

INFORMATION SHEET FOR PARTICIPANTS

REC Reference Number: 14/SC/0172

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Study title: Measuring cognitive processing in chronic fatigue syndrome and other long term conditions (LTCs)

Researchers' names: Alicia Hughes, Prof. Rona Moss-Morris, Dr. Colette Hirsh and Prof. Trudie Chalder

We would like to invite you to participate in this original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. 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. This study forms part fulfilment of a PhD project and will be used for educational purposes.

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.

1. What is the purpose of the study?

You are being invited to take part in a research study on concentration, attention and fatigue in long term health conditions (LTCs). Fatigue is a common symptom across a number of LTCs. Research has also shown that people with LTCs often report attention and concentration difficulties. This research is interested in understanding these issues further, by exploring how people attend to and interpret information in their environment and comparing this to people who have no such condition. It is hoped that this research may inform the development of new and alternative treatments to address these issues for people with LTCs.

2. What would taking part involve?

Once you have agreed to take part in the study and we have checked this is suitable for you, you will be asked to fill in a questionnaire about yourself and various symptoms. This can be completed online or on paper if you prefer. The questionnaire takes about 30 minutes to complete.

You will also be asked to attend a session with a research assistant to complete 3 simple computer tasks. These tasks will measure aspects of cognitive processing based on the speed of your reaction times. The computer tasks will take no more than 60 minutes to complete.

The tasks will be completed in a private room in either King's College London's Institute of Psychiatry, Psychology and Neuroscience in Denmark Hill, or at Guy's Hospital, London Bridge. The session will be scheduled at a location, date and time to suit you.

After you have completed this session, you will be given more detailed information about the purpose of this study. You will have the opportunity to ask questions and discuss your experience.

The research team may access your medical notes for information such as, medication, information about your long term condition, other acute illnesses, your address, telephone number and email address whilst you are involved in the study, but all information will remain strictly confidential.

3. What kind of questionnaires will I have to fill in?

The questionnaires will ask you about your levels of activity and fatigue and your mood.

4. Why was I invited to take part?

You have been invited to join our study because you have a long term condition, such a cancer or multiple sclerosis. Over one hundred people with long term conditions such as these will take part in this study.

5. Can I take part in this study?

You can take part in this study if:

- you have a hospital diagnosis of a long term condition (*if you are unsure if you have a long term condition please speak to the research assistant who provided you with this information sheet*)
- are at least 18 years old
- are fluent in English

6. Do I have to take part?

It is up to you. If after reading this information sheet, you agree to take part, you will sign the consent form at the end of this document. You are free to leave the study at any stage, without giving a reason.

7. Expenses

You will be paid £20 in cash for attending the session.

9. What are the possible disadvantages and risks of taking part?

There no risks to you health by taking part in this study. The only cost to participants in taking part is likely to be time, which will be minimised by keeping tasks as short as possible and scheduling them at a time and place convenient to you.

10. What are the possible benefits of taking part?

A possible benefit of taking part is that we will have a greater understanding of fatigue and its associations in LTCs. We intend to utilise the findings to develop an intervention which will ultimately benefit you and other patients.

11. 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.

12. 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.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

More detail- information you need to know if you still want to take part

1. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. However, we will need to use the data you have provided so far so that we can analyse the results from the study accurately. We will remove any information that can reveal your identity.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (Alicia Hughes via tel: 0207 188 0192 , email: Alicia.hughes@kcl.ac.uk; or Susannah Pick via tel: 0207 848 0965, email: susannah.pick@kcl.ac.uk). This study has liability insurance in place.

3. Will my part in this study be kept confidential?

Yes. The procedures for handling, processing, storing and destroying data are compliant with the Data Protection Act 1998. Data about you will be linked to a number rather than your name in order to maintain anonymity. Information about you will be stored securely and will be available only to members of the research team. It will be used only for the purposes of the current study. Data from this study will be retained until the study has been written up for publication (not more than 5 years) and subsequently disposed of securely.

4. What will happen to the results of the research study?

The results will be used to help the researchers design an intervention to help people with long term conditions cope with symptoms such as fatigue, and attention and concentration difficulties. The study will be written up for publication in scientific journals and may be presented at scientific conferences. All participants will be sent a summary sheet of the results. If you would like to find out more about the findings you can contact Alicia Hughes (via 0207 188 0192 or alicia.hughes@kcl.ac.uk).

5. Who is organising the research?

The research is being organised and conducted by researchers from King's College London, UK.

6. Who has reviewed the study?

This study has been reviewed and given favourable opinion by the NHS Berkshire B Research Ethics Committee.

Contact details for further information

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

Name: Susannah Pick Telephone number: 0207 848 0965

Email: susannah.pick@kcl.ac.uk

Address: Neuropsychiatry Department, 6th Floor, Institute of Psychiatry, Psychology & Neuroscience, KCL, 16 De Crespigny Park, London SE5 8AF

or

Name: Alicia Hughes Telephone number: 0207 188 0192

Email: Alicia.hughes@kcl.ac.uk

Address: Health Psychology Section, Psychology Dept., Institute of Psychiatry, KCL, 5th floor Bermondsey Wing, Guy's Hospital Campus, London Bridge, London SE1 9RT

Thank you for reading this participant information sheet.