Participant Information Sheet

The Role of Metacognitive Beliefs in Emotional Distress in People with Multiple Sclerosis

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You are being invited to participate in a research study. Before you decide whether to participate, 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 feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and your GP if you wish. Take time to decide whether or not you wish to take part. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

What is the purpose of this study?

The University of Liverpool is carrying out a research project to help understand more about depression and anxiety in MS. To do this we ask you to complete six questionnaires based on measures of emotional distress, fatigue and pain, and how you make sense of your MS. There will be around 200 participants in this study and it will run from February 2016 to February 2017.

Why is this research needed?

MS affects more than 100,000 people in the UK. Little is known about the nature of depression and anxiety in this condition. This research will help identify important factors involved in triggering and maintaining depression and anxiety in people with MS.

With an increasing number of people living with the condition, urgent focus is needed to improve our understanding of emotional distress in this population. In future this data can be used to develop new treatments.

What is the difference between research and medical treatment?

Researchers develop a new idea, looking carefully to see what is already known about a condition and identifying gaps in knowledge. They develop a research question (hypothesis) and then put together a research plan (protocol) to try and answer this question. Research is carried out using many different methods, depending on the question.

This study is not a medical trial which is used to test whether or not a new treatment works.

Why have you been asked to take part?

As someone who uses MStrust.org.uk your viewpoint is very important to us. We wish to include adults (aged 18 or over) who have been diagnosed with MS. We are interested in understanding how different factors affect emotional distress in people with MS. This means that we are inviting anyone with a diagnosis of MS to complete a set of questionnaires that ask about how they make sense of their MS, their emotional reactions, and also whether they experience common symptoms like fatigue and pain. It is possible that some people will currently have symptoms of depression and anxiety, or have had these emotional difficulties in the past, whereas others may never have experienced depression and anxiety. It is important to include people with different experiences so we can build a more complete picture of the nature of depression and anxiety and the beliefs that people hold about the psychological aspects of these. The invitation to take part in the study does not mean that we think you are having problems with depression and anxiety or are finding it hard to cope. We are inviting people regardless of how they feel at the moment.
Do I have to take part?
Participation is voluntary so it is up to you whether or not you agree to take part. If you do decide to take part, you will be asked to sign a consent form. If you do decide to take part and then change your mind you are free to do so at any time without giving a reason and without incurring a disadvantage.

What will happen if I agree to take part?
If you do decide to help us in this study, you will be asked to complete a set of questionnaires at two time points. We would like you to complete the first set of questionnaires shortly after you have read all of the information about the study. We would then ask you to complete the same set of questionnaires approximately three months later. Each set of questionnaires will take approximately 30 minutes to complete. In order to complete the second set of questionnaires we need you to provide an email address at which we can contact you and provide you with the webpage to complete the questionnaires.

The questionnaires will ask about a range of symptoms (anxiety, low mood, fatigue and pain) you may have experienced over the last month. The questionnaires will also ask about how you cope with these symptoms. If you have not experienced any of these symptoms in the last month we are still interested in your opinions about these issues.

What are the possible benefits of taking part?
You will not directly benefit from participation in this study. Knowledge gained may lead to a better understanding of psychological factors involved in anxiety and depression in MS.

To thank participants for taking part in the study we are offering the chance to enter a prize draw for one of three £50 gift vouchers. Details will be given at the end of the study to those that have completed both questionnaires.

Will information about my health and results be kept confidential?
All of the information you provide will be stored securely and kept confidential. Your name and contact details will not appear on any of the data collected and an ID code will be used to identify your data. That way, we will not identify you when we analyse the data or write reports about the study. When you complete the questionnaires online, the answers will be transferred automatically to a secure database to enable it to be analysed with data from other participants. For the duration of the study, a database linking email addresses with ID codes will be kept securely a University of Liverpool server. Data will be stored securely on password protected computers at the University of Liverpool in line with data protection requirements. Email addresses will be used solely to contact you 3 months after the first set of questionnaires to see if you wish to take part in the second part of the study. Email addresses will be destroyed after the questionnaires have been analysed and when they are no longer needed.

All the information you provide will not be revealed to anyone not involved in this study. Findings from the study will be published but it will not be possible to identify you from these reports, as any information about you which leaves the university will have your contact details removed so that you cannot be recognized from it. If you wish, we will be happy to send you a summary of the results at the end of the study.

If you choose to withdraw your information from the study, any personal data we hold will be destroyed.

Can I see the information you hold?

Version 2
25.10.2015
Under the Data Protection Act 1998 you are entitled to request access to the personal data we hold. Data collected in this study may be held for up to 5 years.

**What will happen to the results once completed?**
Once the study is complete we will analyse the results and publish it in academic journals. We will not identify you in any way when the results are published. Should you so wish, we will send you a short report of the findings of the study.

**Who is organizing and funding the research?**
The University of Liverpool is organizing this study.

**Has this study been approved?**
The study has been reviewed and approved by the University of Liverpool Ethics Committee.

**What will happen if I want to stop taking part?**
You are free to withdraw at any time without giving a reason and without incurring a disadvantage. Results up to the period of withdrawal may be used, if you are happy for this to be done. Otherwise you may request that they are destroyed and no further use is made of them.

**What if I want to ask questions not included in this information?**
Please raise any further questions you may have with the researchers on this study who will be happy to answer you. Alternatively please feel free to contact the Principal Investigator Dr Peter Fisher on 0151-794-4160 (Peter.Fisher@liverpool.ac.uk)

**Can you give me advice on MS and/or depression?**
We cannot give you any specific advice on these issues but we can suggest a number of sources where information is available.

**What if there is a problem?**
If you are unhappy, or if there is a problem, please feel free to let us know by contacting the Principal Investigator Dr Peter Fisher (0151-794-4160) and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Governance Officer on 0151 794 8290 (ethics@liv.ac.uk). When contacting the Research Governance Officer, please provide details of the name or description of the study (so that it can be identified), the principal investigator, the researcher(s) involved, and the details of the complaint you wish to make.

**Principal Investigator: Dr. Peter Fisher**
Project Title: The Role of Metacognitive Beliefs in Emotional Distress in People with Multiple Sclerosis

**Project Research Ethics Number: IPHS-1516-30**

**Where are the contact details?**
Contact details and the address of the study centre are at the beginning of this document. Thank you for taking the time to read this information sheet.