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Working after brain injury

Submission date
02/01/2014

Recruitment status
No longer recruiting

Registration date
03/01/2014

Overall study status
Completed

Last Edited
01/08/2022

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
As traumatic brain injury (TBI) mostly occurs in young men at the start of their working lives, inability to return to work can have a long-term effect on the person, their family and the wider economy. However, not everybody admitted to an NHS hospital with a TBI has access to support to assist them in returning to work. In some parts of the UK people get specialist support known as vocational rehabilitation (VR), which involves finding ways to 'match' the TBI person's abilities and limitations to the demands of the job and work environment. The VR process involves assessing the person, the job and the workplace and interacting with and educating employers about the nature of the injury, legal responsibilities and any changes that may need to be put in place. It also involves using rehabilitation strategies to prepare a person for work (e.g., improving stamina and concentration, and compensating for problems such as memory aids and negotiating a phased return). It may also involve re-training and negotiating work placements for those unable to return to their previous job. In our initial small study we compared the work outcomes of people who had access to early specialist VR support (ESTVR) to people who didn't have access because of where they lived, and found that people who received ESTVR were more likely to return to work, returned sooner and remained in work 12 months later, and that it only cost health services on average £75 per person more to deliver. However, as this was a small study we can't be certain that the outcomes were due to the ESTVR or whether they were chance findings, therefore a larger study is needed. We also have no way of knowing whether this sort of specialist support can be delivered in other centres and what impact it might have on work outcomes. We don't know how best to measure these outcomes or what effect ESTVR might have on a person's mood, functional ability or quality of life or how best to measure these effects. Therefore we propose a study to find out whether early (starting within 8 weeks of injury) TBI specialist vocational rehabilitation (ESTVR) can be delivered in three new centres and whether its effects on work outcomes (return to work and work retention), benefit status, health, wellbeing and quality of life can be measured and costs captured at different points in time. We would also like to know whether it is acceptable to service users (patients and employers) and staff.
This study will provide all the necessary information to design and conduct a larger study that will tell us whether ESTVR is effective or not.

Who can participate?
Adults (aged 16 and above) living in the London, Preston and Leeds health communities and admitted for 48 hours or more with new TBI and who were in work, intending to work or in full-time education (paid or unpaid) before their injury.

What does the study involve?
Participants will be randomly allocated to receive either the ESTVR intervention or treatment as usual (TAU). The ESTVR intervention group will receive early specialist vocational rehabilitation targeted at preventing job loss delivered by an occupational therapist, supported by a TBI case manager, in addition to usual NHS care. The intervention is structured around individual needs and involves up to 10 individual sessions. TAU is usual NHS care, which may involve efforts to return people to work but does not typically include components of the ESTVR model. Participants will be followed up at 3, 6 and 12 months.

What are the possible benefits and risks of participating?
The intervention may pose a risk of distress caused by raising participants' awareness that their level of functioning may be significantly reduced, in comparison to their abilities and functioning before brain injury. As this is a feasibility study the side effects of the intervention are as yet unknown. We hope to identify these as part of this study to inform the design of future studies. In our single-centre study in Nottingham, this approach resulted in more people in work and fewer living entirely off state benefits at 12 months post injury. Those who received the intervention (participants and their families) were also financially better off. However, as this is only a feasibility study we will not be able to determine whether similar outcomes identified for people who receive the ESTVR intervention in this study are due to the support received or not.

Where is the study run from?
The study is run from the University of Nottingham with study coordination support from the Lancashire Clinical Trials Unit and input from the Nottingham Clinical Trials Unit. There are three participating centres in Preston (Lancashire Teaching Hospitals), London (Barts Health NHS Trust) and Leeds Teaching Hospitals, UK.

When is the study starting and how long is it expected to run for?
The study began in March 2013 and will run until the end of February 2016. Recruitment to the study started in December 2013 and will continue until August 2014.

Who is funding the study?
National Institute for Health Research (UK).

Who is the main contact?
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Study website
http://www.nottingham.ac.uk/go/fresh

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/66/02, 13100

Study information

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

Acronym
FRESH

Study objectives
Can an Early Specialist Traumatic Brain Injury (TBI) vocational rehabilitation package (manual, training and mentoring model) based on an existing NHS service in Nottingham be developed and implemented in three NHS regional traumatic brain injury referral centres and can its effects and cost effectiveness (compared to usual NHS care) on return to work be measured in a multi-centre feasibility randomised controlled trial?

The primary objectives of the feasibility study are:
1. To determine whether an Early Specialist Traumatic Brain Injury vocational rehabilitation package (manual, training and mentoring model) based on an existing NHS service in Nottingham can be developed and implemented in three different NHS regional traumatic brain injury referral centres with differing service configurations.
2. To determine whether we can test the feasibility of delivering early specialist traumatic brain injury vocational rehabilitation in these referral centres and of measuring its impact and cost effectiveness (compared to usual NHS care) on return to work (finding new work for those unable to return to an existing job) and job retention (return to work with an existing employer) in a multi-centre feasibility randomised controlled trial.
3. To determine whether early specialist traumatic brain injury vocational rehabilitation can be

delivered in a way that is acceptable to traumatic brain injury patients, staff and employers when compared to usual NHS rehabilitation.
4. To determine whether we can identify primary outcomes of an NHS early specialist traumatic brain injury vocational rehabilitation service important to service users, NHS service providers and professionals.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/116602

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee East Midlands - Northampton, 21/10/2013, ref: 13/EM/0353
2. School of Medicine Rehabilitation and Ageing, University of Nottingham, 19/12/2013 (REC ref: 13/EM/0353), D14112013 FRESH

Study design
Mixed methods including a three-centre feasibility randomised controlled trial and nested process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Traumatic brain injury (TBI)

Interventions
Planned interventions: an early TBI specialist vocational rehabilitation intervention (intervention group) will be compared to treatment as usual (TAU group).

