Short-term individual experiential schema therapy in adult outpatients with cluster C personality disorders: (How) does it work?

No registrations found.

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

Summary

ID

NL-OMON26352

Source
NTR

Health condition

Cluster C Personality Disorder
short-term experiential Schema Therapy
Overall wellbeing
Multiple Baseline Single Case Experimental design

Sponsors and support

Primary sponsor: GGZ Delfland
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Overall wellbeing (ORS)

To asses change in overall wellbeing, participants will fill in the Outcome Rating Scale (ORS; Miller & Duncan, 2000; Miller, Duncan, Brown, Sparks, & Claud, 2003; Dutch manual by Crouzen, 2010). In phase A1 they will fill it in once every two days, during phase B1 twice a week, during phase B2 and A2 once a week and once at 6 months measurement-FU. Participants will score the ORS with the same frequency as the BTG and NCB, with a total of 53-64 offered measurement points.

The ORS is a short, 4-item, self-report instrument measuring individual, interpersonal, and social functioning as well as overall wellbeing on a visual analog scale (VAS). Assessment time is approximately 1 minute or less. The ORS is designed to assess change in patients following psychological intervention. The ORS provides a total score (overall wellbeing) and four sub-scale/item scores. The ORS has adequate psychometric properties (Campbell & Hemsley, 2009).

Secondary outcome

Severity of cluster C PD (SCID-5-PD)

To asses and evaluate cluster C PD severity, the Structured Clinical Interview for DSM-5 personality disorders (SCID-5-PD; First, Williams, Benjamin & Spitzer, 2015; Dutch translation Arntz, Kamphuis & Derks, 2017) will be administered prior to the final indication session/before the start of phase A1 and at 6 months measurement-FU (A2). This is a semi-structured interview guide for making DSM-5 PD diagnoses. Interview duration is between 30 and 120 minutes. It is administered by an independent trained psychologist that is familiar with the DSM-5 classification and diagnostic criteria.

Behavioral Treatment Goals (BTG)

Participants will rate attainment of two Behavioral Treatment Goals (BTG) on a VAS with the same frequency as the ORS and NCB, with a total of 53-64 offered measurement points. Since ST aims to change the severity of EMS, which includes maladaptive coping patterns (as opposed to the adaptive behavioral treatment goals) (Young, 2003), it is expected that this measures is central to cluster C PD pathology and will be sensitive to change over time. Personal goals are more sensitive to individual change than global measures and there is evidence that setting goals motivates patients to actually reach their goals (Turner-Stokes, 2018).
In order to obtain SMART (Specific, Measurable, Attainable, Realistic, and Timely) formulation of the goals, a semi-structured interview will be administered based on Goal Attainment Scaling (GAS; Kiresuk, Smith & Cardillo, 1994). The interview will last approximately 15 minutes.

Goal attainment will be scored on a VAS from 0-100, with 0 referring to ‘goal not achieved at all’, and 100 ‘achieved a lot more than goal’. Goals are formulated in a positive manner, stating adaptive behavioral patterns contrary to current maladaptive behavioral patterns related to cluster C PD. A possible example of goals are “saying no to someone when I don’t feel like it, at least 50% of the time” (contrary to the maladaptive pattern “saying yes all the

time, even when I don’t feel like it”) or “execute a small activity every day without someone’s assurance” (contrary to maladaptive pattern “ask my partner/friends for assurance several times for all small activities”). VAS-scores will be transformed to ordinal Goal Attainment Levels for analysis (Dekkers, de Viet, Eilander & Steenbeek, 2011).

Assessment time of the BTG is less than a 1 minute. Participants will score the BTG with the same frequency as the ORS and NCB.

At 6 months follow-up, qualitative information about participants’ experience with setting, tracking and evaluating goals with the use of the app (or website) will be gathered during a 15 minutes open-question interview.

