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A Randomized Controlled Trial of Metacognitive Therapy and EMDR for Posttraumatic Stress Disorder

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2016 by Norwegian University of Science and Technology

Sponsor:
Norwegian University of Science and Technology

Information provided by (Responsible Party):
Norwegian University of Science and Technology

ClinicalTrials.gov Identifier:
NCT01955590

First received: September 24, 2013
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History of Changes

Purpose

Posttraumatic stress disorder (PTSD) is a frequently occurring and often debilitating anxiety disorder resulting from exposure to trauma. Trauma-focused cognitive-behavioural therapies, such as **Eye movement desensitization and reprocessing** (**EMDR**), are generally considered to be evidence-based treatments for PTSD. Although a majority of patients achieve improvement, a substantial minority either drop out of treatment, present with residual symptoms following treatment or fail to make any improvement. Furthermore, a substantial portion of the clinical trials on PTSD is characterised by major methodological limitations. In addition, there's a pressing need for research on mediators of treatment outcome. Taken together, these results highlight the need for methodological rigorous and stringent clinical trials comparing treatment modalities for PTSD. The first aim of this study is to investigate whether a treatment not based on the principles of exposure, i.e. metacognitive therapy (MCT) is as efficient as exposure-based treatments. The second aim to elucidate potential mediators of treatments effects by incorporating process-related variables.

Condition	Intervention
Posttraumatic Stress Disorder	Behavioral: Metacognitive therapy Behavioral: **EMDR** Behavioral: Treatment as usual

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized Controlled Trial of Metacognitive Therapy and **Eye Movement Desensitization and Reprocessing** for Posttraumatic Stress Disorder

Resource links provided by NLM:

MedlinePlus related topics: Anxiety Post-Traumatic Stress Disorder

U.S. FDA Resources

Further study details as provided by Norwegian University of Science and Technology:

Primary Outcome Measures:

- Posttraumatic Stress Disorder Scale (PDS) [Time Frame: 8-12 weeks post-treatment] [Designated as safety issue: No]
- Posttraumatic Stress Disorder Scale (PDS) [Time Frame: 12 month follow-up] [Designated as safety issue: No]

Secondary Outcome Measures:

- Anxiety Disorders Interview Schedule (ADIS-IV) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment] [Designated as safety issue: No]
- PTSD Symptom Scale - Interview (PSS-I) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment] [Designated as safety issue: No]

- Impact of Event Scale - Revised (IES-R) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment; 12 month follow-up] [Designated as safety issue: No]
- Beck Anxiety Inventory (BAI) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment; 12 month follow-up] [Designated as safety issue: No]
- Beck Depression Inventory (BDI-II) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment; 12 month follow-up] [Designated as safety issue: No]
- Metacognitions Questionnaire - 30 (MCQ-30) [Time Frame: Pre-treatment/baseline; weekly; 8-12 weeks post-treatment] [Designated as safety issue: No]

  Process outcome / mediator measure

- Posttraumatic Cognitions Inventory (PTCI) [Time Frame: Pre-treatment/baseline; weekly; 8-12 weeks post-treatment] [Designated as safety issue: No]

  Process outcome / mediator measure

- Session Rating Scale (SRS) [Time Frame: Pre-treatment/baseline; weekly; 8-12 weeks post-treatment] [Designated as safety issue: No]

  Process outcome / mediator measure

- Inventory of Interpersonal Problems (IIP-64-C) [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment; 12 month follow-up] [Designated as safety issue: No]
- Posttraumatic Stress Disorder Scale (PDS) [Time Frame: Weekly] [Designated as safety issue: No]
- WHO-5 Well-Being Index [Time Frame: Pre-treatment/baseline; 8-12 weeks post-treatment; 12 month follow-up] [Designated as safety issue: No]

Other Outcome Measures:

- Posttraumatic Stress Disorder Scale (PTSD-S) [Time Frame: Pre-treatment/baseline; weekly; 8-12 weeks post-treatment] [Designated as safety issue: No]

