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Parent-delivered early language intervention for young children with Down syndrome: assessing trial feasibility

Submission date
12/07/2023

Recruitment status
No longer recruiting

Registration date
14/07/2023

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Genetic Diseases

[X] 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
Language difficulties can have a long-term impact on children's educational outcomes and later job opportunities, their ability to take part in social activities and develop friendships, and their emotional wellbeing and mental health. Finding ways to support children's language development is therefore important. One of the most effective ways to do this may be to provide parents with strategies, resources, and support to foster their child's language development in the home. Parents and Children Together (PACT) is a parent-delivered language teaching programme which has previously been shown to boost typically developing preschool children's language and early literacy skills. Researchers have recently worked with families to adapt the programme for children with Down syndrome, as this group have significant language learning difficulties and need support for language development from an early age. This feasibility study aims to explore the adapted intervention (PACT-DS), measures of intervention outcomes, and trial procedures in order to inform a later, definitive trial of PACT-DS.

Who can participate?
Parents/carers of 3-6-year-old children who have Down syndrome can take part. Parents need to be able to read and speak English and families need to live within 40 miles of the University of Manchester or the University of Reading as that is where the project is taking place. Children taking part should have a minimum expressive vocabulary of 10 English words or signs, and a minimum cognitive level of 18 months which would mean for example, that the child would show interest in books, be able to attend to a picture and be able to use two hands together.

What does the study involve?
Eligible families are randomly allocated to one of two groups. The first group (PACT-DS) will be asked to attend training and provided with the PACT-DS intervention programme. They will be asked to work on the programme every day (5 days a week) for about 20 minutes a day over 30 weeks of teaching. The second group will not receive the PACT-DS programme but will instead receive three sessions of general language training throughout the 30-week delivery phase. At the end of the study, families in the control group will be given a choice of receiving PACT-DS or an alternative evidence-based reading and language intervention (RLI) which is designed

specifically for school-aged children with Down syndrome. All children and parents taking part will complete assessments of children's language as well as parent-child interactions, the home learning environment, and parent well-being before the intervention, after the 30-week intervention phase, and 6 months later.

What are the possible benefits and risks of participating?
Families taking part in the study may benefit from participation if the programme has an impact on parent-child interactions and/or the home learning environment, which may lead to gains in children's early language skills. All families will receive a summary of their child's assessment data at each time point which may be useful information about their child's language abilities and progress over the course of the study. There are no perceived serious risks involved in taking part though families in the waiting control group may be disappointed not to receive the programme at the outset. To mitigate this, at recruitment all families will be fully informed about the random allocation and potential for allocation to the control group. In addition, all families in the waiting control group will receive general language training during the delivery phase (as well as their choice of PACT-DS or an alternative intervention at the end of the project).

Where is the study run from?
1. University of Manchester (UK)
2. University of Reading (UK)

When is the study starting and how long is it expected to run for?
April 2022 to April 2025

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
Dr Kelly Burgoyne, Kelly.Burgoyne@manchester.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
ES/V016946/1

Study information

Scientific Title
A randomised controlled feasibility trial of parent-delivered early language intervention for children with Down syndrome (PACT-DS)

Acronym
PACT-DS

Study objectives
This is a feasibility study to assess the feasibility of a definitive randomized control trial of the PACT-DS intervention programme. The study will assess feasibility of trial procedures, adherence and acceptability of the intervention, as well as suitability of parent and child outcome measures in order to inform a full scale trial. Given this is a feasibility study, it is not appropriate to state specific hypothesis related to study outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/07/2023, University of Manchester Research Ethics Committee 1 (Research Governance, Ethics and Integrity; 2nd Floor Christie Building; The University of Manchester, Manchester, M13 9PL, United Kingdom; Nil known; urec1@manchester.ac.uk), ref: 2023-16509-30334

Study design
Multicenter two-armed feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Supporting early language development in children with Down syndrome

Interventions
Randomisation will be at the child level, stratified by site (University of Manchester/University of Reading) and by the child's main form of communication (spoken/sign/spoken+sign) as assessed by parent report. Randomisation will be conducted by an independent randomization service provider.

Children and their parents will be randomly allocated to the intervention (PACT-DS programme) group or to the waiting list control group. Families allocated to the PACT-DS group will be

trained to deliver PACT-DS to their child at home in daily (5 x week) sessions of about 20-25 minutes over 30 weeks of teaching. All materials and resources needed to deliver the programme will be provided. Families in the waiting control group will be offered general training on supporting language development for children with Down syndrome. This will involve three sessions, delivered to parents as a group, over the delivery phase. In addition, on completion of the trial, they will have the option of receiving PACT-DS or an evidence-based reading intervention for children with Down syndrome (RLI).

