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A Randomised Controlled Trial of Metacognitive Therapy and Exposure for Post-Traumatic Stress Disorder

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/03/2012	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0133190183

Study information

Scientific Title

Study objectives
The main aim of the research is to establish if a new treatment that does not involve exposure, will lead to equivalent or superior symptom reduction when compared with a standard psychological therapy incorporating exposure.
Symptoms of PTSD include reliving experiences such as nightmares and flashbacks, arousal symptoms such as increased levels of anxiety and avoidance symptoms such as avoiding people or places related to the original trauma.
Current accepted treatments involve exposure and imaginal reliving of the traumatic experience. However, this approach can require many sessions, exacerbate the client's distress and result in vicarious traumatisation whereby clinicians are exposed to detailed accounts of the traumatic experiences. There is an identified need for a brief, less distressing therapy which is scientifically supported by models of PTSD.
Metacognitive therapy is one such approach that has been shown to be effective in recent trials (Colbear & Wells, In preparation; Wells & Sembi, 2004).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Post-traumatic stress disorder

Interventions

On the basis of the literature reviewed in relation to PTSD, the following hypotheses will be tested:

1. Metacognitive therapy and Exposure therapy will lead to significant improvements in PTSD symptoms.
2. There will be a significantly greater improvement in symptoms in the treatment conditions compared with the waiting list controls.
3. Metacognitive therapy will be superior to waitlist and exposure in reducing worry and negative beliefs about thoughts.
4. Improvements in memory will be associated with improvements in symptoms in the two treatment conditions (a test of memory based models).
5. Reductions in worry will be associated with improvements in symptoms in the two treatment conditions.
6. Reductions in negative beliefs about thoughts will be associated with improvements in symptoms.
7. Changes in beliefs about thoughts will be a better predictor of treatment outcome than changes in memory.

Participants:

Participants will be identified by screening the Psychology waiting lists at the Manchester Mental Health & Social Care Trust; Bolton, Salford & Trafford Mental Health Trust and Pennine Care NHS Trust. These individuals will be awaiting treatment for PTSD. Participants will be deemed suitable if they are between the ages of 18-65, meet diagnostic (DSM–IV) criteria for PTSD, have PTSD as the primary problem and have been experiencing PTSD symptoms for more than three months. Three months as the length of time between the trauma and treatment has been chosen as a cutoff point due to a high spontaneous recovery rate prior to three months.

Method:

Patients will be sent an information letter and consent form advising them of the content of the study and inviting them to the contact the investigator should they wish to take part. At recruitment, participants will be asked if they require a summary of the findings and, if so, contact details will be taken specifically for this purpose and stored in a locked filing cabinet in a locked office. As the research is using a randomised controlled trial design with three conditions, participants will be randomly allocated to one of the three conditions (metacognitive therapy, exposure therapy, waiting list controls) after the initial assessment session has been completed. A randomised controlled trial has been chosen to reduce variables which may affect the outcome of treatment other than the treatment itself and to allow an adequate comparison between the three conditions. The random allocation to conditions will not be undertaken by the principle researcher to avoid bias. The three conditions include two treatment conditions - metacognitive therapy for PTSD core treatment (11 sessions), exposure therapy (11 sessions) or a waiting list control condition followed by individualised treatment using the manualised metacognitive therapy for PTSD core treatment (11 sessions). Manualised packages for both treatment conditions have been chosen to reduce variations between therapist and participant interactions, therefore enabling a more accurate evaluation of the results. The control condition is required to establish if the treatment is more beneficial than time itself. There will be follow-ups at three and six months post treatment for all three conditions. This is to establish if the treatment has an effect beyond the time period of contact with the therapist. Self report measures, assessor measures and an independent assessor will be used to reduce bias. If, following treatment patients are still experiencing distress they will remain on the waiting list for treatment as usual. The departments from which the participants will be recruited have been involved in discussions regarding the benefits of this research. The waiting list time at the

departments is up to twelve months and therefore it is very beneficial for participants to take part in the research as they would otherwise have a long waiting time for treatment. They will be receiving treatment within two to four months (maximum) if they enter the study. Assuming ethical approval has been gained, it is anticipated that assessments will begin in 04/07. Interventions will begin in 06/07 and continue until 01/08. During this period, monthly meetings will take place with the study supervisor. Follow-up assessments will be completed within the following six months, alongside data analysis and report writing. Completion of the research in totality will be by 12/08.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Impact of Events Scale (IES) Horowitz, Wilner & Alvarez (1979). This measure and those in section A49 (apart from the Visual Analogue Measure currently in development, the Heart Monitor which is a physical measure of arousal and the Narrative Task) are validated and used as standard measures in psychology services to assess and monitor patients.

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/12/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
The criteria have been chosen to ensure suitability of the therapeutic treatment for the individual and their difficulties. Participants must:
1. Be aged 18-65
2. Meet diagnostic (DSM-IV) criteria for PTSD
3. Have PTSD as the primary problem
4. Have been experiencing PTSD symptoms for more than three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

65 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/12/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Clinical Psychology
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Bolton, Salford and Trafford Mental Health NHS Trust (UK)

Funder Name
Manchester Mental Health & Social Care Trust (UK)

Funder Name
NHS R&D Support Funding

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	01/07/2008		Yes	No