

# FRESH Flow Diagram

ESTVR Package

development

Feasibility Trial and embedded Process Evaluation

Develop TVR Package (Training Manual, Training Course and Mentoring Model)

Test feasibility of TVR Package delivery in 3 centres

Enrollment

TBI adults in 3 regional TBI referral centres (Preston, Leeds, London) admitted for  $\geq 48$  hours with new Traumatic Brain Injury assessed for eligibility (n= 250)  
 Carers of TBI participants in 3 regional TBI referral centres (Preston, Leeds, London) assessed for eligibility (n= 102)

Focus Groups and Interviews to identify Primary Outcomes

Excluded TBI adults (n= )  
 ♦ Not meeting inclusion criteria (n= )  
   Not intending to work, living  $\geq 1$  hour from the centre or documented drug, alcohol or psychiatric history  
 ♦ Declined to participate (n= )  
 ♦ Other reasons (n= )  
 Excluded TBI carers excluded (n= )  
 ♦ Declined to participate (n= )  
 ♦ Other reasons (n= )

Randomized (n= 102)

Allocation

TBI adults and carers  
 Allocated to Usual Care (n= 51)

TBI adults and carers  
 Allocated to ESTVR intervention (n= 51)

Follow-Up at 3, 6 and 12 mths  
 Blinded Outcome Assessment by Postal Questionnaire in 2 Centres, Independent Assessment in 1 centre

Content of Treatment Analysis

TBI adults and carers  
 Lost to follow-up (give reasons) (n= )  
 Discontinued intervention (give reasons) (n= )

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Feasibility Statistical and Economic Analysis

Analysed (n= )  
 ♦ Excluded from analysis (give reasons) (n= )

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 ♦ Excluded from analysis (give reasons) (n= )

Interviews with Employers, NHS Staff and TBI participants