

Information for typically-developing participants

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Study Title: An investigation of language comprehension in minimally verbal autistic people

CPREC/NRES Code: 2019.080

Dear Participant,

Thank you for your interest in our research project.

We invite you to take part in a research study. Before you decide whether or not to participate it is important that you understand why the research is being done, what it will involve and how the information collected from you is stored and used. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

We want to develop new techniques to measure language comprehension in autistic individuals who have limited or no spoken communication. Language ability varies widely in people on the autism spectrum, with a large number of people having limited or no spoken communication. Anecdotally, it has been suggested that some of these individuals may understand more language than they appear to be able to. This research project seeks to determine whether this is the case using adapted language tests.

Who is organising and sponsoring this research?

Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you and the participant in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for a minimum of 1 year and a maximum of 5 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:

<https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/>

Has the study been reviewed?

This study has been reviewed by an independent group of people – the Cambridge Psychology Research Ethics Committee – who have a duty to protect research volunteers' safety, rights, wellbeing and dignity.

Why have I been invited to take part?

You have been invited to take part in the study because you or your child are a person between **5 and 40 years** of age who falls into one of our groups of interest:

- With a diagnosis of autism, and who have limited or no spoken communication.
- With a diagnosis of autism, who use spoken language
- Typically developing, with no diagnosis of autism or other developmental condition

Who cannot participate in this study? The following people might not be eligible to take part. Please talk to the researcher if either of these apply.

- A person for whom English is not their first language
- A person with severe visual or auditory impairment that would typically inhibited their ability to see images on a screen or hear people talk.

Do we have to take part?

It is up to you whether or not you take part in this study. Before deciding you should read this information sheet and ask about anything that is not clear. If you decide to participate in this study we will ask you to sign a form indicating that you have agreed (consent form). However, even after you have signed that form you can withdraw from the study without having to give us a reason.

On the day of testing, we will seek consent from neurotypical adults, and assent from children (5 -15yrs of age) and non-speakers. We will do this by reading out a simple description of tasks and asking if they are willing to participate. People who are non-verbal and communicate with an assisted communication device will be asked to respond using their preferred method of communication. If you child does not have verbal or non-verbal communication to respond, we will monitor their willingness to participate continually, and stop testing if you or we think they are distressed.

Please be aware that we aim to anonymise our results (separate and remove your personally identifying information) as soon as possible after data collection to protect your privacy. If you decide to withdraw sometime after your participation it may therefore not be possible to identify and remove your specific results.

What happens if we change our minds?

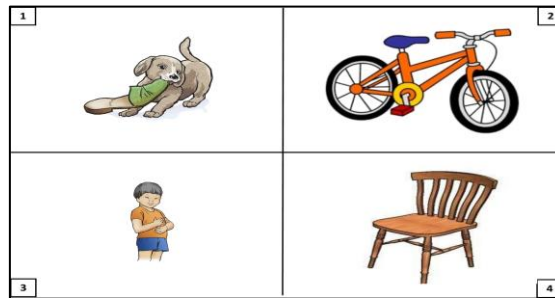
Participation in this project is voluntary and it is important that you are happy to be involved. You are free to withdraw from the research study at any time, without giving a reason and you will still be reimbursed.

How will the study be conducted?

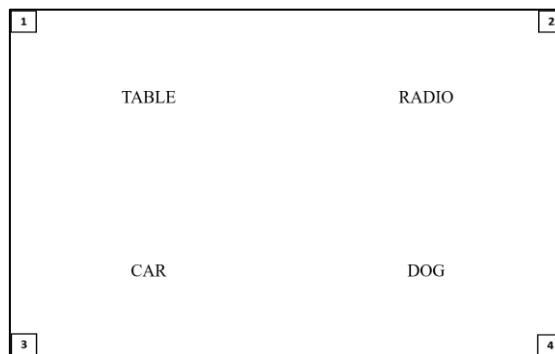
- Testing will take place at the MRC Cognition and Brain Sciences Unit (CBU).
- The testing sessions will take place lasting approximately 1-1.5 hours.
- Participants (or their caregivers) will be asked to fill in questionnaires about the participant.
- Participants will complete a series of computer-based tasks. For this part of the study, participants are asked to point, speak or respond using their assisted communication devices to indicate their responses to the testing material presented.
- Participant's eye movements may be tracked and recorded as they complete tasks on the computer.

Brief Description of the Tasks Used in the Study

The tasks are designed to measure receptive language ability (ability to understand spoken words). One involves the participant viewing 4 pictures at a time and indicating the picture that corresponds to the spoken label. E.g. “point to the boy”. The other involves the participant viewing four words, and indicating the word that matches a spoken description.



Picture version



Word version

Will I be paid for taking part or have my expenses paid?

Participants will be paid £10 per session.

Can the participant use their assisted communication device during the study?

Yes, the use of assisted communication devices to communicate will be encouraged during the study. One of the main aims of this research is to measure how much people comprehend independent of their verbal abilities.

Will video or audio recordings be made?

The participant may be videoed during these tasks for research purposes so that we can code their behaviour later. You can indicate on the consent form whether or not to allow us to use these videos, audio recordings and images in presentations that we give to other researchers or the public.

Are there any risks involved in this research?

There are no obvious risks from the computer tasks that are completed as part of this study. If the participant becomes tired or uncomfortable during any of the tasks please let us or a practitioner know and we can take a break or end the session. Remember you can withdraw from the study at any time without needing to give us a reason. Assessments will be completed either by researchers, who are trained in working with children in schools and have enhanced DBS

Clearance/ Garda vetting, or equivalent overseas police check, or you will complete them online with support from your regular practitioner.