  Only administered in the MCT treatment arm

Estimated Enrollment:	90
Study Start Date:	November 2012
Estimated Study Completion Date:	November 2016
Estimated Primary Completion Date:	November 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Metacognitive therapy The focus of metacognitive therapy (MCT) is on metacognitive beliefs thought to underlie the development and maintenance of posttraumatic symptomatology.	Behavioral: Metacognitive therapy 8-12 sessions of manualized metacognitive therapy
Active Comparator: **EMDR** **Eye movement desensitization reprocessing** (**EMDR**): participant is asked to focus on trauma-related imagery, negative cognitions and body sensations while simultaneously focusing attention to a bilateral physical stimulation.	Behavioral: **EMDR** 8-12 sessions of manualized **EMDR**
Active Comparator: Treatment as usual A group of 30 patients matched for age, gender and personality disorders receiving treatment as usual (TaU) in an outpatient setting will be included as a non-randomized comparative control condition.	Behavioral: Treatment as usual 8-12 sessions of treatment of usual

Detailed Description:

EMDR is based on the assumption that posttraumatic symptoms are due to the traumatic experience(s) being stored in an unprocessed way disconnected from existing memory networks. The procedure in EMDR is postulated to facilitate the processing of the traumatic memory into existing memory networks. There is currently no empirical knowledge as to the therapeutic mechanisms of EMDR, but the protocol overlaps with core components of cognitive behavior therapy (CBT), such as imaginal exposure and cognitive restructuring of negative trauma-related cognitions. Thus, EMDR could be viewed as a form of CBT, although its originator maintains that it is a distinct treatment. EMDR is usually considered an evidence-based treatment of PTSD.

MCT is one of the new approaches in the treatment of PTSD. The metacognitive model posits that adaptation following exposure to trauma depends on metacognitive beliefs that guide how the individual interprets and responds to posttraumatic symptoms and can lead to styles of thinking that facilitate or impede emotional processing. MCT focuses on "unlocking" or removing the barriers to natural adaptation. This equips the client with general skills and therefore protects the individual from the risk of any future re-traumatisation. In contrast to EMDR, MCT does not involve proscribed exposure exercises or restructuring of negative trauma-related cognitions.

In addition we will include a group of 30 patients matched for age, gender and personality disorders receiving treatment as usual (TaU) in an outpatient setting as a non-randomized comparative control condition.

Eligibility

Ages Eligible for Study: 16 Years and older (Child, Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- a primary diagnosis of PTSD according to the Anxiety Disorders Interview Schedule (ADIS-IV)
- not previously received EMDR or MCT for this diagnosis
- not actively suicidal, presenting with suicidal ideation, psychotic or suffering from severe depression
- no evidence of alcohol or drug dependence
- Symptom chronicity of >3 months post-trauma

Exclusion Criteria:

- PTSD is not the primary diagnosis
- expressing suicidal ideation, actively psychotic, or engaging in overt self-harm
- Evidence of alcohol or drug dependence requiring treatment in its own right
- Borderline personality disorder
- Symptom chronicity <3 months post-trauma
- no ability to understand or speak Norwegian

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01955590

Contacts

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Locations

Norway

Outpatient speciality clinic for PTSD and other trauma-related emotional disorders at Østmarka, St. Olav University Hospital **Recruiting**
Trondheim, Norway, 7040
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Sponsors and Collaborators

Norwegian University of Science and Technology

Investigators

Study Director: Hans M Nordahl, Professor Department of Psychology, Norwegian University of Science and Technology
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More Information

Responsible Party: Norwegian University of Science and Technology
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Other Study ID Numbers: PTSD-NTNU-1
Study First Received: September 24, 2013
Last Updated: June 27, 2016
Health Authority: Norway: Regional Ethics Commitee
Individual Participant Data
Plan to Share IPD: Undecided

Keywords provided by Norwegian University of Science and Technology:
Metacognitive therapy
Eye Movement Desensitization Reprocessing (**EMDR**)
Cognitive therapy

Additional relevant MeSH terms:
Disease Pathologic Processes

Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic

Trauma and Stressor Related Disorders
Mental Disorders

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