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

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FEBRUARY 2015 NEWSLETTER

<https://www.nottingham.ac.uk/go/fresh>

What is Fresh?

Otherwise known as 'Working after Brain Injury' FRESH is a feasibility randomised control trial designed to test whether an early job retention intervention to support people with Traumatic Brain Injury (TBI) to return to work, which was developed in Nottingham, can be delivered in three new NHS trauma centres (Preston, London and Leeds) and whether its effects and cost effectiveness can be measured compared to usual NHS rehabilitation. The findings will inform the design of a definitive trial.

FRESH study progress;

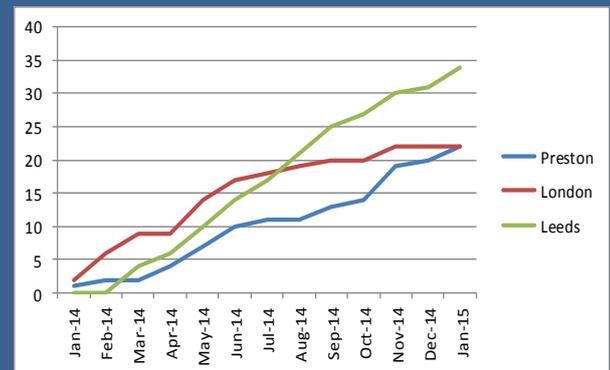
Recruitment has now ended!

Many thanks to all sites for your efforts and congratulations to Leeds for achieving target.

Therapists in each centre will continue to deliver the vocational rehabilitation for up to 12 months.

The next stage of the study is the process evaluation, where we seek to understand the practical issues affecting the delivery of the trial (e.g. recruitment), those relating to the deployment of the Early Specialist TBI VR intervention (ESTVR) and the training required for this; factors that determine how much ESTVR is delivered by trial therapists and the extent to which ESTVR occurs within the usual care of people with TBI. We will be using mixed methods including interviews with staff, patients and employers, treatment records and questionnaires.

Total recruited at the end of the recruitment period n = 78 (Preston = 22, London = 22, Leeds = 34)



Under the spot-light, Denise Forshaw Clinical Trials Manager

The Senior Trial Manager's role is to oversee the work of the Lancashire Clinical Trials Unit (CTU) trials team and ensure that the requirements of the Trial Sponsor (University of Nottingham), Good Clinical Practice, ICH Guidelines and local regulations are met. The CTU offers a variety of bespoke options from total trial management (from inception and design, through ethics and research governance, site selection and activation, recruitment, monitoring and closure) or selected activities dependant on the needs of the Chief Investigator. In Fresh the CTUs role is site management, recruitment oversight, data management and analysis.

Fresh is a feasibility study. This means it is not designed to determine whether the vocational rehabilitation intervention works or not but rather to ascertain the important parameters for designing the definitive trial (i.e. to work out how it can be done). In feasibility studies understanding what's happening in each site through screening logs, recruitment and your feedback is key to setting these parameters. I know it sometimes seem as though we ask a lot of questions but the information you provide is important for future trial design. We aim to have an open and friendly relationship with our sites and we really appreciate your views and the extra work you put in to making it work and importantly telling us what doesn't.

Dr Julie Phillips presented a paper at the Society for Research in Rehabilitation Winter 2015 Meeting in Manchester on 3 February.

The presentation reported the findings of focus groups and interviews to seek the views of people with TBI, TBI service providers and employer regarding the most important outcomes of Early Specialist Traumatic Brain Injury (TBI) Vocational Rehabilitation.

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National Institute for Health Research

This project is funded by the NIHR HTA Programme (project number 11/66/02). The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

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