

Treating trauma during a severely underweight state in anorexia nervosa patients, a multiple baseline case series study.

No registrations found.

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

Summary

ID

NL-OMON29188

Source

Nationaal Trial Register

Brief title

IMRS ED study

Health condition

Trauma, PTSD, Anorexia, Eating Disorders, Severely underweight, Imaginary Rescripting, Intervention Study, Qualitative Research.

Trauma, PTSS, Anorexia, Eetstoornissen, Ernstig ondergewicht, Imaginaire Rescripting, Interventie studie, Kwalitatief onderzoek.

Sponsors and support

Primary sponsor: Psychiatric Hospital GGNet, Amarum
University of Amsterdam
Free University

Source(s) of monetary or material Support: Psychiatric Hospital GGNet, Amarum

Intervention

Outcome measures

Primary outcome

PTSD Symptom Scale-Self-rating (PSS-SR) is self-report questionnaire in which the DSM-IV symptoms for PTSD are addressed in 17 questions (Foa, Riggs, Dancu, & Rothbaum, 1993). The PSS-SR can be used either as a quantitative measure, to indicate the level of trauma-related complaints, or as a qualitative measure used to classify patients as suffering from PTSD yes or no. The PSS-SR will be collected weekly.

VAS scales core emotional problems and beliefs

The visual analog scale (VAS) is an instrument to measure subjective characteristics or attitudes. It is a psychometric response scale. The respondents may indicate on a line with two end points, to what extent they agree with an item. When the CAPS interview diagnosis a PTSD three personalized questions will be asked to personalize the VAS scales about negative thoughts about the self and the body. The VAS scales will be collected biweekly during the baseline period, after each IMRS session, biweekly during the follow up phase and once during the follow up measure.

The following items are presented:

- 1) to what extent did you experience rage in the past three days
- 2) to what extent did you experience guilt in the past three days
- 3) to what extent did you experience shame in the past three days
- 4) to what extent did you experience disgust in the past three days
- 5) to what extent did you suffer from your “personalised negative thoughts about the self/ core belief” in the past three days
- 6) to what extent you suffer from your “personalised negative thoughts about the self/ core belief” in the past three days
- 7) to what extent you suffer from your “personalised negative thoughts about the body” in the past three days

If supported by correlations, average values for negative emotions and for core beliefs will be used as primary outcomes, so that there are two dependent variables based on the set of VASs.

Secondary outcome

Secondary study parameters will be administered at several fixed timepoints

Post-traumatic Cognitions Inventory (PTCI). The PTCI is a 36 item self-report questionnaire designed to measure trauma-related cognitions in three domains: negative cognitions about the world, negative cognitions about the self, and self-blame (Emmerik, Schoorl, Emmelkamp, & Kamphuis, 2006; Foa, Ehlers, Clark, Tolin, & Orsillo, 1999).

BMI growth. BMI is a relative weight measure and is calculated as follows: body weight in kg /body height in m². In the inpatient treatment, height is measured once during initial screening, and weight is measured minimal two times a week. We will ask patients for permission to use the height and weight information from their medical files.

Eating Disorder Evaluation-Questionnaire (EDE-Q). The EDE-Q is a 36-item self-report questionnaire which measures core attitudinal features of the eating disorder, as well as the frequency of core eating disorder behavior over the previous 7 days.

Difficulty with Emotion Regulation Scale (DERS). The DERS is a questionnaire which measures difficulties with emotion regulation, such as lacking emotional awareness, difficulty controlling impulses when distressed, and limited access to effective emotion regulation strategies. The DERS consists of 36 self-report items and can be used in nonclinical and clinical populations (Gratz & Roemer, 2004; Neumann, Van Lier, Gratz & Koot, 2010).

Qualitative outcome measures

- Therapist personal experiences and opinions on treating trauma during a severe underweight state (Therapist interview). We will conduct a semi-structured interview.
- Patient's personal experiences, treatment satisfaction, needs and opinions on treating trauma during a severe underweight state (Patient interview). We will conduct a semi-structured interview to assess the patient's personal experiences and opinions about IMRS during their severely underweight state.
- Collective therapists experiences and opinions on treating trauma during a severe

underweight state. All therapists will participate in a weekly intervention sessions with the other participating therapists, and the researcher (a clinical psychologist trained in ImRs), whenever they are currently or soon will be treating a patient with ImRs. Three weeks before the start of an ImRs patient they will join the intervention group. The researcher will summarize the sessions and send this summary to the therapists for a member check. The researcher will observe the intervention on 7 items.

- Therapist-patient interaction. We will (audio-) record the entire treatment to check the treatment integrity, the interaction and the communication between the therapist and the patient. We will choose 3 tapes randomly from each therapist and score the tapes with the treatment integrity checklist from S. Raabe (in preparation).

