Effectivity and Working Mechanisms of Schema Therapy for patients with a Treatment Resistant Depression

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Main research question:Does group-based schema therapy result in a reduction of depressive symptoms when comparing symptom change during the treatment to patients* baseline symptom level?Sub research questions:Does group-based schema therapy result...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON50591

Source
ToetsingOnline

Brief title
Effectivity and Working Mechanisms of Schema Therapy for patients with TRD

Condition

- Mood disorders and disturbances NEC

Synonym
Chronic Depression, Treatment Resistant Depression

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Pro Persona

Intervention

Keyword: Effectivity, Schema therapy, Treatment Resistant Depression, Working mechanisms

Outcome measures

Primary outcome

Depressive symptoms as measured by the QIDS-SR.

Secondary outcome

Maladaptive schema strength: The five domains of the Dutch translation of the Young Schema Questionnaire 80 (YSQ-80) will be administered at baseline (Rijkeboer, 2008).

Maladaptive and adaptive modi strength: Using the 118 items of the Short Schema Modi Inventory (Short SMI), 16 maladaptive modi 16 maladaptive modi and two adaptive modi will be measured (Lobbestael, van Vreeswijk, Spinhoven, Schouten, & Arntz, 2010).

Selective memory bias: Participants will carry out the Self-Referent Encoding Task (SRET) to measure selective negative memory bias using schema words (Derry & Kuiper, 1981; Hammen & Zupan, 1984). Participants are presented with positive and negative self-descriptive words and have to indicate how self-relevant these words are. After a brief distraction task, their memory for these words is tested via een a free recall procedure.

Propositional memory bias: Using a customised version of the Propositional

Evaluation Paradigm (PEP) computer task, EMS-strength will be implicitly measured (Muller & Rothermund, 2019). Participants are presented with short sentences adapted from the YSQ-80 items and are asked to answer with *true* or *false. Using reaction time differences between *true* and *false* prompts, an implicit attitude can be measured. Mouse-tracking will also be used to assess the implicit attitude whilst an answer is being chosen.

Trait rumination: The Rumination Response Scale (RRS-NL) will be used to measure trait rumination (Raes et al., 2009).

Distancing from modi: The Inclusion of Others in the Self (IOS) measures interpersonal closeness and has previously been adapted for other uses like PTSS (Aron et al., 1992). A new and experimental version of the IOS has been made for measuring overlap with schema modi using the same item as the IOS but replacing *Other* with *Modi* called the Inclusion of Modi in the Self (IMS).

Sense of Mastery: Sense of mastery will be measured using the RemoralisatieSchaal (RS) consisting of 12 items (Vissers, Keijsers, van der Veld, de Jong, & Hutschemaekers, 2010).

Lifestyle: To measure the influence of lifestyle habits and choices the Healthy Lifestyle and Personal Control Questionnaire (HLPCQ) will be administered (Darviri et al., 2014).

Demographics: In addition to the clinical and schema-related questionnaires,

date of birth, gender, mother tongue, living situation, education and

occupation wil be assessed using a demographics questionnaire at the start of

the study,

Study description

Background summary

Despite the increased use of Schema Therapy (ST) within the treatment of patients with a Treatment Resistant Depression (TRD), little research has been done on the effectiveness and the underlying working mechanisms. The limited available literature suggests that ST is successful at treating the underlying risk factors of TRD which results in a reduction of depressive symptoms (Renner & Arntz, 2013; Malogiannis et al., 2014). These studies, although good first steps, are limited by small sample sizes, lack of a good control condition and quantity of studies. Research focussing specifically on underlying working mechanisms of ST for TRD is limited with only one study available. It focussed on two possible mechanisms: changes of maladaptive schemas and therapeutic alliance (Renner et al., 2018). Both mechanisms changed together with depressive symptoms, suggesting that other mechanisms underlie the effect of ST for TRD. Further research is needed to discover these working mechanisms.

One possible working mechanism of ST for patients with TRD is the effect of memory bias on schemas storage and retrieval. Following Beck's theory for depression (1967), schemas develop through early childhood experiences and are stored in memory. Expanding on this theoretical model, Young emphasizes the importance of the Early Maladaptive Schemas as underlying pathological behaviour in his schema theory (Young, 1990). Schemas are assumed to be stored in memory and, when activated by a triggering event, play a role in the development and maintenance of a depressive episode. Previous research in patients with a depression showed that through memory biases patients were more likely to retrieve negative information from memory as opposed to positive or neutral information (Mechera-Ostrovsky and Gluth 2018). This negative memory bias might affect the retrieval and activation of early maladaptive schemas (LeMoult & Gotlib, 2019).

