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

PARTICIPANT INFORMATION SHEET – FEASIBILITY TRIAL
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Title of Study: **FRESH: F**acilitating **R**eturn to work through **E**arly **S**pecialist **H**ealth-based interventions. (Working After Brain Injury)

Name of Researcher: Dr Kate Radford (Chief Investigator)

Introduction

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear. You will be given a minimum of 24 hours to decide if you wish to take part.

If you are still in hospital you will have received this information sheet from your care team. If you are interested in taking part you should let the care team know and a member of the research team will go through this information sheet with you and answer any queries you may have. We anticipate that this should take around 20 minutes.
If you have already been discharged then you will have received this information sheet in a letter from the Consultant. We will contact you to ask if you are interested and arrange a convenient time for a member of the research team to go through the information sheet with you and answer any questions you may have. We anticipate that this should take around 20 minutes. (If you wish you may also contact the research team directly to express an interest or to decline. Contact details are at the end of this information sheet).
The decision to take part or not is entirely yours and only when you have had all your questions answered satisfactorily and are happy to continue will we ask you to sign a consent form.

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. A traumatic brain injury (TBI) is an injury to the brain resulting from a head injury. There are many different causes of injury but the main ones are as a

result of road traffic accidents, falls and accidents, assaults etc. There are also many different levels of injury from minor to the more severe.
We have developed a way of supporting people who have suffered a brain injury, assisting them in returning to work or education. It involves an occupational therapist, experienced in work/educational issues and brain injury, working with you, your family and employer or tutor to identify your individual issues and support a return to work or study. We have tested this support programme in one small study where it appeared to work well.
Now we need to try it with a larger number of patients from different areas, different backgrounds and different levels of injury to make sure it is acceptable and useful to patients.
When we want to introduce a new way of working it is important that we compare it against our usual way of working and measure the results to see which way of treating our patients is best. To do this we will be allocating half (50%) of all people who take part into the usual care treatment group and half (50%) into usual care plus specialist return to work group.
To try and make sure the groups are the same to start with, each participant is put into a group by chance (randomly). This process is called randomisation and to ensure that it is fair, the group you will be allocated to will be decided by a computer programme in the clinical trials unit. None of the researchers or members of the care team will have any input into which group you will be allocated to.

The findings will help us to further develop specialist 'return to work' support programmes. This is a feasibility study (a practice-run before doing a large-scale study). It will help us find out more about:

a) how best to train therapists to deliver this specialist support.
b) how best to measure the costs of that support and how well it works
c) whether people taking part can complete the questionnaires we plan to use, without difficulty.
d) we also want to find out if people who have had a brain injury find this type of trial acceptable and whether they are willing to be randomly allocated to receive the specialist support we have developed, in addition to their usual care; or receive only the usual care that is currently available to them
e) we want to know how helpful people with a brain injury find this support; and how we can improve it.

We can then make changes before we do a larger study. We need to ensure that research meets patient needs and are asking your help to do this. If you are interested in taking part please read the rest of this information sheet.

Why have I been invited?
We are asking you to take part because you have had a brain injury that resulted in an inpatient stay of more than 48 hours and you were working, or a full time student, at the time of your brain injury. Your Consultant has helped us to identify who to ask. We are inviting 102 participants like you to take part.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

The research nurse or therapist can arrange a suitable time with you in the next few days or weeks to meet. This will be in the hospital if you are still an inpatient and if you have been discharged; either at your home or in clinic whichever is more convenient for you.

What will happen to me if I take part?
After you have consented, the therapist will conduct an initial assessment; you will be asked a question to find out what outcomes from a return to work / education programme are important to you. You will then need to complete a questionnaire booklet which asks about: a) your brain injury and some information about yourself; b) your work, c) your current health and ability to do everyday activities and d) about any health appointments you attended and any adaptations/ equipment you may have paid for or received for work since your brain injury. It will take between 35 - 45 minutes to complete

Sometimes when people suffer an injury it can have an effect not just on themselves but also on the health and wellbeing of the people close to them. We will ask you if you would like to nominate what is normally referred to as a carer (this could be a spouse, partner, parent or friend; whoever has the most contact with you). If possible we would ask for this nominated carer to also complete a questionnaire at this initial assessment.

The decision to nominate a carer is entirely up to you and if you would prefer not to, it will not in any way affect your taking part in this study.

After this initial assessment the therapist will contact the trials unit who will allocate (randomise) you into one of the two groups. The therapist will then contact you to let you know which group you have been allocated to. This may take a couple of days depending on which day of the week your initial assessment took place on.
You will receive either:

a. the usual care and access to services provided for people following traumatic brain injury within this Trust
b. the usual care and access to services provided for people following traumatic brain injury within this Trust plus the specialist early return to work support programme being tested in this study.