Study description

Background summary

The aim of this study is to determine whether treatment of PTSD, in an earlier stage during the treatment of anorexia nervosa or an eating disorder NOS (during severely underweight), leads to a better result of the treatment of the eating disorder. The first phase of treatment of anorexia nervosa and eating disorder NOS in severely underweight, is a phase of recovery. Many people who suffer from underweight find this a difficult phase. A proportion of the people who undergoes this treatment, does not complete the treatment. We assume that this maybe because experiencing emotions (can) change during the phase of weight recovery. This means that more PTSD symptoms can be 'felt' during this period of weight recovery. The current directive indicates that treatment should first be aimed at weight restoration. Thereafter, treatment of trauma will be able to take place. We want to examine if simultaneous treatment of trauma and weight recovery is possible and helps someone better or quicker. If this turns out to be of added value we can adjust the treatment accordingly. In this way, we hope that in the future more people will be better faster.

Study objective

The primary hypothesis of this study is that it is possible and effective to treat trauma using Imaginary rescripting (IMRS) in reducing trauma-related complaints in severely underweight eating disordered patients.

The secondary hypothesis is that the treatment of trauma has a favorable effect on the process of weight gain and on eating disorder pathology in general.

We also hypothesize that patients will report satisfaction with the treatment of their trauma and the treatment in general, while being severely underweight.

Finally we hypothesize that the therapists experience that it is possible and effective to treat traumas using IMRS with these patients during severely underweight.

Study design

During this multiple baseline case series study the participant(s) will be measured between 6 and 11 weeks as a baseline period. Of this baseline period, three weeks are a naturalistic baseline before the start of the inpatient treatment and 3 weeks to 8 weeks constitute the varying baseline period during the inpatient treatment. The exact timing of the intervention will be randomly determined when the patient enters the study, given the abovementioned baseline limits. The treatment phase consists of 6 weeks (with twice-a-week IMRS sessions). The post IMRS treatment phase will be three weeks and after three months the follow-up assessment will be conducted.

During the (naturalistic and randomized) baseline phase, IMRS treatment phase and post IMRS treatment phase, the patient(s) will be measured biweekly for the primary outcome variables VAS and weekly for the primary outcome variable PSS-SR. The same measures will be taken at the 3 month follow-up.

Secondary outcome variables will be measured at a lower frequency: (1) At the start of the naturalistic baseline phase; (2) prior to the start of the IMRS treatment phase; (3) halfway the IMRS treatment phase, i.e. three weeks after the start of IMRS treatment; (4) after completion of the IMRS treatment phase; and (5) at three months post IMRS treatment.

The semi-structured interviews to explore patients' and therapists' views on the treatment is scheduled two weeks post IMRS treatment.

Intervention

The IMRS treatment consists of 12 sessions of 90 minutes, and is conducted by either a health psychologist, psychotherapist, or clinical psychologist. The session frequency is twice a week.

Imagery Rescripting (IMRS) is a psychological treatment (Arntz, 2015; Arntz & Weertman 1999; Raabe et al., 2015; Smucker et al, 1995) which will be given in addition to the regular treatment that patients receive at Amarum. The investigational treatment focuses on

changing the meaning of the memories of traumatic experiences by experiencing imagined interventions that correct the dysfunctional emotional and interpersonal meaning attached to the trauma through imagery rescripting. This may temporarily cause affective distress in patients (as do all therapies which focus on working through trauma), yet will help them to overcome their traumatic images and related distress (e.g., flashbacks and nightmares). Patients are fully informed on these effects.

Contacts

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Eligibility criteria

Inclusion criteria

- a BMI between 14 and 16.5
- current DSM IV diagnosis for anorexia nervosa or EDNOS
- a PTSD diagnosis determined with the CAPS interview
- age between 16 and 65 years old
- an indication inpatient treatment

Exclusion criteria

- estimated IQ < 80
- acute suicide risk
- substance dependence
- life threatening physical condition
- start of new medication within 3 months before

start of the study

- ongoing trauma
- medical history of psychosis, bipolar disorder, or borderline personality disorder

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):	01-11-2016
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date: 23-09-2016

Application type: First submission

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
NTR-new	NL5906
NTR-old	NTR6094
Other	Ethic Review Board University of Amsterdam : 2016-CP-7111

Study results

Summary results

Publications will be about:

- * If treating trauma using IMRS is possible and effective in reducing trauma-related complaints in severely underweight eating disordered patients.

- * If the treatment of trauma has a favorable effect on the process of weight gain and on eating disorder pathology in general.

- * How patients experience the treatment of their trauma, and whether it affects their treatment satisfaction, while being severely underweight.

- * About the opinions and experiences of the therapists about feasibility and effectiveness of using the IMRS technique with these patients.