Psychological treatments of post-traumatic stress disorder

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/07/2005		☐ Protocol		
Registration date 22/07/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 25/04/2014	Condition category Mental and Behavioural Disorders	[] Individual participant data		
/3/04//014	Mental and Denayloulal Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

069777

Study information

Scientific Title

A randomised controlled trial of weekly and intensive cognitive therapy for post-traumatic stress disorder and supportive therapy

Study objectives

To compare the efficacy of cognitive therapy for Post-Traumatic Stress Disorder (PTSD), delivered either in weekly sessions or as a one-week intensive treatment, with supportive therapy and a wait list.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. The South London and Maudsley NHS Trust/Institute of Psychiatry Ethical Committee (Research) (ref: 197/03)
- 2. Oxfordshire Psychiatric Research Ethics Committee (ref: O03.038)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Post-traumatic stress disorder (PTSD)

Interventions

Four conditions (N = 30 patients with PTSD each):

- 1. Weekly cognitive therapy for PTSD (12 weekly sessions and up to three monthly booster sessions)
- 2. Intensive cognitive therapy for PTSD, matched for therapist time
- 3. Supportive therapy, matched for therapist time
- 4. 14-week wait list

Second site is Oxford University, Department of Psychiatry.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Severity of Posttraumatic Stress Disorder (independent assessments and self-report).

Secondary outcome measures

- 1. Depression
- 2. Anxiety
- 3. Disability
- 4. Quality of life

Overall study start date

01/11/2003

Completion date

31/03/2008

Eligibility

Key inclusion criteria

- 1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of PTSD following discrete traumatic events in adulthood
- 2. PTSD is main problem
- 3. 18 to 65 years old, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

- 1. Borderline personality disorder
- 2. Psychosis
- 3. Current substance dependence
- 4. Ongoing severe threat (e.g. still living with perpetrator)
- 5. Treatment cannot be conducted without the aid of an interpreter
- 6. Not willing to accept random allocation

Date of first enrolment 01/11/2003

Date of final enrolment 31/03/2008

Locations

Countries of recruitment

England

SE5 8AF

United Kingdom

Study participating centre King's College London London United Kingdom

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

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 069777)

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	01/03/2014		Yes	No