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of a future definitive trial of the PACT-DS programme, assessed using:
1. The number of participants interested in taking part, consented, completed screening, eligible, and randomised [within 18 months of start date].
2. Adherence to and acceptability of the PACT-DS intervention via measures of attendance at training, number of intervention sessions completed, number of participants withdrawing from intervention, and intervention fidelity as well as records of email and telephone support provided to families, surveys and qualitative interviews [within 33 months of start date]
3. The acceptability and experience of the trial process to participants, including randomisation and completion of outcome measures [within 33 months of the start date].
4. The optimal primary outcome measure in a future trial, determined by assessing the performance of selected candidate primary outcome measures with respect to the level of acceptability to participants (completion rates, perceived burden) and reliability [within 33 months of start date].
5. Estimated sample size for a future trial by measuring participant withdrawal, data completeness at follow-up (participant attrition) and group differences and 95% confidence intervals for child language measures at immediate and delayed follow-up [within 33 months of start date]
6. The potential benefits and costs in a future trial including benefits for child and parent outcomes and costs of intervention including intervention materials and resources and staff time for training and support (in line with recent cost guidance from the Education Endowment Foundation) [within 33 months of start date].

Progression to definitive trial will be informed by the results of three main progression criteria:
Recruitment: at least 50% of the proposed sample (n = 28-30) recruited to (i.e. take up an offered place in) feasibility study = Green; 40-49% = Amber; below 40% = Red.
Intervention adherence: will be based on the experimental group delivering the programme; i.e. 50%+ of the intervention group complete =>17 weeks of the programme (the average completion rate in Burgoyne et al., 2018) = Green; 40-49% = Amber; below 40% = Red.
Retention will be based on the proportion of the recruited sample that completes delayed post-testing (i.e. children with quantitative data at delayed post-test); i.e. 80%+ = Green; 50-79% = Amber; <50% = Red.

Key secondary outcome(s))
The outcome measures that will be evaluated within this feasibility study are listed below. The following measures are all collected at baseline (prior to randomisation) and at immediate post-test (immediately following the 30-week intervention phase) and follow-up post-test (6 months after the immediate post-test) with all participants (in both groups) with the exception of the child emergent literacy measure (assessed at 6-month follow-up only):

Child Language:
1. Child vocabulary, assessed using the parent-completed Reading Communicative Development Inventory
2. Child expressive and receptive vocabulary, assessed using the Expressive and Receptive One Word Picture Vocabulary Tests
3. Child expressive information and grammar, assessed using the Action Picture Test
4. Child Narrative Skills, assessed using a story retell task
5. Child intervention vocabulary knowledge, assessed using a researcher-developed task
6. Parent-child interaction, providing measures of child language and parent measures (e.g. responsiveness, use of language boosting strategies), assessed using video recordings of parents and children sharing books and playing together

Child Emergent Literacy (assessed only at 6-month follow-up):
7. Child emergent literacy, assessed using the York Assessment of Reading for Comprehension (assessed at 6-month follow-up only)

Home Learning Environment:
8. Home Learning Environment, assessed using a Home Learning Environment questionnaire

Child Executive Functioning:
9. Child executive functioning, assessed using the Behaviour Rating Inventory of Executive Functioning – Preschool

Parent Measures:
10. Parent Knowledge, Skills, and Confidence in relation to language development, as assessed through a questionnaire based on the Theoretical Domains Framework
11. Parent anxiety and depression, as measured by the Hospital Anxiety and Depression Scale (HADS)
12. Parental quality of life as assessed by the Adult Carer Quality of Life Questionnaire (AC-QoL)

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Child has a diagnosis of Down syndrome
2. Child aged 3-6 years at the start of the study
3. Family home postcode is within 40 miles of the University of Manchester/University of Reading
4. Parents can read and speak English
5. Child has a minimum expressive vocabulary of 10 (English) words/signs (measured via parent-completed Reading Communicative Development Inventory)
6. Child has a minimum cognitive level of 18 months (as assessed by the research team using the Mullen Scale of Early Learning)

Participant type(s)
Carer, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
6 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Twins will be excluded as they had higher levels of attrition in a previous study (with a different population)

Date of first enrolment
01/08/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PR

Study participating centre
University of Reading
Whiteknights
Reading
United Kingdom
RG6 6UR

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (UK Data Service https://ukdataservice.ac.uk/)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/12/2023	08/12/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes