Processes and Outcomes of Cognitive Therapy vs. Cognitive Therapy + Exposure for Eating Disorders: Study protocol for a Randomized Controlled Trial

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CT + (Cue) Exposure is more effective than Pure CT (both in short- and long-term).

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

Samenvatting

ID

NL-OMON27127

Bron
NTR

Verkorte titel
-

Aandoening

Eating Disorders; Bulimia Nervosa; Eating Disorder Not Otherwise Specified / Eetstoornissen; Boulimia Nervosa; Eetstoornis niet anderszins omschreven.

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of specific Eating Disorder pathology (including body satisfaction/esteem); Meeting/not meeting DSM criteria for any of the Eating Disorders.

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive Behavioural Therapy (CBT) has shown to be an effective treatment for various Eating Disorders. However, since approximately 30% of patients do not (or insufficiently) respond to treatment there is room for improvement. When taking a closer look at the protocols that are currently being used in clinical practice, it can be concluded that existing protocols often have a relatively strong focus on diet management. More emphasis on the cognitive aspects of CBT might make treatment more effective. Furthermore, there are indications that specific exposure elements (e.g. cue exposure, forbidden foods exposure, and positive body exposure) might be effective as well. Combining cognitive interventions with these exposure exercises might therefore also increase treatment effects. These ideas were leading ground for designing the current RCT. In this study, 106 adults with an Eating Disorder (BN, BED, and ED NOS) will receive psychotherapy (CT or CT + Exposure) in an outpatient mental health clinic in the Netherlands. Treatment consists of 20 individual sessions of 60 minutes (3 pre-sessions, 16 treatment sessions, 1 booster session). Primary outcome is severity of eating disorder pathology. Secondary outcomes include self-esteem, body satisfaction, mood, general psychological distress, craving, impulsivity and BMI. In addition, measures of various potential mechanisms of change are included. Assessments are taken at baseline, pre- and post-treatment, prior to-, during- and after each therapy session, and at 1, 6, 12 and 24 months follow-up. By including repeated measures of clinical outcomes and multiple potential process measures over the course of 2.5 years, we aim to examine both the clinical effects (acute and long-term) of both interventions, as well as the causal pathways that lead to therapeutic change.

Doel van het onderzoek

CT + (Cue) Exposure is more effective than Pure CT (both in short- and long-term).

Onderzoeksopzet

Intake; pre- and post-treatment; prior to-, during- and after each therapy session; and at 1, 6, 12 and 24 months follow-up.

Onderzoeksproduct en/of interventie

Cognitive Therapy
Cognitive Therapy + (Cue) Exposure

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults with Eating Disorders BN/ED-NOS as primary diagnosis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

BMI < 18; primary diagnosis other than ED; elevated acute suicide risk, concomitant psychological treatment; drugs and alcohol abuse/dependence; insufficient knowledge of the Dutch language; mental retardation (IQ < 80).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44125
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6420
NTR-old	NTR6597
CCMO	NL17291.068.07
OMON	NL-OMON44125

Resultaten

Samenvatting resultaten

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