



Researchers in Newcastle, Manchester and London are developing a new way of measuring how well young children understand speech. Children will point to pictures on a computer screen. The researchers are looking for young children to try out the assessment.

The attached leaflet tells you more about the study.





Developing a new assessment of language comprehension for young children: The UK C-BiLLT

Parent Information Sheet

You are invited to take part in a research study. Before you decide to take part it is important for you to understand why the research is being done and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like some more information.

What is the study about?

This study will develop a new assessment of young children's understanding of spoken language. The assessment is done on a computer. Children will point to pictures to answer questions. For example, Where is the dog? Who is going to play outside? The assessment will be suitable for most young children, including those who have severe disabilities who cannot speak but can control a computer by using special controllers.

Why have I been invited to take part?

You have been approached because you have a child aged between 18 months and 7 1/2 years. The managers of your child's a play scheme, nursery or school have agreed to pass on the information about the study. We will be asking about 480 parents to take part in total.

What will happen if I take part?

A speech therapist and trainee speech therapist will visit your child's play scheme, nursery or school to see all the children whose parents agree to take part. The therapists will work with children individually. They will do three activities:

1. The new assessment of language understanding on a laptop computer. Children will touch pictures on the screen to answer questions. For example, 'Where is the book?' 'Who is walking the dog?'
2. An assessment of children's development. For very young children this involves playing with toys. For older children this involves matching colours and shapes.
3. Another assessment of language understanding. In this assessment children will point to toys or pictures in a book to answer questions, such as 'Show me - Rabbit eating an apple'.

Using all three assessments will show how well the scores on our new assessment match scores on assessments that we know are good indicators of children's development. We will tell if our new assessment is working and is a good measure of children's understanding.



The three assessments will take 40-60 minutes in total. The researchers are trained to make the assessments fun. They will give children breaks between the activities and check that the children are happy to carry on. If children are unwilling to do the activities, they do not have to. If the children indicate that they want to stop (for example, they look sad or anxious or say they want to stop) the researchers will stop the activities.

Sometimes, research suggests that children are having difficulties answering questions for children of their age. If this happens, we will write to parents to make a time to talk through the children's assessment results on the telephone. We will provide information on local services to help with children's language development and their contact details.

What are the possible disadvantages and risks of taking part?

We think that the disadvantages or risks of participating in this study are minimal. Children may get bored, but they will have breaks between the assessments and we will try to do the assessments across a day rather than all together.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cumbria, Northumberland, Tyne and Wear Foundation NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What are the possible benefits of taking part?

People who take part in this study will be given an opportunity to contribute to research that will help to create a new assessment for children with severe disabilities. Current assessments ask children to handle toys, so they are not appropriate for children who cannot move their hands. It is difficult to judge how much these children understand and provide appropriate therapy to help their communication.

As thanks for helping us with this research, we will give your child's play scheme, nursery or school vouchers to buy new books.

Do I have to take part?

Taking part in this study is entirely voluntary; it is up to you to choose whether to take part. If you do decide to take part, you can withdraw from the study at any time.

If you withdraw or your child indicates that they want to stop the activities, we would like to keep the information collected up until that point. All the information will be kept strictly confidential, and any information that is published will always be anonymised. However, we can remove your data if you would prefer.

If you do decide to withdraw, you do not have to give a reason.

What if something goes wrong or if I have a question or complaint?

If you have any questions or concerns about the study, please contact XXXX

Who will know about our participation?

We will ensure that your participation in this study is entirely confidential. Only the study team and your child's play scheme, nursery or school will know that you have taken part. When the research is published there will be no way of identifying anyone who took part in the study.

How will we use information about you?

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

This information will include what you write yourself on your consent form, which is your name for consent purposes. The consent forms will be stored securely and separately from any research data collected. One copy will be stored at the nursery /preschool school from which your child was identified, the other copy will be held with the research team at Newcastle University and then archived with Cumbria, Northumberland, Tyne and Wear (CNTW) NHS who is the Sponsor of this research and holds overall responsibility for the project. You will be given a copy of the signed consent form to keep.

The other information that we will collect and store separately from the consent information and your names is your child's date of birth and gender and the data recorded from the assessments. This research data will be stored under an anonymous code to protect your child's identity and used by the research team at Newcastle University for analysis, and then archived by CNTW internally and then in their contracted external archiving service until 3 years after the youngest participant reaches 18 years old. This is in line with Sponsor regulations. After this time, information will be confidentially destroyed. All information will be treated in line with the Data Protection Act. In summary, people will use this information to do the research or to check your records to make sure that the research is being done properly.

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.

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.

What are your choices about how your information is used?

You and your child 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/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to DPO@cntw.nhs.uk
- by ringing us on Tel: 0191 246 6896

What will happen to the results of this study?

The information from the three assessments will be analysed after the study finishes. We will publish the main results in scientific publications and present our findings at conferences. None of this reporting

will include any information that could identify you as an individual or family. We will provide a summary of the results for each parent taking part in the study on request.

If you give permission, we may use information gathered from this study (e.g. questionnaire totals; definitely no identifiable information about you or your child) in future data analyses by ourselves or other researchers undertaking similar research.

The new assessment will be available for speech therapists to use with children across the UK.

Who is organising and funding the research?

This research is being funded by Action Medical Research and the Great North Children's Hospital Research Foundation. The research 'sponsor', who checks it is done correctly, is Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust.

Who has reviewed the study?

The study has been reviewed by the Newcastle North Tyneside Research Ethics Committee.

Can I talk to someone before agreeing to take part?

If you would like to further information about this study before or after the intervention starts you can contact the Director of the study, Professor Lindsay Pennington (see below). You are welcome to ask us any questions or discuss any worries you may have. In addition, you can ask in general about taking part in research by contacting your local Patient Advice Liaison Service (PALS) on 0800 0320202.

Thank you for reading this information sheet

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