Trauma-focused exposure therapy for posttraumatic stress disorder in patients with eating disorders

Gepubliceerd: 03-09-2020 Laatst bijgewerkt: 15-05-2024

The primary hypothesis is that it is feasible and leads to positive results to treat PTSD using exposure therapy in reducing PTSD symptoms in patients with eating disorders.

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

Samenvatting

ID

NL-OMON28371

Bron
NTR

Verkorte titel
TAPE-study

Aandoening

Eating disorder, posttraumatic stress disorder

Ondersteuning

Primaire sponsor: Parnassia Psychiatric Institute
Overige ondersteuning: Parnassia Psychiatric Institute/PsyQ Eating Disorders The Hague Emergis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter is decrease of weekly measured PTSD symptom severity after the onset of exposure therapy compared to baseline.

Toelichting onderzoek

Achtergrond van het onderzoek

A frequently occurring comorbidity in eating disorders (ED) is posttraumatic stress disorder (PTSD). It is estimated that approximately between 9 and 24 percent of ED patients suffers from a comorbid PTSD diagnosis. However, controlled studies on treatment of PTSD in ED are scarce. Expert opinion states concurrent treatment of ED and PTSD, but research in this field is in its nascent stages. The current study is an initial evaluation of the feasibility and effects of exposure therapy in those suffering from ED and comorbid PTSD. We examine the feasibility and effect of exposure therapy in two separate multiple baseline case series. Both studies will include 10 female adult outpatients who satisfy DSM-5 diagnostic criteria for both ED and PTSD. Study 1 will exclusively enroll patients suffering from Anorexia Nervosa (AN) or atypical AN; study 2 will enroll participants suffering from Bulimia Nervosa (BN) and Binge Eating Disorder (BED), or patients with otherwise specified feeding or eating disorder (OSFED) with BN and BED symptoms. Participants will receive 10 session exposure therapy for PTSD which will be added on treatment as usual (TAU) for ED.

Doel van het onderzoek

The primary hypothesis is that it is feasible and leads to positive results to treat PTSD using exposure therapy in reducing PTSD symptoms in patients with eating disorders.

Onderzoeksopzet

Two different measurement series will be executed:
- Time series: In the two multiple baseline case series, participants will be randomized to five baseline lengths (min 5 and max 9 weeks, with two participants per baseline length per study). They are measured weekly during the baseline phase, during and after the intervention and at follow-up with self-report measures of PTSD symptom severity and ED symptom severity.
- Single time points: Participants are assessed with clinical interviews and self-report measures at the following single time points; baseline, post exposure, at 3 months follow-up and at 6 months follow-up

Onderzoeksproduct en/of interventie

Participants will receive 10 session exposure therapy for PTSD which will be added on treatment as usual (TAU) for ED.

Contactpersonen

Publiek

Leiden University
Maartje Schoorl

06-21270695

Wetenschappelijk

Leiden University
Maartje Schoorl

06-21270695

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Study 1:
- Female outpatients with anorexia nervosa, or otherwise specified feeding or eating disorder with anorexia nervosa symptoms (atypical AN) and posttraumatic stress disorder diagnosis according to DSM-5
- Age 18-65
- Body Mass Index ≥15
- Informed consent
- Enrollment in outpatient eating disorder treatment

Study 2:
- Female outpatients with bulimia nervosa, binge eating disorder, otherwise specified feeding or eating disorder with bulimia nervosa or binge eating disorder symptoms and posttraumatic stress disorder diagnosis according to DSM-5
- Age 18-65
- Body Mass Index ≥15
- Informed consent
- Enrollment in outpatient ED treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Study 1:
- Current PTSD treatment
- Other concurrent psychological treatment during the duration of the study than the studied intervention of exposure therapy and TAU for ED.
- DSM-5 diagnosis of BN, BED, OSFED with BN or BED symptoms, Avoidant Restrictive Food Intake Disorder, night eating syndrome or purging disorder
- Psychotic disorder
- Medical instability (hospital admission required) or pregnancy
- Changes in psychotropic medication in the two months prior to inclusion
- High risk of suicidality in the last two months (High suicidality score on MINI-plus and a suicide attempt in the past 6 months)
- Severe non-suicidal self-injury (NSSI) in the last two months (hospital referral required)
- Insufficient proficiency in the Dutch language
- Alcohol or drug dependency in last two months
- Cognitive impairment (estimated IQ < 70)

Study 2:
- DSM-5 diagnosis of AN, OSFED with AN symptoms, Avoidant Restrictive Food Intake Disorder, night eating syndrome or purging disorder
- Current PTSD treatment
- Other concurrent psychological treatment during the duration of the study than the studied intervention of exposure therapy and TAU for ED.
- Psychotic disorder
- Medical instability (hospital admission required) or pregnancy
- Changes in psychotropic medication in the two months prior to inclusion
- High risk of suicidality in the last two months (High suicidality score on MINI-plus and a suicide attempt in the past 6 months)
- Severe non-suicidal self-injury (NSSI) in the last two months (hospital referral
- required)
- Insufficient proficiency in the Dutch language
- Alcohol or drug dependency in last two months
- Cognitive impairment (estimated IQ <70)

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	03-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52855
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8874
CCMO	NL73138.058.20
OMON	NL-OMON52855

Resultaten

Samenvatting resultaten
N/A