Negative Core Beliefs (NCB)

During the same semi-structured interview as the BTG, participants will also formulate two Negative Core Beliefs (NCB) central to their PD-related dysfunction in daily life. NCB can be frequently assessed, are supposed to be sensitive to short-term change (Videler et al., 2017) and are important representations of EMS underlying PD pathology (Young, 2003). Participants will rate the credibility of these negative core beliefs on a VAS of 0-100%, with the same frequency as the ORS and BTG, with a total of 53-64 offered measurement points. Assessment time of the NCB is less than a 1 minute.

General mental distress (BSI)

To asses general mental distress, participants will fill in the Brief Symptom Inventory (BSI; de Beurs, 2011; translated from Derogatis, 1975) at the start/end of every phase, during an evaluation moment in phase B2 and at 6 months measurement-FU (in total 8 times). The BSI is a shorter version of the Symptom Checklist-90-R (SCL-90; Derogatis, 1975), and consists of 53-items scored on a 5-point Likert scale. The BSI provides a total score and 9 sub-scale scores. Assessment time is approximately 5-10 minutes. The reliability of the BSI scales is good and the convergent and divergent validity has been found to be satisfactory (de Beurs, 2011).

Early maladaptive schemas (YSQ)

To asses EMS, the Young Schema Questionnaire (YSQ; Young & Brown, 1994; Dutch translation Sterk & Rijkeboer, 1997) is used. The YSQ consists of 205 items, stating negative core beliefs that are rated on a 6-point Likert scale. It measures the 16 schemas as defined by Young (2003). Assessment time is approximately 35 minutes. Participants will fill in the YSQ 4 times (start of phases A1 and B2, at the end of A2 and at 6 months measurement-FU). The Dutch YSQ has good reliability and convergent and discriminant validity (Rijkeboer, van den Bergh & van den Bout, 2005).

Schema Mode (SMI-1)

To asses SM, the Schema Mode Inventory (SMI-1; Dutch translation Lobbestael et al., 2005) is used. The SMI-1 measures 14 schema modes. This inventory consists of 118 items, which are rated on a 6-point Likert scale. Assessment time is approximately 20 minutes. Participants will fill in the SMI-1 four times (start of phases A1 and B2, at the end of A2 and at 6 months measurement-FU). The Dutch SMI has excellent test-retest reliability. The convergent and divergent validity of the subscales are satisfactory (Lobbestael et al., 2010).

Experiences of participants with the experiential techniques (4 Q diary)

To gain insight in the experience of participants with the experiential techniques, participants will rate four questions (4 Q diary) on a 0-100 VAS (0 = 'very little' and 100 = 'a lot') after each session during the treatment phases (B1 & B2) and the treatment-FU sessions (A2).

Assessment time is less than 1 minute. Results are not disclosed to the therapist to cease social desirable answers. The questions are:

1. Did the exercise/theme provide you with new insight?

2. Do you think that the exercise/theme will contribute to your recovery?

3. Are you satisfied with the exercise/theme?

4. Open question: Do you have any additional remarks on your experience with the exercise/theme or the session?
At 6 months measurement-FU, additional qualitative information about participants' experience will be gathered during the 15 minutes open-question interview mentioned by BTG.

Study description

Background summary

Rationale:

Cluster C Personality Disorders (PD) are the most frequently diagnosed PD, and are associated with severe impairments in daily life and comorbidity and high societal costs. Nevertheless, cluster C PD has received little attention for specific treatment options. Recent studies have shown preliminary evidence for the effectiveness of Schema Therapy (ST), but study results and literature are not conclusive about the necessary duration of ST to be effective. Meanwhile, the need for effective shorter treatment options is growing in both patients and society. Also, the effective components of ST are still largely unknown. Exploring

the effects of specific ST techniques could make it possible to tailor treatment to an optimum. Experiential techniques provide a unique tool to address underlying needs and blocked emotions common in cluster C PD. Therefore, it is expected that a short-term ST treatment protocol that focuses solely on experiential techniques is effective in achieving (long-term) improvement in overall wellbeing, behavioral treatment goals attainment, negative core beliefs, general mental distress and PD severity.

