ISRCTN49540320 https://doi.org/10.1186/ISRCTN49540320

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

Submission date	Recruitment status	[ ] Prospectively registered
10/03/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/08/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simon Fleminger

Contact details
Consultant Neuropsychiatrist
Lishman Brain Injury Unit
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
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 Bleyenberg, 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)

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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
England

United Kingdom

Study participating centre

Maudsley Hospital
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Institute of Psychiatry
De Crespigny Park
London
England
United Kingdom
SE5 8AF
-
g.dale@iop.kcl.ac.uk

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/10/2016		Yes	No