# TMR-TRAUMA

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28871

**Source**
NTR

**Brief title**
TMR-TRAUMA

**Health condition**

Post-traumatic stress disorder/PTSD (post-traumatische stress stoornis/PTSS)

Targeted memory reactivation/TMR

### Sponsors and support

**Primary sponsor:** VU Medical Center and GGZ inGeest
**Source(s) of monetary or material Support:** NWO, division ZonMw

### Intervention

### Outcome measures

**Primary outcome**

The following primary study parameters will be assessed pre- and post TMR:
1. Subjective (e.g. ratings of distress, vividness and emotionality) and physiological (heart rate and salivary cortisol) indexes of fear and arousal related to the targeted, traumatic memory as probed during a script-driven recall and imagery procedure (symptom

provocation task);
2. Overall PTSD symptom level;
3. Number of intrusions (and related level of distress) of the targeted traumatic memory;
4. Brain activation and functional connectivity patterns as measured with fMRI during a script-driven recall and imagery task.

### Secondary outcome

The following secundary study parameters will be assessed 1 week (or several days) before and during intervention to test their association with the TMR effect:
- Divers sleepparameters such as subjective and objective sleep quality, percentage of time spent in (non-)REM sleep, number and density of sleep spindles and spectral power in the theta, delta and sigma range of the respective sleep phases.

The following secundary study parameters will be assessed one week before intervention and 6 months thereafter:
- Overall PTSD symptom level

## Study description

### Background summary

Post-traumatic stress disorder (PTSD) is a severe mental disorder associated with significant personal and societal burden. Traumatic memories are at the core of its pathophysiology, resulting in key-symptoms such as nightmares and flashbacks. Currently, first-choice treatment, consisting of exposure-based psychotherapy, such as eye movement desensitization and reprocessing (EMDR), proves ineffective in half of PTSD-patients. Hence, there is an urgent need to improve treatment. Sleep is crucial in the treatment of traumatic memories. During exposure-based treatment, traumatic memories get reactivated and subsequently re-encoded with lower fear. This treatment effect is then solidified during memory consolidation while asleep when the 'neutralized' memories get integrated in long-term storage, stabilizing them and further reducing their affective charge. Recent advances in basic memory research show that memory consolidation can be significantly enhanced by presenting reminder cues (sounds/scents that were linked to the memory at encoding) during subsequent sleep (targeted memory reactivation (TMR)). Here, we apply these memory reactivation strategies during sleep for the first time in (PTSD) patients to increase therapeutic effectiveness. Using a controlled design, we predict that re-administering auditory cues, that are already part of a specific PTSD treatment during post-treatment sleep, will increase therapeutic outcome. This is measured as reduced subjective and physiological fear in relation to the targeted memory, as well as reduced overall PTSD symptom level. To visualize the underlying transfer of the memory trace to higher-order memory networks, we will obtain functional MRI during scripted recall of the traumatic event pre/post study.

### Study objective

The two primary objectives of this study are: 1. To increase therapeutic effectiveness of an eye movement desentization and reprocessing (EMDR) treatment session in patients with post-traumatic stress disorder (PTSD) by reactivating the updated traumatic memory during post-treatment sleep using targeted memory reactivation; and 2. To provide a neural base for this augmented treatment effect by showing a (enhanced) system-level reorganization of the targeted memory trace using functional MRI.

**Study design**

Total participation time will be approximately 22 hours over a 2,5-week time period, consisting of 4 lab visits (including 1 night of polysomnographically-monitored sleep).

**Intervention**

Patients will be treated with a single session of EMDR by a certified therapist. EMDR is a first-choice treatment for PTSD, which has been shown to be safe and effective. After successful EMDR treatment, patients will undergo TMR during post-treatment sleep. TMR is a recently described experimental procedure which aims at strengthening memory consolidation processes during sleep by re-administering context cues, such as auditory or olfactory stimuli, that are linked to the targeted memory at awake encoding.

# Contacts

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# Eligibility criteria

## Inclusion criteria

• PTSD diagnosis according to DSM-5 criteria as assessed with the CAPS-5

• PTSD as primary diagnosis

• 18-65 years of age

• Capability to provide informed consent

### Exclusion criteria

• Current bipolar disorder, psychotic disorder, alcohol or substance use disorder (moderate and severe forms) as assessed with the M.I.N.I. International Neuropsychiatric Interview. Note comorbid depressive or anxiety disorders will be allowed if PTSD is present as diagnosis.
• Impossibility to isolate a circumscribed traumatic memory that can be used for the audioscript and for target selection in EMDR.
• Reactivation of the traumatic memory that is used for the audioscript and for target selection in EMDR, leads to severe dissociative complaints/signs”
• Not speaking/understanding Dutch sufficiently
• Active suicidal ideation
• Major head trauma with co-occurring loss of consciousness in the recent past
• (Neurological) disorder of the central nervous system, current or in history
• MRI contraindications such as metal implants, claustrophobia, pregnancy
• Use of psychotropic medication (other than benzodiazepines or other sleep medication), except when on a stable dose for at least 6 weeks (after start or alteration of dosage). Use of benzodiazepines or other sleep medication in the period of 1 week prior to study until end of study (Day 10).
• Use of recreational drugs over the entire study period (Day -7 to Day 10).
• Use of alcohol during Day -7, Day 1, Night 1, Day 2, Night 2, Day 3 and Day 10.
• Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel)
• A sleep window outside 10 pm and 10 am
• Sleep walking or REM sleep behaviour disorder

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2018 |
| Enrollment: | 48 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL6455 |
| NTR-old | NTR6632 |
| Other | NWO : 016176130 |

## Study results