Objective:

The aim of this study is to investigate the effect over time and working mechanisms of a short-term experiential ST protocol in adult outpatients with cluster C PD.
Study design: A non-concurrent randomized multiple baseline single case experimental design consisting of 4 phases (A1-B1-B2-A2), with a 6 months follow-up measurement moment. Primary outcome is assessed frequently, with a total of 53-64 measurements.

Study population:

12 patients with a DSM-5 principal diagnosis of cluster C PD, aged 18-65 years, recruited from a specialized mental healthcare facility in the Netherlands, GGZ Delfland.

Intervention:

Every participant receives the same intervention, starting with a randomised baseline waitlist period (A1), varying from 3 up to 6 weeks. This phase is followed by a pre-treatment phase (B1), consisting of five 45-60 minutes psycho-educative sessions aimed at increasing insight and motivation and developing a therapeutic relationship. Treatment phase (B2) consists of 18 protocolled 45-60 minutes experiential ST sessions. The treatment follow-up phase (A2) consists of 2 evaluative sessions, 1 month and 3 months after treatment.

Main study parameters/endpoints:

Primary outcome measure is overall wellbeing (ORS). Secondary outcomes are attainment of behavioral treatment goals (BTG), credibility of negative core beliefs (NCB), general symptomatic distress (BSI), cluster C PD severity (SCID-5-PD), early maladaptive schema (YSQ), and schema modes (SMI-1). The experience of participants with the experiential techniques in relation to increase in insight, satisfaction with the session and overall recovery will be explored (4 Q diary).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Filling in questionnaires provides an extra time burden of 3.5 up till 5.5 hours and some

participants will have to wait a bit longer than others as a result of randomization (although waiting time is still in line with normal procedures). Participants are assumed to receive state of the art treatment. It is expected that participants will benefit from the treatment. Results are accessible to participants and a final feedback session is offered wherein the final measurement outcomes are discussed, contributing to their insight in the change of their pathology. Participants receive a gift card of 10 euros for participating, the workbook is complimentary, and extra travel expenses will be fully compensated. No major disadvantages or adverse events have been documented before and are not expected.

Study objective

The aim of this study is to investigate the effect of a short-term experiential Schema Therapy (ST) protocol in individual adult outpatients with cluster C Personality Disorders (PD) on overall wellbeing. Secondary outcomes are attainment of behavioral treatment goals, credibility of negative core beliefs, global symptomatic distress, cluster C PD severity, Early Maladaptive Schemas (EMS), and Schema Modes (SM). In addition, the experience of patients with experiential techniques in relation to increase in insight, change in core beliefs, satisfaction with the session and overall recovery will be explored.

A non-concurrent Single Case Experimental Design (SCED) will be used with a randomized baseline length phase (control phase), a pre-treatment phase (second attention-control phase), a treatment phase (ST), a treatment follow-up (FU) phase (2 ST follow-up sessions) and a 6 months measurement-FU (e.g. 6 months after active treatment phase, 3 months after treatment-FU phase).

It is hypothesized that:

1. Pre-treatment phase will not result in change in overall wellbeing, attainment of behavioral treatment goals, credibility of negative core beliefs, global mental distress, EMS and SM compared to baseline phase.

2. Adding experiential ST techniques after the pre-treatment phase is associated with an improvement in overall wellbeing and attainment of behavioral treatment goals and a decrease in credibility of negative core beliefs and global mental distress compared to baseline and pre-treatment phase.

3. At 3 months treatment-FU, EMS and dysfunctional SM will be decreased and healthy SM will be increased compared to baseline and pre-treatment phase.

4. Effects directly after treatment (hypothesis 2 and 3) will be maintained at 3 treatment treatment-FU and 6 months measurement-FU. At 6 months measurement-FU, PD severity will be decreased.

Study design

The timepoints are outlined in the description of the primary and secondary outcomes.

Intervention

Baseline Phase

The baseline phase consists of a period of 3 up until 6 weeks waitlist period. No therapeutic interventions are offered during this phase, only measurements. Duration in baseline phase will differ among participants, depending on moment of allocation to a therapist after the final indication session. Randomization will be performed using the free scientific software Randomizer (https://www.randomizer.org/), creating a pre-determined randomization list.

