintained
a. Does the impact of the Early Talk Boost programme on expressive language vary by the setting type (PVI vs Maintained)?
b. Does the impact of the Early Talk Boost programme on attention and social communication vary by the setting type (PVI vs Maintained)?

RQ5) Quartiles of baseline measure of outcome:
a. Does the impact of the Early Talk Boost programme on expressive language vary by the quartile of the baseline measure of the outcome?
b. Does the impact of the Early Talk Boost programme on attention and social communication vary by the quartile of the baseline measure of the outcome?

RQ6) English as an additional language (EAL):
a. Does the impact of the Early Talk Boost programme on expressive language vary by EAL status?
b. Does the impact of the Early Talk Boost programme on attention and social communication vary by EAL status?

RQ7) If we are able to collect information on practitioners receiving Department for Education (DfE) training, such as those listed here, we will explore:
a. Does the impact of the Early Talk Boost programme on expressive language vary by practitioners having received DfE training?
b. Does the impact of the Early Talk Boost programme attention and social communication vary by practitioners having received DfE training?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/03/2023, Institute for Employment Studies (IES) Research Ethics Committee (City Gate, 185 Dyke Road, Brighton, BN3 1TL, United Kingdom; +44 (0) 1273 763 400; becci.newton@employment-studies.co.uk), ref: None provided

Primary study design
Interventional

Study design
Two-arm cluster randomized controlled efficacy trial with child-level outcomes

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Early years communication and language

Interventions
The evaluation will be conducted as a two-arm cluster (setting-level) randomised waitlist-controlled trial to identify the impact of the Early Talk Boost programme on expressive language, and the attention and communication of 3-4-year-old children who are experiencing delay in speech and language development. Given this is an efficacy trial, an effort has been made to maximise the likelihood of observing an intervention effect if one exists.

The trial will be conducted in nursery settings under two Stronger Practice Hubs - the East of England Early Years Stronger Practice Hubs and Early Years South West Stronger Practice Hub. Given the nature of the intervention, we believe that a setting-level randomisation is best suited for the evaluation design rather than an individual-level randomisation. This allows us to prevent contamination and also to ease delivery in Early Years settings. In conducting the randomisation, to minimise the risk of imbalance across treatment and control groups, we recommend stratification by Stronger Practice Hubs. Randomisation will occur after baseline assessments have been completed to minimize potential attrition bias in ITT analysis.

Settings randomized into the intervention group will receive the Early Talk Boost program that will run for 27 sessions or 9 weeks (3 sessions per week; minimum of 7 weeks) and the settings randomized to the waitlist control group will be business-as-usual for the duration of the trial. Following completion of the trial, the settings in the waitlist control group will have the opportunity to receive Early Talk Boost in the following academic year. We will use an online tool for the randomisation.

The aim of this evaluation will be to assess, using a Randomized Controlled Trial, if Early Talk Boost is able to improve communication and language outcomes among 3–4-year-old children who are behind in terms of language development, in particular in their talking and understanding words. In addition to this, a thorough implementation and process evaluation will aim to establish fidelity in implementation, explore key stakeholder engagement with the programme, identify any factors influencing implementation that may facilitate/hinder impact at the child-level (including wider national/policy contexts), and to inform and contextualise the quantitative findings.

The aim of the implementation and process evaluation (IPE) is to establish fidelity in implementation, identify the factors influencing implementation that may facilitate/hinder impact at the child-level (including wider national/policy contexts), and to inform and contextualise the quantitative findings. We will examine the delivery of and engagement with the Early Talk Boost programme. In line with the Theory of Change, we will examine the experiences and behaviour of the three key stakeholders: practitioners, children, and parents, as well as interviewing the delivery team.

Intervention Type
Behavioural

Primary outcome(s)
Expressive language skills measured using the Expressive Communication subscale from the Preschool Language Scale 5 UK edition (PLS-5) at pre- and post-test (baseline and 9 weeks)

Key secondary outcome(s)
Attention and social communication measured using the Outcomes of Communication Under Six (FOCUS-34) short form (34 items) at post-test (9 weeks)

Completion date
30/04/2025

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. 3-4 years old who may be behind with talking and understanding words.
2. Has to be signed up for at least 2 terms.
3. Should be able to attend the sessions at least 3 times a week.
4. 3 years old and no more than 4.5 years old at the end of the intervention. Only children with birth date between 1 December 2019 and 1 Oct 2020 will be included e.g., the oldest children will just turn 4 on 1 Dec 2023 (and won't be 4.5 until end May of that year so will have finished the intervention by then). And the youngest children will be born on 1 October 2020 and will just turn 3 on 1 Oct 2023 (allows for baselines from 1 Oct 2023).

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
4 Years

Sex
All

Key exclusion criteria
1. SEND concerns - have significant SEND which would prevent them from accessing the assessment and/or would be distressed through completing the assessment and taking part in the intervention.
2. Diagnosed conditions e.g., Down's Syndrome, complex learning needs.

Date of first enrolment
30/03/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute for Employment Studies
City Gate
185 Dyke Road
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Sponsor information

Organisation
Education Endowment Foundation

ROR
https://ror.org/03bhd6288

Funder(s)

Funder type
Charity

Funder Name
Education Endowment Foundation

Alternative Name(s)
EducEndowFoundn, The Education Endowment Foundation (EEF), Education Endowment Foundation | London, EEF

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
At the end of the project, a pseudonymised dataset will be submitted to the Education Endowment Foundation's (EEF's) data archive (i.e., a non-publicly available repository), which is managed by the Fischer Family Trust (FFT). More details about EEF's data archive can be found here: https://educationendowmentfoundation.org.uk/privacy-notices/privacy-notice-for-the-eef-data-archive. These data will be submitted to the archive within 3 months of the end of the project. The format of the dataset will be at an individual level (i.e. one row per child), including information on received treatment and testing outcomes (e.g. at baseline and endline). The data will be included in the data archive indefinitely for purposes related to archiving, historical research or scientific research, and the EEF and FFT will determine the criteria necessary for access.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Information for settings		19/09/2023	No	Yes
Protocol file	version 1.0	01/08/2023	19/09/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes