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Outcomes of Talking Together: Evaluation and Results (oTTer)

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
21/02/2019

Overall study status
Completed

Last Edited
30/06/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Strong language skills underpin children's educational achievement, and have been found to be predictive of both social and scholastic success. Research identifies the home learning environment as the bedrock for children's early language development, and there is a need to support families to foster positive parent-child interactions and supportive home environments that enrich children's early language learning opportunities. There is a trend for children from lower socioeconomic status (SES) backgrounds to show early language weaknesses that are often predictive of later language outcomes. The Talking Together programme is a 6-week home-based intervention that aims to address this need by teaching parents about early language development, and providing practical support for how to support children's language learning. The programme was designed by BHT Early Education and Training, and is delivered by Language Development Workers (LDWs); early years practitioners with extensive training in early language development. This feasibility study aims to provide an in depth understanding of the intervention, outcome measures, and trial procedures, in order to inform a later full-scale trial.

Who can participate?
Parents/carers of 2-3 year old children who have been identified as having language weaknesses by the LDWs are eligible to receive the intervention. In order to be part of the feasibility RCT, the participating child must also be no older than 2 to 2.5 years at the time of their referral, they must be learning a language at home that is spoken by a member of the LDW team (to avoid the use of interpreters), and they should have no known sensory or developmental disorders.

What does the study involve?
All eligible families are randomly allocated to one of two groups; the first group receive the Talking Together programme immediately, and the second receive the intervention after a 6-month wait, if the child still requires the programme at that point. During the waiting period, the control group receive a packet of information and activities to support children's language development that they can use independently. As part of standard practice, assessments of children's language as well as the parent-child relationship, the home environment, and children'

s behaviour are carried out in the first and final week of the intervention, as well as at a 6-month follow-up. To ensure that the control group mirrors standard practice, the families in this condition are also visited and assessed at these times.

What are the possible benefits and risks of participating?
The possible benefit for families taking part in the study is that the programme has a meaningful impact on the home language environment, and this results in improvements in children's language skills. Although no serious risks are anticipated, there is a risk that if the programme is effective, families in the waiting control group are disadvantaged by receiving the programme at a later point in their child's development.

Where is the study run from?
The programme is delivered by BHT Early Education and Training in Bradford (UK)

When is the study starting and how long is it expected to run for?
September 2018 to February 2021

Who is funding the study?
1. The Nuffield Foundation
2. Better Start Bradford

Who is the main contact?
Dr Claudine Bowyer-Crane

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EDO/43407

Study information

Scientific Title
Feasibility controlled trial of Talking Together: a targeted home-based intervention to support children's early language development

Acronym
oTTer

Study objectives
Rationale: This is a feasibility study to assess the feasibility and suitability of potential methods for conducting a randomized control trial of the Talking Together intervention. As this is a feasibility study, hypotheses related to intervention outcomes are not appropriate. However, the study will assess aspects of trial design and how appropriate they are to the specific context of this intervention, with the aim of informing a future full scale RCT of the programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of York, Department of Education Ethics Committee, Heslington, York, YO10 5DD, UK, Tel: +44 (0)1904 323460, Email: education-research-administrator@york.ac.uk, 03/09/2018

Study design
Single-site two-armed unmasked feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early language development in children aged 2-3 years

Interventions
Families eligible for the Talking Together trial will be randomized to either immediate intervention or a waiting control by data analysts outside of the research and project team. The waiting control group will receive the intervention in the same way as the immediate intervention group, but at a 6 month delay to allow for post-test and follow up in the intervention group.

