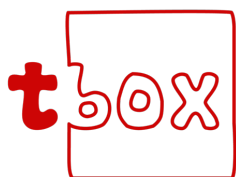


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**Bristol Speech and
Language Therapy
Research Unit**



The Language Explorer Clinical Evaluation Study Participant Information Sheet (Parent/Child)

Invitation to participate in a clinical evaluation of an automated language transcription and analysis software 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, 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. We will

also be asking parents and speech and language therapists about their views and experiences of using Language Explorer.

We are recruiting parents and children from three speech and language therapy services across the country to help us with this. 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 we recruit will be asked to complete the Language Explorer app and additional language assessments. We 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, we hope that the app can be used in NHS services across the country.

Why have I been selected?

You have received this information because you have a child aged between 4 and 8 years old who has received speech and language therapy from one of the services involved in this study.

Please note, your child's participation in this study is separate from their involvement with the clinical service and will not impact on decisions about their care.

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 or your child's care.

If I decide to take part, what happens next?

You and your child will be invited to a Language Explorer Assessment appointment, which will take place remotely if your child is aged between 6 years and 0 months and 7 years and 11 months or in person in a clinical setting if your child is aged 4 years 0 months to 5 years and 11 months).

If your child is in the older group and the assessment is to take place remotely, we will ask you to download the app on a suitable device before the appointment. During the remote appointment, we will confirm that your child is eligible to participate in the study and then ask your child if they are happy to participate. We will then ask you to use the app with your child. On the app, they will hear a story being told. Your child will be asked to retell the story and then answer some simple questions about it. The app will record your child as they retell the story and answer the questions. The study team will use this recording and the automatic print out which the app produces of the recording to analyse how well the app works. After your child has completed the app, they will be asked to complete four other language assessment tasks, using a different online interactive tool, so that we can compare the app with other measures of language ability. The speech and language therapist will explain the assessment results to you and there will be time for you to ask any questions you might have.

If your child is in the younger group and the appointment happens in person in a clinical setting, both you and the speech and language therapist will need to strictly follow the covid-19 guidance on face to face appointments as agreed by the local service. In the appointment in the clinical setting, the speech and

language therapist will use the app with your child. After your child has completed the app, they will be asked to complete two other paper-based language assessment tasks so that we can compare the app with other measures of language ability. The speech and language therapist will explain the assessment results to you and there will be time for you to ask any questions you might have.

If the assessment reveals any new concerns, the speech and language therapist will give you advice regarding any steps needed to access additional help. If difficulties in any another aspect of your child's development are noted during the assessment, the therapist can, with your consent, make onward referrals for your child to be seen by other health professionals. The whole assessment will take between 20 minutes and one hour.

Sometime after the assessment session, a member of the study team from Bristol Speech and Language Therapy Research Unit will invite you to take part in a telephone interview at a time that suits you. The interview will be relaxed and informal and will last approximately 20-30 minutes. We are interested to hear about your experiences and views of using the Language Explorer app.

We will audio-record the interview, if you consent to this, so that we can capture what you say. We will write down what you say in a document called a transcript, so we can look at your comments in combination with what other parents tell us. We would like to share the transcript from your interview with the other researchers to enable us to carry out the analysis. Before we share the transcript, we will take out any information which might identify you or your child. We may want to use a direct quote of what you have said during the interview in research publications, but please be assured that it will not be possible to link you to the quote. When the analysis of the data is finished, we can share the findings of the study with you if you wish.

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

While there are no benefits to you by participating in this study, the information from this study will provide information on how children perform on the Language Explorer app and what your views and experiences of using the app are. This information will help complete the development of the app which in turn hopes to 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 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?

We will need to use information from you for this research project.

This information will include your name and contact details and your child's names, gender, date of birth, whether they have any speech and language needs or any other disabilities. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

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?

Yes, your information will be shared only with your child's speech and language therapy service and the study team.

The information is collected in a way that keeps your child's identity anonymous i.e. we only ask for your child's birth month and year and for the location we only ask you for the first half of your postcode. We will use a unique study ID code to link your child's data in the app from other data in the study rather than using their name.

The consent form will contain you and your child's identifying information, and this form will be stored securely at the Bristol Speech and language Therapy Research Unit. This information will be used to contact you to arrange the interview that is mentioned above.

The audio recording of your child collected via the app and your interview audio recording, are also identifying information. However, apart from you and your child's voice, the recording will contain no identifying information. The audio recordings of your child will be kept by Therapy Box indefinitely. The audio recordings of your interview will be kept securely at BSLTRU for 25 years. North Bristol NHS Trust (where Bristol Speech and Language Therapy Research Unit is based) and Therapy Box are the sponsors for this study based in the United Kingdom. This means that they have legal responsibility for the study. We will be using information from you in order to carry out 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, telephone number and email address on the consent form, however, your details will not be directly linked to the transcript of the study interview, or your child's data.

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 (Bristol Speech and Language Therapy Research Unit) who will have access to information that identifies you will be people 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.

The Bristol Speech and Language Therapy Research Unit will keep identifiable information about you (the consent forms) from this study for 5 years after the study has finished.. Therapy box will keep data regarding your child's gender, birth month and year, first half of your post code, whether your child has any speech, language and communication needs or any other known disabilities indefinitely. Your child will not be able to be identified from this information.

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.

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).

If you want to take part in this study, please initial, sign and date the consent forms (one for you and one for your child) and return them in the prepaid envelope. If you require any additional information, please contact the study team at Bristol Speech and Language Therapy Research Unit by email (yvonne.wren@bristol.ac.uk) or by phone (0117 4143951).

If you have any further questions or would like to find out any further information, please contact me via email Yvonne.Wren@bristol.ac.uk or telephone: 0117 41 43951

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

Bristol

Sirona Care and Health Customer Care Service
Kingswood Civic Centre, (2nd Floor)
High Street, Kingswood, Bristol
BS15 9TR
Tel: 0300 124 5400

Hackney

Complaints Service
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
E9 6SR
Tel: 020 8510 5113 / 7467

Newcastle

Patient Advice and Liaison Service
The Old Stables
Greys Yard
Morpeth
NE61 1QD
Tel: 0800 032 02 02

If you feel distressed and would like extra support at any time, you can contact Afasic.

Afasic is as a parent-led organisation to help children and young people with speech and language impairments and their families. Afasic provide information and training to parents and members meet in local groups in many areas in the UK.

Afasic

Helpline: 0300 666 9410
Tel: (administration) 020 7490 9410
Fax: 020 7251 2834
Afasic.org.uk