The University of Nottingham

Working After Brain Injury

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

NHS National Institute for Health Research

EMPLOYERS INFORMATION SHEET

FRESH: Supporting return to work after brain injury Identifying Primary Outcomes of importance

Introduction

We are inviting you to take part in a focus group 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 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 a case manager and occupational therapist, who are 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. We are now currently testing it in three more cities to see if we can deliver the specialist support in the same way and measure its effects. However, before we go on to do a larger study ***we need to know which outcomes of this type of support are important to people who employ or have employed or who may employ people with traumatic brain injury.*** Possible outcomes from this type of support are varied and may include ***return to work, increased participation in social and leisure activities, voluntary work, early retirement. We want to find out what would be important to you.***

Why have I been invited?

We are inviting you to take part in a focus group because you employ or have employed or know someone with a traumatic brain injury and are an employer. The aim of the interview will be to explore what you think are the most important outcomes of a specialist return to work intervention for people who have had a traumatic brain injury.

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. If you decide to take part, we will ask you to sign a consent form and return it to: Dr 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 wish to take part, you will be contacted by telephone, and a time will be arranged with you to take part in an interview either by face to face, by telephone or by email. We will do our best to arrange a time and venue that is convenient for you. The interview will last no longer than 60 minutes. We will confirm this in writing to you. The interviews will be conducted by our researcher Dr Julie Phillips and/or a research assistant.
The content of the interview will be audio recorded and notes made to capture inaudible or contextual information. The content will be written up and analysed to identify the outcomes that matter most to employers who know someone with a traumatic brain injury in relation to a return to work or education.

Expenses
You will be fully reimbursed for any expenses incurred in travelling to an interview 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 traumatic brain injury.

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?
In case have a complaint on your treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator, Dr Kate Radford, Chief Investigator, on 0115 8230226. If this achieves no satisfactory outcome, you should then contact the Ethics Committee Secretary, Mrs Louise Sabir, Division of Therapeutics and Molecular Medicine, D Floor, South Block, Queens Medical Centre, Nottingham, NG7 2UH, Telephone 0115 8231063, Email louise.sabir@nottingham.ac.uk
Should any issues or information that may pose a risk of harm to yourself or others, be disclosed, the researcher will discuss it with the Chief Investigator and take the most appropriate course of action.

What will happen to the results of the research study?
We will be using these findings to plan a large scale study testing out this early specialist work focused intervention. The findings from this pilot study will be written up and submitted for publication to enable other NHS brain injury rehabilitation services to 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.

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 the researchers leading the study at the address below:

Dr Julie Phillips
Julie.phillips@nottingham.ac.uk
Tel: 01 823 0244

Dr Kate Radford
Kate.radford@nottingham.ac.uk
Tel: 0115 823 0226

Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham
Queens Medical Centre, Nottingham NG7 2UH

Finally, thank you for reading this information sheet. Please keep this information leaflet. We will ask you to sign a consent form if you agree to take part and give you a copy of the form to keep.