Optimizing exposure therapy for Posttraumatic Stress Disorder

Published: 01-08-2020
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To test whether maximizing inhibitory learning can improve exposure efficacy for those suffering from PTSD.

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

Summary

ID

NL-OMON54936

Source
ToetsingOnline

Brief title
OPEN up

Condition

- Anxiety disorders and symptoms

Synonym
PTSD; trauma-related symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO VENI beurs (Vi.VENI.191G.061)

Intervention

Keyword: exposure therapy, inhibitory learning, mechanisms of change, Posttraumatic

stress disorder

Outcome measures

Primary outcome

The main outcome will be change from baseline to one week follow-up in subjective fear (i.e. Subjective Units of Distress; SUDs) and physiological fear responses (i.e. heart rate and skin conductance) during a personalized trauma-script.

Secondary outcome

Secondary study outcomes will be change from baseline to one week follow-up in:

• Avoidance behavior

• Self-reported PTSD symptoms over the past week (with the PCL-5).

Long-term effect of the intervention on symptoms (i.e. PTSD symptoms) will be explored at the three month follow-up (T4).

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a disruptive disorder, with large psychological, social and economic impact. Exposure therapy is a first-line treatment for PTSD. Although it has proven to be an effective treatment for PTSD, 50 percent of people remain symptomatic after treatment. Extinction learning is thought to be the most important mechanism of action of exposure therapy. Extinction is based on the learning of non-threat inhibitory associations. Pre-clinical studies have established strategies to enhance inhibitory learning and thereby improve treatment effects. These strategies are summarized within Inhibitory Learning Theory (ILT). This project examines ILT-based strategies and techniques to improve exposure treatment outcome in PTSD.

Study objective

To test whether maximizing inhibitory learning can improve exposure efficacy for those suffering from PTSD.

Study design

The planned study comprises three separate randomized controlled trial (RCT*s), with identical study designs and consecutive participant enrollment. Per study, 60 patients suffering from PTSD will be randomly allocated to:
1. Standard exposure (n =30)
2. ILT-enhanced exposure (n =30)

In the separate RCT*s, three ILT-enhancement strategies will be tested, one per study:
Study 1: Maximizing expectancy violation
Study 2: Increasing fear and stimulus variability
Study 3: Increasing context variability

Assessments will take place prior to the exposure session (T1), during the exposure session (T2), post intervention at one-week follow-up (T3), and at 3 month follow-up (T4).

Intervention

Irrespective of group allocation, participants will receive one 90-minute exposure session. The control group will receive *standard exposure*, that is, exposure as it is currently delivered in routine clinical practice. The experimental group will receive ILT-enhanced exposure. ILT-enhancement strategies will consist of 1) maximizing expectancy violation; 2) increasing fear and stimulus variability; 3) increasing context variability.

Study burden and risks

Participants commit to being present at two research visits scheduled within two weeks* time. During these visits, participants will be exposed to their trauma-memory, their behavioral and physiological responses to trauma-related stimuli will be assessed, and they will complete interviews and questionnaires related to their PTSD symptoms. Exposure to trauma-related memories and stimuli will be upsetting to participants. However, effective treatment for PTSD includes confrontation with trauma memories and, although upsetting, confrontation with trauma memories is harmless. Immediately upon completion of the study, participants will enroll in trauma-focused treatment at the treatment center for further processing of trauma memories.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

A. Satisfying DSM-5 defined criteria for Post-Traumatic Stress Disorder
B. One specific memory related to the index trauma
C. Age between 18 and 70 years

Exclusion criteria

A. Entry of patients with other psychiatric disorders will be permitted in order to increase accrual of a clinically relevant sample; however, in cases where PTSD is not judged to be the predominant disorder, participants will not be eligible.
B. Current psychotherapeutic trauma-focused treatment (e.g. exposure; EMDR)
C. Patients with significant suicidal ideations or who have enacted suicidal

behaviors within 6 months prior to intake will be excluded from participation.
D. Mental retardation
E. Substance or alcohol dependence
F. Somatic illness that interfere with exposure interventions or planned assessments (e.g. cardiac conditions)
G. Pregnancy
H. Participants that use psychotropic medication will not be excluded but have to be on a stable dose for at least 6 weeks prior to enrollment.
I. Participants that cannot commit to refraining from using sedative medication/alcohol on the days of the intervention and testing.
J. Insufficient ability to speak and write Dutch

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-11-2020
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	01-08-2020
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20527
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73480.058.20

Study results

Date completed:	14-09-2023
Actual enrolment:	60

Summary results
Trial ended prematurely