

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

Chief Investigator: Dr Kate Radford [Kate.Radford@nottingham.ac.uk](mailto:Kate.Radford@nottingham.ac.uk) Tel: 01128230226

### **SHORT SUMMARY**

**Background:** People who have a traumatic brain injury (TBI) may experience problems that affect their ability to work or study. Vocational rehabilitation (VR) is a Government priority but VR services supporting people with TBI in returning to work or education are rare in the UK. In a Nottingham pilot study we compared work outcomes of people with access to early specialist traumatic brain injury vocational rehabilitation (ESTVR) to people who didn't (because of where they lived) and found more people who got ESTVR returned to and remained in work 12 months later. This only cost around £75 more per person to deliver. However, as this was not a randomized controlled trial (RCT) we can't be certain that the outcomes were really due to ESTVR. We also don't know whether this type of specialist support can be delivered in other NHS settings. Therefore, a larger RCT is needed.

**Aims:** The FRESH study aims to develop a treatment manual, training package and mentoring model, based on the Nottingham ESTVR model and test the feasibility of delivering it and measuring its effects and costs in three new NHS sites in a multi-centre feasibility RCT. This study will provide the necessary information to design and conduct a definitive trial that will tell us whether ESTVR is effective or not.

**Methods:** 102 patients will be recruited over one year from three TBI referral centres (34 per cent) and randomly allocated to receive either ESTVR in addition to usual NHS rehabilitation (intervention group) or usual NHS rehabilitation only (control group). Therapists will be trained and supported to deliver ESTVR. Work/ educational and benefit status will be measured as will support received, mood, wellbeing, functional ability and carer strain. Participants will be followed up at 3, 6 and 12 months. A nested qualitative study will investigate participants' (service users and employers) and staff beliefs about important outcomes following vocational rehabilitation, perceptions of acceptability and usefulness of the ESTVR training and intervention, changes in practice resulting from training, the effects (including costs) of implementation on supporting services and longer term sustainability. Detailed records of the intervention delivered will be kept so that we can describe the intervention delivered and determine who benefitted from which components.

**The ESTVR Intervention:** The intervention, targeted at preventing job loss, will be delivered 'one-to-one' by an occupational therapist, supported by a TBI case manager with an average of 10 sessions over 12 months. Intervention will be tailored to the individuals' needs and delivered in addition to usual care.

**Inclusion Criteria:** Patients with a new TBI, admitted to hospital for  $\geq 48$  hours, over 16 years of age, who are working or in full time education at the time of injury and intending to return.

**Recruitment:** Ward staff will identify patients meeting inclusion criteria, alert them to the study, and ask if they are interested in being involved. Interested patients will be approached by a member of the research team, given an information pack and the opportunity to ask questions. Once they have had time to consider and decide to take part, the research team will obtain consent, collect baseline data and randomly allocate the patient, via a computer programme, to the intervention or control group. Collecting study outcome data will be done by the research team. A flow-chart of this process is provided in a separate document (FRESH Study Recruitment, Consent and Intervention Processes).

