ISRCTN48524925 https://doi.org/10.1186/ISRCTN48524925

Psychological treatments of post-traumatic stress disorder

Submission date	Recruitment status
22/07/2005	No longer recruiting
Registration date	**Overall study status**
22/07/2005	Completed
Last Edited	**Condition category**
25/04/2014	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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

United Kingdom

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

Sponsor information

Organisation
King's College London (UK)

Sponsor details
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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