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

Short Title: The Language Explorer Clinical Evaluation Study

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NRES reference:

Chief Investigator of Clinical Evaluation Work Package:

Dr Yvonne Wren – North Bristol NHS Trust

Chief Investigator of NIHR Grant 200889, which provides the funding for this work and the development of the app, is Ms Rebecca Bright, CEO of Therapy Box.

Clinical Queries

(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?

Sponsor

North Bristol NHS Trust (employer of Chief Investigator and host for this work)

and

Therapy Box (lead applicant for research grant and developers of Language Explorer).

Funder

NIHR i4i Programme (NIHR200889)

This protocol describes the study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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STUDY SUMMARY

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 (DLD).

DESIGN This study is a clinical evaluation using a mixed methods research design consisting of analysis of quantitative assessment data and qualitative interview data

AIMS

(1) Determine whether Language Explorer can distinguish children with DLD from those who have typically developing language
(2) Determine whether patterns of performance on Language Explorer can be observed for different groups of children with DLD
(3) Understand clinician and parent/carer views of Language Explorer

POPULATION Children aged 4;0 – 7;11 years who have been identified by a speech and language therapist as having DLD.

CHILD ELIGIBILITY

INCLUSION CRITERIA

- Children aged between 4;0 and 7;11 years
- Children who speak and are exposed to only English in the home
- Children who have been identified by a speech and language therapist as having DLD or suspected DLD
- Case histories that are unremarkable in terms of birth, overall development and general health

EXCLUSION CRITERIA

- 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)
- Evidence of structural or neurological disorders (e.g. cleft palate, cerebral palsy, autism)
- Children with significant speech difficulties which impact their intelligibility

DURATION 24 months

Three clinical sites are involved in this study:

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1. INTRODUCTION

1.1 BACKGROUND

Approximately 10% of children present with delayed language in the early preschool years. Some children make spontaneous progress while others benefit from advice or interventions by health visitors or speech and language therapists (SLTs). However, a substantial number of children have language delay which continues beyond age 4, at which point they are at risk of long-term difficulties with language development. Children with persisting difficulties may be diagnosed as having a Developmental Language Disorder (DLD). Children with DLD are at substantially increased risk of poor outcomes in education, employment, relationships and mental health. Unfortunately, more than half of children with DLD are not identified and so do not receive any additional support.

1.2 RATIONALE FOR CURRENT WORK

Language sampling provides SLTs with important information about the patient's use of spoken language within a naturalistic communication environment and is considered a cornerstone of clinical practice (Miller, 1996). Such samples inform the design of intervention and the identification of children in need of support. Consistent with previous research into language sampling practices, the main barrier to more detailed language sample analysis is the time needed for transcription.

The primary problem that the Language Explorer will address is the time taken in the process of manually transcribing and analysing language produced by children during language assessment. Currently it takes 30 minutes to collect a sample of language within an assessment session and up to 90 minutes after the session to transcribe and analyse the sample. This is time that SLTs do not have but is nevertheless shown to be essential for planning effective and efficient intervention. The software will reduce the time from 120 minutes to less than 20 minutes. Furthermore, the software can be completed by a speech and language therapy assistant, freeing up the SLT's time further. This will enable SLTs to assess more children, more quickly and free up time for intervention as well as provide detailed data to inform clinical management and outcomes from intervention.

There is currently no technology which enables the transcription and analysis of child language to happen on a mobile app with supported transcription and automated language analysis and which provides a report or scaled score for performance.

We know from our survey of 90 SLTs that 100% of SLTs said they would purchase an app if it cut down on time spent transcribing and analysing language samples. This was confirmed by attendees in our focus group at the Royal College of SLTs as part of the i4i Connect project.

A survey of 257 SLTs in Australia showed that language samples were generally short, often not recorded, and analysed informally, meaning that management decisions are being made on insufficient data. Consistent with previous research into language sampling practices, the main barrier to more detailed language sample analysis is the time needed for transcription (Westerveld and Claessen, 2014). This review also indicated that by transcribing the samples, detailed analysis of children's language performance can be undertaken, allowing for effective goal-setting and assisting in objective progress measuring during and following intervention.

1.3 PATIENT AND PUBLIC INVOLVEMENT (PPI)

The Language Explorer application is being developed with funding from the NIHR i4i programme. The proposed project covered by this ethics application is one stream of work within the awarded grant. In the development of the original grant PPI representation was embedded at all points. This has been maintained in the development of the proposed work covered by this application. Currently, the tool is being used by parents and carers with their children in a citizen science activity which will lead to a normative dataset and provide information on functioning of the tool which will be used to make further developments. Children with language impairments were also supported to complete the app in schools in Bristol and Hackney.

The plans for the clinical evaluation, as described in this protocol, have been reviewed by our PPI partner, the CEO of the Association For All Speech Impaired Children (AFASIC), and amendments made in light of her comments. The protocol has also been reviewed and agreed by the local PIs.

2. PARTICIPANT ENTRY

2.1 SETTINGS

The evaluation will take place across three clinical sites: Sirona Care and Health (Bristol), City & Hackney NHS Trust and Newcastle Upon Tyne NHS Foundation Trust. The speech and language therapy service delivery model for the three clinical sites varies: Bristol and Hackney have similar care pathways while Newcastle's is different. Some study procedures will therefore vary for Newcastle; details of how will be explained throughout the protocol.

2.2 RECRUITMENT

There are three groups who will be recruited to the study:

- *Clinicians* – these are the SLTs who will carry out the Language Explorer Assessments and will be interviewed after all clinic assessments have been completed for the qualitative research activity in this study.
- *Children* – these will provide assent to be assessed at the Language Explorer Clinics.
- *Parents/carers* – these will provide consent for their children to participate in the Language Explorer Assessments and will also consent to being interviewed after the assessment for the qualitative research activity.

Clinicians

Clinicians recruited to the study have a dual role: they will be the data collectors for each of the Language Explorer assessment clinics and will therefore liaise with child and parent/carer participants on the study. They will also be participants themselves through their involvement in interviews to be carried out after the clinics. These interviews will obtain information on their views on the new app and how it can be used in and contribute to clinical care.

The Service Leads in Bristol, Hackney and Newcastle will be the Principal Investigators (PI) for each of the three recruiting sites and will be responsible for recruiting the clinicians at their

own site. They will invite SLTs who meet the 'SLT eligibility criteria' (see below) to participate in the study, i.e., will carry out Language Explorer Assessment appointments and consent to being interviewed afterwards. The PI will send an email inviting them to participate (Appendix B 'Recruitment Email (Clinicians)' together with Appendix C 'Participant Information Sheet (Clinicians)' and Appendix D 'Consent Form (Clinicians)') for return to the PI. It will be made clear that participation in the study is entirely voluntary and there will be no negative consequence if they choose not to participate. The clinician will keep one copy of the consent form for themselves and return another to the PI. The PI will retain copies of the consent forms for their own records and return the originals to the study team at Bristol Speech and Language Therapy Research Unit (BSLTRU).

Eligibility criteria for clinicians

SLTs:

- Qualified SLT working within the paediatric services who have three or more years' experience working with children with DLD and are currently working with children with DLD
- Employed by SLT service at one of the recruiting sites

All SLTs involved in recruitment (excluding those involved just in identification of eligible children) or data collection will complete GCP training prior to their involvement with the study to enable them to receive completed consent forms and collect data at the Language Explorer Assessment Clinics. They will be allocated a unique study ID number which will be used on all study documentation related to them, to maintain confidentiality (see details below re study ID).

Children

SLTs will be asked by their service leads (study PIs) (see Appendix E 'Email to Identifying Clinicians') to identify children from existing caseloads and from those who have been recently discharged (within previous three months) who meet the study criteria. A

recruitment pack containing a cover letter from local service (Appendix F), Participant Information Sheet (Parent;Appendix G), Participant Information Sheet (Child 6 to 7 yrs; Appendix R) and Participant Information Sheet (Child 4 to 5yrs; Appendix S) and Consent Forms for parents/carers (Appendix H) and children (Appendix I) will be sent out to parents/carers of eligible children with a prepaid envelope for return of the consent and assent forms to the PI of the local service. If no response has been received after two weeks, the local SLT site will contact parents by phone or email to ask if they would like more information or if they have decided not to participate. Parents/carers may want to discuss the study prior to their involvement. The Participant Information Sheet includes information on who to contact from the study team at BSLTRU in that event.

Following receipt of the consent and assent forms by the local site, the PI will allocate the child and parent/carer with a unique study ID number which will be used on all study documentation related to them (see details below re study ID). Twenty ID numbers will be provided to each site by the study team at BSLTRU prior to the start of the study. The PI, or one of the SLTs participating in the study, will then contact the parent/carer to thank them for their involvement and invite them to a Language Explorer Assessment appointment. This appointment will take place either remotely or in person on a clinical site - for further details on this, see section on Data Collection below.

At the start of the assessment, the SLT will take assent from the study child using the 'Child Assent Form' (Appendix J). If the child is too young or unable to tick the boxes themselves, or the assessment is taking place remotely, the SLT will initial the boxes. If a child is felt not to have provided assent, the assessment session will not go ahead.

<u>Eligibility criteria for children</u>

Inclusion criteria:

- Children aged between 4;0 and 7;11 years
- Children who speak and are exposed to only English in the home
- Children who have been identified by a speech and language therapist as having DLD or suspected DLD. (DLD is defined here as having moderate to severe language difficulties, not associated with other conditions but which is likely to affect their

functioning in school/preschool and likely to persist – based on the clinical judgment of a SLT)

- Case histories that are unremarkable in terms of birth, overall development and general health

Exclusion criteria

- 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)
- Evidence of structural or neurological disorders (e.g. cleft palate, cerebral palsy, autism)
- Children with significant speech difficulties which impact their intelligibility

Parents/Carers

The 'Consent Form (Parents/Carers)' (Appendix H) seeks consent for the parent to participate in a semi-structured telephone interview carried out by the study team following their child's attendance at the Language Explorer Assessment Clinic. During the interview they will be asked about the experience of their child using the Language Explorer. Consent for this will be an optional element; the parent can consent for their child to participate in the study but choose not to consent to themselves being interviewed. Parents/carers recruited to the study will be assigned a separate but related ID number to that of their child. Processes for maintaining security and confidentiality of the parents/carers identifying information will be the same as that for the child described above.

