

# Improving speech, language and communication in pre-school children: implementation and effectiveness of the Sign 4 Programme, Luton, UK

<b>Submission date</b> 15/02/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/05/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The Sign 4 Programme uses sign language to support understanding and language development in hearing pre-school children. Nursery staff and parents read to children using Sign 4 story books and dolls to reinforce key words with sign language to facilitate story telling. Repeated use may help to improve children's comprehension, use of linking words, help with pronunciation and use of more complex words, as well as helping children to identify different emotions which allows them to 'name and tame' more challenging behaviours (such as 'frustrated' and 'angry'). The aim of this study is to find out whether the Sign 4 Programme improves language, speech and communication in pre-school children.

### Who can participate?

Children aged under 5

### What does the study involve?

Pre-school children take part in story time sessions in their nurseries as part of usual day-to-day activities. Children are assessed by nursery staff in four areas: listening and attention; understanding; speaking; and managing feelings and behaviour. These are part of standard assessments and are largely made through daily observation and activities. These assessments allow the tracking of progress over a period of months to assess the effectiveness of Sign 4 compared with a database of children who have not been part of the programme.

### What are the possible benefits and risks of participating?

Early results suggest that children make better than expected progress in communication skills when attending Sign 4 story sessions. There are no anticipated risks.

### Where is the study run from?

1. University of Bedfordshire (UK)
2. Flying Start Luton (UK)

When is the study starting and how long is it expected to run for?  
February 2016 to November 2018

Who is funding the study?  
1. University of Bedfordshire (UK)  
2. Flying Start Luton (UK)

Who is the main contact?  
Dr Rosemary Davidson  
rosemary.davidson@beds.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Rosemary Davidson

**ORCID ID**  
<http://orcid.org/0000-0002-0010-4809>

**Contact details**  
Institute for Health Research  
University of Bedfordshire  
University Square  
Luton  
United Kingdom  
LU1 3JU  
+44 (0)796 667 6974  
rosemary.davidson@beds.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Prof Gurch Randhawa

**ORCID ID**  
<http://orcid.org/0000-0002-2289-5859>

**Contact details**  
Institute for Health Research  
University of Bedfordshire  
Putteridge Bury Campus  
Hitchin Road  
Luton  
United Kingdom

LU2 8LE

-

gurch.randhawa@beds.ac.uk

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

FS\_Sign4\_LT\_BF

## **Study information**

**Scientific Title**

Improving speech, language and communication in pre-school children: a process and outcome evaluation of the Sign 4 Programme, Luton, UK

**Acronym**

Sign 4 Little Talkers (S4LT) and Sign 4 Big Feelings (S4BF)

**Study objectives**

The Sign 4 Programme improves language, speech and communication in pre-school children when compared with a matched control group as measured by Early Years Outcomes (EYO).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University Research Ethics Committee, University of Bedfordshire, 10/04/2017, ref: UREC104

**Study design**

Single-centre non-randomised study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

School

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Development of speech, language and communication in pre-school children, with particular focus on children who are not showing expected levels of development

### **Interventions**

Targeted intervention in early years settings versus statutorily collected Early Years Outcome (EYO) control data

The Sign 4 Programme uses British Sign Language to support understanding and language development in hearing children.

Approach 1: Designated Safeguarding Officers led, Luton wide

Approach 1 aims to implement Sign 4 Big Feelings across Luton to children assessed as having lower levels of expected development as efficiently as possible given limited resources. The intervention will be incorporated into existing safeguarding processes across the town in 50-60 schools, registered child minders, and private, voluntary or independent (PVI) nursery settings. Designated Safeguarding Officers (DSOs) will follow agreed protocols to identify and monitor a minimum of two children per setting who are below expected levels in communication and language development (and may show signs of emotional distress) as part of the evaluation, although many more children in each setting will use Sign 4. DSOs will attend a briefing session where they will learn about the intervention and receive the Sign 4 Big Feelings book and dolls. A 'light touch' ensures as great a reach as possible with early years professionals who already work with children judged to be at risk. Practitioners are asked to incorporate the story books and signing into daily routines with children, with data collected at baseline and follow-up at three months (one school term).

Approach 2: Targeted, 8 Early Years settings

Eight settings have been identified for a comprehensive roll out of the Sign 4 approach. These settings have reported lower than expected progress and attainment in communication and language as demonstrated by the Early Years Foundation Stage Outcomes data routinely collected and inputted into the Luton Borough Council Tracking System (LATS database). Children from these settings also do less well than Luton and National levels in Communication and Language and Managing Feelings and Behaviour when they are assessed using the EYFS Profile at aged 5. Head teachers and senior staff in each setting must be committed to implementing Sign 4 Little Talkers and be able to incorporate the intervention by embedding the approach into daily routines such as story time. All children in the specified age ranges appropriate for Sign 4 can access materials combining Little Talkers and Big Feelings materials, however, practitioners are led by stage of development of each child rather than chronological age. In addition, settings will identify approximately 10 children who need additional support and invite their families along for Sign 4 Little Talkers sessions so they can learn how to use the materials with their children. Practitioners are asked to incorporate the story books and signing into daily routines with children, with data collected at baseline and follow-up at six months (two school terms).

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Listening and attention, speaking, managing feelings and behaviour, and understanding are measured using Early Years Outcomes at baseline and 6 month follow-up

### **Secondary outcome measures**

Children's well-being is measured using Leuven Well-being scales at baseline and 6 month follow-up

### **Overall study start date**

01/02/2016

### **Completion date**

01/11/2018

## **Eligibility**

### **Key inclusion criteria**

1. Children under 5 years
2. Early years practitioners
3. Head Teachers/Managers of pre-schools
4. Sign 4 Trainers
5. Sign 4 Managers
6. Local Authority commissioners

### **Participant type(s)**

Mixed

### **Age group**

Child

### **Upper age limit**

5 Years

### **Sex**

Both

### **Target number of participants**

1000

### **Total final enrolment**

111

### **Key exclusion criteria**

1. Persons with no experience of Sign 4
2. Persons with no experience of working in the early years sector

### **Date of first enrolment**

01/05/2017

### **Date of final enrolment**

01/12/2017

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### University of Bedfordshire

Institute for Health Research

University Square

Luton

United Kingdom

LU1 3JU

## Study participating centre

### Flying Start Luton

The TOKKO Building

7 Gordon Street

Luton

United Kingdom

LU1 2QP

# Sponsor information

## Organisation

University of Bedfordshire

## Sponsor details

Institute for Health Research

University Square

Luton

England

United Kingdom

LU1 3JU

## Sponsor type

University/education

## Website

<https://www.beds.ac.uk/research-ref/ihr>

ROR

<https://ror.org/0400avk24>

**Organisation**

Flying Start Luton

**Sponsor details**

The TOKKO Building  
7 Gordon Street  
Luton  
United Kingdom  
LU1 2QP

**Sponsor type**

Government

**Website**

<https://www.flyingstartluton.com>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Bedfordshire

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

**Funder Name**

Flying Start Luton

**Results and Publications**

## Publication and dissemination plan

Study protocol is available on request and is to be submitted for publication. Participant information sheets and topic guides are available on request.

Two outcome articles and one process evaluation article. The outcome articles will report on data analysed from eight targeted settings and from childminders and Designated Safeguarding Officers. The process evaluation article will report on implementation and progress of the Sign 4 Programme.

## Intention to publish date

15/03/2018

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		20/05/2022	23/05/2022	Yes	No