



The University of  
**Nottingham**



FRESH - Facilitating Return to work through  
Early Specialist Health-based interventions



**National Institute for  
Health Research**

## **PARTICIPANT INFORMATION SHEET – Primary Outcome Focus groups Interviews**

### **FRESH - Facilitating Return to work through Early Specialist Health-based interventions: Identifying primary outcomes of importance**

#### **Introduction**

We are inviting you to take part in an interview as part of a research study. Before you decide, you need to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. One of our team will go through this information sheet with you and answer any questions you have. Ask us if there is anything that is not clear to you or if you would like more information. We can be contacted on the telephone numbers at the end of this sheet. Take time to decide whether or not you wish to take part.

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

People who have had a traumatic brain injury (TBI) may experience problems that can affect their ability to work or study. We have developed a way of supporting these people in returning to work or education. It involves an occupational therapist, who is experienced in work issues and brain injury, working with the person, their family and employer or tutor to support a return to work or education. We tested it in one small study, where it appeared to work well and are currently testing it in three more cities to see if we can deliver the specialist support in the same way and measure its effects. But before we go on to do a larger study, ***we need to know which outcomes (e.g. return to work, early retirement, participation in social and leisure activities, voluntary work) of this type of support are important to people who have had a TBI*** and who may be eligible to receive it.

#### **Why have I been invited?**

We are inviting you to take part in an interview because you have had a traumatic brain injury. The aim of the interview will be to explore what you think are the most important outcomes of an NHS based TBI specialist job retention intervention

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

It is up to you to decide whether you wish to take part. Take your time to consider taking part and if you decide to, we will ask you to sign a consent form and return it, including a witness signature, to Julie Phillips in the freepost envelope provided. You will have a copy of the consent form to keep and you should also keep this information sheet. You are free to withdraw at any time, without giving a reason.

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

If you agree to be interviewed, you will be contacted by telephone and a time will be arranged with you to either take part in a focus group with other people who have had a TBI or to be interviewed at your convenience. Focus groups lasting about 90 minutes will be held either at the University of Nottingham or at a local Headway Centre and will be conducted by our researcher Julie Phillips and a research assistant. Individual interviews will be held in person either at your home; another mutually agreed location; or by telephone. This interview would last about half an hour.

The content of the focus groups or interviews will be audio recorded and field notes made to capture inaudible or contextual information. The content will be transcribed and analysed to identify the outcomes that matter most to people with traumatic brain injury when receiving rehabilitation to support a return to work or education.

### **Expenses**

You will be fully reimbursed for any expenses incurred in travelling to a focus group or interview (if necessary) and if transport is a problem, we can arrange this for you.

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

The information you provide during the interview will help us to design future studies and improve health-based return to work, or education, programmes for people with TBI.

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

We do not expect there are any disadvantages or risks to you. We will do our best to arrange the group or individual interview at a time to suit you.

### **What happens when the study stops?**

When the study ends you will continue with your routine care from the hospital or GP as usual.

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

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, any data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you will be anonymised and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 7 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved

to maintain your confidentiality, only members of the research team will have access to your personal data.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

**What will happen if there is a problem?**

If you have a concern about any aspect of this study, you should in the first instance ask to speak to the researchers who will do their best to answer your questions (contact Dr Kate Radford, Chief Investigator, on 0115 8230226). **If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.**

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

We will be using these findings to plan a large scale study testing work advice interventions. The findings from this pilot study will be written up and submitted for publication to enable other NHS brain injury rehabilitation services learn from our experiences. You would not be identified in any report or publication.

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

The study is being organized by the Division of Rehabilitation and Ageing, University of Nottingham. It is being funded by the Government's Health Technology Assessment Programme.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by The University of Nottingham Medical School Research Ethics Committee and given favourable opinion.

**Further information and contact details**

If you have any questions about the study, wish to discuss taking part or have any concerns, you can contact **Dr Kate Radford** on 0115 823 0226. Alternatively, you can contact the researchers leading the study:

<b>Dr Julie Phillips</b> Division of Rehabilitation and Ageing B Floor, Queens Medical Centre Nottingham NG7 2UH Tel: 0115 823 0244	<b>Dr Kate Radford</b> Division of Rehabilitation and Ageing B Floor, Queens Medical Centre Nottingham NG7 2UH Tel: 0115 823 0226
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**Finally**, many thanks for reading this information sheet. Please keep this information sheet. We will ask you to sign a consent form if you agree to take part and we will give you a copy of this to keep.