# Optimizing exposure therapy for Posttraumatic Stress Disorder - a single case experimental design

Published: 14-09-2023
Last updated: 30-11-2024

The current project investigates whether ILT-based exposure (strategies and techniques based on insights from ILT) leads to symptom reduction and is an acceptable treatment (for both patients and therapists). Additionally, we will examine whether...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Anxiety disorders and symptoms |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53620

**Source**
ToetsingOnline

**Brief title**
OPENup - SCED

### 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 PTSD symptom decline as assessed by self-report via a diary method (time-series analyses). Participants will complete this diary during baseline (12-18 days), treatment (4 weeks), post treatment (2 weeks) and follow-up (2 weeks).

The primary objective is to investigate whether ILT-based exposure leads to a reduction in PTSD symptoms, to examine the feasibility and acceptability of ILT-based exposure, and to gain further insight into the mechanisms of action of both ILT-based exposure and HAB-based exposure.

We will examine treatment effects at three levels: i) the construct level (PTSD symptoms and related psychopathology), ii) the target level (symptoms directly targeted by the exposure intervention), and iii) the process level (indicators of processing mechanisms).

We will investigate whether ILT-enhanced exposure will lead to symptom improvement, as evidenced by a greater reduction in target symptoms (primary outcome measure). We will track changes over time by using a diary method to assess the change in target symptoms across the different stages of the study

(i.e., baseline (A), treatment (B), and follow-up (C)).

**Secondary outcome**

We will assess and compare changes in fear responses to a personalized trauma-script and clinician rated PTSD symptoms. Assessments will take place at baseline (T0), post-treatment (T1) and follow-up (T2).

Additionally, to monitor changes at the process level: We will assess fear levels and expectancies during exposure sessions

To gain more insight in the acceptability for patients and therapists, we will conduct interviews.

# 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). These strategies concern A) focus on expectation falsification; B) focus on distress tolerance; C) increasing variability. A combination of these strategies during exposure has not been studied before. in addition, there is stull much unclear about the (specific) mechanisms of change of ILT-based exposure and the comparability with the other variant of exposure therapy, which is focused more on distress reduction (habituation based exposure).

**Study objective**

The current project investigates whether ILT-based exposure (strategies and techniques based on insights from ILT) leads to symptom reduction and is an acceptable treatment (for both patients and therapists). Additionally, we will examine whether ILT-based exposure results in a reduction in the proposed mechanisms of change (expectancy violation and increased distress tolerance) and whether these are specific to ILT-based exposure.

## Study design

We will use a randomized direct sequential replication single-case ABC phase design, wherein 16 participants will be randomly allocated to either 12 sessions of inhibitory learning theory (ILT)-based exposure or standard (habituation-based; HAB) exposure. Moreover, the length of the baseline period will be randomized.

The study consists of several phases.

Phase A: Multiple Baseline
Participants conduct daily diary measurements during a baseline period. The length of the baseline is randomized between 12 and 18 days.

Phase B: Intervention
Consisting of 4 weeks of exposure therapy (3 sessions of 90 minutes per week). During this phase, participants will perform daily diary measurements. Participants will also complete daily measurements two weeks after their last treatment session.

Phase C: 3-Month Follow-Up
Participants will conduct daily diary measurements for two weeks. After this two-week period, participants will have a final feedback session with their therapist.

Measurements:
Assessments (including questionnaires and clinical interviews) will be conducted at baseline (T0), post-treatment (T1), and 3-month follow-up (T2).

## Intervention

All participants will receive a full course of prolonged exposure (PE) therapy for PTSD (i.e. 12 sessions, 90 minutes each). Participants will be randomly allocated to receive A) ILT-enhanced exposure; ILT-exposure interventions will be tailored to 1) maximize expectancy violation; 2) increase fear and stimulus variability; 3) increase context variability; or B) Standard (HAB) exposure; In HAB exposure no specific attention is paid to expectancies and participants will be repeatedly exposed to the same stimuli (i.e. low variability).

**Study burden and risks**

Participants commit to being present at three research visits scheduled, 12 sessions of exposure therapy and filling out daily measures. Participants will spend max 12 hours in total on research-related assessments. All participants will receive exposure therapy for PTSD, which is an evidence-based guideline intervention for PTSD. There are no specific risks related to this treatment.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

In order to be eligible to participate in either study a participant must meet all of the following criteria:
A. Diagnosed with current PTSD and satisfying DSM-5 defined criteria for

Post-Traumatic Stress Disorder as established by CAPS-5 interview (primary diagnosis), following repeated trauma
B. Three specific memories related to the index trauma
C. Self-reported PTSD symptoms above clinical cut-off (i.e. PCL-5 score > 31; Meer et al., 2017)
D. Three trauma-related negative cognitions with a high credibility rating (VAS score > 70)
E. Ownership of a smart phone and being able to daily complete the digital diary
F. Age between 18 and 70 years

### Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
A. Current trauma-focused treatment (e.g. prolonged exposure; EMDR)
B. Prolonged exposure treatment for PTSD in the past (>3 sessions)
C. Ongoing traumatization
D. Patients with significant suicidal ideations/serious self-injurious behavior or who have enacted suicidal behaviors or serious self-injurious behavior within 3 months prior to intake will be excluded from participation.
E. Autism spectrum disorder (established diagnosis by the referring institution)
F. Mental retardation (estimated IQ < 80)
G. Severe substance use disorder
H. Somatic illness that interfere with exposure interventions or planned assessments (e.g. cardiac conditions)
I. Pregnancy
J. 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.
K. Participants that cannot commit to refraining from using sedative medication/alcohol on the days of the intervention and testing.
L. Insufficient ability to speak and write Dutch

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

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| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-03-2024 |
| Enrollment: | 16 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 14-09-2023 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL83302.058.22 |