

[Trust Logo]



Bristol Speech and
Language Therapy
Research Unit



The Language Explorer Clinical Evaluation Study Participant Information Sheet (Clinician)

Invitation to take part in a 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

We hope that this information sheet will help you to decide whether or not to take part in this study.

Who am I?

My name is Dr Yvonne Wren and I am the Director of Bristol Speech and Language Therapy Research Unit (BSLTRU).

What is this project about?

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 (DLD), which can impact on 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 benefit from advice and monitoring only. The Language Explorer app could save money in the NHS by reducing the time required to carry out language assessment and potentially ensure more children receive the help they need.

BSLTRU is carrying out a clinical evaluation of the Language Explorer app. We are asking SLTs from your service to use the app with children who have been already identified by your service as having DLD. For children aged 6 years 0 months to 7 years 11 months this will happen remotely with parents using the app at home. For children aged 4 years 0 months to 5 years 11 months the children will be supported to complete the app in person during an assessment session in a clinical setting. In addition to completing the app, the children in the younger cohort (aged 4 years 0 months to 5 years and 11 months) will be assessed in person using the CELF-2 UK and the older cohort (aged 6 years and 0 months to 7 years and 11

months) will be assessed remotely using the Q-Interactive version of the CELF-5 UK. After the session, we will also ask the parents and SLTs about their views and experiences of using Language Explorer.

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 a sample of their language which is recorded and automatically transcribed by the app. The automatic transcription is then used as the basis for the automatic language analysis, which is carried out by the app, leading to a report of the child's language abilities in a narrative story retell task. The app also carries out a basic comprehension task, using the story as stimuli, and a sentence repetition activity.

The evaluation of the app is taking place at three NHS Trusts across the country. It will provide preliminary information regarding how effective and efficient the software is at identifying children with DLD and will determine whether a full scale clinical evaluation with a large sample size is needed. Ultimately, and if the clinical evaluation supports it, the aim is to produce an app that is fit for purpose to be used in NHS services across the country.

Why have I been selected?

[Sirona Care & Health in Bristol] / [City & Hackney NHS Trust] / [Newcastle Upon Tyne NHS Foundation Trust] is one of the research sites involved in this project and will be collecting data which will be used in the clinical evaluation. Your service lead has sent you an email asking if you would consider participating in the study, because you are a qualified SLT with 3 or more years' experience working with children with DLD and currently working with children who have DLD. If you decide you would like to participate in the study, your role will be to carry out Language Explorer assessment appointments with children from your organisation who are participants in the study. You will then become a participant in the study yourself and be interviewed about your experience of using Language Explorer.

Participation in this study is entirely voluntary. You can choose not to participate and should you agree, you can withdraw from the study at any time with no consequences.

Do I have to take part?

No, taking part in this study is entirely voluntary. You can choose not to participate and, if you agree to participate, you can withdraw from the study at any time with no consequences to you.

What will my role on the Language Explorer study be?

Parents of eligible children who are known to your service will be sent information about the study and asked if they want to consent to their child being assessed for the study. Appointments for the Language Explorer Assessment will be made for those parents who return consent forms. Your role will be to carry out the Language Explorer Assessment appointments. This appointment will happen remotely for children aged 6 years 0 months to 7 years 11 months and in person in a clinical setting for children aged 4 years 0 months to 5 years 11 months.

For the remote appointment for the older cohort of children, you will liaise with the parents prior to the appointment to ensure they can download the Language Explorer app onto a suitable device. At the time

of the appointment, you will explain to the parents and child what will happen during the assessment appointment. You will confirm eligibility (i.e. that the child is eligible to participate in the study) and ask the child if they are happy to continue with the assessment and take assent. You will then ask the parent to complete the Language Explorer Assessment with their child, observing the process as they do it. You will provide their unique user ID to do this so that the child's name does not need to be used on the app. The app is very easy to use and will only require minimum guidance. After they have completed the app, you will assess the children on the Q-Interactive version of the CELF-5.

For the younger cohort of children for whom the the appointment will happen in person in a clinical setting, you will need to exactly follow all covid-19 infection control protocols for assessing children face to face, as advised by your service.

In the appointment taking place in person in a clinical setting, you will not need to ask the parent to download the app but instead will have it available to use yourself with the child on a suitable device provided for the study. After explaining to the parents and the child what will happen during the appointment and confirming eligibility and taking assent from the child (as in the remote session), you will assess the child using the Language Explorer app. After this, you will carry out subtests of the CELF-Preschool 2 UK (specifically the Word Structure and Recalling Sentences subtests). Immediately after the appointment, whether remote or face to face, you complete a clinical judgement form which provides brief information on your clinical assessment of the child. This will be used by the study team together with the data from the Q-Interactive version of the CELF-5 / CELF- Preschool 2 UK to evaluate the Language Explorer app.

Once all of the Language Explorer clinics have been completed, we would like to interview you on the phone to discuss your views and experiences of using the app. This interview will take place at a time and date to suit you. The interview will be informal and will last approximately 20-30 minutes.

Are there any benefits or risks to participants involved in the study?

While there are no direct benefits to you by participating in this study, the information from this study will help to refine the Language Explorer app.

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

How will we use information about you?

This information will include your name and work contact details. Members of the research team will use this information to check your records to make sure that the research is being done properly. People outside the research team or regulatory authorities auditing the project will not be able to see your name or contact details. Other than on the consent form, all the other data you provide will have a code number. All information about you will be kept secure.

We will write our reports in a way that no-one can identify you or any of your patients.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
- by sending an email to Yvonne.wren@bristol.ac.uk, or
- by ringing us on 0117 41 43951.
- by contacting Helen Williamson (Head of Information Governance) at helen.e.williamson@nbt.nhs.uk or by ringing 0117 41 44767

Will the information I provide be confidential?

The consent form you complete and the audio recordings from the interview will contain your identifying information. You will give the consent form to your manager and your manager will post it to the BSLTRU, where it will then be stored securely. This information will only be used to contact you to arrange the interview. The audio recordings will be stored securely within BSLTRU using your study ID number not your name.

If I decide to take part, what happens next?

If you would like to participate, please read and sign the clinician consent form and return this to [Lesley Hemmings / Annabelle Burns / Lucy Paterson] as soon as possible. This will be sent on to the study team at BSLTRU and stored securely. A start date for data collection will be agreed between yourself, your manager and the study team at BSLTRU/Therapy Box.

Who has reviewed this study?

The North Scotland Research Ethics Committee has reviewed the research protocol and all other documents associated with this study (Reference Number: 20/NS/0128).

Further information

North Bristol NHS Trust and Therapy Box are the sponsors for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We are asking you to provide your name and signature and telephone number on the consent form and this form will be kept, however, your details will not be directly linked to the transcript of the study interview. Direct quotes of things you say in the interview may be used in research publications, but it will not be possible to link you to the quote.

North Bristol NHS Trust will use your name and contact details to contact you about the research study, and to oversee the quality of the study. Individuals from North Bristol NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in North Bristol NHS Trust who will have access to information that identifies you will be members of the study team who need to contact you to arrange a time for the interview, to check you are happy with the content of the transcript or to audit the data collection process.

North Bristol NHS Trust will keep identifiable information about you (the consent form) from this study for five years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at: www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research or by contacting myself, Dr Yvonne Wren.

If you have any further questions or would like to find out any further information, please contact me on via email at yvonne.wren@bristol.ac.uk or by Telephone: 0117 41 43951

If you would like to talk to someone regarding a question or a complaint the Patient Liason Services details are:

Advice & Complaints Team (ACT)
Beaufort House
Beaufort Way
Southmead Hospital
Bristol
BS10 5NB
Tel: 0117 414 5669 Ext 44571