What happens to my personally identifiable information?

You have provided us with two types of information. *Personally identifiable information* includes video and audio taken during the sessions and your names, addresses and dates of birth – information from which a person could be identified. We use this personally identifiable information to contact you, calculate age, help score behavioural data and so on. Anonymised research data includes information like the buttons the participant pushed on a computer task; in other words, once this information is no longer connected to your Personally Identifiable Information, information from which it would not be possible, or would be very difficult, to identify you personally.

We separate the participants Personally Identifiable Information from their Anonymised Research Data and treat these two types of information very differently.

The University of Cambridge Data Protection Officer is the Data Controller for any Personally Identifiable Information that you have given us. Contact details: The Old Schools, Trinity Lane, Cambridge CB2 1TN data.protection@admin.cam.ac.uk.

Personally identifiable information is treated with strict confidentiality and in line with the EU General Data Protection Regulations 2016/679 and the Data Protection Act 2018, which regulates the collection, storage, processing and disclosure of such information. This information is held very securely and only for as long as is necessary (e.g. for contacting you and for the management of the research).

Electronic Personally Identifiable Information is either entered directly into a secure area of our computer system or transferred there as soon as possible after collection. Videos taken by yourselves or by practitioners will be transferred to us using our file sharing servers which are owned and operated by the MRC CBU and employ multiple layers of security to prevent unauthorised access. Since this server is accessible from the internet, and we cannot guarantee that unauthorised access will not occur but we will move video files from this server to our secure data area as quickly as possible.

Personally Identifiable Information on paper records, such as consent forms with your name on, or questionnaire forms which contain both the participant's name and your answers, will be kept in a locked filing cabinet within a secured building.

Access to personally identifiable data will normally be restricted to members of the research team who need access to it to run the study (i.e. when a participant comes in for a second time, their new data needs to be connected to their data collected during their first visit). Personally identifiable data is secured in a digital safe haven, which can only be accessed by members of the team who have permission to access it. These data will be stored securely at the MRC Cognition and Brain Sciences Unit for a minimum of 1 year and a maximum of 5 years after project completion. Retention for 1 year is to enable use to send participants a summary of the research outcomes. Alternatively, if the family has consented to being contacted in relation to future research, personal data will be retained for the maximum 5 years. If the family consents to be contacted in relation to future research, their personal data may be shared with other CBU scientists running related studies.

What happens to anonymised research data?

The participant's *anonymised* research data, typically combined with similar information from other volunteers, will be used for scientific research. The results are presented in scientific papers and talks, in teaching and in explaining our science to health professionals, school groups and the public in general. We take great care to ensure that individuals cannot be identified from our research outputs.

Undertaking scientific studies is expensive and relies on the generous contribution of time from volunteers. To make the most of participant's *anonymised* research data we plan to look after it for the long term and may use it to answer research questions beyond those for which it was originally collected. This may include combining *anonymised* University of Cambridge, 15 Chaucer Road, Cambridge CB2 7EF

research data from this study with *anonymised* data from other studies in the CBU in which you have been involved (e.g. brain scanning studies). In addition to our own analyses, we agree with the principle that research data, often collected with public money, are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner. Many of the bodies that fund our research insist that we follow this principle. In line with this we may also share *anonymised* research data with other researchers in the UK and around the world and may make anonymised research data available as “Open Data”. Open data can be downloaded free of charge by anyone interested in the research or who wishes to repeat or conduct new analyses. This allows others to check our results and helps avoid research duplication. If research data is made Open we have no control over how that information is used.

We are very aware that, sometimes, anonymised research data could be used to identify an individual (for example, questionnaire responses about life events could identify a particular person to someone who knows him or her or who had read a newspaper story of similar events). In such cases we take great care to reduce the chances of this individual being identified by omitting critical details or not sharing even anonymised data with anyone outside of the research team.

Are there any circumstances in which you would divulge my Personally Identifiable Information to anyone outside of the research team?

We have a duty of care to volunteers and the general public. If the participant or their carer give us information that indicates a real risk of harm to themselves, or another person, we have a responsibility to share that information with relevant services. You should only consent to taking part if you understand this possibility.

Can I get access to my results from the study?

It is important that, as researchers, we minimise potential harm to volunteers in our studies. We often use new techniques and interpreting research data can be complicated and has the potential to cause undue concern. For this reason we do not divulge individual results. If you have concerns about your performance please discuss these with the researcher. At the completion of the study, we will send you an email about this research explaining what the study’s findings were at the group level.

Are there compensation arrangements if something goes wrong?

The study has insurance to deal with any claim in the very unlikely event of anything going wrong that causes harm.

What should I do if I have a complaint about the study?

Our volunteers should feel informed and well treated when they take part in our research. If you have a complaint about this study please contact the Principle Investigator listed at the end of this information sheet in the first instance. If you are not happy with the response, please contact the Director of the Cognition and Brain Sciences Unit (director@mrc-cbu.cam.ac.uk). Further steps can be taken through the University of Cambridge if necessary.

Please read the information above and confirm with your child, if appropriate, that he or she is happy to take part before signing the form. If you have any further questions, please ask the researcher before you sign the consent form. You will be given another copy of this sheet to keep for your own records.

Thank you for considering taking part in this study. Our research depends entirely on the goodwill of potential volunteers such as you. If you require any further information, we will be pleased to help you in any way we can.

If you require more information, please contact:

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e: Alexandra.Woolgar@mrc-cbu.cam.ac.uk

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