

# A pilot study of cognitive behavioural therapy for persistent post-concussional symptoms

<b>Submission date</b> 10/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/08/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

### Study information

**Scientific Title**  
A pilot study of cognitive behavioural therapy for persistent post-concussional symptoms

**Study objectives**  
To determine the effectiveness of cognitive behavioural therapy (CBT) for individuals with persistent post-concussional symptoms after at least mild traumatic brain injury, in terms of post-concussional symptoms and quality of life.

Additional goals for the study include development of a treatment practice manual suitable for dissemination, and analysis of data to identify patient characteristics that may be related to differential treatment response.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institute of Psychiatry/South London and Maudsley Ethics Committee, ref: 311/02

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Postconcussional syndrome

### **Interventions**

Participants will be randomly assigned to either:

#### 1. Immediate Treatment:

Standard CBT. This will comprise of up to a dozen one-hour sessions of therapist contact, planned to be provided over a 3 - 4 month period. Treatment will also include provision of handouts explaining the features of PCS, identifying some of the factors considered to have a role in its development and maintenance over time, and suggested strategies for tackling symptoms.

#### 2. Waiting List:

For 3 - 4 months. At the end of this period individuals will be offered a course of CBT identical to those provided in the 'immediate treatment' group.

Randomisation will utilise minimisation according to injury severity (based on post-traumatic amnesia), length of time since injury, site at which the individual is seen, and whether a medicolegal claim had or is being pursued.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

1. Post-concussional symptoms, as assessed using the Rivermead Post Concussion Symptoms Questionnaire (RPQ; King, Crawford, Wenden et al., 1995)
2. Quality of life, assessed using the Brain Injury Community Rehabilitation Outcome Scale (Bicro-39; Powell, Beckers and Greenwood, 1998) and an individualised measure, the Quality of Life Assessment Schedule (QOLAS; Selai, Trimble, Rossor and Harvey, 2000)

### **Key secondary outcome(s)**

1. Symptoms of anxiety and depression (The Hospital Anxiety and Depression Scales [HADS]; Zigmond and Snaith, 1983)
2. Symptoms associated with PTSD (The Impact of Events Scale - Revised [IES-R]; Weiss and Marmar, 1997)
3. Fatigue (Checklist of Individual Strength [CIS20R]; Vercoulen, Swaninck, Fennis, Galama, Van Der Meer and Bleyenbergh, 1994)
4. Pain (McGill Pain Questionnaire: Melzack, 1975)
5. Anger (State-Trait Anger Expression Inventory 2 [STAXI 2]; Spielberger, 1999)
6. An additional Quality of Life measure (Visual analogue scale from EQ-5D: Rabin and de Charro, 2001)

### **Completion date**

31/07/2007

## **Eligibility**

### **Key inclusion criteria**

1. Individuals aged between 18 and 65
2. Individuals who meet criteria for post-concussional disorder (ICD-10)
3. Individuals who have had a documented head trauma leading to a probable loss or alteration of consciousness, satisfying criteria for at least a mild brain injury (American Congress of Rehabilitation Medicine [ACRM] criteria)

These symptoms should have persisted for at least 6 months following the injury.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Individuals with severe cognitive impairment (defined in this study as Mini Mental State Exam scores of less than 20 and/or Frontal Assessment Battery scores of less than 10)
2. Individuals with moderate-severe physical disability (defined in this study as Barthel score less than 15). N.B. The Barthel activities of daily living (ADL) index will not be given as a matter of routine, but only if concerns regarding prominent physical disability are noted in one of the initial assessments.
3. Individuals who have had 4 or more sessions of CBT with a clinical or counselling psychologist, or cognitive-behavioural nurse therapist, subsequent to their head injury

4. Individuals who are not fluent in English
5. Presence of other neurological disorder independent of the head injury (e.g. non-post-traumatic epilepsy)
6. Presence of drug/alcohol misuse meeting International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10) criteria for a dependence syndrome (F1x.2), as specified in ICD-10. However, individuals who may be using drugs or alcohol to a lesser extent, to the point of harmful use (F1x.1) will not be excluded on this criterion.
7. Where the initial assessment indicated factors such as risk of self-harm or psychosis that would necessitate the involvement of a Community Mental Health Team

**Date of first enrolment**

01/01/2003

**Date of final enrolment**

31/07/2007

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Maudsley Hospital**

London

United Kingdom

SE5 8AZ

## Sponsor information

**Organisation**

King's College London (UK)

**ROR**

<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**

Government

## Funder Name

South London and Maudsley NHS Foundation Trust (UK) - Blackheath Brain Injury Rehabilitation Centre funding contract

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2016		Yes	No