SLEEP DEEP: sleep deepening as treatment augmentation for post-traumatic stress disorder

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON53336

Source
ToetsingOnline

Brief title
SLEEP DEEP

Condition

- Anxiety disorders and symptoms

Synonym
post-traumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Brain and Behavior Research Foundation (Narsad Young Investigator grant). Hersenstichting (programma Op weg naar genezing)

Intervention

Keyword: Memory, PTSD, Sleep, Trauma treatment

Outcome measures

Primary outcome

PTSD symptom level post-treatment (1 week and 3 months after end of treatment) is measured with the Clinician-administered PTSD scale for DSM-5 (CAPS-5, previous week version) and the self-administrated PTSD checklist for DSM-5 (PCL-5).

Secondary outcome

Related to the secondary objective 1, the subjective ratings related to the traumatic memories under treatment measured with the index Trauma Memory Interview (ITMI) will be obtained at the beginning and end of each treatment day and the following day. During the interview heart rate will be measured using an ambulatory heart rate monitor. Also, at the beginning of each treatment day the PTSD symptom level (PCL-5) will be assessed.

Related to the secondary objective 2, the objective sleep depth, sleep continuity measures, sleep architecture measures, and other physiological sleep measures will be obtained during each night of treatment. Also, sleep quality will be measured with a sleep diary.

Study description

Background summary

Post-traumatic stress disorder (PTSD) is a severe and highly prevalent psychiatric disorder in which traumatic memories result in debilitating symptoms such as flashbacks and nightmares. With one-third of patients not responding to standard psychotherapy, new treatment strategies are urgently needed. Sleep represents a unique time-window to enhance therapeutic interventions. Traumatic memories that are neutralized in therapy need to be stored back into memory during deep sleep to solidify the treatment effect. Sleep however, is typically disturbed in PTSD. Studies in healthy individuals now show that sleep can be deepened and memory storage can be boosted by EEG-guided acoustic stimulation. Yet despite its clinical potential, this technique has rartely been tested in patients.

Study objective

The primary objective of this study is to test whether deepening post-treatment sleep each night of a 5-day treatment program for PTSD using EEG-guided acoustic stimulation, will result an augmented overall treatment effect. In addition, two secondary objectives will be investigated: 1. To test whether deepening sleep each night of the 5-day treatment program for PTSD, will result in an augmented treatment effect of the daily treatment session, and 2. To test whether diverse sleep parameters, measured during each night of the 5-day treatment program for PTSD are associated to the effect of sleep deepening.

Study design

We will perform a double-blind, randomized, sham-controlled, between-subjects study to test the effectiveness of sleep deepening as augmentation strategy for PTSD.

Intervention

During each night of a 5-day treatment program for PTSD, we will use ambulatory, EEG-guided, closed-loop stimulation to administer subtle, non-arousing sounds, phase-locked to the up-phase of slow waves (SWs) during deep (non-REM) sleep (intervention group). In the control group, the same set-up is used to detect SWs but no acoustic stimuli are presented (sham stimulation).

Study burden and risks

Total participation time will be approximately 69 hours, consisting of 5 hours of clinical interviews and questionnaires and 8 nights of sleep recording (3 baseline and 5 treatment nights). The risk associated with participation can be considered neglectable and the burden also minimal. No adverse effects of sleep deepening have been reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- PTSD diagnosis according to DSM-5 criteria as assessed with the Clinician-administered PTSD scale for DSM-5 (CAPS-5, previous month version)
- Indication to receive 5-day treatment program for PTSD
- 18-65 years of age

Exclusion criteria

- Current episode of psychotic or bipolar disorder or alcohol or drug dependence
- Use of benzodiazepines or other sleep medication during study period
- Use of other psychotropic medication than benzodiazepines/sleep medication, except when on a stable dose for at least 6 weeks (after start or alteration of dosage)

- Irregular sleep/wake rhythm (outside PTSD itself) (imposed by e.g. regular nightshifts or cross timeline travel)
- Severe hearing loss
- Sleeping on stomach
- Inability to understand or meet the study requirements, as assessed by the researchers

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	EEG wearable in combination with closed loop acoustic stimulation set-up
Registration:	No

Ethics review

Approved WMO

Date:	10-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	02-05-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL83671.018.23