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

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Primary Objective: To determine whether short-term experiential ST improves overall wellbeing in adult out-patients with cluster C PD, directly after treatment, at 3 months treatment follow-up (treatment-FU), and at 6 month measurement-FU. 6 months...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON46626

Source
ToetsingOnline

Brief title
SIEST-C

Condition

- Personality disorders and disturbances in behaviour

Synonym
and Obsessive-Compulsive Personality Disorder., Cluster C personality disorders. Patients in the anxious, Dependent, fearful personality cluster, including the Avoidant

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Delfland (Delft)
Source(s) of monetary or material Support: Dit onderzoek wordt verricht als onderdeel van de postmaster opleiding tot klinisch psycholoog (RINO);binnen GGZ Delfland. Het onderzoek wordt gefinancierd door 'het Leerhuis' van GGZ Delfland.

Intervention

Keyword: 'Cluster C Personality Disorder', 'Experiential Schema Therapy', 'Overall wellbeing', 'Single Case Experimental Design'

Outcome measures

Primary outcome

See the METC protocol 8.1 (page 20) for more information about the measurement

method, instruments and assessment moments.

Overall wellbeing (ORS)

To asses change in overall wellbeing after pre-treatment, treatment, 3 months

treatment-FU and at 6 months measurement-FU (compared to baseline),

participants will fill in the Outcome Rating Scale (ORS; Miller & Duncan, 2000;

Miller, Duncan, Brown, Sparks, & Claud, 2003; Dutch manual by Crouzen, 2010).

Participants will fill in this questionnaire once every two days during phase

A1, twice a week during phase B1, once a week during phase B2 and A2 and once

at 6 months measurement-FU, with a total of 53-64 offered measurement points.

Secondary outcome

See the METC protocol 8.1 (page 20-22) for more information about the

measurement method, instruments and assessment moments.

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

To asses and evaluate change in cluster C PD severity at 6 months measurement--FU (compared to before baseline), 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.

Behavioral Treatment Goals (BTG)

To asses progress in two SMART formulated Behavioral Treatment Goals (BTG) after pre-treatment, treatment, 3 months treatment-FU and at 6 months measurement-FU (compared to baseline), participants will score these goals on a VAS from 0-100, with 0 referring to *goal not achieved at all*, and 100 *achieved a lot more than goal*. Participants will score their goals with the same frequency as the ORS and NCB, with a total of 53-64 offered measurement points.

At 6 months measurement-FU, qualitative information about participants* experience with setting, tracking and evaluating goals will be gathered during a 15 minutes open-question interview.

Negative Core Beliefs (NCB)

To asses change in credibility of Negative Core Beliefs (NCB) after pre-treatment, treatment, 3 months treatment-FU and at 6 months measurement-FU (compared to baseline), participants will rate the credibility of their two most prominent 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.

General mental distress (BSI)

To asses change in general mental distress after pre-treatment, treatment, 3 months treatment-FU and at 6 months measurement-FU(compared to baseline), participants will fill in the Brief Symptom Inventory (BSI; de Beurs, 2011; translated from Derogatis, 1975). Participants will fill this in at the start/end of every phase, during an evaluation moment in phase B2 and at 6 months measurement-FU (in total 8 times).

Early maladaptive schemas (YSQ)

To asses change in EMS after pre-treatment, 3 months treatment-FU and at 6 months measurement-FU (compared to baseline), the Young Schema Questionnaire (YSQ; Young & Brown, 1994; Dutch translation Sterk & Rijkeboer, 1997) is used. 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).

Schema Mode (SMI-1)

To asses change in SM after pre-treatment, treatment, 3 months treatment-FU and at 6 months measurement-FU (compared to baseline), the Schema Mode Inventory (SMI-1; Dutch translation Lobbestael et al., 2005) is used. 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).

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 (phases B1, B2 and A2).

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

See 'METC onderzoeksprotocol chapter 1 (introduction, pages 8-10) for more information.

Cluster C Personality Disorders (PD) are the most frequently diagnosed PD, and are associated with severe impairments in daily life, high co-morbidity and high societal costs (Bamelis, Evers, Spinhoven & Arntz, 2014; Drago, Marogna & Søgaard, 2016; Eurelings-Bontekoe, Verheul & Snellen, 2012; Kenniscentrum Persoonlijkheidsstoornissen, 2016; Olsson & Dahl, 2012; Skodol et al., 2005; Weinbrecht, Schulze, Boettcher & Renneberg, 2016). Nevertheless, cluster C PD has received little attention for specific treatment options (Arntz in van Vreeswijk, Broersen & Nadort, 2012; Drago et al., 2016; Kenniscentrum Persoonlijkheidsstoornissen, 2016; Renner et al., 2013). Fortunately, recent studies have shown that, among others, Schema Therapy (ST) is a promising psychotherapeutic intervention for mixed PD and cluster C PD*s. Duration of ST treatment differed largely among these studies, with the total session amount ranging between 20 and 65 sessions (Renner, et al, 2013; Renner et al., 2016; Skewes, Samson, Simpson & van Vreeswijk, 2015; Van Vreeswijk et al., 2012; Videler, et al., 2014; Videler, et al., 2017; Weertman & Arntz, 2007).

