



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

Christmas Newsletter 2013

Let's celebrate! The project commenced on 1st March 2013. After a challenging start, recruitment to the Trial is finally underway.

THE TEAM -

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What is FRESH?

FRESH is a feasibility randomised controlled trial (RCT) of an early specialist traumatic brain injury vocational rehabilitation (ESTVR) intervention to support job retention. The findings of a single centre study in Nottingham, suggest that this type of support may be helpful in preventing job loss in people with traumatic brain injury. The purpose of this study is to find out whether therapists in three new centres in Preston (Lancashire Teaching Hospitals NHS Foundation Trust), London (Barts Health NHS Trust) and Leeds (Leeds Community Healthcare NHS Trust) can be trained to deliver the intervention and whether its effects and cost effectiveness can be measured.

With your help we hope to recruit 102 people between now and the 31st August 2014.

Set up progress:

Ethics and R&D approvals: Ethical approval for the trial was granted on 21.10.13 and R&D approvals for Preston and London on 13.12.13. Site setup meetings have taken place in all three sites.

Securing Excess Treatment Costs: Following huge uncertainty to secure the excess treatment costs to support the therapy input to the trial, we have heard that these will be supported in each site.

Recruitment is Finally underway!

Delays in getting started and approved mean the project is three months behind schedule. Recruitment was due to commence in September and continue for 12 months. Two sites (Preston & London) are now open, so we are hopeful of recruitment before the year is out. Our feasibility target of 102 people over 12 months—34 per centre—worked out at about 3 people (2.8) per centre per month.... To achieve the same number of people in the remaining 8 months means recruiting around 4 per month. Watch this space for regular updates on progress!

Training development and delivery

The ESTVR Package (manual, training and mentoring model) has been developed and Therapists in all three centres have been trained. The therapists all have different backgrounds and pre- trial experience so we have tailored the training to suit their needs. A further day of training is scheduled for 4th April. Each therapist has been allocated a mentor and an online knowledge sharing and peer support mechanism is being created. Jain Holmes who was part of the training development group will join the project team to study for a PhD in January. The focus of her PhD will be about the implementation of the training and assessment of its fidelity.

Project Management: The Trial manager is Ali Gibson who is based in the new Lancashire Clinical Trials Unit (Lancs CTU), University of Central Lancashire. Ali is the first point of contact for the study and will endeavour to ensure all runs smoothly. She can be contacted at amgibson@uclan.ac.uk or 01772 893792

The FRESH Trial Management Group would like to express a great deal of thanks for your part in getting this Project off the ground and your future assistance in its success.

We would also like to this opportunity to wish you all a very merry Christmas and a successful New Year