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

Gepubliceerd: 23-09-2016 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON29188

Bron
NTR

Verkorte titel
IMRS ED study

Aandoening

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

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

Ondersteuning

Primaire sponsor: Psychiatric Hospital GGNet, Amarum
University of Amsterdam
Free University
Overige ondersteuning: Psychiatric Hospital GGNet, Amarum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

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:	01-11-2016
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-09-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5906
NTR-old	NTR6094
Ander register	Ethic Review Board University of Amsterdam : 2016-CP-7111

Resultaten

Samenvatting resultaten
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.