Meanwhile, the need for effective shorter treatment options is growing in both patients and society ((Olsson & Dahl, 2012; Skodol et al., 2005; (van Vreeswijk & Broersen, 2017). Although the common tenet is that PD*s are difficult to treat and requires long and intensive treatment (Skewes, Samson, Simpson & van Vreeswijk, 2015), a few studies showed that even short-term protocolled cognitive schema group therapy (20 sessions) achieved improvement in overall symptoms, overall wellbeing, EMS, SM, depression and PD severity (Renner et al, 2013; Skewes, Samson, Simpson & van Vreeswijk, 2015; Van Vreeswijk et al., 2012; Videler et al., 2014). These results of short-term ST are promising, but need to be extended.
Also, the effective components of ST are still largely unknown (Arntz, 2016; Nordahl & Nysaeter, 2005). More insight in the effects of, and experiences with, specific techniques on their own increases the possibility to tailor treatment to a more optimum level (Arntz, 2016; Weinbrecht et al., 2016; Renner et al., 2016).
Experiential techniques provide tools to reach and change underlying (repressed) emotions and longings, which are generally seen as less sensitive to cognitive techniques (Arntz, 2016; Artnz, 2012; Muste, 2016; Videler, 2016; Young, 2003). Since patients with cluster C PD are inclined to put up a wall and have the tendency to block underlying emotions and longings (e.g. avoidant or controlling coping strategies) (Artnz, 2012; Muste, 2016), experiential techniques are expected to be specifically potent at achieving (long-term) improvement in pathology.
As a result, the aim of this non-concurrent Single Case Experimental Design (SCED) study is to investigate the effect of a short-term experiential ST protocol in individual adult outpatients with cluster C 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, satisfaction of patients with the different experiential techniques and their experience with the techniques in relation to increase in insight and recovery will be explored.

Study objective

Primary Objective:
To determine whether short-term experiential ST improves overall wellbeing in adult out-patients with cluster C PD, directly after treatment, at 3 months treatment follow-up (treatment-FU), and at 6 month measurement-FU.
6 months measurement-FU is defined as a measurement moment 6 months after completion of the active treatment phase (B2) and thus 3 months after completion of the treatment-FU (A2). This is due to the evaluative nature of the treatment-FU sessions. No active interventions are performed during this phase, thus it is not seen as active treatment.

Secondary Objectives:
- To investigate the impact of short-term experiential ST on attainment of

behavioral treatment goals, credibility of negative core beliefs, and global symptomatic distress, directly after (pre)treatment, at 3 months treatment-FU and at six months measurement-FU.
- To investigate the impact of short-term experiential ST on EMS and SM at 3 months treatment-FU and at 6 months measurement-FU.
- To determine the impact of short-term experiential ST on cluster C PD severity at 6 months measurement-FU.
- To gain qualitative insight in the experience of patients with the different experiential techniques. In specific, satisfaction with the different experiential techniques and experience with the techniques in relation to increase in insight and recovery will be explored.

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 (ORS) and two secondary outcomes (BTG and NCB) are assessed frequently, with a total of 53-64 measurement points.

Intervention

See the METC protocol 5.1 (page 16-17) for more information.

Pre-treatment (B1)
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 their 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.

Treatment phase (B2)
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). 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.

Treatment-FU phase (A2)
Following protocol, the treatment follow-up 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.

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

Study burden and risks

See the METC protocol 11.4 (page 30) for more information.

Extra time burden related to participating in the study is approximately 3.5 up until maximum 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).
Also, filling in questionnaires and undergoing SCID-5-PD interview can be confrontational. However, most of the used measurements are standard and applied frequently in Dutch health care (exceptions being the BTG, NCB and 4 Q diary). To the knowledge of the researcher, no serious adverse events have been documented related to filling in the used questionnaires or to VAS-scoring (as used for the BTG, NCB and 4 Q diary). Moreover, scoring BTG and monitoring therapy progress could be considered a motivational factor in working on goals/practicing new adaptive behavior (Turner-Stokes, 2018).
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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) Principal diagnosis of a DSM-5 cluster C PD (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

(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-P)
(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 (see chapter 9 AEs, SAEs). 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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2018
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26352
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65135.078.18
OMON	NL-OMON26352