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

Published: 23-07-2020
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The current study is an initial evaluation of the feasibility and effects of exposure therapy in those suffering from ED and comorbid PTSD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52855

Source
ToetsingOnline

Brief title
TAPE-study

Condition

- Other condition
- Eating disorders and disturbances

Synonym
Eating disorder, Posttraumatic stress disorder, PTSD

Health condition

Angststoornissen en symptomen (posttraumatische stressstoornis)

Research involving
Human

Sponsors and support

Primary sponsor: Parnassiagroep
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Comorbidity, Eating disorders, Exposure therapy, Posttraumatic stress disorder

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 initial 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). 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.

Study objective

The current study is an initial evaluation of the feasibility and effects of exposure therapy in those suffering from ED and comorbid PTSD.

Study design

Two separate multiple baseline case series.

Intervention

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

Study burden and risks

No significant risks are associated with participation. The burden for the patients is relatively low, involving additional measurements incorporated in clinical routine. There are no direct benefits for participants.

Contacts

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Parnassiagroep

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	19-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-07-2022
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: 28371
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73138.058.20