FRESH - FACILITATING RETURN TO WORK THROUGH EARLY SPECIALIST HEALTH-BASED INTERVENTIONS

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SYNOPSIS

Title	FRESH - Facilitating Return to work through Early Specialist Health-based interventions
Acronym	FRESH
Short title	'Working after Brain Injury'
Chief Investigator	Dr Kate Radford
Objectives	i) To assess the feasibility of delivering **E**arly **S**pecialist **T**raumatic brain injury **V**ocational **R**ehabilitation (**ESTVR**) in 3 NHS regional TBI referral centres ii) To test the feasibility of conducting a randomised controlled trial comparing ESTVR in addition to usual NHS rehabilitation with usual NHS rehabilitation alone. iii) To determine whether ESTVR can be delivered in a way that is acceptable to TBI Patients, staff and employers when compared to usual NHS rehabilitation iv) To identify the primary outcome of importance
Trial Configuration	Randomised feasibility clinical trial in three centres with concurrent process evaluation and feasibility economic evaluation.
Setting	Primary and Secondary care services
Sample size estimate	As this is a feasibility study, no power calculation has been performed.
Number of participants	Feasibility Trial: 102 people with TBI and up to 102 'carers' of TBI participants to be recruited in the three centres in 12 months. Process Evaluation: 15 NHS staff with a role in managing, commissioning or delivering TBI rehabilitation 6 OTS and case managers with a role in delivering ESTVR 15 TBI service users (trial participants) Up to 52 employers of participants randomised to receive ESTVR
Eligibility criteria	**Feasibility Trial Participants** **Patients** **Inclusion Criteria** • aged 16 years and above • living within 1 hour or reasonable travelling distance of recruiting centre • diagnosis of TBI requiring admission to hospital for ≥ 48 hours • in work or full time education prior to TBI • intending to return to work

	Carers Spouse, partner, parent or the person whom the TBI patient has most contact with. **Staff** NHS staff in the three centres with a role in managing, commissioning or delivering TBI rehabilitation Therapists and case managers who have been trained to deliver the ESTVR intervention **Employers** Employers of TBI patient participant in the trial randomised to receive ESTVR and whose employee consents to their being approached for interview.
Description of interventions	**Feasibility trial** The ESTVR model (intervention) will be compared to a usual care (control) group. **Intervention group:** Participants (TBI patients) will receive up to 10 sessions of ESTVR tailored to individual needs according to the following menu of components: • individual work-related goal setting and problem solving • negotiating voluntary work placements • vocational counselling • planning and implementing graded return to work, • work site assessment and job evaluation • job modifications or 'accommodations' • psychosocial and informational strategies • liaison with employers and occupational health • liaison with family members and carers • partnership work with statutory and voluntary service providers **Control group:** Participants allocated to the control group (Treatment As Usual [TAU]) will continue to avail themselves of usual health and social care services as necessary. **Employers** Employers whose employees are participants in the trial and randomised to receive the ESTVR intervention and whose employee consents to employer contact being made, may receive advice and education about TBI and the impact of TBI on a specified work role in relation to their employee as part of the intervention.
Duration of study	**Study Duration:** 3 years **Participant Duration** **Staff:** OTs and case managers trained to deliver the ESTVR intervention will be involved in the study for 28 months (Training period, Recruitment (12 months + 12 months follow-up), post-trial interviews). Other NHS staff in participating centres will only be involved for a one-off

	interview or focus group lasting about an hour. **Patient:** Recruitment 12 months + 12 months follow-up. Trial Participants: will be asked to participate in interviews up to 2 months following completion of follow up and will therefore be engaged in the study for up to 14 months from the time of recruitment. **Carer:** Carers will be involved for 12 months from the point of recruitment. **Employer:** 12-14 months from the point of their TBI participant employee's recruitment (Intervention + follow up interview).
Randomisation and blinding	Randomisation will be carried out using web-based randomisation set up by the Nottingham Clinical Trials Unit (NCTU).
Outcome	**Primary Outcome** Study Completion **Secondary Outcomes** Identification of the primary outcome of importance. Successful delivery of Early Specialist TBI Vocational Rehabilitation (ESTVR) in 3 NHS TBI referral centres. Measurement of the effectiveness and cost effectiveness of ESTVR Vs.TAU on work return and job retention (at 3, 6 and 12 months). Acceptability of ESTVR to TBI patients, staff & employers when compared to usual NHS rehabilitation (TAU). Identification of: recruitment rate, proportion of potentially eligible TBI patients recruited, reasons for non-recruitment and spectrum of TBI severity among recruits, proportion lost to follow up and reasons for loss to follow up. Integrity of study protocol (e.g. inclusion / exclusion criteria, staff training, adherence to intervention, and reasons for non-adherence. Ascertainment of completeness of data collection for primary outcomes. Acceptability of recruitment and randomisation to TBI patients and staff. Identification of;- the most appropriate methods of measuring primary/important outcomes (return to work, retention) and estimation of parameters necessary to calculate the sample size for a larger trial. Identification of gains in using face-to-face rather than postal data collection.

Statistical methods	**Statistical analysis** Estimation of eligibility, consent and attrition rates (both overall and by subgroups, e.g. site) will use descriptive statistics, supported by 95% confidence intervals. Effectiveness outcomes will be described at each time point and compared between groups using descriptive and inferential methods for categorical, continuous and/or ordinal health outcome measures using an intention-to-treat approach, although imputation of missing outcome data will not be performed for the primary analysis; inferential analysis of outcomes will be presented as 95% confidence intervals. Exploratory logistic modelling will be used to investigate factors previously found to be related to work return and estimates of intervention effectiveness will be adjusted for baseline factors which are found or deemed likely to affect the main outcome (return to work or not). Investigation of the distribution of responses for health outcome measures and of patterns in work status over time will be performed to inform the design (primary outcome, follow-up duration, analysis, sample size etc.) of a future trial. Data will be analysed using SPSS and Stata. A detailed Statistical Analysis Plan will be written by the Trial Statistician, in consultation with the Study Steering Committee and Trial Management Group, prior to unblinding of the data. **Intervention content** Detailed records of the ESTVR intervention will be maintained and content analysed retrospectively to identify components for future trial design and replication. **Economic evaluation** This feasibility study will allow us to determine whether we can effectively capture economic data from TBI survivors and the completeness of economic data collection needed to undertake a cost-effectiveness study that compares the overall per patient cost and effectiveness of ESTVR, to standard practice in managing working age TBI survivors. Levels of resource use and health-related quality of life will be monitored, with a view to informing decisions as to how costs and benefits would be measured and valued as part of any definitive study. Additionally, a preliminary within-study cost-effectiveness analysis will be conducted to assess whether ESTVR plus usual care is likely to offer value for money compared to usual care without ESTVR for people with TBI. Finally, value of information analysis, to estimate the value of undertaking further research, will also be undertaken. Costs will be estimated costs from the perspective of the NHS and personal social services (PSS), as recommended by the National Institute of Health and Clinical Excellence. We will estimate employment related and patient/carer costs, to monitor levels of resource use associated with the VR intervention, other NHS and PSS resource items, employment related and patient/carer related costs and attach unit costs to all items of resource use for a single price year, in order to estimate the mean overall cost in each study arm.

	Within the economic analysis both a cost-effectiveness analysis, employing the studies primary outcome, and a cost-utility analysis, using the EQ-5D-3L to estimate Quality Adjusted Life Years, will be conducted. These analyses will enable both the employment and health-related quality of life implications of the VR intervention to be estimated. **Embedded qualitative studies** All interviews/ groups will be fully transcribed and analysed using the Framework approach. Transcripts will be indexed using Nvivo software and arranged into charts to reflect the thematic framework. References, quotes and notes will be added to reflect the analysis of each interview and the emerging themes to allow comparison between responses.

ABBREVIATIONS

AE	Adverse Event
AtW	Access to work
BSRM	British Society for Rehabilitation Medicine
CEA	Cost-Effectiveness Analysis
CEACs	Cost-Effectiveness Acceptability Curves
CI	Chief Investigator overall
CLAHRC	Collaboration for Leadership in Applied Health Research and Care
CLRN	Comprehensive Local Research Network
CMP	Condition Management Programme
CRF	Case Report Form
CTU	Clinical Trials Unit Cost Utility Analysis
CUA	Curriculum Vitae
CV	
DAP	Data Analysis Plan
DEA	Disability Employment Advisor
DMC	Data Monitoring Committee
DWP	Department for Work and Pensions
EOT	End of Trial
EQ-5D-3L	EuroQol 5D
ESTVR	Early Specialist TBI Vocational Rehabilitation
GCP	Good Clinical Practice
GCS	Glasgow Coma Scale
GOS	Glasgow Outcome Scale
HADS	Hospital Anxiety and Depression Scale
NEADL	Nottingham Extended Activities of Daily Living Index
NHS	U.K. National Health Service
NSF	National Service Framework
OT	Occupational Therapist
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PSS	Personal Social Service
PTA	Post Traumatic Amnesia
QALYs	Quality Adjusted Life Years
REC	Research Ethics Committee
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
R&D	Research and Development
SAE	Serious Adverse Event
TAU	Treatment As Usual
TBI	Traumatic Brain Injury
TMG	Trial Management Group
SSC	Study Steering Committee
VR	Vocational Rehabilitation
WAPI	Work Activity Productivity and Impairments Questionnaire

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TRIAL / STUDY BACKGROUND INFORMATION AND RATIONALE

The size of the Problem

Approximately one million people in the UK sustain traumatic brain injury (TBI) each year and up to 150,000 incur moderate or severe injury (Headway, 2012) resulting in cognitive and psychological problems, such as impaired insight, executive dysfunction, anxiety and fatigue that interfere with daily living activities including work. The societal cost of TBI in terms of lost time at work and dependency on benefits is estimated to be 2.8 Billion Euros per year (Rickels et al., 2010). It is also a known cause of personal bankruptcy (Relyea –Chew et al., 2009) and people who don't return to work are more likely to be depressed (Franulic et al. 2004).

Returning to work following Traumatic Brain Injury

Returning to work is a primary rehabilitation goal yet reported success varies widely (range 11-82%). Only around 41% of TBI survivors who were working before their injury are in work at one and two years later (Van Velzen et al. 2009). Although study heterogeneity and known difficulty in following TBI people up over time (Langley et al. 2010) explains some of the difference in reported outcomes, inadequate rehabilitation is also a possible cause. Keeping TBI people in work is also problematic. Many TBI survivors return prematurely but drop out once the impact of the brain injury on their job is realized (Possl et al. 2001).

What is vocational rehabilitation?

Vocational Rehabilitation (VR) defined as whatever helps someone with a health problem return to or remain in work (Waddell et al., 2008) involves helping people find work, helping those who are in work but having difficulty and supporting career progression in spite of illness or disability. Clinical guidelines and professional recommendations (BSRM, 2003, 2010, Tyerman and Meehan, 2004) state that it should be provided and keeping people with long term conditions in work (job retention) is both a recognized health outcome (The Outcomes Framework, 2011) and an important role for health care professionals (Black and Frost, 2011). Despite this, health based services supporting TBI people in returning to work are rare in the UK (Deshpande and Turner Stokes, 2004, Playford et al. 2011).

Few TBI people have access to vocational rehabilitation

For many TBI people, NHS provision does not typically extend to VR. It focuses on getting people home from hospital and their physical recovery. People with milder TBI (Glasgow Coma Scores (GCS) of 13-15) are frequently discharged home after one or two days with minimal support or follow up. Those with more severe TBI (GCS of ≤12) are typically followed up by the treating physician in routine out-patient clinics and those with identified rehabilitation needs referred for community or out-patient rehabilitation but not all of these services address people's work needs. Where they do, this typically happens towards the end of rehabilitation, after goals for independence in mobility and daily function have been achieved. People with hidden disabilities, such as cognitive, hearing or visual impairment and those with milder TBI are often discharged without follow up.

What evidence is there to support vocational rehabilitation following TBI?

As part of a systematic review of VR interventions following acquired brain injury (ABI) (http://www.clahrc-ndl.nihr.ac.uk/clahrc-ndl-nihr/research/stroke-rehabilitation/index.aspx), we found a lack of evidence to support the effectiveness or cost effectiveness of VR for people with TBI. Out of 23 VR models (8 TBI specific) identified, only one had been evaluated as part of a randomised controlled trial. Trexler et al. (2010), examined the effectiveness of additional Resource Facilitation (a partnership that supports people to make informed choices and achieve their goal, which involves active engagement with a previous employer) in 22 people with ABI, (11 Resource Facilitation (3 with TBI) and 11 controls (4

with TBI) who were working pre-injury and recruited as either in or out patients. The RF group received a median of 8 hours of intervention. At 6 months from recruitment, 7/11 (64%) of the RF group were employed, compared with 4/11(36%) controls. However, as numbers were small, there were only 7 people with TBI and discrepancies existed between the groups in time since injury before intervention began (controls were on average one month longer post injury), it is not possible to draw any conclusions as to whether the work outcomes resulted from the RF intervention and the effects for different categories of brain injury cannot be determined.

Other trials (Vanderploeg et al. (2008), Salazar et al. (2000) have compared rehabilitation interventions for people with TBI and reported work outcomes but the interventions themselves were not VR specific and no significant differences in outcome according to approach were identified. Three main approaches to VR have been identified (Fadyl at al. 2009) 'program based', 'supported employment' and 'vocational case co-ordination', with the strongest evidence in support of case-coordination, which is characterised by early hospital based identification and intervention, employer education and supporting people in the workplace.

Evidence for Early specialist TBI vocational rehabilitation (ESTVR)
In our single centre cohort comparison we compared an early TBI specialist VR intervention (ESTVR) delivered by an OT, supported by a TBI Case Manager to usual NHS rehabilitation (whatever support was available locally) and found it to be more effective (27% more people with moderate and severe TBI in work at 12 months) at returning TBI people to work and keeping them there 12 months after injury than usual care (UC) (Radford et al., 2013). The mean per-patient difference in health and social care costs was only £75.00. This was because usual care participants received roughly the same amount of input but from GPs and other non-coordinated community services.

ESTVR included people with traumatic brain injury who were working at injury onset. The primary focus was on preventing job loss by picking people up early after injury and promoting a return to work with an existing employer (Job Retention). ESTVR doesn't overlap with existing services delivered via Job CentrePlus but rather works in partnership with them.
However, as ESTVR was an existing part of the Nottingham Traumatic Brain Injury Service provision and the intervention was delivered by a single therapist in one centre, uncertainty exists around whether the successful outcomes were attributable to ESTVR or whether it can be delivered by therapists elsewhere. Therefore a feasibility randomised controlled trial is needed.

TRIAL / STUDY OBJECTIVES AND PURPOSE

PURPOSE:

PRIMARY OBJECTIVE

The ***health care*** objective is to improve the quality of people's lives after TBI by enabling them to return to work. This could potentially increase physical and mental health status and maintain financial status in the short and long-term.

The ***research*** objectives are to;

To assess the feasibility of delivering Early Specialist Traumatic brain injury Vocational Rehabilitation (ESTVR) in 3 NHS regional TBI referral centres

To test the feasibility of conducting a randomised controlled trial comparing ESTVR in addition to usual NHS rehabilitation with usual NHS rehabilitation alone.

To determine whether ESTVR can be delivered in a way that is acceptable to TBI Patients, staff and employers when compared to usual NHS rehabilitation

To identify the primary outcome of importance

SECONDARY OBJECTIVES

The secondary objectives are to determine:

1. integrity of study protocol (e.g. inclusion / exclusion criteria, staff training, adherence to intervention, and reasons for non-adherence
2. whether ESTVR can be delivered in a way that is acceptable to TBI patients, staff & employers (views of TBI patients, staff and employers on the interventions (ESTVR Vs TAU))
3. rate of TBI patients recruited in each centre
4. proportion of potentially eligible TBI patients recruited
5. reasons for non-recruitment (missed, medical, logistic, other)
6. proportion lost to follow up and reasons for loss to follow up
7. spectrum of TBI severity among recruits
8. views of TBI patients and staff on recruitment and randomisation
9. most appropriate methods of measuring primary/important outcomes (return to work, retention) and estimate of parameters necessary to calculate sample size for a larger trial
10. completeness of data collection for primary outcomes
11. gains in using face-to-face rather than postal data collection.
12. how return to work is related to mood, wellbeing, function, work capacity, social participation, quality of life and carer-strain.

As part of the concurrent process evaluation we will explore retrospectively:

1. What service interventions are most valued in practice by an employee with TBI?

2. What service interventions are most valued in practice by an employer?

3. Clinical NHS staff views of the acceptability and usefulness of the ESTVR training package, including the manual and mentoring system.

4. Service user, employer and NHS staff views about the factors likely to affect the way ESTVR vocational rehabilitation can be implemented and delivered clinically in the NHS.

TRIAL / STUDY DESIGN

TRIAL / STUDY CONFIGURATION

A mixed methods approach is proposed.

1) **A feasibility trial** to test the feasibility of delivering ESTVR in 3 new centres and measuring its effects and costs and to test the feasibility of doing the trial.

2) **A nested process evaluation** to;
   i) Explore practical issues relating to the deployment of the intervention with NHS service providers
   ii) Explore practical issues relating to the training provided and required for NHS staff and participants to deploy ESTVR (Participant and Therapist feedback)
   iii) Investigate participants' (service user and employer) and service providers' (staff) views of the acceptability and usefulness of the ESTVR package (manual, training and mentoring system) and of the ESTVR intervention.
   iv) explore participants views of the recruitment process and study documentation
   v) Explore implementation barriers and perceived changes in practice resulting from training and the anticipated and actual effects (including costs) of implementation on supporting services.

During this phase, which will run throughout the trial period we will also;

i) Check the fidelity of the ESTVR intervention.
ii) Measure the content of ESTVR and the content of usual care delivered in each centre.
iii) Determine the extent to which ESTVR occurs in usual care.

1. Multi-centre feasibility RCT:

The purpose of the trial is to test the feasibility of delivering and measuring ESTVR for people with TBI, case managed by an occupational therapist vs. TAU.

A manualised training programme based on the original Nottingham Pilot (Radford et al. 2013; Phillips et al. 2010) [REC Reference 06/Q2404/138], will be developed and delivered centrally to OTs and Case Managers (a nominated member of the rehabilitation team who will be trained to adopt a Vocational Rehabilitation Case Manager role) in each of the three NHS centres. Training will be delivered by members of a Training Sub Group (Co-applicants, Phillips J, Tyerman A, Holmes J and Jones T plus consultants Yash Bedekar and Ruth Tyerman) over 2 days during month 6, followed by a refresher ½ day 6 months later.
The training will ensure that the ESTVR package can be implemented and supported alongside existing NHS TBI rehabilitation service delivery. During the trial, trainers will provide telephone and email mentoring support to the therapists and case managers. Quality monitoring will assess adherence to the interventions (see Process Evaluation).

We will employ a randomised design where consenting participants will be allocated to receive either ESTVR or TAU, which may involve efforts to return people to work but does not typically include components of the ESTVR model.

ESTVR is an early, specialist, health based, case management 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;

- assessing people's functional capacity for work
- detailed job evaluation and safety assessment
- liaison with employers regarding necessary accommodations (equipment and adaptations) and graduated return to work programs
- individual work-related goal setting and problem solving sessions
- partnership working with statutory and voluntary service providers such as disability employment and benefits advisors and Headway
- negotiating voluntary work placements
- 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.

Primary endpoint
Study Completion

Secondary Endpoints

1. Identification of the primary outcome of importance

2. Successful delivery of Early Specialist TBI Vocational Rehabilitation (ESTVR) in 3 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;

a) Persons returned to work in the same role with an existing employer
b) Persons returned to a different role with an existing employer
c) Persons returned to work with a different employer i.e. new work in the same or a different role.
d) Persons returned to self-employed work

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)

In addition 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 trials. Therefore we propose to collect outcome data related to the intervention including:

- Accidental injury resulting from non-compliance with equipment or work place adaptations recommended by the FRESH Occupational Therapists
- Work accidents resulting in injury requiring hospital admission.
- Incidents of aggression+ of the participant towards the researcher, staff or others (e.g. work colleagues)
- Attempted suicide

+ defined as excessive verbal aggression, physical aggression against objects, physical aggression against self, and physical aggression against others.

At 12 months *only* we propose to measure Glasgow Outcome Scale score (TBI outcome) Measures will be collected by post and non-responders followed up by telephone in two centres; those requesting help to complete the measures will be offered a home visit by the research assistant (RA). In one centre, measures will be collected face-to-face by the research associate.

Detail of the secondary outcome measures and time points for administration is shown in the schedule below. For each participant, both controls and intervention, the measures described below will be collected at recruitment to the study (baseline).

Schedule of Questionnaires (for Patients)

		Follow Up time points		
Measure	**Baseline**	**3 month**	**6 month**	**12 month**
Demographic information	☑	-	-	-
Duration PTA	☑	-	-	-
GCS Score	☑	-	-	-
Duration unconsciousness	☑	-	-	-
Specific VR focused questions	☑	☑	☑	☑
EQ-5D-3L (Euro-QOL)	☑	☑	☑	☑
Hospital Anxiety and Depression Scale (HADS)	☑	☑	☑	☑
Nottingham Extended Activities of Daily Living (NEADL)	☑	☑	☑	☑
Community Integration Questionnaire (CIQ)	☑	☑	☑	☑
Resource use of health and social Care	☑	☑	☑	☑
Self-Efficacy - single question from work ability index.	☑	☑	☑	☑
Work Productivity and Activity Impairment Questionnaire V2 (WPAI)	☑	☑	☑	☑
Glasgow Outcome Scale score (GOS)				☑

Schedule of Questionnaires (for Carers)

		Follow Up time points		
Measure	**Baseline**	**3 month**	**6 month**	**12 month**
Carer-Strain Index (CSI)	☑	☑	☑	☑
Specific impact on carer's work questions	☑	☑	☑	☑

Figure 1, (in study regimen section) provides the CONSORT flow diagram for our study, in line with the recommendations (Boutron et al, 2008) modified for individual randomized, controlled trials of non-pharmacological intervention.

Secondary Endpoints (cont'd)

4. Acceptability of ESTVR to TBI patients, staff & employers when compared to usual NHS rehabilitation (TAU)
5. Rate of recruitment, identification of proportion of potentially eligible TBI patients recruited, reasons for non-recruitment and spectrum of TBI severity among recruits
6. Proportion of TBI and carer participants lost to follow up and reasons for loss to follow up
7. Integrity of study protocol (e.g. inclusion / exclusion criteria, staff training, adherence to intervention, and reasons for non-adherence)
8. Completeness of data collection for primary outcomes
9. Acceptability of recruitment and randomisation to TBI patients and staff
10. Identification of the most appropriate methods of measuring primary/important outcomes (return to work, retention) and estimate of parameters necessary to calculate sample size for a larger trial.
11. Identification of gains (reduction in attrition) in using face-to-face rather than postal data collection.
12. Relationships between return to work and mood, wellbeing, function, work capacity, social participation, quality of life and carer-strain.
13. Collection, analysis and interpretation of process evaluation data which informs the design of the definitive trial in terms of the fidelity and quality of intervention deployed, enablers and barriers to deployment, contextual factors associated with variations in outcome across the intervention groups and how the intervention can be improved.

Safety endpoints

Deterioration in a participant's physical or psychological health resulting in either inpatient acute admissions, use of emergency health or social care services. Safety will be assessed as part of the feasibility by collecting all adverse events considered related to the ESTVR intervention.

RANDOMIZATION AND BLINDING

Patient participants will be randomised using stratified randomisation (strata based on centre) via a computer generated random allocation sequence created by Nottingham Clinical Trials Unit (CTU) and access to it will be web-based to allow randomisation to take place off site. The randomisation will be based on a computer generated pseudo-random code using random permuted blocks of randomly varying size, created by Nottingham CTU in accordance with their standard operating procedure (SOP) and held on a secure server. Participants will be enrolled either by the research assistant or the research therapist and randomised by the research assistant. The participants will be un-blinded to the intervention group allocation. Other members of the research team (CI, health economist, data coordinator and trial management team) including the research assistant responsible for

collecting ~~postal~~ face-to-face follow-up outcome measures and data entry staff will be blinded to group allocation. Allocation will remain concealed until interventions are all assigned and recruitment, data collection, and analyses are complete.

Staff, Employers and Carers will not be randomised.

Maintenance of randomisation codes and procedures for breaking code

The treatment code will be stored with Nottingham CTU in a code break envelope to be collected by the Chief Investigator at the end of the trial. The code may be broken early at the request of the Study Steering Committee in the event of serious adverse events.

TRIAL MANAGEMENT

The trial will be managed by the Trial Management Group (TMG). The Study Steering Committee (SSC) will meet independently prior to the start of the study to agree terms of reference and will monitor un-blinded data and the conduct of the study. Only the SSC will have access to un-blinded data until the final outcome assessment has been completed. The SSC will recommend discontinuation of the study if significant ethical or safety concerns arise.

The trial sponsor is the University of Nottingham, which will clarify with the funding body (the HTA) and local centre R&D departments their precise responsibilities. The CI, delegated by the sponsor, is responsible for the proper conduct and management of the trial. Two committees will be assembled to help the proper management and conduct of the trial, and to ensure the safety and wellbeing of the patients enrolled.

The following committees have been formed;
Study Steering Committee (SSC)
Trial Management Group (TMG)
The general purpose, responsibilities, and structures of the committees are described in this protocol. However, it is assumed that these committees will develop their own rules and procedures which may evolve with time, during the preparation and conduct of the trial.

Study Steering Committee (SSC)

A Study Steering Committee composed of representatives from the medical, academic and lay communities and from the TMG. Members from the TMG may not have voting privileges on the SSC.

The SSC has overall responsibility for ensuring a scientifically sound study design, a well-executed trial and accurate reporting of the study results. They must address and resolve scientific, medical and practical issues encountered during the trial. The SSC will draw up its own guidelines and will review the criteria and guidelines of the other committees in order to provide advice and suggestions if necessary. The SSC will convene either in person or via teleconference, as often as deemed necessary to carry out its responsibilities, but at least once per year.

The Lancashire CTU will provide statistical support to the SSC to investigate any additional database questions that the SSC raises, which may include possible additional analyses to those outlined prospectively in the trial protocol.

Trial Management Group (TMG)

A Trial Management Group composed of the Chief Investigator, representatives from Nottingham and Lancashire CTUs, the Trial Manager and Senior Trial Manager, Trial Statistician, Health Economist (where appropriate), Research Associate, Service User, and Local PIs (where appropriate) will oversee the operational aspects of the trial, including the processes and procedures employed and the day to day activities involved in the study conduct. Day to day management of the trial will be undertaken by Trial Managers at the Lancashire CTU. The TMG will meet regularly, in person or by conference call to review the progress of the trial and to address any urgent issues. The TMG will provide recommendations and helpful suggestions to the SSC.

The Lancashire CTU will follow University of Nottingham Standard Operating Procedures and employ its own systems and procedures in the conduct of the trial, using Lancashire CTU personnel including a IT and Data Management staff, Trial Statistician, Senior Trial Manager, Trial Manager, data co-ordinators and administrative staff in liaison with the Chief Investigator.

The Chief Investigator has overall responsibility for the study and shall oversee all study management.

The data custodian will be the Chief Investigator.

Definition of a protocol deviation

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of a study inconsistent with the protocol, consent document or other study procedures.

Violations of eligibility criteria and other deviations from protocol will be assessed by TMG and discussed with the SSC during study evaluation before data lock and un-blinding.

DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT

The feasibility trial will commence in September 2013 and run until September 2015 and the study will complete in February 2016 (3 years). Enrolment in the trial will commence in September 2013. Individual participants in the study will be either interviewees, members of the focus group(s), or participants in the clinical trial component. Some trial participants will also participate in focus groups (s) or interviews as part of the process evaluation.

Interviews with trial participants, and focus groups and interviews with employers will commence in September 2013. Enrolment in the trial will commence in September 2013.

Participants in the clinical trial will be involved in the trial for a period of 12 months, from the point of recruitment, and randomly allocated to either the experimental arm (ESTVR in addition to Treatment As Usual [TAU]) or the control arm (Treatment As Usual [TAU]). Participants will be followed up at 3, 6 and 12 months post-randomisation.

End of the Trial

For individual participants in the clinical trial the end-point will be completion of the 12 month follow-up, post-randomisation to either the experimental or control group.

However the end point for the overall study (Trial + Process Evaluation) is completion of the trial and the post-trial process evaluation interviews. The end of the study is therefore

defined as the last scheduled visit of the last participant interviewed during the process evaluation. The Ethics Committee will be notified within 90 days of the end of the study.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

PATIENT

Patient Recruitment

Potential participants will be identified by members of the existing clinical care team, from among those of working age (aged 16 and above) admitted for ≥ 48 hours to The Royal London Hospital, The Royal Preston Hospital, and The Leeds General Infirmary with a diagnosis of TBI using existing TBI registers. It is intended that this study will be adopted and supported by the Comprehensive Local Research Network research nurses who will assist with recruitment by 'spotting' eligible participants and handing out information sheets or notifying the research team of those patients wishing to be approached.

The initial approach will be from a member of the patient's usual care team, and information to remind clinical staff about the eligibility criteria for participation in the trial will made available to members of the clinical care team.

The investigator or their nominee from the research team (RA, CLRN Network Research Nurse or Research Therapist) or a member of the participant's usual care team, will inform the participant or their nominated representative (other individual or other body with appropriate jurisdiction), of all aspects pertaining to participation in the study.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

The sponsor's screening log will be used to monitor and identify recruitment against eligibility criteria and demonstrate that those recruited are representative of the group as a whole and record the proportion of refusals and reasons for refusal (where given). Every person with TBI admitted fitting the inclusion criteria during the trial recruitment period will be entered onto the screening log by the RA or CLRN Network Research Nurse. Minimum data recorded will be age (in years), gender, meeting eligibility criteria (Y / N), consented (date) or reason for non-consent. This will be anonymised before transfer from site (e.g. to Lancashire CTU).

Potential participants will be identified by the RA or Research Therapist using the eligibility criteria and the screening log.

Completeness of recruitment will be verified by cross checking with existing trauma and local TBI registers. This will be done by the RA employed by the participating acute Trust in each centre and administrative staff from the clinical care team, supported by the local CLRN research nurse, working within the trust, who will be familiar with local mechanisms and trust policies and procedures.

Discharged Patients will be sent a participant information sheet with covering letter from the consultant informing them about the project, and stating that the researcher will be contacting them to ask if they are interested in taking part. If the patient expresses interest then an appointment will be made for the researcher to visit, answer any questions and, if applicable, take informed written consent.

Eligibility criteria (Patients)

Inclusion criteria

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 ~~or intending to~~ work (paid or unpaid) or in full time education prior to their injury.

Exclusion criteria

People will be excluded if they;

a) do not intend to return to work/study
b) are unable to consent for themselves
c) live more than 1 hour (or reasonable) travelling distance from the recruiting centre

People with a language barrier either resulting from TBI (e.g. aphasia) or for whom English is not their first language will not be excluded. We propose to seek help from family members and interpreters to include people who meet the inclusion criteria wherever possible.

Expected duration of participant participation (Patients)

The exact duration of the ESTVR is not yet known as it will be tailored to individual needs and not to a pre-determined number of sessions or period of time. This will be one of the findings of this feasibility study. However, follow up assessment will take place by questionnaire at 3, 6 and 12 months post-randomisation. It is not anticipated that the intervention would continue beyond the 12 month point. However participants who have agreed to take part in post-trial focus groups may be involved until 14 month post-randomisation.

Removal of participants from therapy or assessments (Patients)

Participants may be withdrawn from the trial either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

Those who withdraw consent will be withdrawn from the study. Data will wherever possible be collected at specified time points as planned. Any deviations from this will be noted.

It is intended that withdrawn participants who are not yet randomised will be replaced but participants who withdraw after randomisation will not be replaced.

CARER:

Carer Recruitment

Carers will be identified by participants. Every consenting participant with TBI will be asked if they wish to nominate a carer (their spouse, partner, parent or the person they have the most contact with) during the baseline assessment visit. Carers will be sent a Carer's information sheet with covering letter from the consultant informing them about the project, and stating that the researcher will be contacting them to ask if they are interested in taking part. If the carer expresses interest then an appointment will be made for the researcher to visit, answer any questions and take written consent. NB Carers will only be recruited with consent from

the TBI participant i.e. they will not be approached until and unless the TBI participant has identified this person and gives explicit consent for this approach to be made.

The investigator or their nominee from the research team (RA, CLRN Network Research Nurse or Research Therapist) will inform the carer of all aspects pertaining to participation in the study.
It will be explained to the potential carer participant that entry into the trial is entirely voluntary and that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Completeness of carer recruitment will be verified by cross checking TBI participants with nominated carers and the proportion of identified consenting carers recruited. This will be done by the RA employed by the participating acute Trust in each centre supported by the Lancashire CTU.

Eligibility criteria (Carers)

Inclusion criteria

Carers of 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 were in work (paid or unpaid) or in full time education prior to their injury.

Exclusion criteria

Carers who are not nominated by a TBI participant.

People with a language barrier or for whom English is not their first language will not be excluded. We propose to seek help from family members and interpreters to include people wherever possible.

Expected duration of carer participation

Follow up assessment will take place by questionnaires at 3, 6 and 12 months post-randomisation. Carers will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis. Those who withdraw consent will be withdrawn from the study. Data will wherever possible be collected at specified time points as planned. Any deviations from this will be noted.
If the TBI participant dies, no further attempts will be made to contact the carer. If the TBI participant withdraws from the study, data will still be collected from the nominated carer unless the participant explicitly states that they do not want their carer to be contacted.

STAFF:

Staff Recruitment

NHS staff will be recruited to participate in interviews as part of the process evaluation which runs alongside the feasibility trial.
6-8 OTs and case managers who received training to deliver the ESTVR intervention will be interviewed to explore their views on the acceptability and usefulness of training and supporting materials and mentoring systems (so that training and resources may be

adjusted) and their perceived changes in practice resulting from training and the anticipated and actual effects (including costs) of ESTVR implementation on supporting services.

Therapists who apply for an opportunity to be involved in the trial and who are trained in ESTVR will be informed at the time of training that their views on the intervention will be sought and they will be invited to participate in interviews. They will be contacted by telephone by a member of the Nottingham based research team who is known to them and consent sought to pass their contact details onto an independent research associate at the University of Nottingham who has not be involved in training delivery or mentoring. NHS staff will be given a copy of Information Sheet 5 and informed consent will be sought.

15 NHS staff with a role in managing, commissioning or delivering TBI rehabilitation (5 each per site) will be identified by Local PIs and local therapists involved in the ESTVR delivery. They will be contacted by letter and invited to participate in interviews to explore their views of barriers and facilitators to ESTVR implementation and contextual factors influencing its sustainability and outcome. These interviews will be conducted by telephone by the University of Nottingham research fellow or in person by research associates in each centre. NHS staff will be given a copy of Information Sheet 6 and informed consent will be sought.

Eligibility criteria (Staff)

NHS staff who either received training to deliver the ESTVR intervention or who have a role in managing, commissioning or delivering TBI rehabilitation in each of the three centres participating in the feasibility trial (5 each per site).

Inclusion criteria

OTs and case managers who received training to deliver the ESTVR intervention or NHS staff involved in the management commissioning or delivery of TBI rehabilitation in each of the three centres participating in the feasibility trial (5 each per site).

Exclusion criteria

Expected duration of staff participation

Staff involved in delivering the ESTVR intervention will be involved for up to 28 months (training delivery, recruitment, intervention delivery and follow up interviews). Other NHS staff will be interviewed only once and interviews are likely to last for approximately 45 minutes.

EMPLOYERS:

Employer Recruitment

Employers of TBI participants, who consent to their employer being approached by the study team, will be asked by the ESTVR therapist or case manager towards the end of the intervention period if they are happy for their contact details to be passed on to the study team. Those who agree will be contacted by letter and invited to take part in a telephone interview at a mutually agreed time to explore their views of the acceptability and usefulness of the ESTVR intervention. The letter will be sent by and followed up by a telephone call from a Nottingham-based research fellow.

Eligibility criteria (Employers)

Inclusion criteria

Employers of TBI participants in the trial randomised to receive the ESTVR intervention and who consent to their employer being approached by the study team.

Exclusion criteria

Employers will be excluded if their TBI participant employee does not consent to their employer being contacted by the study team.

Expected duration of Employers participation

Employers are routinely involved in the process of supporting an employee in a return to work. This is typically part of the ESTVR intervention (where TBI patient participants consent for their employer to be contacted). This may last for up to 12 months from the point the TBI patient is recruited. At the end of this process, consenting employers who have engaged with the ESTVR therapists and case managers as part of the intervention will be interviewed. This will occur only once and interviews are likely to last for approximately 45 minutes.

Participant Withdrawal (Carers, Staff and Employers)

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent (all Participants)

The process for obtaining informed consent will be in accordance with the REC guidance, Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced.

All participants will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator or their nominee (RA, CLRN Network Research Nurse or Research Therapist) will explain the details of the relevant study and provide the relevant information sheet, ensuring that the participant has sufficient time to consider participating or not.

The Investigator or their nominee will answer any questions that any participant has concerning study participation. The Investigator or their nominee (RA, CLRN Network Nurse or Research Therapist) and participant shall sign and date the informed Consent Form before the person can participate in the study.

Informed consent will be collected from each participant before undergoing any interventions (including history taking) related to the study. One copy of this will be kept by the participant, one will be kept by the Investigator, and a third will be retained in the patient's hospital records (Patients Only).

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent Form which will be signed by the participant.

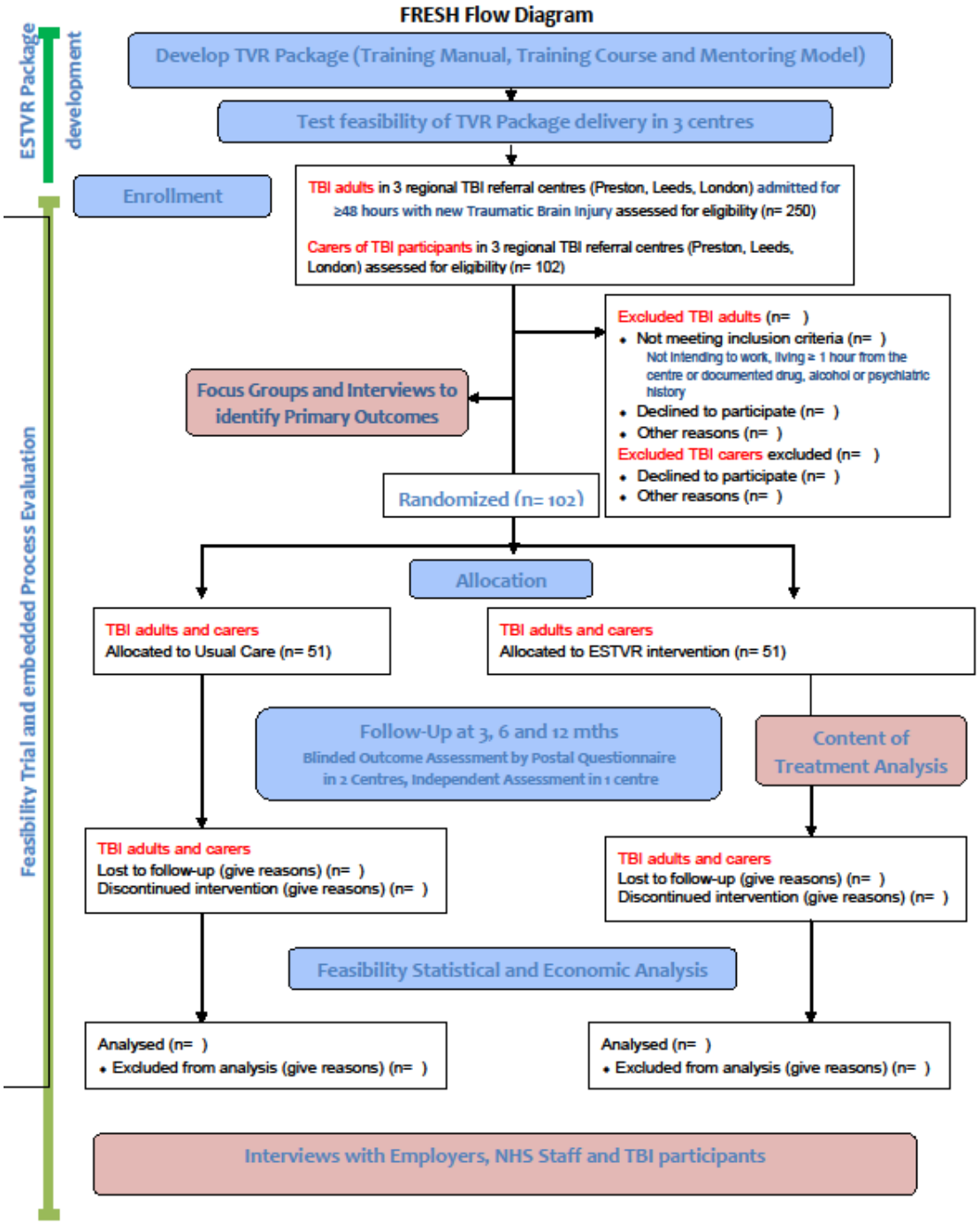
Consenting Carers in London, Preston and Leeds will be sent a brief questionnaire asking about carer strain and the impact of the TBI participant's injury on their working hours and income.

In addition consenting carers in London, Preston and Leeds will be asked to complete a measure of carer strain at 3, 6 and 12 months post the TBI Participant's injury.

For carer participants at London and Preston, the follow-up questionnaires will be sent in the post. For carer participants in Leeds, they will be contacted by telephone at the corresponding follow up time points and arrangements made to gather the follow up data in person either by telephone or face to face visit.

TRIAL / STUDY TREATMENT AND REGIMEN

Figure 1: Proposed CONSORT diagram –: Exact numbers will be an output of this feasibility work.



PATIENT

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 will be consistent with the model developed and tested in the Nottingham Pilot (Phillips et al. 2010) and based on a set of best practice guidelines formed from expert opinion (Tyerman and Meehan, 2004). These guidelines identify relevant components of the vocational rehabilitation process and include:

1. **Assessment:**
    - Asking questions about occupational status and vocational aspirations and needs
    - Responding to questions about return to work, education or training, or referring to relevant staff (medical consultant, neuropsychologist, physiotherapist) or agencies (JobcentrePlus, occupational health) if this falls outside the research therapist's expertise or remit.

2. **Intervention:**
    - Providing interventions to promote optimal recovery and management of difficulties, which may affect the prospects of a successful return to work, education or training; including one or more of the following:

        1. Education about difficulties, likely to affect work or study (The ESTVR occupational therapist (OT) will explicitly address with participants their level of functioning, their insight and their ability to return to work).
        2. Development of skills or behaviours necessary for work or study
        3. Restoring work related routines
        4. Building up attention, work/study tolerance and stamina
        5. Extending coping strategies for use in the workplace or for study
        6. Work on material drawn from or relevant to the persons work or study

    - Consultation with Occupational Health, Disability Employment Advisors (DEAs), Job Centre Plus occupational psychologist or other VR service provider to discuss relevant action if there is doubt about a client's ability to cope with a supervised and graded return to work.

    - Prior to return to work, education and or training, the OT will:

        1. Provide clear written and verbal advice about appropriate timing, gradual build up of hours and responsibilities,
        2. Seek the client's consent to contact the employer, education and or training provider to discuss needs.
        3. Liaise with the relevant occupational health department for advice or where unavailable seek advice via the NHSPlus Website.
        4. Agree and discuss the disclosure of information to an employer or Occupational Health (providing clients with draft submission for comment prior to disclosure).

- Taking account of family and personal circumstances and the required motor sensory and cognitive behavioural and emotional skills in plans for a return to work. Discussing these with the client and a close relative.

- Planning return to work or return to study with relevant agreed accommodations, such as equipment, graded return, voluntary trial, restricted hours/duties, advice/support in the workplace, job coaching, support from work colleagues, off site support e.g. from Research OT or other relevant agencies. In the case of study return these may include adjustments to course, learning support equipment, individual learning support, exam support and personal support e.g. personal tutor.

3. **Monitoring and Review**
    - Reviewing progress with on-going advice, support and feedback for client and employer (supervisor and work colleagues as appropriate) and feedback from family members about the impact of work on personal and family life and relationships.

    - Liaising with DEA where long term adjustment and support are needed (e.g. major adjustments to work duties and ongoing advice or support), including the need for specialist equipment in the workplace or help with travel to work.

NB. In the London Centre, some of the ESTVR intervention may be delivered by therapists from University College Hospital. However all recruitment will take place at The Royal London.

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 TBI 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 / SSD / 3rd sector services is anticipated alongside 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.

Carer

Consenting Carers in London, Preston and Leeds will be sent a brief questionnaire asking about carer strain and the impact of the TBI participant's injury on their working hours and income.

In addition consenting carers in London, Preston and Leeds will be asked to complete a measure of carer strain at 3, 6 and 12 months post the TBI Participant's injury.

For carer participants at London and Preston, the follow-up questionnaires will be sent in the post. For carer participants in Leeds, they will be contacted by telephone at the

corresponding follow up time points and arrangements made to gather the follow up data in person either by face to face visit or telephone.

Staff

Therapists in the three recruiting centres who wish to be involved in delivering the ESTVR intervention will be trained in ESTVR delivery and provided with expert mentoring during the trial intervention period. They will deliver the ESTVR intervention. They will also take part in a single interview seeking their views on aspects of the training, mentoring and intervention delivery. They will be given a copy of Information Sheet 5 and informed consent will be sought.

Towards the end of the trial period (months 24+) 15 NHS staff with a role in managing, commissioning or delivering TBI rehabilitation (5 each per site) will be interviewed in person individually or in groups or by telephone to explore their views of the usefulness and acceptability of the ESTVR intervention, barriers and facilitators to its implementation and contextual factors influencing sustainability and outcome. These interviews will be conducted by telephone by the University of Nottingham Research fellow or in person by research associates in each centre. They will be given a copy of Information Sheet 6 and informed consent will be sought.

Interviews will be digitally recorded and field notes made to capture inaudible or other contextual information. All interviews/ groups will be fully transcribed and analysed using the Framework approach. The findings will inform the design of the definitive trial, the delivery of the ESTVR and the challenges likely to be faced in sustaining its delivery in the longer term.

Employers

Employers whose employees are participants in the trial and randomised to receive the ESTVR intervention and whose employee consents to employer contact being made, may receive advice and education about TBI and the impact of TBI on a specified work role in relation to their employee as part of the ESTVR intervention.
These employers (n= ≤ 52) will also be invited to participate in individual telephone or face to face interviews lasting around 45 minutes. This will be a single interview after which participation will be complete. Employers will be asked whether they would be willing to provide feedback about the ESTVR service, to evaluate the impact of the intervention and to identify the most and least useful interventions.

Compliance

As this study includes a feasibility trial, measuring compliance with and attempting to describe the intervention are important features. The 'gold standard' VR intervention for the ESTVR arm includes key features described by Phillips et al. (2010) and as recommended in guidelines for VR in people with ABI (Tyerman and Meehan, 2004) These include: early intervention, disclosing the TBI to the employer, liaison with the employer and other statutory service providers (DWP and Occupational Health), work place visits, provision of:- a) written and verbal advice about graded work return, b) interventions to promote optimal recovery and management of difficulties, which may affect the prospects of a successful return to work, education or training; c) return to work planning and progress review with on-going advice, support and feedback for client and employer.

Compliance will be measured in a number of ways including participation in assessment, intervention (no of treatment sessions accepted out of the total advised, whether the participant consents to liaison with their employer or not, gives permission for workplace

visits to take place, accepts interventions/treatments to promote optimal recovery and management of difficulties (visits from the OT) or accepts advice only) and evaluation (on-going monitoring and progress review) and follow up (responses to and return of questionnaires).

In the TAU group we will attempt to record all interventions received and cross check the validity of the control group responses where possible. However, compliance with the TAU will not be recorded.

Criteria for terminating the study

The study may be stopped as a whole because of a change of opinion of the REC or overwhelming evidence of major safety concerns or issues with the study conduct (e.g. poor recruitment, loss of resources). Adverse events will be recorded throughout the trial following GCP principles and local governance procedures as described below.
Should concern warranting discontinuation of the trial arise, the decision to terminate will be reached by the Study Steering Committee and the Trial Sponsor. If evidence is limited to one centre a decision to stop in only one centre may be made.
Should a decision to terminate the study as a whole or in a single centre be made, research data will not be destroyed and will be archived according to the archiving section below.

MEASUREMENTS

Baseline assessment

Baseline assessment will be carried out by the RA, or research therapist in hospital or the participant's home following discharge. A minimal amount of information (basic demographics) required for randomisation will be collected from each participant by the RA or research therapist at the baseline visit (see schedule of assessments page 8).

All baseline measures will be collected face to face by the research assistant or research nurse either in hospital or at the participant's home if they have been discharged from hospital at the time of being recruited to the study.

STATISTICS

Methods

We have taken advice from Nottingham CTU and Lancashire CTU and Dr Chris Sutton. The study has also undergone external peer review. Following discussion the following analyses will take place.

Feasibility Trial

As this is feasibility work, the trial will enable us to measure, eligible numbers, recruitment rate, the spectrum of disease among recruits, reasons for non-recruiting, compliance with VR in the treatment group and with usual care in controls and the completeness of follow up of the primary endpoint. It will also enable us to determine whether participants can be randomised to the intervention and the likely effect on drop out of randomisation to the control group.

Estimation of eligibility, consent and attrition rates etc. (both overall and by subgroups, e.g. site) will use descriptive statistics, supported by 95% confidence intervals.
Effectiveness outcomes will be described at each time point and compared between groups using descriptive and inferential methods for categorical, continuous and/or ordinal health

outcome measures using an intention-to-treat approach, although imputation of missing outcome data will not be performed for the primary analysis; inferential analysis of outcomes will primarily be presented as 95% confidence intervals. Exploratory logistic modelling will be used to investigate factors previously found to be related to work return and estimates of intervention effectiveness will be adjusted for baseline factors which are found or deemed likely to affect the main outcome (return to work or not). Investigation of the distribution of responses for health outcome measures and of patterns in work status over time will be performed to inform the design (primary outcome, follow-up duration, analysis, sample size etc.) of a future trial. Data will be analysed using SPSS and Stata. A detailed Statistical Analysis Plan will be written by the Trial Statistician, in consultation with the Study Steering Committee and Trial Management Group, prior to unblinding of the data.

We will also maintain detailed records of the OT intervention and analyse the content retrospectively on a case by case basis to identify components of the return to work intervention for future trial design and replication. Features of treatment in those with successful and unsuccessful work outcomes will be identified and described using the Proforma developed for the original Nottingham pilot (Phillips et al. 2010).

Economic evaluation

This feasibility study will allow us to determine whether we can we design a questionnaire based tool to effectively capture economic data from TBI people and the completeness of economic data collection needed to undertake a cost-effectiveness study that compares the overall per patient cost and effectiveness of the ESTVR, to standard practice in managing working age TBI survivors.

The feasibility of collecting cost and benefit data will be assessed from a Health (NHS) and Social Care (personal social service (PSS) system) perspective to determine the frequency and costs of all NHS and social services and medication provided and from a societal perspective to determine the frequency and cost of TBI on the carers/partners work status, the employer and services provided by the Government such as the use of benefits advisers and Disability Employment Advisors.

Cost analysis involves comparing the overall and incremental costs for the intervention to standard practice. This study will identify the resource items likely to change as a result of the new intervention, explore how best to measure these changes and find appropriate unit cost sources to value them. In particular, we will test using case report forms completed by the clinical team, and patient questionnaires or diaries to capture patient costs (drawing on Thomson) (Thompson and Wordsworth, 2001). The feasibility of estimating local unit costs versus using national published data will be explored. As will the ease with which patients find self-reporting patient and carer costs. We will also attempt to capture the costs to employers of making ‘reasonable adjustment’ for TBI survivors returning to work, who as a result of TBI sequalae require changes or modifications to be made in order for them to work. These may include pieces of equipment or modifications to the workplace (if not paid for by the Access to Work scheme), changes to the employee’s role and responsibilities that mean other input is needed e.g. help from employees, additional breaks, greater flexibility in terms of hours and support or supervision. However, in this feasibility study, our starting point will be to record and describe these changes and attempt to quantify them using local (data from interviews with participants and employers where reasonable adjustment has been made) and published sources.

Should data be sufficient to proceed to analysis:

The second stage will be to combine the cost analysis with outcome measures to perform cost-effectiveness (CEA) and cost-utility analyses (CUA). This feasibility study will examine how best to elicit primary outcome data (occupational and benefit status) in order to monetarise benefit to patients. It is common in economic evaluations to measure health-related quality of life. The EuroQol EQ-5D-3L offers a generic measure that enables assessment of the impact of vocational rehabilitation case management on general life quality in a way that can be compared to the outcome of interventions in other disease areas. However, as there are a number of different instruments available, we will explore the appropriateness of these for this intervention, in terms of completion rates and construct validity.

CEA and CUA produce ratio statistics in terms of cost per unit of outcome (the outcome being the percentage difference between groups of participants in work or education) and cost per Quality Adjusted Life Year (QALYs), Area under the curve analysis with EQ-5D-3L estimates will be used to calculate QALYs. Point estimate incremental cost effectiveness ratios (ICERs) will be generated where appropriate (e.g. where the new intervention is both more expensive and more effective or less costly and less effective. Uncertainty surrounding the economic results will be explored using cost-effectiveness acceptability curves (CEACs). All data will be subject to statistical and sensitivity analyses using bootstrapping methods (Briggs et al. 1999).

Embedded qualitative studies

All interviews/ groups will be fully transcribed and analysed using the Framework approach [25] Transcripts will be indexed using NVIVO software and arranged into charts to reflect the thematic framework. References, quotes and notes will be added to reflect the analysis of each interview and the emerging themes to allow comparison between responses.

Sample size and justification

As this is a feasibility trial – no power calculation has been performed. The sample size was chosen based on the following: We expect to recruit approximately 100 participants from 300 patients approached over a 12 month period. This will enable us to estimate the recruitment rate to within +/-6% (with 95% confidence) and the attrition rate to within +/-7% (with 95% confidence) (assuming attrition rate ≤15%).

As this is a feasibility study interview data gathered as part of the process evaluation is intended to highlight issues important to the design of the definitive study, rather than answer definitive questions, therefore interview sample sizes reflect what is considered practical to collect.

With this in mind we anticipate that we will interview all the therapists trained in ESTVR delivery, between 10 and 20 employers (not all TBI participants will agree to employer contact); 15 NHS staff and 30 trial participants (15 in each arm of the trial).

We anticipate that not all of the TBI participants will have carers and some will not be willing to pass on carer details, however we hope that at least 50% of carers of TBI participants can be included.

Assessment of effectiveness

As this is a feasibility trial the provisional primary effectiveness endpoint for the main trial to be confirmed by this feasibility trial will be the proportion (percentage) of TBI survivors enabled to return to work or education) (variables) in the intervention group, compared to participants in the TAU group.

Similarly the, secondary effectiveness endpoints to be confirmed will include indicators of change in response to the intervention (compared to usual care) on secondary outcome measures.

Assessment of safety

No specific safety investigations are proposed. No additional safeguards will be put in place over and above those adhered to by any occupational therapist in the delivery of therapy. It is not anticipated that any special conditions need to be imposed for monitoring safety over and above those for eliciting and recording adverse outcomes. However, as this is feasibility work it is envisaged that safety factors which may need to be accounted for in a larger trial may be revealed and described during this trial.

Procedures for missing, unused and spurious data

As the primary purpose of the trial described here is 'Feasibility', we will be describing the nature and extent of missing data, rather than imputing it for analysis.

Definition of populations analysed

As this is a feasibility study our findings will primarily be concerned with measuring eligible numbers, recruitment rate, the spectrum of disease among recruits, reasons for non-recruiting, compliance with vocational rehabilitation in the treatment group and with usual care in controls and the completeness of follow up of the primary endpoint. It will also enable us to determine whether participants can be randomised to the intervention and the likely effect on drop out of randomisation to the control group. It is hoped that our findings will inform future definitions of the populations whose data will be analysed – both for the primary analysis and any applicable secondary analyses.

ADVERSE EVENTS

The adverse event risks of taking part in this study have been assessed adopting The Ottawa Hospital Rehabilitation Centre Research Ethics Board distinction between adverse events occurring in drug studies and those occurring in non-pharmacological trials. The result of this assessment is the conclusion that the ESTVR intervention is extremely low risk and unlikely to have any negative consequences. As a result, no serious adverse *events* (or adverse *events*) will be recorded or reported as such for this study.

In order to provide formal reassurance that the study is of extremely low risk, the SSC will be provided with a report detailing adverse outcomes. These will also be analysed and form part of the final report for this project.

Adverse outcomes will be classified as follows (some outcomes may be included in more than one of the categories below):

- Accidental injury resulting from non-compliance with equipment or work place adaptations recommended by the FRESH VR Occupational Therapists
- Work accidents resulting in injury requiring hospital treatment*.
- Incidents of aggression+ of the participant towards the researcher, staff or others (e.g. work colleagues)
- Attempted suicide*

+ defined as excessive verbal aggression, physical aggression against objects, physical aggression against self, and physical aggression against others.
* Hospitalisation due to attempted suicide or a work related injury will be captured as Serious Adverse Outcomes.

Identification of adverse outcomes

Questions which will help identify adverse outcomes are included in the questionnaire booklets at 3, 6 and 12 months and will be extracted by:

- the Research Associate collecting outcome data in Leeds
- the Lancashire CTU trial and/or data management staff on receipt of questionnaires

(from responses provided to questions regarding hospital and GP visits recorded from participant reported service use questionnaires). These will be enhanced by records of any deaths (obtained from hospital records, GP contact and/or reports from carers and VR therapists during the trial). Other adverse outcomes may also be identified ad-hoc by the following:

- FRESH VR occupational therapist
- Research staff in study sites (e.g. incidents of aggression+ towards researcher collecting outcome data in Leeds);

although any outcomes identified only by such means will be analysed separately as they will not be collected in this way in the usual care arm.

+defined as excessive verbal aggression, physical aggression against objects, physical aggression against self, and physical aggression against others.

Trial Intervention-related Serious Adverse Outcomes shall be reported immediately of knowledge of their occurrence to the Chief Investigator and the Sponsor and will be reviewed by the Independent Study Steering Committee.

The Chief Investigator will:

- Assess the outcome for seriousness, expectedness and relatedness to the trial intervention.
- Take appropriate action, which may include halting the trial and inform the Sponsor of such action.
- If the outcome is deemed related to the trial intervention shall inform the REC using the reporting form found on the NRES web page within 7 days of knowledge of the event.
- Shall, within a further eight days send any follow-up information and reports to the REC.
- Make any amendments as required to the study protocol and inform the REC as required

2. PROCESS EVALUATION

A parallel process evaluation, nested within the clinical trial will be used to identify VR outcomes of importance to TBI survivors, fidelity and quality of implementation (e.g. enablers and barriers to the deployment of the intervention, reasons for success or failure, contextual factors associated with variations in outcome across the intervention groups and how the intervention can be improved).

Process evaluation data will be collected by research associates and research assistants in each trial site during the feasibility trial; the analysis of the process data will be iterative and overall evaluation conducted at the time of analysis of the full trial data. Evaluation of process will include:

a) Identification of Primary Outcomes

Those recruited to the feasibility trial will be interviewed (prior to randomisation) to explore what outcome from vocational rehabilitation would be important to them. 30 participants with TBI (15 in each arm of the trial) will be interviewed 12 months later and asked the same questions.

Inclusion criteria
Fitting the criteria for the trial i.e. adults (aged 16 and over) living in the London, Preston or Leeds health communities and admitted for 48 hours or more with new TBI who were work (paid or unpaid) or in full time education prior to their injury.

Exclusion criteria
People with TBI will be excluded if they;

1.1. do not intend to return to work/education
1.2. are unable to consent for themselves
1.3. live more than 1 hour (or reasonable) travelling distance from the recruiting centre

Expected duration of participant participation

Trial Participants will take part in one interview lasting less than 15 minutes. They will be given a copy of Information Sheet 1. Some participants may agree to be re-interviewed following the trial intervention (i.e. up to 12 months later). They will be given a copy of Information Sheet 3 and informed consent will be sought. The second interview will last less than 40 minutes. No further contact will be made.

Up to 52 employers of trial participants randomised to ESTVR will be invited to participate in individual telephone or face to face interviews lasting around 45 minutes. This will be a single interview after which participation will be complete. Employers will be asked whether they would be willing to provide feedback about the ESTVR service, to evaluate the impact of the intervention and to identify the most and least useful interventions. They will be given a copy of Information Sheet 4 (employers) and an opportunity to ask questions and discuss this information with a researcher before signing a consent form.

All participants will be afforded a minimum 24 hour hours to read and review the participant information sheet before written consent is sought.

a) Factors that determine how much VR intervention is delivered (Content of treatment records completed by therapists and participant feedback (interviews)

Detailed records of the OT led ESTVR intervention will be maintained and ESTVR Intervention content will be recorded following each treatment session by the OTS and Case Managers (CM) delivering the intervention. This will be done using a proforma developed by

Phillips and co-workers (2010), which measures components of the vocational rehabilitation intervention in units of 10 minutes. Completed proformas will be collected by the research associate who will visit OT and CM staff at recruiting centres on a three monthly basis during the trial intervention period.
The content proformas will be used to assess fidelity of the VR intervention in relation to the Nottingham Pilot.

b) Practical issues relating to the deployment of the intervention (NHS staff feedback)

The research associate's visits will allow monitoring of practical issues with regard to the screening, recruitment and consent of participants and deployment of the intervention in each group. This will be done through informal discussion at site monitoring visits using a topic list that will evolve over the period of collecting process information.

c) Practical issues relating to the training provided and required for NHS staff and participants to deploy the VR intervention (Participant and Therapist feedback) (Month 12)

During months 12-24 the Nottingham Research fellow supported by research associate(s) in each centre will conduct interviews with the treating OTs and Case Managers to explore their views on the acceptability and usefulness of training and supporting materials and mentoring systems (so that training and resources may be adjusted); and their perceived changes in practice resulting from training and the anticipated and actual effects (including costs) of ESTVR implementation on supporting services. They will be given a copy of Information Sheet 5 and informed consent will be sought.

Following intervention completion (between months 6 and 30), Semi-structured interviews with 15 TBI service users will explore acceptability and usefulness of the ESTVR intervention. They will be asked to comment on practical difficulties, comprehensibility and emotional load required to complete outcome measures. These interviews will be conducted by telephone by the research associate or in person by research assistants in each centre. They will be given a copy of Information Sheet 1 and informed consent will be sought.

Towards the end of the trial period (months 24+) semi-structured interviews will be conducted by the research fellow with 15 NHS staff with a role in managing, commissioning or delivering TBI rehabilitation (5 each per site) to explore their views of the usefulness and acceptability of the ESTVR intervention, barriers and facilitators to its implementation and contextual factors influencing sustainability and outcome. These interviews will be conducted by telephone by the University of Nottingham Research fellow or in person by research associates in each centre. They will be given a copy of Information Sheet 6 and informed consent will be sought.

Interviews will be digitally recorded and field notes made to capture inaudible or other contextual information. All interviews/ groups will be fully transcribed and analysed using the Framework approach. The findings will inform the design of the definitive trial, the delivery of the ESTVR and the challenges likely to be faced in sustaining its delivery in the longer term.

We will hold an end of study meeting at each recruiting centre. Participants and therapists involved in the study and other NHS staff (including commissioners of hospital and community services) will be invited to discuss the conduct of the study, its implications and

barriers and enablers to implementation. This will also include feedback on the issues described above as well as general issues such as the use of ESTVR in the context of rehabilitation.
This feedback will be facilitated at each centre by the clinical researcher using a small working groups approach based at local centres.

d) Content of usual care and ESTVR in the two groups (Content of treatment records, therapist and participant feedback, resource use data) (Months 6-30)

and

e) To determine the extent to which ESTVR occurs in usual care (the routine rehabilitation of people with TBI).

To describe the content of usual care, we will use a questionnaire developed for a related mapping study (Playford et al. 2011), which allows components of the VR (vocational rehabilitation) intervention delivered in any service to be mapped against a 'gold standard' (best practice recommendations for vocational rehabilitation for people with long term neurological conditions, BSRM, 2010). This questionnaire will enable us to identify and describe components of VR service delivery in usual care and identify differences between usual care and the ESTVR model in the proposed study.
We will use data from the original mapping study (Playford et al. 2011) to identify VR providers in health services in each centre. Also we will use the local knowledge of PIs and local therapists, to identify usual care providers and ask them to complete the questionnaire at the study outset and again at the end. In this way we will be able to capture data about the actual VR components offered by services in usual care at the study outset and to describe if usual care changes (potential Hawthorne effect or contamination) during the course of the study. As this is feasibility study, this descriptive data will allow us to characterise the variation in usual care across the three centres and pre-set criteria for planning a larger study.

In addition, during participant interviews described above, the extent to which support similar to ESTVR is delivered in usual care will be explored among participants interviewed from the TAU group.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Trial Master File. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the trial.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for on-going participants).

RECORDS

Case Report Forms

Each participant will be assigned a trial identity code number (study number), allocated at randomisation, for use on CRFs other trial documents and the electronic database. The

documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in case additional follow-up is required.

CRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.
The Chief Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the Lancashire CTU site for Trial participants and the Chief investigator's site for participants in the Process Evaluation and may include but are not limited to, consent forms, baseline data forms and current OT treatment records, audio recordings and interview transcripts from the process evaluation studies. A CRF may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents, including progress notes and medical/psychological and other agencies test results shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The CRF will only collect the minimum required information for the purposes of the trial. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).
Information about the trial in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

TRIAL CONDUCT

Trial conduct will be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of trial materials and equipment calibration logs.

TRIAL DATA

Monitoring of trial data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Trial Manager, or where required, a nominated designee of the Sponsor, shall carry out monitoring of trial data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10%) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Ethics, the Chief Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File, Site files and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Study Steering Committee as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participants' medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.
The University will fully cooperate with requests for information involving a court subpoena.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this trial will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

The study results will be published in peer reviewed scientific journals, presented at scientific conferences (Society for Research in Rehabilitation, College of Occupational Therapists Annual Conference, Vocational Rehabilitation Association Annual Conference) and disseminated via user forums both locally and nationally by presenting to local groups and writing lay summaries of the findings for the Headway magazine. Participants will not be identified in any publications.

USER AND PUBLIC INVOLVEMENT

This project is informed by an interactive approach to research (Scott et al. 1999) in which research users (in this case, voluntary sector organisations, people affected by TBI, and service providers occupational therapists, psychologists and consultants in rehabilitation medicine) have contributed to the development of research questions and studies and the design of the intervention. This is managed through a Study Steering Committee with representatives from academia, clinical practice and the TBI population.

We have recruited two service user representatives as members of the Study Steering Committee to govern the project and ensure it is delivered according to the protocol and its agreed milestones. We have also and will continue to engage additional co-opted service users in specific activities to shape the design, implementation and evaluation of the ESTVR intervention and to disseminate the findings.
One of them Trevor Jones, TBI survivor and retired accountant was part of the initial TBI project team and remains part of this research team. His experience inspired him to become an NIHR grant reviewer and join the CLAHRC-NDL consumer group.

The service users will;

- Help ensure our participant facing information is user friendly, aids recruitment and that our outcome measures booklet is simple and easy to complete.
- Assist in the training development and delivery
- Assist in decisions about the study conduct, delivery and governance as members of the TMG and Study Steering Committee.

We hope that these expert service users will continue to engage with us in all stages of the project to ensure that it is a success and that the findings are communicated effectively to TBI people and the wider health community as well as among the academic and health service communities.

Principles for good practice outlined by INVOLVE UK (Involve, 2009) will be adhered to in relation to active public involvement in this research project. People with personal experience relevant to the research have been involved as early as possible taking into account equality and diversity issues. Individuals will be given a choice about how they want to be involved and plans made for sufficient time and resources to support this involvement. Equitable access will be ensured by giving information in good time and ensuring meetings are inclusive. People's time and involvement will be highly valued and recognized.

STUDY FINANCES

Funding source

National Institute for Health Research HTA Commissioned call.

Participant stipends and payments

Participants will not be paid to participate in the trial. Travel expenses will be offered for any hospital visits in excess of usual care.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature:_____

Date: _____

Co- investigator: (name) _____

Signature:_____

Date: _____

Trial Statistician: (name)_____

Signature:_____

Date: _____

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