

Psychological treatments of post-traumatic stress disorder

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Depression
2. Anxiety

- 3. Disability
- 4. Quality of life

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

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

Funder(s)

Funder type
Charity

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

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?
Results article	results	01/03/2014		Yes	No