

## **PARENT/CAREGIVER INFORMATION SHEET**

### **Pilot testing of an adapted observational parent-child interaction measure for the ASTAR feasibility trial**

We would like to invite you to take part in our research study.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your son/daughter, or the child for whom you are the carer 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?**

People of all ages with autism spectrum disorders (ASD) may experience a range of additional concerning emotions and behaviours. The most common problems are disruptive behaviour, anxiety and attention deficit hyperactivity disorder (ADHD).

We are currently developing a new treatment aiming to reduce concerning behaviour and emotions in children with autism. In order to test the treatment, we are planning to use an observation measure, where we will observe behaviour whilst parents/carers are playing or interacting with their child. This type of measure is important because the behaviour will be rated by people who won't know whether or not the family received the treatment. Knowing that someone has received a treatment can affect a persons' judgement of behaviour after treatment.

The observation measure will be similar to ones used with children with other disorders. However, it is important for us to test it before we use it in a treatment trial so we can see if anything needs to be changed. For example, we want to make sure the observation does not take longer than 40 minutes, that the tasks are interesting for children, and that we are able to observe the behaviours that we want to.

We would like to invite you to take part in a test of this observational measure before we use in treatment trial.

#### **Why have you been invited?**

We are looking to test the measure on both children with ASD and typically developing children, along with their parents or caregivers. This is why you have been invited to take part.

## **What will you be asked to do?**

Once you have decided if you wish to take part in our research, we will arrange a time to complete the study at a time convenient to you. We can complete the study at your home, your child's school or on site at the Institute of Psychiatry, Psychology and Neuroscience, depending on what is easiest for you. This can be during weekdays, evenings or weekends depending on what is most convenient for you.

The study will take up to 45 minutes in total. When we first meet you we will run through the information sheet with your child once more, ask whether either of you have any questions, and check you and your child are still happy to participate. If your child is able to do so, we will also ask them if they agree to take part in the study. When obtaining their agreement, we will check for any signs of distress or reluctance to participate. If your child shows signs of distress or reluctance to take part we will discuss this with you and how best to proceed.

The study comprises of a series of tasks and games for you and your child to do together which should take about 40 minutes. With your permission we will video record the study so that as a research team we can evaluate how well the measure is working and how to improve it. At the end of the series of tasks, we will ask you and your child how you found the tasks, and whether you have any general feedback. Participating families will receive a £20 voucher.

## **Do I have to take part?**

It is up to you and your child/person you care for whether or not you would like to take part. Your involvement in the research is entirely voluntary. If you do decide you would like to take part, you are free to withdraw from the research study at any time. You do not need to give us a reason if you no longer wish to take part.

If you do decide to withdraw from the study, we would like to continue to use any information that you have provided up until that point. However, this is up to you. If you decide that you do not want us to use the information you already provided, you have until the 31<sup>st</sup> December 2016 to let us know.

## **What happens to my information?**

We will follow ethical and legal practice and all information about you and your child/person you care for will be handled in confidence.

Data collected for the study will be looked at by authorised individuals from King's College London who are organising this research. It may also be looked at by authorised individuals to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

All information that is collected about you or your child/person you care for during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database.

Any information about you or your child/person you care for will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

We will ask you whether you wish to be contacted about any future research projects you or your child/person you care for may be interested in participating in. You are not obliged to agree to be contacted for future research. If you do agree to be contacted, you and your child/person you care for are not obliged to take part in any future studies we may tell you about. You can request for your details to be deleted at any time.

Your personal data (address, telephone number) will be kept for 3 years after the end of the study in accordance with the rules of clinical trials. We will keep details for longer if you agree to be contacted about future research. Your research data will be kept for 4 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, and only members of the research team will have access to your personal data.

### **When might confidentiality be broken?**

Although the information you give is confidential, should you or your child/person you care for disclose anything which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. This is uncommon and we would expect to obtain your consent first to share this information.

### **Possible risks or disadvantages of taking part**

There is very little risk associated with this study but participating in this research will take up some of your time. We will require you to meet with us either at your home, your child's school or on site at the Institute of Psychiatry, Psychology and Neuroscience.

### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet.

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Chair of the PNM RESC

Email: [rec@kcl.ac.uk](mailto:rec@kcl.ac.uk)

Phone: 0207 848 4020

### **Who is organising and funding the research?**

This research is being funded by the National Institute for Health Research. The research is being carried out by King's College London, at the Institute of Psychiatry, Psychology and Neuroscience.

### **Who has reviewed the study?**

This research has been assessed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by: Psychiatry, Nursing and Midwifery (PNM) Research Ethics Subcommittee (RESC) at King's College London (REMAS ref: 3175).

### **Further information and contact details**

If you require further information please contact:

#### **Melanie Palmer**

Email: [melanie.palmer@kcl.ac.uk](mailto:melanie.palmer@kcl.ac.uk)

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