Early specialist TBI vocational rehabilitation (ESTVR)
ESTVR is an early, specialist, health-based, case management vocational rehabilitation (VR) community outreach model. It selects people early (at point of injury) and intervenes to prevent job loss. It is delivered by health care professionals with TBI specialist knowledge and VR-specific knowledge working in the NHS. It both facilitates work return and supports job retention. Most interventions are delivered in the community. VR based on best practice guidelines is delivered by an occupational therapist (OT), supported by a health-based TBI specialist case manager (CM).

The OT VR intervention seeks to lessen the impact of TBI by assessing the patient's role as a worker and finding acceptable strategies to overcome problems e.g. assessing and addressing new disabilities which might have a direct impact on work activities in relation to work demands - these may be physical, cognitive or psychological interventions. The OT provides pre-work training to prepare the person for work by establishing structured routines with gradually increasing activity levels; opportunity to practice work skills e.g. computer use to increase concentration, cooking to practice multi-tasking; liaises with employers/tutors and disability employment advisors (DEAs) to advise about the effects of TBI and plan and monitor graded work return; conduct worksite and job evaluations; identify the need for workplace or job adaptations and serve as the link between health and DWP services to access additional support. TBI case managers co-ordinate the overall TBI care package, provide support, education and advice to patients, family and others e.g. NHS staff, social services, Headway and solicitors, remaining in contact with patients and families whilst there are achievable rehabilitation goals.

The ESTVR model will follow recommended guidelines for VR following ABI and will involve:
1. Assessing people's functional capacity for work
2. Detailed job evaluation and safety assessment
3. Liaison with employers regarding necessary accommodations (equipment and adaptations) and graduated return to work programs
4. Individual work-related goal setting and problem-solving sessions
5. Partnership working with statutory and voluntary service providers such as disability employment and benefits advisors and Headway
6. Negotiating voluntary work placements
7. Providing information and advice to TBI patients, their families and employers and counseling

Intervention will be structured around individual needs and involve up to 10 individual, plus group sessions.

Treatment as usual (TAU)
We will attempt to measure and describe the current focus of usual care. The pre-clinical and process evaluation phases are designed to elicit detail needed to describe what existing services currently offer stroke survivors hoping to return to work.

In addition our questionnaire booklet includes questions intended to capture the nature of any intervention received by the control group. This will be costed and described retrospectively.

Concomitant therapy: continued use of NHS/Systems and Service Delivery (SSD)/3rd sector services is anticipated alongside the ESTVR intervention. We will attempt to capture and describe this as part of this study. Indeed, our questionnaire booklet includes questions intended to capture the nature of concomitant therapy and any intervention received by the control group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint is study completion

Secondary endpoints:
1. Identification of the primary outcome of importance
2. Successful delivery of Early Specialist TBI Vocational Rehabilitation (ESTVR) in three NHS TBI referral centres
3. Measurement of the effectiveness and cost effectiveness of ESTVR vs TAU on work return and job retention
The likely primary measure of effectiveness for the main trial is work status at 12 months defined as competitive employment (full or part time paid work in an ordinary work setting, paid at the market rate [Crowther 2004], although exploration of this is a key component of this study [see 1. above]). The corresponding primary success criteria for the intervention at 12 months post randomisation will be the proportion of:
3.1 Persons returned to work in the same role with an existing employer
3.2 Persons returned to a different role with an existing employer
3.4. Persons returned to self-employed work

Secondary outcome measures
Secondary measures of effectiveness to be collected at 3, 6 and 12 months post randomisation will be:

1. Hospital Anxiety and Depression scale (mood)
2. Extended Activities of Daily Living (functional ability)
3. Community Integration Questionnaire (participation)
4. EuroQol EQ-5D-3L (health-related quality of life)
5. Work Productivity and Activity Impairment Questionnaire (productivity)
6. Use of health and social care resources
7. Carer-Strain Index (carer strain)
8. Single question from work ability index (work self-efficacy)

Overall study start date
01/03/2013

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Adults (aged 16 and above) living in the London, Preston and Leeds health communities and admitted for 48 hours or more with a new Traumatic Brain Injury
2. Were in work or intending to work or in full-time education (paid or unpaid) prior to their injury

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

102

Total final enrolment
78

Key exclusion criteria
People will be excluded if they:
1. Do not want to take part
2. Do not intend to work/study
3. Are unable to consent for themselves
4. Live more than 1 hours travelling distance from the recruiting centre

Date of first enrolment
01/12/2013

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) ref: 11/66/02

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2015		Yes	No
Results article	results	01/05/2018		Yes	No
Results article	Results of feasibility study assessing fidelity	29/07/2022	01/08/2022	Yes	No
HRA research summary			28/06/2023	No	No