Optimizing Exposure Therapy for Posttraumatic Stress Disorder

Gepubliceerd: 02-09-2020 Laatst bijgewerkt: 15-05-2024

Optimizing inhibitory learning will enhance treatment efficacy for PTSD.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20527

Bron
Nationaal Trial Register

Verkorte titel
OPENup

Aandoening

Posttraumatic stress disorder

Ondersteuning

Primaire sponsor: Leiden University, Institute of Psychology
Overige ondersteuning: NWO (VI.VENI.191G.061)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 trauma imagery procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Posttraumatic stress disorder (PTSD) is a disruptive disorder, with a 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, fifty 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 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 current project examines ILT-based strategies and techniques to improve exposure treatment outcome in PTSD.

The project comprises three separate randomized controlled trials (RCTs), with identical study designs and consecutive participant enrolment. Per study, patients suffering from PTSD will randomly allocated to standard exposure or ILT-enhanced exposure. ILT enhancement strategies include maximizing expectancy violation, increasing fear and stimulus variability and increasing context variability.

Doel van het onderzoek

Optimizing inhibitory learning will enhance treatment efficacy for PTSD.

Onderzoeksopzet

Data will be collected prior to the exposure session (T1), during the exposure session (T2), one week after the exposure session (T3) and at 3-month follow-up (T4).

Onderzoeksproduct en/of interventie

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, such as 1) maximizing expectancy violation, 2) increasing fear and stimulus variability and 3) increasing context variability.

Contactpersonen

Publiek

Leiden University

Rianne de Kleine

+31 71 527 5435

Wetenschappelijk

Leiden University
Rianne de Kleine

+31 71 527 5435

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a participant must meet all of the following criteria:
• Diagnosed with current PTSD and satisfying DSM-5 defined criteria for Post-Traumatic Stress Disorder as established by SCID-5-SV interview
• Self-reported PTSD symptoms above clinical cut-off (i.e. PCL-5 score > 31)
• Index trauma is related to physical or sexual violence
• One specific memory related to the index trauma
• Age between 18 and 70 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential participant who meets any of the following criteria will be excluded from participation in this study:
• Current trauma-focused treatment (e.g. exposure; EMDR)
• Patients with significant suicidal ideations/serious self-injurious behaviour or who have enacted suicidal behaviours or serious self-injurious behaviour within 3 months prior to intake will be excluded from participation
• Mental retardation
• Substance or alcohol dependence
• Somatic illness that interfere with exposure interventions or planned assessments (e.g. cardiac conditions)
• Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	02-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54936
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8864
CCMO	NL73480.058.20
OMON	NL-OMON54936

Resultaten