The Talking Together programme is a 6-week intensive training course delivered by Language Development Workers (LDWs; early years practitioners with extensive training in children's language development). The programme takes a two-stepped approach to intervention. Firstly, a universal language screening is provided to the community. From this screening, LDWs identify families who may benefit from the programme based on both child factors (i.e. weak language development) and parent or home characteristics (e.g. parent-child interaction, a lack of developmentally appropriate materials in the home).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 30/07/2019:
The feasibility of a future, full-scale trial of the Talking Together programme:
1. Recruitment and retention of Talking Together by establishing the number of participants who were identified, eligible, approached, consented, randomised, completed the programme, and followed up 6 months after baseline [within 24 months of the beginning of the start date]
2. Representativeness of those participants eligible and recruited to the trial as compared to the wider population receiving the intervention based on key demographic indicators [within 18 months of the beginning of the start date]
3. Acceptability of the intervention and trial procedures for practitioners and families, including randomisation and completion of outcome measures [within 24 months of the beginning of the start date]
4. The most appropriate primary outcome measure for future full-scale RCT by considering the acceptability, reliability, and data quality (completeness) of currently administered outcome measures [within 24 months of the beginning of the start date]
5. Fidelity to the standardised procedures by assessing the intervention content, and the frequency and duration of support received by participants [within 18 months of the beginning of the start date]
6. Barriers and facilitators to engagement with the intervention and the trial [within 18 months of the beginning of the start date].
7. Time and resources required to train practitioners to administer the intervention, in order to make appropriate recommendations for resource requirements for full-scale RCT development [within 18 months of the beginning of the start date]
8. Intervention completion and attrition rates, along with outcome data group differences and variability across conditions, to inform sample size calculations for full-scale trial [within 30 months of the beginning of the start date]

The feasibility trial has the following progression/continuation criteria, and the results of these specific indicators will be used to inform the recommendation of whether to progress to full-scale RCT.
1. Recruitment – The proportion of participants identified and offered the intervention eligible to participate in the trial, and the number of these eligible participants who agree to participate in the trial. These numbers will be assessed cumulatively over the course of the recruitment phase: Progression criteria are as follows based on:
1.1 Eligibility
1.1.1 Green - 60% and above
1.1.2 Amber - 50%-60%
1.1.3 Red - below 50%
1.2 Consent:
1.2.1 Green - 50% and above
1.2.2. Amber - 40-50%
1.2.3 Red - below 40%
2. Protocol adherence - The proportion of participants who are seen within 4 weeks of the specified assessment timepoints at all 3 assessment points (pretest, 2 month post-test, 6 month follow up):
2.1. Green - 80% of participants have compliant assessment schedules
2.2. Amber - 60-80% of participants have compliant assessment schedules
2.3. Red - less than 60% of participants have compliant assessment schedules
3. Attrition rates - the proportion of the recruited participants that complete the 6 month follow up assessment point:
3.1. Green - 80% of participants complete this assessment point
3.2. Amber - 70-80% of participants complete this assessment point
3.3. Red - below 70% of participants complete this assessment point

Previous primary outcome measure:
The feasibility of a future, full-scale trial of the Talking Together programme:
1. Recruitment and retention of Talking Together by establishing the number of participants who were identified, eligible, approached, consented, randomised, completed the programme, and followed up 6 months after baseline [within 24 months of the beginning of the start date]
2. Representativeness of those participants eligible and recruited to the trial as compared to the wider population receiving the intervention based on key demographic indicators [within 18 months of the beginning of the start date]
3. Acceptability of the intervention and trial procedures for practitioners and families, including randomisation and completion of outcome measures [within 24 months of the beginning of the start date]
4. The most appropriate primary outcome measure for future full-scale RCT by considering the acceptability, reliability, and data quality (completeness) of currently administered outcome measures [within 24 months of the beginning of the start date]
5. Fidelity to the standardised procedures by assessing the intervention content, and the frequency and duration of support received by participants [within 18 months of the beginning of the start date]
6. Barriers and facilitators to engagement with the intervention and the trial [within 18 months of the beginning of the start date].
7. Time and resources required to train practitioners to administer the intervention, in order to make appropriate recommendations for resource requirements for full-scale RCT development [within 18 months of the beginning of the start date]

