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Social communication intervention for young children with Down syndrome

Submission date
31/07/2020

Recruitment status
No longer recruiting

Registration date
25/08/2020

Overall study status
Completed

Last Edited
07/10/2024

Condition category
Genetic Diseases

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

Plain English summary of protocol

Background and study aims
Down syndrome (DS) is a relatively common genetic condition which affects about 1 in every 700 babies. DS is the most common cause of learning disability. Children with DS have particular difficulties with speech and language. This makes it difficult for them to participate fully in life, access healthcare services and educational opportunities. As DS is detected before or at birth, support can be provided from early on. There are currently no standard interventions for improving the language skills of young children with DS. Existing research suggests that the earlier an intervention is carried out, the better the outcomes. Evidence suggests that early parent-based interventions might be effective in improving language. Preliminary work shows that an intervention focusing on early social communication skills (e.g. the child's ability to share focus of attention with an adult) can lead to better language in children with DS. Parents who participated in the preliminary study reported an overwhelmingly positive effect of the intervention on their children's communication. Improving the language skills of young children with DS is vital for their future social and emotional well-being and behaviour, and consequently contribution to society. The aim is to carry out a feasibility study to inform a future pilot/full trial to test whether the intervention is effective in improving language skills before children with DS start school. The feasibility study will establish whether the researchers can recruit enough children and parents through NHS Trusts for a full-sized trial, how acceptable a parent-led intervention would be for parents and speech and language therapists, and provide information on how to run a full trial.

Who can participate?
Children with Down syndrome aged between 12 and 23 months and their parents/carers

What does the study involve?
The parents receive an intervention manual which they need to follow. The sessions involve structured activities with the child playing with toys. During the parent-led intervention period, the parent can access their child's speech and language therapist (over the phone) and designated members of the research team for support. The parent will need to complete questionnaires about their child's development and also parental health and wellbeing at three timepoints (before and after the intervention, and 6 months later).

What are the benefits and risks of participating?
By taking part, parents and their children with Down syndrome will help to build the evidence base of improving children's communication skills to help others. The researchers don't foresee any disadvantages to the children or parents/carers.

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

When is the study starting and how long is it expected to run for?
August 2019 to March 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof Vesna Stojanovik
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
252332

Central Portfolio Management System (CPMS)
43910

Study information

Scientific Title

Evaluating an early social communication intervention for young children with Down syndrome: a feasibility study

Acronym
ASCEND

Study objectives
Supplementing standard speech and language treatment with a parent-led early social communication intervention, focusing on shared attention, will improve the language skill of children with Down syndrome (DS).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 04/08/2020, South Central Berkshire Research Ethics Committee (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 2071048129; berkshire.rec@hra.nhs.uk), ref: 19/SC/0572

2. Approved 27/04/2020, University of Reading Research Ethics Committee (Academic and Governance Services, Whiteknights House, PO Box 217, Reading, RG6 6AH, United Kingdom; +44 118 3787119; urec@reading.ac.uk), ref: UREC 20/15

Primary study design
Interventional

Study design
Multi-centre mixed methods randomized controlled feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Down syndrome

Interventions
The intervention focuses on developing the child's social communication skills through a structured play for which a manual and toys are provided.

Randomisation:
Once informed consent has been given and baseline assessments have been completed, participants will be randomised to receive standard care (Control) or standard care plus the intervention (Intervention). Randomisation will be achieved using a secure web-based randomisation platform, SortitionTM provided by the University of Oxford.

Intervention:
Parents/guardian will be provided with an intervention manual (paper-based) with explanation and brief training.
Parents/guardian will be advised to progress through the stages of the intervention step by step and practice three times a week for 10 weeks.

Support to deliver the intervention from the child's Speech and language therapist (SLT) will be available at the request of parents by telephone/email. SLTs may provide support by telephone /email or face to face as needed. The SLT will record all contacts from parents in the child's case notes including the duration and content of each contact.
Two telephone calls from the PI, one at week 4 and the second at week 8.

Intervention Type
Behavioural

Primary outcome(s)
Language (expressive and receptive) measured using a well-established parental questionnaire (Communicative Development Checklist) pre-intervention, immediately post intervention and at 6 months follow up.

Key secondary outcome(s)
Responding to joint attention as measured by the Communication and Symbolic Behaviour Scales (also a parental questionnaire) measured pre-intervention, immediately post and at 6 months follow up.

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Parent or guardian willing and able to provide informed consent on behalf of participant
2. Confirmed diagnosis of trisomy 21 (DS)
3. Male or female child, 12 to 23 months old at study entry
4. Parent/carer giver has the literary and language skills needed to use intervention manual
5. The participant has not previously been entered into this study
6. The child is not currently taking part or planning to take part in a language based interventional study

Participant type(s)
Patient, Health professional, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 Months

Upper age limit
36 Months

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Children with co-morbid conditions (for example Down syndrome and Autism Spectrum Disorder) as determined by the PI
2. Any reason in the opinion of the Principal Investigator that the child is not suitable for study participation

Date of first enrolment
01/09/2020

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Warneford Hospital
Oxford Health Foundation NHS Trust
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
North East London NHS Foundation Trust
West Wing, SEME Centre
Marsh Way
Rainham
London

United Kingdom
RM13 8GQ

Sponsor information

Organisation
Berkshire Healthcare NHS Foundation Trust

ROR
https://ror.org/03t542436

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data are available through the University of Reading repository https://doi.org/10.17864/1947.000470

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/10/2024	07/10/2024	Yes	No
Protocol article		17/01/2022	22/08/2022	Yes	No
Dataset			07/10/2024	No	No
HRA research summary			28/06/2023	No	No
Preprint results		25/08/2023	23/10/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes