Early, specialist vocational rehabilitation to facilitate return to work after traumatic brain injury: the FRESH feasibility RCT

Kate Radford,[1]* Chris Sutton,[2] Tracey Sach,[3] Jain Holmes,[1] Caroline Watkins,[2] Denise Forshaw,[2] Trevor Jones,[1] Karen Hoffman,[4] Rory O'Connor,[5] Ruth Tyerman,[6] Jose Antonio Merchán-Baeza,[7] Richard Morris,[1] Emma McManus,[3] Avril Drummond,[1] Marion Walker,[1] Lelia Duley,[1] David Shakespeare,[8] Alison Hammond[9] and Julie Phillips[1]

[1]Division of Rehabilitation and Ageing, School of Medicine, University of Nottingham, Nottingham, UK
[2]Faculty of Health and Wellbeing, University of Central Lancashire, Preston, UK
[3]Health Economics Group, Norwich Medical School, University of East Anglia, Norwich, UK
[4]Centre for Trauma Sciences, Queen Mary University of London, London, UK
[5]Academic Department of Rehabilitation Medicine, School of Medicine, University of Leeds, Leeds, UK
[6]Community Head Injury Service, Buckinghamshire Healthcare NHS Trust, Aylesbury, UK
[7]Department of Physiotherapy, University of Málaga, Málaga, Spain
[8]Lancashire Teaching Hospitals Trust, Preston, UK
[9]Health Sciences Research Centre, University of Salford, Salford, UK

*Corresponding author Kate.Radford@nottingham.ac.uk

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Scientific summary

The FRESH feasibility RCT

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Scientific summary

Background

Up to 160,000 people incur traumatic brain injury (TBI) each year in the UK, resulting in cognitive, social and psychological problems that interfere with daily activities, including the ability to work. This has a significant societal impact in terms of lost productivity and dependency on state welfare. It also has a negative impact on the person and their family, owing to financial and mental health problems and poor quality of life (QoL).

A return to work (RTW) is an important rehabilitation goal. However, services to support this are rare and evidence of their effectiveness is lacking. In 2011, the National Institute for Health (NIHR) identified the need to determine whether or not rehabilitation targeted at RTW was feasible in patients with TBI. The NIHR commissioned FRESH (Facilitating Return to work through Early Specialist Health-based interventions).

Aim

To determine the feasibility of conducting a multicentre randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of Early Specialist Traumatic brain injury Vocational Rehabilitation (ESTVR), delivered by NHS occupational therapists (OTs) in addition to usual NHS rehabilitation, with usual NHS rehabilitation alone [usual care (UC)] on work (work return and job retention) and health outcomes at 12 months post injury.

An embedded process evaluation aimed to identify the primary outcome of the importance of ESTVR to service providers, service users and employers, and explore factors related to the trial process and outcomes, intervention delivery, training provided and factors affecting NHS clinical implementation. Overall, this informed whether a definitive evaluation trial was feasible and, if so, how its design could be optimised.

Objectives

The objectives were to:

1. assess the integrity of the protocol (e.g. inclusion/exclusion criteria, staff training, adherence to intervention and reasons for non-adherence)
2. estimate recruitment rate
3. estimate the proportion of potentially eligible TBI patients recruited and identify reasons for non-recruitment
4. estimate the proportion of, and reasons for, participants lost to follow-up
5. determine the spectrum of TBI severity among recruits
6. explore the views of TBI patients and staff on recruitment and randomisation acceptability
7. determine the most appropriate method(s) of measuring key outcomes (RTW and job retention)
8. estimate parameters necessary to calculate sample size for a definitive trial
9. describe the completeness of data collection for potential primary outcome(s) for a definitive trial
10. compare gains in using face-to-face versus postal data collection
11. investigate how RTW is related to mood, well-being, function, work capacity, social participation, QoL and carer strain
12. determine whether or not ESTVR could be delivered in a way that was acceptable to patients, staff and employers.

Methods

The FRESH study was a multicentre, individually randomised controlled parallel-group feasibility trial, with an embedded mixed-methods process evaluation. Adults (aged ≥ 16 years) admitted to one of three major trauma centres (MTCs) for ≥ 48 hours with new TBI (≤ 8 weeks) and in work (paid or unpaid) or full-time education were invited to take part. Those not intending to return to work/study, unable to consent or living beyond reasonable travel distance from the recruiting centre were excluded. Carers nominated by patients were invited to take part. Patients were randomised and stratified by centre. Primary analysis was at 12 months using an intention-to-treat approach.

Feasibility economic evaluation assessed the completeness of the economic data collection needed to undertake a definitive cost-effectiveness study.

Follow-up at 3, 6 and 12 months post randomisation was by post (in two centres) and face to face (in one centre).

The process evaluation used both qualitative and quantitative methods. Interviews with 30 trial participants (15 ESTVR and 15 UC) and six employers explored perceptions of the ESTVR intervention's acceptability and usefulness and, in patients and staff only, their views on recruitment and the acceptability of randomisation. Interviews with 15 NHS staff with a role in managing, commissioning or delivering TBI rehabilitation explored practical issues relating to delivery, the training provided and required for NHS staff to deliver it, and its implementation. Group interviews with staff in each site explored screening, recruitment and consent of participants. Interviews with people early and late after injury, NHS staff with experience of delivering TBI rehabilitation and employers were used to identify primary outcomes of importance.

Multiple quantitative data collection methods were used to describe the content of UC and ESTVR. In addition a pre–post intervention mapping survey of existing service provision enabled identification and description of vocational rehabilitation (VR) service delivery in UC and any differences between UC and the ESTVR model.

Setting

Three NHS MTCs in England with interventions mainly delivered in the community in people's homes and in the workplace.

Intervention and control treatments

ESTVR intervention

ESTVR was a job retention intervention. It involved assessing the impact of TBI on work roles and responsibilities and finding acceptable strategies to overcome problems and prevent job loss.

The therapist co-ordinated the overall TBI rehabilitation package and provided support, education and advice to patients, family and others involved in the patient's care.

The individually tailored intervention commenced within 8 weeks of injury and included as many contacts as necessary, up to 12 months post randomisation. Therapists were trained according to a predefined manual and mentored in intervention delivery. Delivery was quality and fidelity monitored.

Usual care NHS rehabilitation

Participants allocated to UC received health and social care services as would happen in routine practice. No recruiting sites had existing specialist VR services. UC NHS rehabilitation was measured using resource use questions in the trial outcomes and in qualitative interviews with UC participants.

Main outcome measures

The primary outcome was self-reported RTW status at 12 months post randomisation, defined as paid or unpaid (full- or part-time) work in an ordinary work setting.

Other outcomes included participants' perceptions of mood (Hospital Anxiety and Depression Scale), functional abilities (Nottingham Extended Activities of Daily Living), participation (Community Integration Questionnaire), QoL (EuroQol-5 Dimensions, three-level version) and work ability [Work Productivity and Activity Impairment questionnaire, work self-efficacy (single question from the Work Ability Index)]. Carers completed the Caregiver Strain Index.

Assessment of objectives

Protocol integrity was assessed using predetermined feasibility criteria including clear parameters of what constitutes success.

Results

Feasibility trial

Participants

Of 1446 people with TBI screened, 200 (14%) were eligible for inclusion. The main reasons for ineligibility were unemployment (216, 19%) and retirement (563, 48%). Of those who were eligible, 76 (38%) refused consent and 29 (15%) did not respond to a letter inviting them to take part. Among those who declined and volunteered a reason, most believed the intervention would be overburdensome or of no benefit, or that they did not need help.

In total, 78 TBI patients were recruited (39% of those eligible and 5% of those screened), which gave a consent rate of 43% of those invited. A total of 39 were randomised to UC and 39 to UC plus ESTVR. Participant age ranged from 16 to 62 years (mean 39.3 years) and 85% of participants were men. Over half (56%) were classified as having mild injuries [Glasgow Coma Scale (GCS) score of 13–15], 18% as having moderate injuries (GCS score of 9–12) and 26% as having severe injuries (GCS score of ≤ 8).

Approximately 2.2 patients were recruited per site per month; however, recruitment varied by site.

A proportionately greater recruitment of people with mild TBI (56%) is thought to have been due to repatriation of more severely injured patients requiring ongoing rehabilitation.

A total of 78 TBI participants nominated 45 carers, and 32 were recruited. Carers were typically female and either a spouse/partner (72%) or a parent (28%).

In total, 52 out of 78 (67%) TBI participant questionnaires were available for analysis at 12 months (UC, $n = 23$; ESTVR, $n = 29$). Follow-up of the primary end point at 12 months was also 67%. There was a 31% loss to follow-up (non-response, $n = 22$; withdrawals, $n = 4$). Strategies to reduce loss to follow-up, including text messages and telephone calls, were tested during the trial.

A total of 90% of bespoke work questions were completed in returned questionnaires.

No participants died. Four participants (intervention, $n = 1$; control, $n = 3$) and four carers (intervention, $n = 3$; control, $n = 1$) withdrew consent.

Face-to-face follow-up was no more effective than postal follow-up, and was more resource intensive.

Return to work was most strongly related to social participation and work self-efficacy, with a weaker relationship with impairment and, for competitive work or full-time study, with depression. Interview findings suggest that an outcome measure relating more broadly to participation in work or other activities might offer a potentially more sensitive outcome than RTW.

Economic evaluation

Although data completeness was good for those participants completing questionnaires (> 80%), dropout and missing resource use data meant that only 37 out of the original 78 participants (47.4%) could be included in the early-stage complete-case, base-case analysis. Therefore, although it is feasible to measure and value health economic data in a subsequent definitive study this is not without potential challenges.

Process evaluation

Our process evaluation gave contextual meaning to our findings and identified areas for consideration in a definitive trial.

What are the most important primary outcomes of vocational rehabilitation?

- The priorities of people with TBI priorities differed according to time since injury. Newly injured people said RTW and symptom management were the most important outcomes. Late-after-injury people prioritised self-confidence and understanding the impact of TBI on life activities.
- Employers prioritised communication with NHS VR services and understanding the TBI impact on workability.
- Service providers said QoL and insight were more important than work outcomes.

Was the training seen as acceptable and useful by the therapists who received it?

- Therapists valued the training package (training, manual and mentoring), but especially valued case discussions and mentoring, which increased confidence in ESTVR delivery and supported fidelity. Therapists needed about 15 minutes of mentoring per day of intervention delivered. Therapists with no previous community rehabilitation experience needed longer.

Did the therapists deliver the ESTVR intervention as intended?

- Yes.

Did the intervention meet patients' and employers' expectations?

- Participants found the intervention useful. They particularly valued the practical support.
- Employers valued timely communication and the patient advocacy.
- No one indicated that randomisation was unacceptable or declined participation because they wanted to be certain to receive the intervention.

What were the practical difficulties, comprehensibility and emotional load required to complete outcome measures?

- Questionnaire completion was relatively free of difficulty. Some found it hard to distinguish between the impact of the TBI and other serious injuries incurred at the same time.

What factors will affect the running of the definitive trial?

- Acquiring Excess Treatment Costs from the newly reconfigured Clinical Commissioning Groups delayed recruitment.
- Deploying experienced OTs to the trial was problematic. Options to backfill therapists' existing clinical caseloads were limited.
- Identifying and screening potential participants was complicated. Not every patient fitting the inclusion criteria was admitted to a designated trauma unit. Some were geographically dispersed across sites. In two sites, recruiting staff had no access to clinical registers to identify head injury admissions. Mild TBI was sometimes missed or poorly recorded in patients admitted with other severe injuries. The lack of a clear definition of TBI may have affected eligibility and inflated the proportion of patients screened. A future trial should include a working definition of TBI rather than rely on local clinical diagnostic procedures, which differed between centres.
- Recruitment was affected by repatriation of potential participants with moderate and severe TBI in new 'hub and spoke' MTCs.

To what extent was ESTVR already being delivered in usual care?

- Although mapping failed to identify VR-specific services local to the sites, interviews with participants revealed that three ESTVR participants and three UC participants had received support with RTW from local rehabilitation teams.
- Patient-reported resource use data indicated that people receiving ESTVR had twice as much OT and more general practitioner visits than UC participants but that UC participants paid more visits to NHS walk-in centres. For all other services used, the two groups were comparable.

What factors will affect the use of ESTVR in the context of usual NHS rehabilitation?

- Better communication between OTs and commissioners is required to demonstrate the benefits of ESTVR.

Conclusions

The FRESH study demonstrated feasibility across most objectives and, when criteria were not met, strategies to achieve them in a definitive trial were identified.

Although we recruited people at a satisfactory rate, actual recruitment from the total number of eligible patients was low; 61% of eligible patients were not recruited, some of whom are likely to have had significant problems. We also recruited a disproportionate number of people with mild TBI, who, as was demonstrated in UC, may be a low-risk population for employment problems or whose employment problems may be sufficiently well managed by their employer to enable them to remain in work despite ongoing issues. Higher attrition in UC, particularly in people with mild TBI who did not return to work, potentially inflated the estimate of success in this group.

Although recruitment was as hoped, strategies for recruiting more people with moderate and severe TBI in a larger study have been identified. The issue of how to reduce attrition of the primary end point at 12 months, especially among UC participants, remains. It is believed that successfully recruiting more

people with moderate and severe TBI may have a positive impact on attrition rates and ensure that rehabilitation is directed to those who most need it.

It is feasible to collect health economic data to assess the cost-effectiveness of VR following TBI. Although challenges remain in terms of minimising dropout and missing resource use data, value-of-information analysis suggests that the cost of a future trial is likely to be lower than the value of undertaking the research.

In this feasibility study, we have demonstrated that NHS OTs can be trained and mentored to deliver an early TBI VR intervention with high levels of fidelity. Upskilling community OTs with specialist VR experience is considered the best way of delivering the intervention.

Recommendations for further research

A further study is warranted; however, the design may need to be modified to recruit more people with moderate and severe TBI, so that intervention is targeted at those most likely to benefit. This may be achieved using a two-stage recruitment process that enables potential participants to return home and live with their injury before recruitment and by recruiting from referring MTC 'spokes' for up to 12 weeks post injury. However, further work may first be needed to test the proposed mechanisms for recruitment and retention.

The findings imply that a broader outcome measure, relating to the ability to work, confidence in working or participation in work or other activities, might potentially be a more sensitive outcome.

A definitive cost-effectiveness study should take a broader perspective when measuring and valuing costs, and capture information on carer time and costs via participant questionnaires. It should also re-evaluate how best to capture the intervention costs distinct from wider NHS resource use.

Training for OTs should allocate sufficient time for discussing cases and concerns about intervention delivery.

A future study should engage commissioners, therapy services, research networks and local research and development early to ensure 'buy-in' and explore optimal methods for the identification and screening of potential participants in each site, including access to NHS registers and systems.

Trial registration

This trial is registered as ISRCTN38581822.

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