By increasing our understanding of ST for TRD, its application in the clinical practice can be better substantiated and ST theory can be improved. Understanding the working mechanism of ST in TRD can lead to better tailored

treatment.

Study objective

Main research question:
Does group-based schema therapy result in a reduction of depressive symptoms when comparing symptom change during the treatment to patients* baseline symptom level?

Sub research questions:
Does group-based schema therapy result in a reduction of schema strength frequency in depressed patients?

Does group-based schema therapy lead to a relief in strength of maladaptive modi?

Does group-based schema therapy lead to an increase in strength of adaptive modi?

Zorgt groepsschematherapie voor een vermeerdering van de sterkte van adaptieve modi?

Are changes in emotional memory bias, schema self-associations or state rumination possible mechanisms of changes of group-based schema therapy?

Is reduction of depressive symptoms preceded by frequency of maladaptive modi, distancing of maladaptive modi and sense of mastery?

Group schema therapy is expected to lead to a reduction in depressive symptoms, when comparing patients with their own baseline as a reference point in a multiple-baseline design. additionally, it is expected that the various possible mechanisms of change can partially explain the reduction of symptoms.

Study design

Due to the vulnerable target group and the long duration of the group schema therapy, a RCT is not appropriate nor feasible. A *non-concurrent multiple-baseline between subject design* will be used (Morley, 2018). During a period of two years, participants in treatment through the schema therapy group at the TOPGGz, Pro Persona Expert Center for Depression will be included and assigned to the different baseline starting measurements. During a period varying from 32 to a maximum of 38 weeks, participants will complete the QIDS-SR weekly at home to precisely assess depressive symptoms. At the start of the study, a baseline test battery will be administered which will take approximately 10 minutes to complete. During the further study period, participants will additionally visit the site six times for a more extensive

battery of trests. During these extended measurements, early maladaptive schemas, schema modes, depressive symptoms, overlap between self and schemas, remoralisation, trait rumination, implicit association, implicit attitude, mood, arousal, childhood trauma, and lifestyle will be measured. The instruments summarised below will , varying in frequency, be administered at these six moments. The extensive measurement moments will last from 30 to 90 minutes each. The weekly measurements will take less than two minutes.

Inventory of Depressive Symptomatology-Self Report
Young Schema Questionnaire-80
Short Schedule Modes Inventory
The Inclusion of Maladaptive Modi and Self
RemoralizationScale
Rumination Response Scale
Implicit Relationship Assessment Procedure
Propositional Evaluation Paradigm task
Visual Analogue Scale for mood and arousal
Healthy Lifestyle and Personal Control Questionnaire

Study burden and risks

Not applicable.

Contacts

Public
ProPersona (Nijmegen)

Nijmeegsebaan 61
Nijmegen 6525 DX
NL
Scientific
ProPersona (Nijmegen)

Nijmeegsebaan 61
Nijmegen 6525 DX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Adult defined as 16 years or older;
• Primary diagnosis is treatment resistant or recurrent depression according to DSM-5 criteria evident from the MINI 5.0;
• IDS-SR score of 26 or higher, indicating average, severe or very severe depressive symptoms;
• Evident from the intake interview report: a pattern of noticeable behaviour or internal experience which can be typed as traits of a personality disorder;
• Evident from the intake interview report: a previously used evidence based psychological treatment (e.g. CBT, IPT, CBASP) or pharmacological treatment for treatment resistant depression or for the current depression in case of recurring depression;

Exclusion criteria

• Primary diagnosis is personality disorder;
• Current psychotic disorder;
• Lifetime bipolar disorder, substance use disorder or autism spectrum disorder;
• Insufficient mastery of the Dutch language;
• Impossibility to give a valid informed consent;
• Cognitive or intellectual impairments (IQ below 80) interfering with participation judged by the therapist;
• Changes in treatment policy caused by suicidal ideations or medication changes;
• Contraindication to group therapy at the end of the case conceptualization. The two most obvious indications are presence of Angry Child-Bully and Attack-Enraged Child coping mode.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2022
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-08-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80090.091.21