Pre-treatment

In line with general guidelines and the used protocol in this study (e.g. short-term schema therapy, experiential techniques by Broersen and Van Vreeswijk, 2017), a pre-treatment phase is included. The aim of this phase is to increase insight, develop a therapeutic relationship and increase motivation to work on EMS and SM in the following phase. No active ST interventions aimed at changing pathology are conducted. Therefore, it is seen as a (second) 'attention' control phase (in line with the study of Renner and colleagues (2006)).

This phase comprises 5 sessions. Sessions are held on a weekly basis, with a duration of approximately 45-60 minutes per session. During the first session, the rationale of ST is discussed and patients are informed about their dominant EMS en modes. In the second and third session, a case-conceptualization and personal schema/mode model is made and psycho-education is provided about the common dysfunctional views in patients with cluster C PD on (children's) needs and emotions. The fourth session provides the opportunity to discuss the content of the former sessions more thoroughly and to make a crisis plan if needed. During the fifth session a schema/mode treatment contract is made, outlining the most important personal complaints, goals (BTG), EMS, SM and signs of change. In line with the protocol, this contract will be evaluated again in the first follow-up session.

If a session is cancelled due to illness or other circumstances, the session planned for that moment will be moved to the next session, extending the trajectory of treatment with 1 week. Only in case of a crisis situation, an extra individual crisis-intervention session will be held. If an extra session took place, this will be registered by the therapist.

Treatment phase

The treatment phase consists of 18 experiential ST sessions as written in the protocol 'short-term schema therapy, experiential techniques' of Broersen and Van Vreeswijk (2017).

In the first 10-15 minutes of a session homework and relevant experiences of the past week

are addressed, in relationship to EMS/SM. After that, the technique as described in the protocol will be executed, related to the content of what has been discussed in the beginning of the session. At the end of the session, new homework is provided and explained. Session 1 through 15 are held on a weekly basis, with a duration of approximately 45-60 minutes per session. In line with the normal procedure to spread out sessions over several weeks when treatment progresses, session 16, 17 and 18 are held once every two weeks.

If a session is cancelled due to illness or other circumstances, the session planned for that moment will be moved to the next session, extending the trajectory of treatment with 1 week. Only in case of a crisis situation, an extra individual crisis-intervention session will be held. If an extra session took place, this will be registered by the therapist.

Treatment follow-up phase (A2)

Following protocol, the treatment-FU phase (A2) consists of 2 sessions with a duration of approximately 45-60 minutes per session, respectively 1 month and 3 months after the end of phase B2. These sessions are purely evaluative. No ST interventions are offered. At 3 months treatment-FU, results of the questionnaires will be discussed with the participant.

Every session outlined in the protocol has to take place in the same order for everyone and no sessions are skipped. In the event of a cancelled session, weekly measurements continue irrespective of session planning.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

(1) Principal diagnosis of a DSM-5 cluster C (e.g. avoidant, obsessive-compulsive and/or dependent) PD, determined by a structured interview (SCID-5-PD)

(2) Age between 18 and 65 years

(3) Possession of a smartphone, laptop or a desktop computer

(4) Written informed consent, including consent to audiotape the sessions

(5) Ability to read, write and speak the Dutch language

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

(1) Non-detoxified alcohol- or drugs dependence (inclusion is possible after detoxification)

(2) Full diagnosis of comorbid DSM-5 cluster A or B PD, determined by a structured interview (SCID-5-PD)

(3) Level of education lower than preparatory secondary vocational education

(4) Experience with ST in the past year

(5) Following other psychological treatments during the study. Pharmacotherapy is allowed as a co-intervention if it was already started before participating in the study. It is protocol that medication (dose) will not be changed during participation in this study, except when a crisis situation requires deviation from protocol. Participation in the study will end if dosages are changed

(6) High suicide risk as determined by the treating therapist (suicide taxation when suicidal ideations are present)

(7) A (history of) psychotic or bipolar disorder

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46626
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7413
NTR-old	NTR7638
CCMO	NL65135.078.18
OMON	NL-OMON46626

Study results

Summary results

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