There is a possibility that you may be disappointed by which group you have been allocated to, but each of the groups is **equally important** to developing this specialist early return to work support programme and we hope that whatever the outcome you will continue to take part.

<u>During the 12 months in the study</u>
If you are allocated to the usual care group you will receive all the usual support and access to services provided by your care team.

If you are allocated to receive the specialist return to work or education support programme from the occupational therapist**,** you will be contacted by the therapist to arrange an initial appointment at your home or a mutually agreed location. The support will include up to 10, 1-hour meetings dependent on your needs. It may involve working together with your employer or tutor if you have one. We will only contact your employer or tutor (if applicable) if you provide written consent for us to do so. We will also seek your verbal consent each time we

wish to contact your employer or tutor. The content of this support will be discussed and agreed with you. This specialist support will last for a maximum of 12 months, after which you will continue to receive only the usual care available to you.

Follow-up

While in the study (regardless of which group you are in) we would like to follow your progress and will ask you to complete questionnaire booklets at the start of the study and again at 3, 6 and 12 months. When these questionnaires are due the research assistant will contact you to confirm that you are happy to continue and arrange a mutually convenient time to meet with you, at your home, to complete the questionnaire booklets. There will be a separate questionnaire for your nominated carer to complete (if applicable). If your nominated carer can't be present to complete the questionnaire, we will contact them to arrange a convenient time to complete the questionnaire with them.

We will also collect information from your medical notes about the amount of support you have received and which services you have accessed. We will only collect information directly relevant to your participation in this study and nothing else.

Additionally, after we have received your returned questionnaire booklets at 12 months, we may wish to interview you (and your employer if you received the specialist support and are happy for us to contact them) for about 20 minutes by telephone. If you are willing to do this, your contact details will be provided to a researcher at the University of Nottingham who will contact you to conduct the interview. This interview may be audio recorded. We will ask you about the support you have received and the things you found useful or most helped you return to or remain in work or education. You do not have to agree to this interview to be able to take part in the study.

Expenses and payments

Participants will not be paid to participate in the study. We will visit you at your home to complete the follow-up questionnaires and we will contact you for the telephone interview to avoid you having to incur any untoward expenses.

What are the possible disadvantages and risks of taking part?

We do not expect there are any disadvantages or risks to you. We will arrange any interviews and appointments at times to suit you

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study will help us plan a larger study to test how effective the specialist return to work support programme is. In the future, this could help improve rehabilitation services for other employed people who have a brain injury.

What happens when the study stops?

When the study ends after 12 months, you will continue with your usual care from your hospital or GP.

What if there is a problem?

If you have a concern about any aspect of this study, you should 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's Patient Advice and Liaison Service (PALS). Telephone 0113 206 6261, Monday to Friday, 9.00am to 4.30pm.

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, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham, who are organising the research, and the Lancashire Clinical Trials Unit. It 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 which leaves the hospital will have your name and address removed (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.

We would ask for your permission for the anonymised data set to be used to inform future projects and for education purposes and this permission is included within your consent form.

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.

Involvement of the General Practitioner (GP)
If you do decide to take part in the study, we will inform your GP and provide them with a copy of this information sheet.

What will happen to the results of the research study?
We will use these findings to support the design of a large scale study to test whether this specialist return to work support programme results in more people in work/education after brain injury. The findings will be written up and submitted for publication to enable other NHS

brain injury rehabilitation services to learn from our experiences. All reports and publications will be anonymised and you would not be identified in any report or publication.

Who is organising and funding the research?
The study is being organised by the University of Nottingham and is being funded by the National Institute for Health Research's Health Technology Assessment (NIHR HTA) Programme (project number 11/66/02).

Who has reviewed the study?
All research in the NHS is looked at by independent groups of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Northampton Research Ethics Committee (reference 13/EM/0353).

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:

Ali Gibson (Trial Manager) Brook Building 417 Lancashire Clinical Trials Unit (LCTU) School of Health University of Central Lancashire Preston PR1 2HE Tel: 01772 893792 Email: amgibson1@uclan.ac.uk	Dr Kate Radford (Chief Investigator). Division of Rehabilitation and Ageing B Floor, Queens Medical Centre Nottingham NG7 2UH Tel: 0115 823 0226 Email: kate.radford@nottingham.ac.uk

General information about taking part in research studies can also be obtained from your hospital's Patient Advice and Liaison Service (PALS). Telephone 0113 206 6261, Monday to Friday, 9.00am to 4.30pm.

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 it to keep.

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NHS National Institute for Health Research