

The language explorer clinical evaluation study

Submission date 12/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/01/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ten percent of children have delayed language in the preschool years. Some make progress without help; others need advice from a health visitor or a speech and language therapist (SLT). If a child's problems with language development continue, they may be diagnosed with Developmental Language Disorder, which can affect their learning and development. A technology company called Therapy Box has developed an app called Language Explorer. The aim of this app is to help SLTs analyse children's language abilities. It is hoped that it will support SLTs to make timely decisions about which children need therapy and what the focus of therapy should be, as well as which children may need advice and monitoring only. The Language Explorer app could save money in the NHS by reducing the time needed to carry out language assessment and potentially ensure more children receive the help they need. The app requires children to listen to a story told with pictures via the app, and then re-tell the story in their own words. This will provide an example of their language which is recorded and analysed by the app to provide a report on the child's language skills. The children will also be asked questions about the story and to repeat ten sentences. The aim of this study is to trial the app with children who have problems with their language development to see whether the Language Explorer app can be used to assess their language skills accurately. The researchers will also be asking parents and speech and language therapists about their views and experiences of using Language Explorer.

Who can participate?

Children aged between 4 years and 7 years 11 months old who have a developmental language disorder, and their parents

What does the study involve?

Children aged 6 years and 0 months to 7 years and 11 months will be invited to attend a remote appointment session with their parents. Children aged 4 years and 0 months to 5 years and 11 months will be invited to attend a face-to-face appointment in a clinical setting with their parents. All children will be asked to complete the Language Explorer app and additional language assessments. The researchers will also ask parents if they are happy to be interviewed about their child's experiences using the app. Once the software has been evaluated, it is hoped that the app can be used in NHS services across the country.

What are the possible benefits and risks of participating?

While there are no benefits to the participant, the study will provide information on how children perform on the Language Explorer app and participants' views and experiences of using the app. This information will help complete the development of the app which in turn may give speech and language therapists more time to work with more children and to reduce waiting times.

It is believed that there are no risks to the participant. However, in the unlikely event that something does go wrong and the participant is harmed during the research study there are no special compensation arrangements. If the participant is harmed and this is due to someone's negligence then the participant may have grounds for legal action for compensation against North Bristol NHS Trust but the participant may have to pay participants' legal costs. The normal National Health Service complaints mechanisms will still be available to the participant.

Where is the study run from?

The study is being run and co-ordinated by the Bristol Speech and Language Therapy Research Unit (UK)

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

November 2020 to October 2021

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Yvonne Wren, Yvonne.Wren@bristol.ac.uk

Study website

<https://www.languageexplorer.app/>

Contact information

Type(s)

Scientific

Contact name

Dr Yvonne Wren

ORCID ID

<http://orcid.org/0000-0002-1575-453X>

Contact details

Bristol Speech and Language Therapy Research Unit

Pines and Steps

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

+44 (0)117 414 3951

Yvonne.Wren@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

276718

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 276718, CPMS 44784

Study information

Scientific Title

Clinical evaluation of an automated language transcription and analysis app to assist speech and language therapists with clinical decision making in the evaluation of developmental language disorders

Acronym

ATLAS

Study objectives

1. Does Language Explorer distinguish children with Developmental Language Disorder (DLD) from children who have typically developing language skills?
2. Does the Language Explorer identify patterns of performance which distinguish groups of children with DLD?
3. What are clinicians' (speech and language therapists) and parents/carers' views of Language Explorer?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/11/2020, North of Scotland Research Ethics Committee 1, (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), ref: 20/NS/0128

Study design

Multi-site prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

See additional files for children aged 4-5 years

(ISRCTN12718815_PIS_Child4to5yrs_06Nov20_V1), children aged 6-7

(ISRCTN12718815_PIS_Child6to7yrs_06Nov20_V1), parents

(ISRCTN12718815_PIS_Parent_06Nov20_V2), and clinicians

(ISRCTN12718815_PIS_Clinician_06Nov20_V2) (added 02/12/2020)

Health condition(s) or problem(s) studied

Children with or suspected to have Developmental Language Disorder (DLD)

Interventions

Three types of participants will be enrolled in the trial:

1. Children with confirmed or suspected DLD
2. The parents/carers of these children
3. The SLTs carrying out the Language Explorer assessments

Following enrolment into the study, the child will attend for a single assessment session held either remotely or in an SLT clinic, lasting 20 minutes to 1 hour. Children aged 6 years and 0 months to 7 years and 11 months will attend a remote appointment session at home with their parent/carer, facilitated by the local SLT in the clinic. In this session, the child will be asked to complete the Language Explorer App, and the CELF-5 UK assessment, with support from a parent /carer to access these resources on a tablet device. Children aged 4 years and 0 months to 5 years and 11 months will attend a face to face appointment in a clinical setting with their parent /carer. In this session, the local SLT will support the child to complete the Language Explorer App, and the CELF- Preschool 2 UK assessment.