<u>Parent/Carer eligibility:</u>

- Parent/carer of a child meeting the inclusion criteria for this study

3. **OBJECTIVES**

(1) Determine whether Language Explorer can distinguish children with DLD from those who have typically developing language

(2) Determine whether patterns of performance on Language Explorer can be observed for different groups of children with DLD

(3) Understand clinician and parent/carer views of Language Explorer

4. DESIGN

4.1 TYPE OF STUDY:

This study will use mixed methods. Quantitative assessment data will be collected from the children via a novel tool (the Language Explorer app – the tool under investigation in this clinical evaluation, described below), one of two standardised assessments depending on age of the child (Clinical Evaluation of Language Fundamentals Preschool - Second Edition (CELF-Preschool 2 UK, Appendix K 'CELF-Preschool 2 UK Form) or the Q-Interactive version of the Clinical Evaluation of Language Fundamentals – Fifth Edition (CELF-5 UK, Appendix L 'CELF-5 UK Form') i.e. the 'CELF Assessments', and a 'Clinical Judgement Form' (Appendix M), completed by SLTs immediately following the Language Explorer assessment appointment.

Children's performance on the Language Explorer app will be compared with that of a normative sample, collected from 600 children in 6 month age bands from across the UK in a separate Citizen Science workstream (ethics approval for this has been granted by the University of Bristol and data collection is in process). This analysis will enable us to determine whether the app can be used to distinguish children with DLD from those who are typically developing.

Children's performance on the app will also be compared with scores on subtests of the standardised CELF assessments and also the SLT clinical judgement of the child's needs. This analysis will enable us to determine whether the Language Explorer can be used to distinguish different patterns of performance in children with DLD which could be used to provide guidance on clinical need and management to speech and language therapy services in the future.

The sample size will be too small to determine sensitivity and specificity and predictive values but instead will provide exploratory data to determine whether a fully powered study to determine validity is required.

Qualitative data will be collected from SLTs and parents/carers through semi-structured interviews to determine the value of the app to clinicians and service users and to identify any modifications which might be needed to improve its functioning and appeal.

4.2 DATA COLLECTION:

Four types of data will be collected and analysed:

1) Language Explorer transcription and analysis scores (screenshots in Appendix N)
2) Clinical Evaluation of Language Fundamentals (specifically CELF- Preschool 2 UK and CELF-5 UK) assessment forms and subtest scores (Appendix K and L).
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 following the protocol below. 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) following the protocol below.

This means that data from all children in the study will be able to be used to address the first aim of the study – to determine the ability of the Language Explorer app to distinguish children with DLD from those who have typically developing language. The Clinical Judgement Form will also be available for all children to investigate the second aim of determining whether patterns of performance can be observed on the Language Explorer app which fits with needs identified by a SLT. Further investigation of this aim will be carried out using the additional data from the comparator assessment for a subsample.

More details on each type of data are as follows:

1) Language Explorer

The Language Explorer is an app which has been developed with funding from the NIHR i4i programme to provide a tool for SLTs to use to assist in assessing children's language abilities. Details of each of the tasks within Language Explorer which children are asked to complete are as follows:

Story Re-Tell:

This task requires the child to listen to a story and then re-tell it to produce a sample of narrative language skill. The story is about a boy and a dog going on an adventure to find some treasure. The story is narrated and contains static pictures which change automatically as the story progresses. The adult will tell the child to first listen to the story whilst looking at the pictures and that it will then be the child's turn to re-tell the story. The child will then listen to the story and then re-tell it using their own words. The app automatically records the child's response and provides an automatic transcription, which is checked and corrected as necessary by the SLT and then used by the app to provide an automatic analysis of the child's expressive language functioning on the story retell task.

Story re-tell was chosen as the means of receiving a narrative from children as this has been found to be more useful in identifying strengths and weaknesses in oral narrative skills than story generation or personal narratives (Westerveld and Gillon, 2010) and story generation may underestimate syntactic ability (Frizelle et al, 2018).

Comprehension Task:

The second task follows on immediately after the story re-tell task. It requires the child to listen to ten questions about the story they have just heard and re-told. For each question, four possible answers will be shown in pictures. The child will then be required to indicate their response by selecting one of the four pictures. The app saves the child's responses and provides a total number of correct responses in the final report. The app then automatically moves on to the last task.

Sentence Repetition Task:

The last task requires the child to listen to a total of ten sentences which have been pre-recorded in the app. The child must then repeat each sentence to the best of his/her ability. The app automatically records the child's responses and provides a percentage of words that were the same/different in the final report. The sentence repetition task is included in the app as these tasks have been found to be sensitive to identifying DLD (Conti-Ramsden et al, 2001).

2) Clinical Evaluation of Language Fundamentals Preschool - Second Edition (CELF- Preschool 2 UK) and Clinical Evaluation of Language Fundamentals – Fifth Edition (CELF-5 UK Q-Interactive version) the 'CELF Assessments'

These are standardised assessments which consist of subtests addressing receptive language, expressive language, language content and language structure. Due to the age range of the children in this study, two different versions of the CELF assessments will be used. The Clinical Evaluation of Language Fundamentals Preschool - Second Edition (CELF- Preschool 2 UK; Appendix K 'CELF-Preschool 2 UK Form') will be used for children aged 4 years 0 months to 5 years and 11 months and the Q-Interactive version of the Clinical Evaluation of Language Fundamentals – Fifth Edition (CELF-5 UK; Appendix L 'CELF-5 UK Form') will be used for children aged 6 years 0 months to 7 years and 11 months. The subtests involve stimuli in the form of pictures and verbal requests which they must respond to, either verbally or through picture selection. For example, within the 'Formulated Sentences' subtest, the child is shown a picture and asked to use a specific word (e.g. 'book') in a sentence about that picture. The child's response is notated verbatim in the score sheet and their responses within and across subtests are scored according to the test manual to provide raw scores which can then be converted to standardised scores (scaled score, percentile rank, age equivalent, confidence interval).

The following subtests are included in each of the two assessments and will need to be completed in the order as follows:

<u>CELF- Preschool 2 UK:</u>

1. Word Structure (Expressive Core)
2. Recalling Sentences (Expressive)

CELF- 5 UK:

1. Word Structure (Expressive Core)
2. Recalling Sentences (Expressive Core)
3. Formulated Sentences (Expressive Core)
4. Understanding Spoken Paragraphs

3) SLT Clinical Judgement Form

A SLT will be asked to complete the 'Clinical Judgement Form' (Appendix M 'Clinical Judgement Form'). This could be the SLT completing the Language Explorer and CELF assessments or another SLT in the team, if they have greater knowledge and experience of the child's skills and areas of need. This form has been designed to gather information about the SLT's clinical judgement of the child based on their observations during the assessment and the child's performance on the subtests and any previous knowledge they have about the child from clinical notes or their own experience.

The data from this will be used to identify whether patterns of performance on the Language Explorer can be matched to observations from the SLTs regarding the child's needs.

4) SLT and Parent Interviews

An interview schedule will be used to guide qualitative data collection from SLTs and parents/carers, (Appendix O 'Interview Schedule (SLT)' and Appendix P 'Interview Schedule (Parent)').

4.3 PROCEDURES FOR DATA COLLECTION:

The procedures for collecting the data vary for each data type and will be described here:

1) The Language Explorer

Each clinical site will collect data from 20 children. Two protocols for collection of Language Explorer data are provided: one for remote facilitation for children aged 6 years 0 months to 7 years 11 months and one for when the app is used in person in the clinical setting for children aged 4 years 0 months to 5 years 11 months.

Remote (ages 6 years 0 months to 7 years 11 months):
Parents will be contacted in advance of the remote appointment by the local SLT and asked to download the Language Explorer app to a compatible device. Wherever possible this will be on a tablet, but if that is not available, the child could be assessed on a mobile phone. At the agreed time for the remote assessment, the SLT will take assent from the child and confirm eligibility and confirm consent as outlined in the consent forms. S/he will then ask the parent facilitating the session to open the Language Explorer app. The SLT will ask the parent to use the child's unique study ID number as their username for the tool. This will ensure that the data can be retrieved by the developers and provided to the local SLT and to the study team at BSLTRU. The parent will then be asked to use the Language Explorer app to collect a language sample from the child using the usual processes involved in the tool (i.e. child hears a story and retells it and then completes comprehension and sentence repetition tasks as described above). The app will record the child's speech as they respond to the stimuli and questions on the tool. For the data to be useful and the child's data to be included in the analysis, the story retell task must be completed as a minimum. The app will use this recording to generate an automated transcription. See Appendix N 'Language Explorer Screen shots' for images taken from the app.

During this, the SLT will observe the process. This is important to facilitate transcription of the recorded sample and for the process of being interviewed by the study team later.

In person in a clinical setting (to include NHS clinics, schools, early years settings) (ages 4 years 0 months to 5 years 11 months):

The SLT carrying out the assessment sessions will follow exactly the coronavirus infection control protocols for carrying out assessments in person in a clinical setting, as specified by their service. At the start of the assessment, the SLT will take assent and confirm eligibility and consent as described above. The SLT will then open the Language Explorer app and use the child's unique study ID number as their username and use the app to collect a language sample, as described for the remote setting. The SLT service will have been provided with iPads with Language Explorer already loaded. Once data collection for the Language Explorer app is complete, the SLT will begin the assessment on the Clinical Evaluation of Language Fundamentals assessment as described below.

2) The CELF Assessments and Clinical Judgement Form

Remote (ages 6 years 0 months to 7 years 11 months):

When the child has completed all tasks of the Language Explorer app, assessed using the Q-Interactive version of the CELF-5, completing these tasks in order: Word Structure (Expressive Core), Recalling Sentences (Expressive Core), Formulated Sentences (Expressive Core), Understanding Spoken Paragraphs. The child's direct involvement in data collection ceases at this point and the appointment can be concluded.

In person (ages 4 years 0 months to 5 years 11 months):

When the child has completed all tasks of the Language Explorer app, the child will be assessed by the SLT using the CELF-Pre-school 2 assessment. The subtests of the CELF assessments will be carried out in the order: Word Structure (Expressive Core) followed by Recalling Sentences (Expressive).

The SLT will be able to carry out any additional assessments that s/he would typically use to inform clinical judgement of the child's language competence but data from these will not be collected by the study team or used in the research.

Following completion of the CELF assessments carried out by the SLT, the SLT will score the CELF assessment for raw scores, sum of subtest scaled scores, standard scores, percentile ranks and confidence intervals, following the scoring guidelines in the manuals. Once the scoring has been carried out, the SLT will complete the Clinical Judgement form. Alternatively, the SLT who has completed the Language Explorer and CELF assessments can ask another SLT in the team who is more familiar with the child to complete the Clinical Judgement Form.

To ensure robustness, the scoring of the CELF assessments, scoring will be repeated by the study team on receipt of the forms to the study team at BSLTRU. Any subtests that were discontinued outside of the discontinuation rules described in the CELF manuals will be discarded.

(3) Correcting the Language Explorer automatic transcript

After the assessment session (either remote or in in person in the clinical setting, after the CELF assessment has been completed), the SLT will access the Language Explorer app recording and automatic transcript for the child. (This will be available on the app for those children who have been assessed in person in a clinical setting. For those assessed remotely, this will be made available by Therapy Box to the SLT). This should take place as soon as possible after the assessment session but within a maximum of 3 days. S/he will correct the transcription as necessary, consistent with the usual procedures for the tool. The corrected transcription will then be automatically collected via the app and transferred to a secure AWS server. This will require a Wi-Fi connection. If this is not available in the clinic where the Language Explorer Assessment takes place, the SLT will go to an NHS setting where there is a Wi-Fi connection and initiate the transfer there within one week of receiving the transcript for correction. In the meantime, the device holding the data will be stored in a secure setting. The audio recording and transcription will also be securely transferred to BSLTRU so that the study team can measure inter-rater reliability between the SLT checked transcriptions and those transcriptions corrected by the study team. A proportion (20%) of transcripts will also

be transcribed twice by the same transcriber from the study team at BSLTRU to measure intra-rater reliability of the corrected transcription process.

Once the corrected transcript data has been received at Therapy Box offices, a report of scores from the automatic analysis of the corrected transcription will be generated. This report will be made available to the SLT and to the study team at BSLTRU by the app developers Therapy Box.

The clinicians recruited to the study will make a copy of all study documentation for the child's speech and language files/medical records, ensuring to redact the child ID and replacing it with the child's name on the photocopies for the files/medical records only. All original documentation will be sent to the study team at BSLTRU, North Bristol NHS Trust, where they will be stored securely in a locked filing cabinet. The documentation will also be scanned and stored on the North Bristol NHS trust server in folders which are password protected and can only be accessed by the study team.

4) Clinician and Parent/Carer Interviews

Following the Language Explorer assessment clinic, the study team will contact the parents/carers of those children who have been assessed using the Language Explorer app and who consented to be interviewed. They will also contact the SLTs who carried out the Language Explorer assessment clinics to arrange a suitable time for the telephone interview. While the parent interviews will be arranged to take place within one month of the child's assessment, the SLT interviews will take place after all Language Explorer Assessment appointments have been completed at the recruiting site. The interviews will be undertaken by the study team from BSLTRU. At the start of the interview, the participant will be reminded that the interview will be audio recorded and check again that the participant consents to this. It will also be explained that the recording will be transcribed to allow for analysis of the data and that any identifying information will not be transcribed but will be pseudonymised using the participants' study ID codes. The research associate will then start the recording and begin the interview, using the interview schedule. North Bristol NHS Trust telephone system allows for telephone calls to be recorded and the audio file to be directly emailed to a secure

NHS email address. This process will allow the researcher to directly save the generated .mp3 file onto North Bristol NHS Trust server in the study folder, using the participants' study ID codes as the identifier. The audio recordings will be manually transcribed by the research associate or by an administrator employed by BSLTRU.

The flowchart below outlines the procedures for recruitment and data collection for child participants in the study:

Site initiation visit (can take place on site or remotely)

IDENTIFICATION

- Local site PI asks SLTs to identify children who fulfil eligibility criteria from their caseloads and from recently discharged cases
- SLTs send recruitment packs (prepared by the study team at BSLTRU) to parents/carers of eligible children in the post or by email
- SLTs contacts by phone or email if no response received within two weeks
- If parents/carers have any concerns/questions, details of who to contact from the study team are available in the Participant Information Sheet

RECRUITMENT

- Parent/carer returns consent forms to local site PI in prepaid envelopes included in recruitment packs.
- Parent/carer and child are allocated unique study IDs by the local site PI, from a list provided by the study team at BSLTRU
- Parent/carer is contacted by local site PI or a SLT participating in the study to arrange a suitable time for a remote or clinic based Language Explorer assessment appointment
- All consent forms copied for local site and originals sent to BSLTRU

LANGUAGE EXPLORER ASSESSMENT APPOINTMENT

carried out by a GCP trained SLT either remotely or in person in a clinical setting

Remote (6;0 – 7;11)**:**

- Prior to appointment, SLT provides information to parent/carer for download of the Language Explorer app onto a suitable device.
- SLT takes assent from the child and confirms eligibility at the start of the appointment
- SLT asks parent/carer to open Language Explorer app
- SLT provides parent/carer with unique study ID number to use as username on app
- Parent/carer uses app with child (minimum data collection = story retell task)
- SLT observes process
- SLT completes subtests on CELF assessment
- Appointment ends
- SLT scores CELF

Clinical Setting (4;0 – 5;11)**:**

- SLT takes assent from the child and confirms eligibility
- SLT opens Language Explorer on Ipad provided by app developers
- SLT uses unique study ID number for username on Language Explorer app
- SLT uses app with child (minimum data collection = story retell task)
- SLT completes subtests on CELF assessment
- Appointment ends
- SLT scores CELF

After the assessment appointment:

- SLT completes Clinical Judgement Form – or asks colleague who knows child better to do this
- SLT accesses Language Explorer automatic transcript and corrects it (App developers Therapy Box will provide access to the automatic transcript for those which have been carried out remotely)
- SLT ensures all study documentation is labelled only with child's unique study ID and no identifying information
- All study documentation sent to study team at BSLTRU using prepaid envelopes provided by study team
- Automatic transcriptions and recordings sent to study team at BSLTRU by app developers Therapy Box
- Automatic report from Language Explorer generated by automatic transcript will be made available to local SLT and study team at BSLTRU (with unique study ID only and no identifying data)

5. DATA MANAGEMENT

A full data management policy is given in Appendix Q. The four data types will be managed and stored as follows:

1) Language Explorer Data

All data will be collected on the Language Explorer app. This will consist of: recordings of the child carrying out the story retell task and the sentence repetition task; the child's responses to the comprehension task; the corrected transcript from the story retell task; and the automatic analysis report from the story retell and sentence repetition tasks. All data collected in the app will be labelled with the child's study ID code and stored on a secure AWS server. The data will be made available to the study team in Bristol who will be able to download the data to the secure servers at North Bristol NHS Trust. Access to the data will be password protected and limited to members of BSLTRU.

A database will be constructed by the study team at BSLTRU which will contain participants' study ID codes and data from each data source. Scores from each of the Language Explorer Assessment tasks will be added when the data are received from Therapy Box.

2) CELF Assessment Data

The CELF assessment forms will be labelled with the child's Study ID number, the date of the assessment and the child's date of birth (to facilitate confirmation of the child ID and calculation of standard scores). No identifying information will be included. The forms will be returned along with other study documentation (consent and assent forms) to the study base at BSLTRU in prepaid envelopes given to the recruiting site. Alternatively, they can be scanned on site and emailed to the study team using a secure email address. On receipt at BSLTRU, the forms will be scanned (if hard copy) onto a secure server at North Bristol NHS Trust. The scores from the assessment forms will be added to the study database.

3) Clinical Judgement Forms

These forms will be labelled in the same manner as the CELF assessment forms and sent with them to the study team at BSLTRU. On receipt, the information on the Clinical Judgement forms will be added to the database.

4) Interview data

The recordings and transcripts will be securely stored in the study folder, held on the secure NBT server and labelled with the participants' study ID codes

6. DATA ANALYSIS

Descriptive statistics for the Language Explorer tasks and the CELF assessment scores will be generated.

Initial qualitative analysis of the Language Explorer automatic language analysis report will be carried out to determine scores for outputs obtained in the report (e.g. mean length of utterance, types of words used e.g. nouns, verbs, adjectives and grammatical markers used e.g. regular plural s, possessive s and past tense -ed). Performance on these sub-scores for the clinical sample will be compared with those obtained from children assessed in the separate Citizen Science workstream. Using a known groups methodology, we will determine if the children with DLD can be distinguished from children with typically developing language based on scores on the Language Explorer.

Further analysis will use Language Explorer scores in a correlation analysis with the CELF assessment sub-scores to determine the strength of the relationship between the sub-scores on the Language Explorer and children's performance on the CELF assessment subtests and core scores (also continuous scores).

Cluster analysis of the sub-scores from the Language Explorer app will be carried out to determine if patterns of performance can be observed. Any patterns identified will be

considered against the information on areas of clinical need identified on the Clinical Judgement form and sub-score performance on the CELF.

Transcripts of the SLT and parent/carer interviews will be analysed using thematic analysis, following the process outlined by Braun and Clarke (2006). After reviewing the data, the team will identity initial codes representing themes that arose during the interviews. These initial codes will be discussed through meetings with members of the study team and a common set of initial codes will be agreed upon, named, and defined. Each researcher will apply these codes to their data, all the while remaining open to new codes. Through discussions, these initial codes will be subsequently further refined and re-named as necessary and will then be grouped into sub-themes and cross-checked to ensure that they capture the meanings in the data.

7. ARCHIVING

Archiving of this project will follow the sponsors (NBT) guidelines, as outlined in SOP RI/QMS/SOP/010

8. Safety Reporting

Serious and other adverse events will be recorded and reported in accordance with the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines, MEDDEV guidance on medical devices and the Sponsor's Research related adverse event reporting policy.

8.1 Definitions

Investigational Medical Device: Medical device being assessed for safety or performance in a clinical investigation

Adverse Event: Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device.

A serious adverse event (SAE): Any serious untoward clinical occurrence as a result of a trial related procedure, that:

- Results in death
- Is life threatening – defined as an event in which the subject was at risk of death during the time of the event
- Requires hospitalisation or prolongation of existing hospital admission
- Results in persistent or significant disability or incapacity

Device deficiency: Inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer.

Adverse Device Effect (ADE): Adverse event related to the use of an investigational medical device.

Serious Adverse Device Effect (SADE): Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated Serious Adverse Device Effect (USADE): Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

Clinical judgement should be exercised in deciding whether an adverse event/reaction should be classified as serious in other situations. Important adverse events/reactions that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

8.2 Expected AEs, SAEs, ADEs, and SADEs

8.2.1 Expected AEs

- Parent or child dropping or otherwise breaking the Language Explorer device

- Injury received due to the breakage of the language explorer device

- Child withdraws assent to participation in the assessment

8.2.2 Expected SAEs

- No SAEs are expected as a result of the trial.

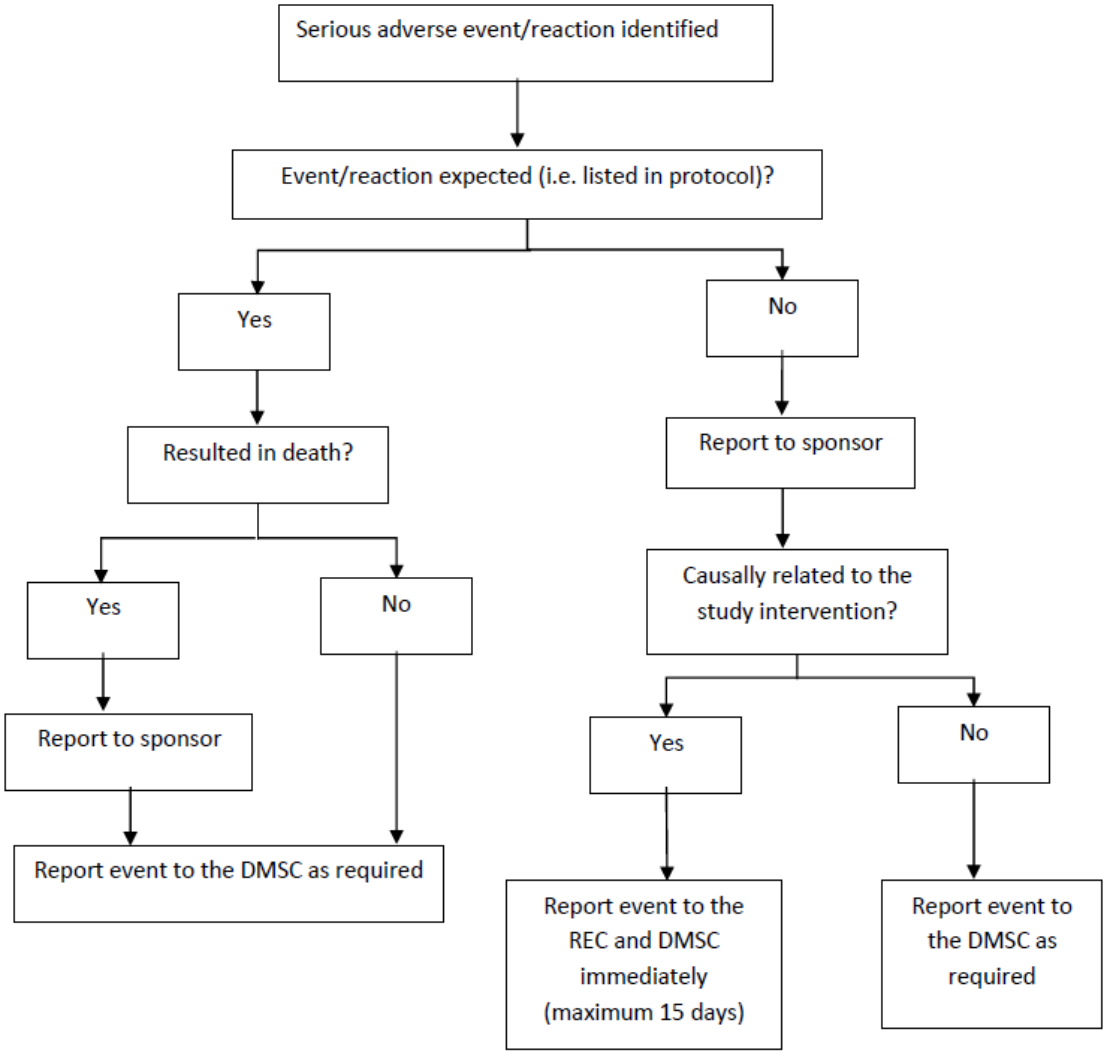
8.2.3 Expected ADEs

-Instructions not clear and users not able to access or use the device.

8.2.4 Expected SADEs

- No SADEs are expected as a result of the trial.

Adverse and serious adverse event reporting flow chart:



8.3 Recording and reporting procedures Any questions concerning adverse event reporting should be directed to the trial manager at BSLTRU in the first instance, who will in turn contact other necessary personnel depending on the nature of the query.

Events that meet criteria for an unexpected SAE should be documented on an SAE form and be reported to the BSLTRU within 24 hours of the event occurring. BSLTRU will forward this to the site PI, study CI and Sponsor. BSLTRU will report suspected unexpected serious adverse reactions (SUSARs) to the REC and copy all reports to the sponsor.

All reported events should be followed to resolution, including those which lead to withdrawal from the trial. The decision to withdraw a patient from the trial due to an adverse event or reaction rests with the local PI. Should a patient request withdrawal, outcome data will still be gathered unless consent for this is also withdrawn.

8.4 Period for recording serious adverse events

Data on adverse events will be collected from recruitment for the duration of the individual's participation in the trial, to the end of their participation, i.e., completion of data collection.

9. REGULATORY ISSUES

9.1 ETHICS APPROVAL

Once Sponsorship approval has been obtained, the Integrated Research Application System (IRAS) will be used to obtain ethical approval and a submission will be made for Health Research Authority (HRA) approval as well. Medicines and Healthcare products Regulatory Agency (MHRA) approval will also be sought.

9.2 CONSENT

Consent forms from clinicians (Appendix D 'Consent Form (Clinicians)') recruited to the study will be collected by the site Service Lead, copied and the originals sent to the study team at BSLTRU.

All consent forms, together with the child participants' assent forms (Appendix J) will be copied and the originals sent to the study team at BSLTRU. On receipt of all consent forms and assent forms at the study base at BSLTRU, they will be scanned and saved to the North Bristol NHS Secure Server. Access will be limited to members of BSLTRU.

An electronic site file will be maintained at each site. All documents will be password protected within a folder on each site's shared drive. The site file will include a subject recruitment log; one each for clinicians, children and parents/carers. The recruitment logs will contain all participants' names and study ID numbers. Limited information from the recruitment log will be sent to the study team at BSLTRU using a password protected document containing the ID numbers for all recruited SLTs, children and parents/carers.

The electronic site file will also include a delegate log to indicate which individuals are GCP trained and have also received training from the study team at the site initiation visit. The site initiation visit will cover the process of ensuring eligibility prior to identification, ensuring consent from completed consent forms and taking assent from children as well as how to carry out the Language Explorer assessment with child participants following the study protocol.

9.3 CONFIDENTIALITY

All data will be kept confidentially and pseudonymised using unique study ID number for all participants. The full identity of each study ID number will be known only to the local site team and the study team at BSLTRU. The document held at each clinical site and the study site linking the study ID with the child's identifying information will be kept securely and confidentially. Each clinical site will only have study ID information for those children recruited at their site.

Clinicians, parents and children who consent to participate in the study will be allocated a study ID number on receipt of the completed consent form. The clinicians will be informed of their own study ID code so that they can use this on all documents related to the study (e.g.

CELF assessment forms) rather than their own names. These codes will be used to label all data collected in the study.

The subject recruitment log and the consent/assent forms will be the only places where identifiable information is available. These will be stored securely as described above and separate from any data collected in the study.

Generating Unique Study ID Number:

The unique study ID number will be generated as follows: The first two digits will be the clinical site number (e.g. Bristol = 01, Hackney = 02, Newcastle = 03). The next two digits will describe the participant (e.g. child = 01, parent/carer = 02, SLT = 03. The final two digits will represent the order in which consent was received.

Example ID Code = 010101 (Bristol clinical site, child, first child consent form received).

Example ID Code = 020302 (Hackney clinical site, SLT, second clinician consent form received).

Language Explorer:

The data collection methodology for Language Explorer ensures the data collected is pseudonymised, using the child's study ID number. Although the Language Explorer app collects some information about the user, this is limited to ensure that identification is not possible. Specifically, when recording the age of the participant, only their Birth Month and Year are collected; when requesting the user's location, the user is only required to provide the first half of their Post Code.

Interview Data:

SLTs and parents/carers will be asked not to provide identifying information about themselves, their service, or any third parties during the interview. If any identifying information is provided, this will be made anonymous during transcription. The SLTs' and parent/carers' unique study ID number will be used in any written documentation. Recordings will be saved using the unique study ID number as the titles. The recordings will be securely stored on a password protected computer at BSLTRU, on the NBT server. Transcription of recordings will be undertaken by the RA/administrative clerk at the BSLTRU.

9.4 INDEMNITY

This is an NHS-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an *ex-gratia* payment may be considered in the event of a claim.

9.5 SPONSOR

North Bristol NHS Trust and Therapy Box will be adopting a co-sponsorship model.

NBT will monitor protocol compliance, safety and deviation reports where it relates to the conduct of the study (not the device). All deviations will be reported to MHRA.

Therapy Box will be responsible for the device and its function and design.

9.6 FUNDING

This study is funded by NIHR i4i programme (NIHR200889).

9.7 MONITORING

Monitoring is an integral role in the quality control of a research study and is designed to verify the quality of the study. According to ICH GCP (paragraph 5.18.1), the purpose of monitoring is to verify that:

(a) The rights and well-being of the human subjects are protected;
(b) The reported trial data are accurate, complete, and verifiable from source documents; and
(c) The conduct of the trial is in compliance with the currently approved protocol/amendments, with GCP, and with the applicable regulatory requirements.

As the CI is an employee of NBT and NBT are sponsoring this pilot project, SOP RI/QMS/SOP/014 will be followed in relation to monitoring.

10. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated by Dr Yvonne Wren, Director, Bristol Speech and Language Therapy Research Unit, Pine and Steps, Southmead Hospital, Bristol, BS10 5NB.

11. PUBLICATION POLICY

The research findings will be disseminated in the following manner:

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 BSLTRU newsletter
4 Emailing the clinical teams of the three research sites (Bristol, Newcastle, Hackney) through their service leads.

12. REFERENCES

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13. APPENDICES

- Appendix A ‘Protocol’
- Appendix B ‘Recruitment Email (Clinicians)’
- Appendix C ‘Participant Information Sheet (Clinicians)’
- Appendix D ‘Consent Form (Clinicians)’
- Appendix E ‘Email to Identifying Clinicians’
- Appendix F ‘Cover Letter to Parents’
- Appendix G ‘Participant Information Sheet (Parent)’
- Appendix H ‘Consent Form (Parent)’
- Appendix I ‘Consent Form (Child)
- Appendix J ‘Child Assent Form’
- Appendix K ‘CELF-Preschool 2 UK Form’
- Appendix L ‘CELF-5 UK Form’
- Appendix M ‘Clinical Judgement Form’
- Appendix N ‘Language Explorer Screenshots’
- Appendix O ‘Interview Schedule (SLT)’
- Appendix P ‘Interview Schedule (Parent)’
- Appendix Q ‘Data Management Policy’
- Appendix R ‘Participant Information Sheet (Child 6 to 7yrs)’
- Appendix S ‘Participant Information Sheet (Child 4 to 5yrs);