8. Intervention completion and attrition rates, along with outcome data group differences and variability across conditions, to inform sample size calculations for full-scale trial [within 30 months of the beginning of the start date]

The feasibility trial has the following progression/continuation criteria, and the results of these specific indicators will be used to inform the recommendation of whether to progress to full-scale RCT.
1. Recruitment – The proportion of participants identified and offered the intervention eligible to participate in the trial, and the number of these eligible participants who agree to participate in the trial. These numbers will be assessed cumulatively over the course of the recruitment phase:
1.1. Green - a minimum of 60% of participants are eligible, and a minimum of 50% of eligible participants participate
1.2. Red - less than 60% of participants are eligible, and less than 50% of eligible participants participate
2. Intervention adherence - The proportion of participants who are seen within 4 weeks of the specified assessment timepoints at all 3 assessment points (pretest, 2 month post-test, 6 month follow up):
2.1. Green - 80% of participants have compliant assessment schedules
2.2. Amber - 60-80% of participants have compliant assessment schedules
2.3. Red - less than 60% of participants have compliant assessment schedules
3. Outcome data – The proportion of the recruited participants with complete data at the 6 month follow up assessment point:
3.1. Green - 80% of participants have complete data
3.2. Amber - 70-80% of participants have complete data
3.3. Red - below 70% of participants have complete data

Secondary outcome measures
The outcome measures under consideration as part of the feasibility trial are all collected at pre-test and at 2 months (post-test) and 6 months (follow-up) post pre-test. All measures will be used throughout the recruitment phase with all participants:
1. Parent-child relationship, assessed using the Maternal Objects Relations Scale (MORS)
2. Home learning environment, assessed using the Home Learning Environment Questionnaire (HLEQ)
3. Child behaviour, assessed using the Strengths and Difficulties Questionnaire (SDQ)
4. Child vocabulary, assessed using Oxford Communicative Development Inventory, Short From (CDI)
5. Child broader language, assessed using the WellComm Assessment

Overall study start date
01/09/2018

Completion date
01/02/2021

Eligibility

Key inclusion criteria
1. Families must live within specified areas of Bradford
2. Families must have a child aged 2 to 2.5 years who is referred into the Talking Together programme following a screening assessment by a Language Development Worker (LDW)

3. Families must speak English, Urdu, or Punjabi at home
4. Families must be willing to receive the intervention delivered by a LDW in their home
5. Families must identify one parent/carer who will be the primary recipient of the programme, who will be present for all sessions
6. Families must be will to be randomly allocated to treatment or control group and consent to additional data collection if allocated to the control group
7. Families must be taking part in the programme voluntarily and not being required to receive Talking Together by an outside service e.g. Social Services

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
120 (60 intervention, 60 waiting control)

Total final enrolment
102

Key exclusion criteria
1. Children who have any known significant developmental disorder or sensory impairment
2. Children who are older than 2yrs 6 months at assessment
3. Children who are not singletons (twins, triples)
4. Families where the primary carer/parent to whom the intervention programme will be delivered may vary from session to session

Date of first enrolment
10/10/2018

Date of final enrolment
14/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
BHT Early Education and Training
16 Teasdale Street
Off Wakefield Road
Bradford

United Kingdom
BD4 7QJ

Sponsor information

Organisation
University of York

Sponsor details
Dept of Education
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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
Nuffield Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Better Start Bradford

Results and Publications

Publication and dissemination plan
A protocol paper is planned, and will be submitted for publication. When this is available, the registration will be updated with the reference and URL for this publication. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date
01/02/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The current research study is being carried out by collaborators at the University of York, who are data processors only. The rights to data sharing are held by the data controllers, Bradford Institute for Health Research, and the current data sharing agreements do not allow for third party data sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/10/2019	08/11/2019	Yes	No
Results article		29/06/2023	30/06/2023	Yes	No