

Social communication intervention for young children with Down syndrome

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| Submission date 31/07/2020 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 25/08/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/10/2024 | Condition category Genetic Diseases | <input checked="" type="checkbox"/> 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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Study website

<https://research.reading.ac.uk/speech-language-communication-development/ascend/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

252332

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 252332, 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

Study design

Multi-centre mixed methods randomized controlled feasibility study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/08/2019

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/carers given 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

Age group

Child

Lower age limit

11 Months

Upper age limit

36 Months

Sex

Both

Target number of participants

30

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**

England

United Kingdom

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

Sponsor details

Fitzwilliam House
Skimped Lane Hill
Bracknell
England
United Kingdom
RG12 1BQ
+44 (0)7767 481 879
Stephen.Zingwe@berkshire.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.berkshirehealthcare.nhs.uk/>

ROR

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

Publication and dissemination plan

The study protocol has been published. The study results are expected to be published in Pilot and Feasibility Studies.

Intention to publish date

31/10/2023

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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 17/01/2022 | 22/08/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Preprint results | | 25/08/2023 | 23/10/2023 | No | No |
| Dataset | | | 07/10/2024 | No | No |

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|---------------------------------|------------|------------|-----|----|
| Results article | 05/10/2024 | 07/10/2024 | Yes | No |
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