VOLUNTEER INFORMATION SHEET

Please read this if you think you might want to take part in our research

It is completely up to you

Study Title: DECOP
Decision making, context and psychosis

Relatives-ESM
(Version 3 of 25/06/2014)

Information on the study

You are being asked to take part in a study being conducted at the Institute of Psychiatry by Dr Sukhi Shergill and Dr Anne-Kathrin Fett. Before you decide you need to understand why this research is being done and what it would involve for you if you decide to take part in it. Please, take your time to read the following information carefully.

What is the purpose of the study?

This study aims to investigate how decision making and information processing in different social and non-social contexts impacts upon the illness symptoms of schizophrenia. We are hoping that in the long run learning more about the mechanisms will allow us to design intervention programs that can improve patients' lives.

Why have I been approached?

For this study we are recruiting three groups of participants; patients who have or have had a diagnosis of schizophrenia or another non-affective psychosis, their healthy first degree relatives and healthy controls. You have been approached because you have a relative who has been diagnosed with a disorder of non-affective psychosis – and you do not suffer from any psychosis symptoms. Research suggests studying healthy relatives of patients is important to understand the role of genetic factors in the mechanisms that predispose and protect individuals with a genetic liability for the disorder from getting ill.

Do I have to take part?

It is up to you to decide. Please take your time over the decision and of course, you might wish to discuss it with relatives or friends. If, after having read this information sheet, you decide that you would like to take part, please contact us to arrange an appointment. Furthermore, you are free to withdraw at any time, without giving a reason, and any data collected about you will be deleted.

What will the study involve?

Firstly, a researcher will explain the study to you. If you want to participate in the study you will be asked to sign a consent form to formally agree to your participation. The study involves two testing sessions.

1. During the first we will ask you to provide some background information about yourself and to complete several standard questionnaires and a short computer-based task. After completing the questionnaires a member of the research team will explain how the iPod-diary works. You will receive an iPod from us for one week, which you will take home with you. During the next 7 days the iPod will beep 10 times a day at unpredictable moments between 8 am and 10.30 pm. The moment that you hear the beep you need to complete a short questionnaire on the iPod. In this way we can get a good picture of your decision making processes within their real daily-life context. This first session will take approximately 1 hour and 15 minutes.

2. After one week you will come back to the Institute of Psychiatry again to hand in the iPod and to evaluate how the ESM week went. In addition we will ask you to complete several short questionnaires and two computer-based decision making tasks. In the first task you will be connected with different persons through the internet and you will be asked to make investment decisions concerning these persons. The other decision making task is a lottery task which also involves making investment decisions but which will be played against a computer. This second session will take approximately 1 hour and 25 minutes.

Both testing sessions will take place at the Institute of Psychiatry, De Crespigny Park, SE5 8AF.

What are the possible benefits of taking part?

The study will not help patients directly but it will further the understanding about the development of psychotic symptoms and about how these are associated with decision making and functioning in real life (social) contexts. If you wish, we can inform you of the developments and publications which arise from this study. You can specify on the consent form whether or not you'd like to receive this information.

What will happen to the results of the study?

We will make the results available to you if you wish and we plan to publish our findings in scientific journals. All personal data will be treated in strict confidence and you will not be identified personally in any subsequent publication.

Will my taking part in the study remain confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. The research team will not pass on your personal details to anyone else.

Professional standards of confidentiality will be adhered and the handling, processing, storage and destruction of data will be conducted in accordance with the Data Protection Act (1998).

Reimbursement of expenses and payment

We will pay you with £40 as compensation for your time and we will also reimburse your travel expenses. In addition, you can earn an amount of money in the decision making computer tasks. This amount can vary between £0 and £30 and will be randomly selected. Please note that payments for this research may have an impact on benefit payments. If this issue concerns you we can provide you with further information.

What if there is a problem?

Safety and well-being

Your well-being throughout the study is very important to us. Some of the questions that we ask are personal and it is possible that you might feel distressed by these. Please, let the researcher know if this happens so that we can take appropriate measures to support you. Also, you are of course free to withdraw from the study at any time, without giving a reason.

Complaints

If you have any concerns or wish to discuss any aspect of the study, the way you have been approached or treated you should initially contact Dr Fett or Dr Shergill who will do their best to answer your questions. Their contact details are provided at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this through the Research Governance Sponsor of this study, the Institute of Psychiatry, KCL. Please write to the Research & Development Office (P005), Room W108, Institute of Psychiatry, King's College London, De Crespigny Park, London SE5 8AF. All communication will be dealt in strict confidence.

Harm

Every care will be taken to ensure your safety during the course of the study. However, the Institute of Psychiatry, KCL has (insurance) arrangements in place for no-fault compensation in the unlikely event that something unforeseen does go wrong, and on the balance of probabilities, harm is attributed as a result of taking part in the research study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

Who is organising and funding the study?

This study is being organised by Dr Fett and Dr Shergill. The research is funded by the Netherlands Organization for Scientific Research (NWO).

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights and wellbeing. This study has been reviewed and given a favourable opinion by the London - Harrow Research Ethics Committee.

You can contact the researchers during or after the study if you have any questions. You will be given a copy of this information sheet and the signed consent sheet to keep. Please contact us if you would any like any further information to help you decide. Thank you for taking the time to read this information sheet.

Contact

You can contact us on 07599005900 or by emailing DECOP@kcl.ac.uk.