

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

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| <b>Submission date</b><br>28/09/2007   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>28/09/2007 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>29/03/2012       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> 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**  
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 traumatising 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

### Study type(s)

Treatment

### 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 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(s)**

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.

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

**Division of Clinical Psychology**

Manchester

United Kingdom

M13 9PL

## Sponsor information

**Organisation**

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

## 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

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/2008   |            | Yes            | No              |