Parents and carers who consent to be interviewed will complete a session by telephone on a separate occasion within 1 month following their child's appointment. The session will take 20 to 30 minutes and will involve an interview about their child's experiences using the Language Explorer app.

The SLTs facilitating the Language Explorer assessment sessions will be enrolled as study participants, as the researchers will collect interview data about their experience of using the Language Explorer app. Immediately following the assessment session, a member of the research team will complete the telephone interview with the participating SLT, which will take 20 to 30 minutes.

Four types of data will be collected and analysed:

1. Language Explorer transcription and analysis scores
2. Clinical Evaluation of Language Fundamentals (specifically CELF- Preschool 2 UK and CELF-5 UK) assessment forms and subtest scores
3. SLT Clinical Judgement Form
4. Parent and SLT interview

All children recruited to the study will be assessed on the Language Explorer app. All children will also have the SLT Clinical Judgement Form completed for them. Where the appointment happens remotely, the child will be assessed on the Q-Interactive version of the Clinical

Evaluation of Language Fundamentals(CELF-5). Where it takes places in person in a clinical setting, the child will also be assessed on the Clinical Evaluation of Language Fundamentals (CELF-Preschool 2 UK).

Intervention Type

Other

Primary outcome measure

Language ability will be measured using the Language Explorer subscores and total score at a single timepoint (assessment session)

Secondary outcome measures

1. For children aged 4 years and 0 months to 5 years and 11 months, language ability will be measured by CELF-preschool 2 UK word structure and recalling sentences subtests at a single timepoint (assessment session)
2. For children aged 6 years and 0 months to 7 years and 11 months, language ability will be measured by CELF-5 UK Word Structure, Recalling Sentences, Formulated Sentences, and Understanding Spoken Paragraphs subtests at a single timepoint (assessment session)
3. Areas of language impairment will be identified via the clinical judgement form using Catalise consortium categories, completed by an SLT at a single timepoint
4. Clinician and parent views of the Language Explorer app will be measured by deriving themes from semi-structured interviews completed within 1 month of the Language Explorer assessment session

Overall study start date

01/11/2020

Completion date

31/10/2021

Eligibility

Key inclusion criteria

1. Children aged between 4 and 7 years inclusive
2. Children who speak and are exposed to only English in the home
3. Children who have been identified by a speech and language therapist as having DLD
4. Case histories that are unremarkable in terms of birth, overall development and general health

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

7 Years

Sex

Both

Target number of participants

60

Total final enrolment

15

Key exclusion criteria

1. Children with history of significant hearing problems (e.g. sensori-neural hearing loss or use of hearing aids in the case of severe and recurrent otitis media)
2. Evidence of structural or neurological disorders (e.g. cleft palate, cerebral palsy, autism)
3. Children with significant speech difficulties which impact their intelligibility
4. Children who have been assessed using one of the Clinical Evaluation of Language Fundamentals (CELF) tools in the previous 6 months

Date of first enrolment

16/11/2020

Date of final enrolment

31/08/2021

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Children's Speech and Language Therapy Sirona Care & Health

Eastgate Centre

Eastgate Road

Bristol

United Kingdom

BS6 6XX

Study participating centre

Children's Integrated Speech and Language Therapy Service for Hackney and the City

Homerton University Hospital NHS Foundation Trust & Hackney Learning Trust

London

United Kingdom

E9 6SR

Study participating centre
Paediatric Speech and Language Therapy
Newcastle upon Tyne NHS Foundation Trust
Level 3, Regent Point
Regent Farm Rd
Newcastle upon Tyne
United Kingdom
NE3 3HD

Sponsor information

Organisation

Therapy Box Limited

Sponsor details

Sun Studios
Unit 3
30 Warple Way
London
United Kingdom
W3 0RX
+44 (0)208 7493474
rbright@therapy-box.co.uk

Sponsor type

Industry

Website

<https://therapy-box.co.uk/>

Organisation

North Bristol NHS Trust

Sponsor details

Research and Innovation
Level 3, Learning and Research Building
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149330
researchsponsor@nbt.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.nbt.nhs.uk/research-innovation>

ROR

<https://ror.org/036x6gt55>

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

1. Submitting abstracts for verbal and poster presentations at conferences such as RCSLT conference, DLD Clinical Excellence Networks
2. Submitting research papers to journals such as International Journal of Language and Communication Disorders, Child Language and Teaching Therapy
3. Through the Bristol Speech and Language Therapy Research Unit newsletter
4. Emailing the clinical teams of the three research sites (Bristol, Newcastle, Hackney) through their service leads
5. Planned publication in high-impact peer-review journals

Intention to publish date

01/02/2022

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?
Participant information sheet	version V2	06/11/2020	02/12/2020	No	Yes
Participant information sheet	version V2	06/11/2020	02/12/2020	No	Yes
Participant information sheet	version V1	06/11/2020	02/12/2020	No	Yes
Participant information sheet	version V1	06/11/2020	02/12/2020	No	Yes
Protocol file	version V2	06/11/2020	02/12/2020	No	No
Basic results			13/01/2023	No	No
HRA research summary			28/06/2023	No	No