Schema therapy for Anorexia Nervosa

Published: 07-07-2023
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This study evaluates the efficacy and applicability of schema therapy for anorexia nervosa.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eating disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON53672

Source
ToetsingOnline

Brief title
Schema therapy for Anorexia Nervosa

Condition

- Eating disorders and disturbances

Synonym
eating disorder, feeding disorder

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Groep.
Source(s) of monetary or material Support: Parnassia Groep Den Haag

Intervention

Keyword: anorexia nervosa, eating disorder, multiple case series design, schema therapy

Outcome measures

Primary outcome

This study investigates the effects of a thirty week schema therapy in reducing eating disorder symptoms of patients with anorexia nervosa.

Hypothesis:

Based on previous research (McIntosh et al., 2016; Pauwels, Dierckx, Schoevaerts, & Claes, 2016; Pugh, 2015; Simpson et al., 2010; Waller, Dickson, & Ohanian, 2002) it is expected that schema therapy will improve eating disorder symptoms for patients with anorexia nervosa.

Secondary outcome

This study seeks to examine the changing nature of schema*s and modes in patients with anorexia nervosa during schema therapy.

Hypothesis: It is expected to demonstrate a reduction in schema*s and modes for patients with anorexia nervosa during schema therapy.

Study description

Background summary

Treatment outcomes in anorexia nervosa are poor and limited evidence is available in how to treat patients with anorexia nervosa.

Study objective

This study evaluates the efficacy and applicability of schema therapy for anorexia nervosa.

Study design

A multiple baseline case series design. After a baseline phase of five, six,

seven or eight weeks, fifty weeks of protocoled schema therapy follows. Six months after therapy is ended, a follow-up measure will be done

Intervention

45 sessions schema therapy (in 50 weeks time)

Study burden and risks

Number of site visits is comparable with treatment as usual, assessment of BMI is part of the standard procedures at PsyQ, hence not an extra burden associated with participation. No risks are expected to be associated with participation in this study. It takes about two and half hours to complete the questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

- A DSM-5 diagnosis anorexia nervosa
- Age between 16-65 years
- BMI >= 15 and somatically stabile as is defined in the department*s crisis protocol and evaluated by a physician specialised in eating disorders.

Exclusion criteria

- Patients in an acute state of mental crisis who need immediate hospitalization or treatment for high suicide risk
- Patients with intellectual disability
- Patients who cannot complete the questionnaires because of insufficient language skills, practical or cognitive limitations
- Not willing (or being able) to sign the informed consent form of this study

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):	25-10-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2023
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL79795.058.23