Ms. Aleya Marzuki
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University of Cambridge
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Participant Information Sheet

Title: The cognitive profile of early-onset obsessive-compulsive disorder

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve. Please take time to read it 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.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of this study?
We are interested in studying the cognitive processes that characterise young people with obsessive-compulsive disorder. We would like to administer a battery of computerised cognitive tasks, each of which is designed to assess a different cognitive process (e.g. decision-making). We would like you to complete these tasks in order to help us with our research. We will also ask you to complete several questionnaires in order that we may examine the relationship between performance on the cognitive tasks with clinical characteristics. In addition, we will also invite your siblings and/or parents to complete the same tasks, if you give consent.

Why have I been invited?
You have been invited because you are a young person who fits the criteria to join this study as a control participant.

Do I have to take part?
It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?
If you decide to take part, then you will first be interviewed via telephone by a researcher, who will ask you questions in order to ensure that you are suitable for this study. If you are indeed suitable for the study, then we will invite you to participate and arrange a testing

session at a mutually convenient date and time. On the day of testing, you will first be interviewed briefly by a researcher from the University of Cambridge in order to gather more information about you. Then, you will be asked to perform simple computerised tasks that involve evaluating items, such as letters or numbers or pictures, and responding to them by pressing buttons. The tasks are perceived as simple games or puzzles and do not usually present volunteers with any significant problems. Finally, you will be asked to complete several questionnaires that assess clinical characteristics, such as severity of obsessive-compulsive symptoms and anxiety.

For participants willing to travel to Cambridge for testing: All study procedures will take place in a dedicated testing room in the Behavioural and Clinical Neuroscience Institute, Downing Site, Cambridge, CB2 3EB or in the Herchel Smith Building, Addenbrooke's Site, Cambridge, CB2 0SZ. Following the interview with the researcher, computerised tests and questionnaires will be intermixed. After you have completed 2 tests (or after approximately 45 minutes), we will let you have a 5-10 minute break. For example, you will complete 1 test on the computer, then 1 questionnaire, then you will have a break. The testing session will be no longer than 3 hours.

Expenses and payments
Each family will be compensated for their time at the rate of £8 per hour (one person); additionally, you will be reimbursed for travel expenses.

What are the possible disadvantages and risks of taking part?
In the unlikely event that you become agitated during the testing session, then we will suspend the session, and the researcher will discuss with you what has caused you to become upset. We will resume only if you wish to continue.

What are the possible benefits of taking part?
You would have the pleasure of knowing that you made a contribution to the understanding of obsessive-compulsive disorder. However, there will be no direct therapeutic benefits of taking part in this study.

What happens when the research study stops?
When data from several volunteers have been collected, they will be analyzed and written up for publication in a scientific journal. The results may also be presented at scientific meetings or during lectures at academic institutions. Data will be presented without reference to your name or other identifiers.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Part 2

What if relevant new information becomes available?
If new information pertains specifically to your health, you will be informed. Otherwise, new information will be disseminated through traditional scientific channels (journal articles and conference presentations).

What will happen if I don't want to carry on with the study?
You are free to withdraw at any time, without giving a reason. If you withdraw from the study, any data that has been collected from you will be destroyed.

What if there is a problem?
If you have a concern(s) about the study, you can bring it immediately to the attention of the experimenter, Aleya Marzuki (telephone: 07845667907; email: aa2017@cam.ac.uk), and/or you can contact the Chief Investigator, Professor Barbara Sahakian, whose contact information can be found on the last page of this information sheet.

Will my taking part in this study be kept confidential?
All data are handled in compliance with the relevant UK statutory and Data protection laws. All information that is collected from or about you during the course of the study will be kept strictly confidential. All data will be catalogued by participant identification number, thus strictly without reference to participant name or other identifiers. All consent forms, clinical scales, and questionnaires, and the master list linking names with participant identification numbers will be stored in a locked cabinet in a locked office in the Department of Experimental Psychology at the University of Cambridge and will be accessible only to the members of the study team and regulatory authorities, who monitor the quality of research, such as the University of Cambridge. If you agree, the clinical scales and questionnaires may be shared with the Trust in which you are receiving treatment. All computerised data will be stored electronically in password-protected files. The data will be evaluated and analyzed by the study team for research purposes only. Analysis will take place in the Department of Psychiatry. The data may be reported in the form of internal reports and scientific papers and presentations. As per established guidelines, research data will be stored for 10 years after the conclusion of the study using participant identification numbers to ensure anonymity. All inquiries concerning access to data held by the Departments of Experimental Psychology and Psychiatry at the University of Cambridge should be addressed to the Administrator, Dr. Jeanne Estabel, in the first instance.

Confidentiality will broken only if you disclose information indicating risk of harm to yourself or others, in which case the researcher will notify the appropriate authority.

What will happen to the results of the research study?
The results will be communication to other members of the study team and will be reported in scientific papers and presentations. You will not be identified in any of the above. The results of the study will contribute to the understanding of obsessive-compulsive disorder.

Who is organising and funding the research?
This study is being organised by the Departments of Experimental Psychology and Psychiatry at the University of Cambridge and in part fulfilment of an MPhil. (Aleya Marzuki). It is being funded by a Wellcome Trust Programme Grant.

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 a favourable opinion by the Essex 1 Research Ethics Committee.

Are there compensation arrangements if something goes wrong?
In the unlikely event of anything unfavorable happening, the Chief Investigator has arranged insurance for negligent and non-negligent harm to volunteer participants in this research project. If you wish to make a complaint, formally or informally, you could contact the experimenter, the chief investigator (see contact information below), or Dr. Jeanne Estabel, who is the administrator of the Department of Experimental Psychology at the University of Cambridge.

Contact information:

Chief investigator

Name: Professor Barbara Sahakian
Address: Department of Psychiatry
Box 189, Level E4, Addenbrooke's Hospital, Hills Road
Cambridge CB2 2QQ
Contact No: 01223 768009
E-mail: bjs1001@cam.ac.uk (cc: bjs-sec@medschl.cam.ac.uk)

Local principal investigator

Name: Dr Emilio Fernandez-Egea
Address: Herchel Smith Building for Brain and Mind Sciences
Forvie Site | Robinson Way | Cambridge Biomedical Campus | CB2 0SZ
Contact No: 07515657016
E-mail: ef280@cam.ac.uk

The Patient Advice and Liaison Service

Name: Marie McKearney
Address: Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House, Fulbourn Hospital, Fulbourn
Cambridge CB21 5EF
Contact No: Freephone 0800 376 0775, T 01223 726774
E-mail: marie.mckearney@cpft.nhs.uk

Thank you for considering taking part in this study. Our research depends entirely on the cooperation of potential volunteers like you. Please let us know if you would like any further information.