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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28371

Source
Nationaal Trial Register

Brief title
TAPE-study

Health condition

Eating disorder, posttraumatic stress disorder

Sponsors and support

Primary sponsor: Parnassia Psychiatric Institute
Source(s) of monetary or material Support: Parnassia Psychiatric Institute/PsyQ Eating Disorders The Hague
Emergis

Intervention

Outcome measures

Primary outcome

The primary study parameter is decrease of weekly measured PTSD symptom severity after

the onset of exposure therapy compared to baseline.

Secondary outcome

The secondary parameters are to investigate the feasibility of exposure therapy for PTSD in ED population, to measure the effect of exposure therapy on secondary clinical outcomes and to measure whether the intervention effects are maintained over time.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	03-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52855
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A