

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

Parent Information Leaflet for Mainstream School Children

We would like to invite you and your child to take part in our research study to help us find out whether we can use an App we have developed, based on a pirate adventure story, which may help us when we are seeing children with possible autism. In this part of the study we want to test children who do have a diagnosis of autism with children who do not have a diagnosis. Before you decide we would like you to understand why the research is being done and what it would involve for you and your child.



Part One tells you the purpose of this study and what you will need to do if you decide to take part. Part Two gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear. **One of our team will be happy to go through the information sheet with you and answer any questions you have.** We would be grateful if you could return the signed consent form to us within 1 week of this to let us know if you wish to take part.

The study will be run from the Mid Sussex Child Development Centre in Haywards Heath

Part One:

What is the Purpose of the Study?

We need to test the app in children who we know do not have autism or any related conditions, so that we can tell if it can discriminate between children who do and do not have autism.

Why have we been invited?

We are inviting children attending (name of school) primary school to take part.

Do we have to take part?

No. It is up to you to decide if you want your child to join the study. If after reading this information leaflet you agree for your child to take part, we ask that you sign the consent form and return it to us in the enclosed stamped addressed envelope. If you have any questions please feel free to contact us on the phone number below. We would be grateful if you could read the child information leaflet with your child to check they are happy to take part as well. Your child is free to withdraw at any time, without giving a reason. This will not affect the standard of care your child receives.

What will happen if my child takes part?

We will come into school, or you can come to clinic or we can come to your home to play on the app with participating children. One of the research team will play the app with your child and ask the questions included. This will take about 10 minutes. We will also ask them some questions about what they think of the app. We will do this close to their classroom so they can still see their class/teacher. The app presents a series of questions (such as in the picture opposite) presented as a pirate adventure game exploring the child's ability to recognise facial expressions, think what someone else is thinking, to recognise sarcasm and the use of a lie, and to understand idiom. These are all based on tests we use when assessing a child for possible autism. Some skills being tested only emerge in school aged children so we want to find out at what age children

can answer the questions. Please reassure your child therefore that they do not need to know all the answers - we will also reassure them whilst playing the app with them. The app has already been used with a number of children attending Child Development Clinics across W. Sussex with parents, children and doctors all giving positive feedback on its use.

What are the possible benefits and risks of taking part?

We hope that in time we will be able to use this app to improve our diagnostic process in assessing children with possible autism. As autism affects over 1 in 100 children you or your child may well have friends or relatives who will need such an assessment. We also hope your child will enjoy playing the app - it is meant to be a fun game to play. We will exclude children with epilepsy who are sensitive to flashing lights or TV screens, to avoid setting off any seizures.

Part Two

What will happen if my child doesn't want to carry on with the study?

Your child is free to leave the study at any point, and you may request that any data relating to your child's involvement in the study be destroyed. This will have no effect on any ongoing treatment with the child development team.

What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. If you or your child have any concerns about the conduct of the study, you can discuss these with the Chief Investigator, Dr Will Farr on 01444 414100. You may contact our complaints department, who will investigate your concerns:

The Patient and Liaison Service (PALS) experience team,
Sussex Community NHS Foundation Trust,
Freepost (BR117),
Elm Grove,
Brighton BN2 3EW.
01273 242292

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against our organisation (Sussex Community NHS Foundation 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). NHS Indemnity

does not offer no fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.

Will my child's taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you and your child will be handled in confidence. Individual data will be recorded on paper questionnaires and test score sheets. These will be stored securely at the Child Development Centre in a locked cupboard. Anonymised data will be entered onto a password encrypted computer for statistical analysis. Results may be reported in medical journals but this will be done so anonymously. All information which is collected about your child during the course of the research will be kept strictly confidential, and any information about your child which leaves the Child Development Centre will have your child's name and address removed so that you and your child cannot be recognised.

Data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to your child taking part in this research, for the purposes of auditing and monitoring.

What will happen to the results of the research study?

We hope to present the results of the study at national meetings attended by other medical professionals and to publish our findings in the medical press. This is so children outside of the study can benefit from our findings. We will also display a poster at the Child Development Centres showing the results. Whenever the results are publicised you and your child will remain anonymous.

Who is organising and funding the research?

The study is being run by Dr Ian Male, Consultant Community Paediatrician, and Dr William Farr, Research Psychologist, at the Mid Sussex Child Development Centre, employed by Sussex Community NHS Foundation Trust. Our research team is being supported by Dr Dido Green, Reader in Rehabilitation, and Dr Anjum Memon from the local Research Design Service, and Prof Francesca Happé, Professor of Psychology at the Maudsley Hospital, Kings College, London. We also discussed the use of this app with a local parents support group for parents who have a child with autism and with your headteachers of primary schools. The study is sponsored by the Sussex Community NHS Foundation Trust and the British Medical Association. There is no financial or other benefit to the research team resulting from this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Research Ethics Committee.

Further information and contact details

1. General information about research: contact The Patient and Liaison Service (PALS) experience team, Sussex Community NHS Trust, Freepost (BR117), Elm Grove, Brighton BN2 3EW. 01273 242292.

2. Specific information about this research project: contact Dr William Farr or Dr Ian Male at the Mid Sussex Child Development Centre on 01444 414100.
3. Advice as to whether you/your child should participate: you can discuss with Dr William Farr or Dr Ian Male as above
4. If you have any concerns about the study please contact Dr Ian Male as above, in the first instance.

