ISRCTN30480505 https://doi.org/10.1186/ISRCTN30480505

Randomised controlled trial of brief cognitive therapy for posttraumatic stress disorder (PTSD)

Submission date
12/10/2010

Recruitment status
No longer recruiting

Registration date
22/10/2010

Overall study status
Completed

Last Edited
04/05/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Recent research indicates that posttraumatic stress disorder can be treated effectively. The study compares two forms of a psychological treatment for posttraumatic stress disorder named Cognitive Therapy for PTSD. There is already evidence that this treatment is effective, but we do not know what way of delivering the treatment is the most effective and most acceptable to patients.

Who can participate?
Adults suffering from posttraumatic stress disorder as a result of traumas in adulthood (e.g., assault, accidents, disaster) who can regularly attend treatment sessions either in South London or Oxford.

What does the study involve?
Participants will receive one of the two forms of psychological treatment for posttraumatic stress disorder that are being compared in the study. No drugs are involved in the treatment. Two thirds of the participants will start treatment right away. The remaining third will wait 3 months before starting treatment, and will then receive one of the forms of psychological treatment. The decision about which treatment participants receive and when they start treatment will be made by chance.
In the first three months of treatment, participants receive either up to 12 weekly sessions with a therapist or up to 6 sessions with a therapist and 6 home sessions where they work through the therapy materials at their own pace. In the following three months, they receive either up to 3 or up to 2 further sessions with the therapist. Before and after treatment (or waiting for treatment), participants complete a number of assessments to monitor their improvement. They are interviewed and asked to fill in a number of questionnaires before, midway through and after the first three months of treatment, and three months, six months, one year and two years later.

What are the possible benefits and risks of participating?
All participants will receive an effective psychological treatment. The treatment involves talking

and writing about the participants' memories of their trauma, and participants may experience short-term distress when confronting their memories. The discussion of the traumatic experience will be handled with sensitivity. Previous results showed that the treatment is well tolerated.

Where is the study run from?
1. Centre for Anxiety Disorders and Trauma, South London and Maudsley NHS Foundation Trust, London in collaboration with the Institute of Psychiatry, King's College London (UK)
2. Oxford Centre for Anxiety Disorders and Trauma, University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2010 to May 2016

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Jennifer Readings
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Contact information

Type(s)
Scientific

Contact name
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United Kingdom
OX1 1TW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
069777

Study information

Scientific Title
A randomised controlled trial of brief self-study assisted and standard cognitive therapy for posttraumatic stress disorder

Acronym
CTPTSD

Study objectives
Brief self-study assisted cognitive therapy for posttraumatic stress disorder (PTSD) is effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East London Research Ethics Committee (REC) 4, 07/09/2010, ref: 10/H0807/38

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Posttraumatic stress disorder

Interventions
1. Brief self-study assisted cognitive therapy for PTSD: up to 12 weekly sessions over 13 weeks, plus up to 3 sessions over next 3 months, last follow-up 2 years after end of weekly sessions
2. Standard cognitive therapy for PTSD: up to 6 sessions over 13 weeks, plus up to 2 sessions over next 3 months, follow-up 2 years after 13 week assessment
3. Wait list: 13 weeks wait, then random allocation to either standard or brief CT

Intervention Type
Behavioural

Primary outcome measure
Measured at initial assessment and 13, 26, 39, 65 and 117 weeks:
1. Clinician-Administered PTSD Scale (CAPS)
2. Posttraumatic Diagnostic Scale (PDS)
3. Percent meeting DSM-IV criteria for PTSD

Secondary outcome measures
Measured at initial assessment and 13, 26, 39, 65 and 117 weeks:
1. Beck Depression Inventory
2. Beck Anxiety Inventory
3. Work and Social Adjustment Scale
4. Endicott Quality of Life Scale
5. Client Satisfaction Questionnaire

Overall study start date
07/09/2010

Completion date
30/05/2016

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnosis of PTSD
2. Current PTSD is linked to 1 to 2 discrete traumas
3. PTSD is the main mental health problem requiring treatment
4. Willing to accept random allocation
5. Aged 18 years and above, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Current substance dependence
2. Immediate suicide risk
3. Borderline personality disorder requiring treatment in its own right
4. History of psychosis
5. No memory for the trauma

6. Unable to conduct the therapy in English
7. Serious ongoing threat (e.g. still living with perpetrator)

Date of first enrolment
01/10/2010

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Institute of Psychiatry, Kings College London (UK)

Sponsor details
c/o Jennifer Liebscher
Research and Development Office
In collaboration with Centre for Anxiety Disorders and Trauma,
South London and Maudsley NHS Foundation Trust
Room W 1.08
De Crespigny Park
London
England
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk/departments/?locator=26

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/05/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date