Concurrent Treatment for Patients with Severe Anorexia Nervosa and Post-Traumatic Stress Disorder: A Feasibility Study

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

Summary

ID

NL-OMON56517

Source
ToetsingOnline

Brief title
Cocoon Study

Condition

- Other condition
- Psychiatric disorders

Synonym
anorexia, anorexia nervosa

Health condition

post-traumatische stress-stoornis

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: ZonMW - programma DoelmatigheidsOnderzoek

Intervention

Keyword: Anorexia nervosa, Feasibility study, Post-traumatic stress disorder, Psychological treatment

Outcome measures

Primary outcome

Feasibility will be assessed by examining by assessing attrition rate and by

assessing trauma treatment acceptability.

The primary outcome measure is attrition rate (percentage of participants who

stop out or are withdrawn of the trauma-focused treatment due to negative

effect on the course of AN treatment. Negative effects on the AN treatment can

be not being able to stick to agreed daily meal plans anymore or for stopping

regaining weight. If attrition is attrition is <= 40%, indicating the completion

rate is equal to or over 60%, it is assumed synchronous trauma treatment is

feasible..

Secondary outcome

The secondary outcomes in this study are factors that may moderate attrition,

including duration of anorexia, AN subtype and AN onset, baseline BMI (kg/m2),

somatic disorders and emotion regulation measured using the Difficulties in

Emotion Regulation Scale (DERS; Gratz & Roemer, 2004). It is suspected that

these factors may moderate attrition.

Other secondary outcomes include treatment effects such as changes in eating disorder pathology measured using the Eating Disorder Examination Interview (Cooper &; Fairburn, 1987) and changes in trauma pathology measured using the PTSD Checklist for DSM-5 (PCL-5).

In addition, other measures will assess the acceptability of combined treatment. To measure the acceptability of the AN-PTSD treatment, a qualitative interview will take place in which patients will be asked about their experiences. Practitioners are also interviewed about their experiences before and after treatment. Client satisfaction will be measured using the client satisfaction questionnaire (CSQ-8; de Brey, 1983) at the end of the IE treatment and at the end of the AN treatment. Finally, the Working Alliance Inventory (WAI; Hatcher & Gillaspy, 2016) will be used to examine patients' therapeutic alliance.

Study description

Background summary

Childhood maltreatment is a known risk factor for developing AN, a debilitating disorder with poor treatment response (Waller, 2016) and high associated treatment costs (Van den Berg et al., 2022). According to the self-medication hypothesis AN pathology as starvation serves as a coping mechanism for dealing with trauma-related intrusive symptoms (Brewerton, 2018). Childhood maltreatment can also lead to the development of PTSD. Although guidelines recommend an integrated treatment approach when dealing with AN and PTSD (Ten Napel et al., 2022), up till now no integrated approaches have been developed

as severely underweight AN patients are not offered trauma treatment. The present feasibility study is a necessary first step in building high quality knowledge on an integrated treatment approach for severely underweight patients with significant important PTSD symptoms.

Study objective

The primary objective of the study is to determine the feasibility of concurrent treatment for AN and PTSD. This study aims to determine whether (a) participants are able to complete the trauma sessions while staying adherent to the AN inpatient treatment and (b) whether trauma treatment is acceptable for both participants and AN therapists.

Once this feasibility study indicates that trauma treatment can be completed while receiving and staying adherent to co-occurring AN treatment, an integrated AN-PTSD treatment approach can be developed. Next, the longterm efficacy and cost-effectiveness of such an approach can be examined in a high quality, sufficiently powered randomized controlled trial.

Study design

The study design of this feasibility study is a pre-experimental cohort study. Due to the 12-months duration of this grant, a limited number of eligible patients will be available. Therefore, findings on feasibility will be preliminary and warrant a study design with a longer inclusion period and an additional follow up period, in order to have sufficient power for findings to be robust.
The inpatient unit of Novarum consists of 12 beds and serves between 57 and 60 inpatients during a 12-months period, around 80% of hospitalized inpatients have a AN diagnosis. At Novarum, all AN inpatients have a body mass index under 17.5 kg/m2.
Assuming a 23% rate of co-occuring PTSD, around 11 patients might be eligible. We expect 5-10% of inpatients who are not willing to participate (Ten Napel, 2022). As we aim to examine feasibility of the trauma-focused intervention within a real-world clinical AN population, minimal exclusion criteria will be applied. Inclusion is aimed at around 10-11 patients.

When completion rate is equal to or over 60%, it is assumed synchronous trauma treatment is feasible. Due to the modest number of eligible patients, statistical findings will not be robust and will be more qualitative by nature. "The Journal Article Reporting Standards" and the "Strengthening the Reporting of Observational Studies in Epidemiology"statement will be used for study design and reporting of the results.

Intervention

Individual CBT-based trauma-focused treatment (IE) for 8 weeks, twice a week, will be offered by specialized trauma therapists, during a 12-weeks hospitalization period for AN in a specialized eating disorder clinic. After two weeks of hospitalization, trauma treatment will start.
The inpatient AN stay has a duration of 12 weeks and aims at regaining psychiatric and physical stability in order for outpatient psychotherapy to start
following hospitalization. During AN hospitalization, interventions are offered on a voluntary basis by a multidisciplinary group of psychiatrists, medical doctors, dieticians, nurses, and psychologists.

Study burden and risks

When participants are processing their trauma through imaginal exposure, they may experience temporarily increased emotional distress which may present through increased AN or PTSD symptoms, particularly directly after imaginal exposure sessions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

The study sample consists of consecutive referrals by general practitioners or general hospitals with adult patients with severe anorexia nervosa (AN) and (subthreshold) posttraumatic stress disorder (PTSD). Patients are eligible if they meet all of the following criteria:
•Being over 18 years of age
•A DSM-5 diagnosis of AN with a body mass index under 17.5 kg/m2 , as assessed by a psychiatrist or clinical psychologist. These AN patients have been offered and accepted inpatient treatment
•Being exposed to childhood maltreatment prior to the onset of the eating disorder, as assessed by the Dutch version of the Childhood Trauma Questionnaire (CTQ; Thombs et al., 2009)
•Having a diagnosis of PTSD or sub-threshold PTSD as assessed by the Dutch version of the Clinical-Administered PTSD Scale for DSM-5 (CAPS; Boeschoten et al., 2018) defined as having two or three of the DSM-5 criteria B - E
•Agrees to terms and conditions of the study and has provided informed consent
•Dutch speaking

Exclusion criteria

Acute suicidal or psychotic decompensation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2023
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	21-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84705.100.23