

## **The role of perseverative negative thinking in predicting depression in people with CHD: Prospective cohort study**

### **Participant Information Sheet**

We would like to invite you to take part in our research study. Before you decide it is important that you understand why the research is being done and what it would involve. Please read the following information carefully and ask if there is anything that is not clear. You may talk to others about the study if you wish.

#### **What is the purpose of the study?**

Some people who have recently had an admission to hospital with a heart problem (such as a heart attack or angina) may feel low in their mood, anxious and frightened for some time afterwards. Occasionally some people can even go on to develop depression after their heart problem, and this can last for months. These feelings could be important as they might affect the way someone recovers from their heart problem (e.g. how quickly they get back to their usual activities). We don't understand exactly what factors sometimes cause people to feel low, anxious or frightened, however.

The purpose of this research is to understand whether the extent to which people tend to repeatedly think about and dwell on frightening or unhappy thoughts (that is the extent to which they worry or ruminate) in the days following their heart problems might cause them to feel low, anxious or frightened. This research is important because it may lead to new treatments that help stop people feeling low, anxious or frightened and therefore help them get back to their normal selves as quickly as possible.

#### **Why have I been chosen?**

We are asking 250 people recently admitted with a heart problem (such as a heart attack or angina) to take part in this study.

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

It is completely up to you whether or not you take part. You do not have to take part in the research, and if you decide not to participate this will not affect your treatment in any way.

#### **What will happen to me if I take part?**

You will be asked to complete the enclosed questionnaire pack when you join the study. The questionnaires ask about your recent feelings, health, activity levels, how you cope with problems, and the support you receive from friends and family. You can complete this pack at home and return it to us in your own time. You will be asked to complete the same questionnaire pack again 2 months later and 6 months later. It will take around 1 hour to complete each questionnaire pack. A researcher will telephone you to remind you about the study before each questionnaire pack is sent to you. You will also be asked to complete a short memory exercise and a spelling exercise over the telephone with a researcher at around

the same time you complete each questionnaire pack. These tasks will take approximately 5-10 minutes each, and we will agree a convenient time with you to do this.

If you take part we will also look at your medical records in order to collect information about your heart problem and any medication or treatments you may have been given.

60 people who take part in this study will be contacted by telephone after approximately 2 months to see if they would be willing to take part in an additional part of the study which would involve completing some computerized exercises. You will be given more information about this additional part of the study at the time you are contacted, and you will be free to choose whether or not to take part.

### **What do I have to do in order to take part?**

Please fill in the enclosed 'participant consent form' and questionnaire pack and return them in the stamped addressed envelope provided. A researcher will telephone you before each questionnaire pack is sent out to remind you about the study. If you have any queries about the questionnaires, or would like help completing them, please contact the researcher.

### **What are the possible disadvantages and risks of taking part?**

The questionnaires measure your feelings of lowness and anxiety. Sometimes when people are asked to think about their feelings it can remind them of unhappy events in the past which can cause them to feel upset temporarily. If any of the questions make you feel upset please let the researcher know. If you do feel upset you are free to withdraw from the study at any time. We can also provide information about support services available in Exeter. If you are worried about any thoughts or feelings you have which are triggered by completing the questionnaires please telephone the researcher using the contact details at the end of this letter.

### **What are the possible benefits of taking part?**

It is hoped that the information gathered in this study will help to provide more information about the link between the ways people think in the days following admission to hospital with a heart problem and how they feel in their spirits. It is hoped that this will lead to better ways to support people after they have had a heart problem.

### **What would happen if we were concerned about your safety?**

Some of the questionnaires may show you that you are experiencing severe problems with your mood, such as depression. If you are found to be very depressed, your safety will be our priority and we may talk to you about letting your GP know about your feelings so that he or she can offer you the best treatments available. Under these circumstances, a researcher may also want to talk to you more about how you are feeling and the support you may need. If we are still concerned about your safety after we have spoken to you, we will contact your GP if we think it is in your best interests.

### **Will my taking part in the study be kept confidential?**

All information collected about you during the study will be stored securely at the University of Exeter, and will be treated in confidence. Personal data will not be kept once the study has ended – e.g. your name, date of birth, address etc. Data obtained from questionnaires may be stored for up to five years, though there will be no way in which you can be individually identified from the data we store.

**What if I don't want to continue with the study anymore?**

You are free to withdraw from the study at any time, without giving a reason. If you decide to withdraw from the study your treatment will not be affected in any way. If you decide to withdraw any questionnaires that you have already completed and information from your medical records will be kept, but any personal identifying information that you have provided (such as your name, date of birth, address etc) will be destroyed. We will not ask you to provide additional information after you tell us you wish to withdraw.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the main researcher (Leanne Trick, telephone: 01392 725947 or email: [L.V.Trick@exeter.ac.uk](mailto:L.V.Trick@exeter.ac.uk)).

**What will happen to the results of the study?**

The results will be written up and submitted for publication in an academic journal. The work may also be presented at academic conferences. None of your personal information will be revealed and you will not be identifiable in any written reports, or other presentations. If you wish to know the results of the study you can request this information from the researchers.

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

This research is being funded by the University of Exeter. The research is being carried out as part of a PhD being undertaken by the main researcher (Leanne Trick).

**Who has reviewed the study?**

All research in the NHS is looked at by an 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 **NRES Committee South West – Frenchay REC**.

**Contact for further information**

Leanne Trick is the main researcher for this study. Please contact Leanne if you have any questions about this study: University of Exeter Medical School, St Lukes Campus, Heavitree Road, Exeter EX1 2LU (telephone: 01392 725947 or email: [L.V.Trick@exeter.ac.uk](mailto:L.V.Trick@exeter.ac.uk)).

The other researchers involved in this study are Professor Chris Dickens (University of Exeter Medical School, St Lukes Campus, Heavitree Road, Exeter EX1 2LU), Professor Ed Watkins (University of Exeter Mood Disorders Centre, School of Psychology, Perry Road, Exeter EX4 4QG) and Dr Manish Gandhi (Consultant Cardiologist, Royal Devon & Exeter NHS Foundation Trust, Cardiology Department, Gladstone Road, Exeter EX1 2ED).

**Thank you for taking the time to read this information.  
Please keep this information for your own records.**