The effectiveness of group schematherapy combined with individual sessions in older adults with cluster B and/or C personality disorders

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The aim of this study is to investigate the effectiveness of a more intensive and longer protocol group ST (12-15 months) combined with individual sessions in older adults (aged 60 and older) diagnosed with Cluster B and/or C PDs.

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

Summary

ID

NL-OMON50945

Source
ToetsingOnline

Brief title
Group schematherapy in older adults with personality disorders

Condition

- Personality disorders and disturbances in behaviour

Synonym
personality disfunctioning, personality disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Breburg Groep (Rijen)

Source(s) of monetary or material Support: GGZ Breburg

Intervention

Keyword: Group schematherapy, individual schematherapy, older adults, Personality disorders

Outcome measures

Primary outcome

As a primary outcome measure, the credibility of the core beliefs (which are central to the PD) are assessed weekly. Participants will rate the credibility of their core beliefs on a Visual Analogue Scale (VAS) from 0 to 100 percent. The core beliefs are rated weekly during baseline phase and during treatment phase. The VAS will be scored at the start of each group session. During follow-up they will rated two times a month. The therapist will not be present when participants fill in this form to assure integrity.

Secondary outcome

PD Diagnoses are assessed with the Structured Clinical Interview for DSM-5 for PDs (SCID-5-P) (First et al., 2016). This is a generally accepted and widely used instrument for diagnosis of DSM-5-PDs. This semi structured interview consists of 134 open-questions. Criteria for PDs are rated on a 3-point scale ranging from 0) *absent*; 1) *subthreshold*; 2) *threshold*; and *?* in case not enough information is available. Reliability and validity are not yet available, but are expected to be similar to the Dutch version of the Structured Clinical Interview for DSM-IV Axis II disorders (Weertman et al., 2000). Inter-rater agreement appeared excellent in adults with an average age of 35.5 years (range 18-61), with a mean value of Cohen*s kappa .84 (Lobbestael

et al., 2011).

Early maladaptive schemas are measured with the Dutch Young Schema Questionnaire (YSQ; Young & Brown, 1994; Dutch translation Sterk & Rijkeboer, 1997). This is a self-report assessment instrument of 205 items, to assess the 16 core maladaptive schemas at the time of assessment. The items are phrased as negative core beliefs and rated on a 6-point Likert scale ranging from *completely untrue* to *describes me perfectly*. Research on the Dutch YSQ showed good reliability and convergent and discriminant validity (Rijkeboer et al., 2005; Rijkeboer & van den Berg, 2006) and appeared to be highly age neutral when applied to older adults (Pauwels et al., 2014).

Schema modes are assessed by the Dutch Short Schema Mode Inventory (SMI) (Young et al., 2007). This is a self-report measurement of 118 items divided into 14 subscales or schema modes. The items must be rated on a 6-point Likert scale. The Dutch SMI has acceptable internal consistencies (Cronbach*s α from 0.79 to 0.96) and moderate construct validity (Lobbestael et al., 2010).

Positive schemas are measured with the The Young Positive Schema Questionnaire (YPSQ; Louis et al., 2018). It has 56 items divided in 14 scales. The factorial validity and cross-cultural stability are good, and the reliability is excellent in the English version.

Personality functioning is measured with the Severity Indices of Personality

Problems short form (SIPP-SF) (Verheul et al., 2008). This is a self-report questionnaire aiming to measure the severity of limitations in personality functioning that corresponds to Criterion A of the alternative model of PDs of DSM-5. The SIPP-SF consists of 60-items and covers five domains: self-control, identity integration, responsibility, relational capacities, and social concordance. Participants are asked to answer on a 4-point scale to what extent they agree with the statement presented, referring to the past three months. The construct validity of the SIPP-SF for older adults was demonstrated with a structure of five higher order domains of personality functioning (Rossi et al., 2017). Among community-dwelling younger and older adults the SIPP-SF appeared age-neutral (Debast et al., 2018), and in a clinical sample of older adults the SIPP-SF domains showed good to excellent internal reliability (Cronbach's α = .75-.91) and effectively discriminated between participants with and without a PD (van Reijswoud et al., 2021).

Personality traits are measured by the Personality Inventory for DSM-5 (PID-5; van der Heijden et al., 2015). The PID-5 (short version) is a self-report measure designed to measure maladaptive personality domains according to Criterion B of the Alternative model of PDs of DSM-5, and consists of 25 items rated on a 4-point Likert scale ranging from *often untrue* to *completely true*. The PID-5 has five domains: negative affectivity, detachment, antagonism, uninhibitedness, psychoticism (Krueger et al., 2012). The original five-factor structure of the PID-5 has been confirmed in the Dutch version (van der Heijden et al., 2015). It has adequate reliability and convergent and

discriminant validity (Bastiaens et al., 2016).

Psychological distress is assessed by the Symptom Questionnaire-48 (SQ-48; Carlier et al., 2014). This is a self-report measure and consists of 48 items. The items are rated on a 5-point Likert scale ranging from *never* to *very often*. The SQ-48 consist of 7 scales (anxiety, depression, social phobia, agoraphobia, somatic complaints, hostility, cognitive complaints) and two subscales (vitality, work). The SQ-48 has excellent test-retest reliability and good responsiveness to therapeutic change (Carlier et al., 2014).

Recovery is assessed by the Dutch version of the Individual Recovery Outcomes Counter (IROC; Monger et al., 2013). This self-report assessment consists of 12 questions and covers areas of life that are important to mental health and well-being. The questions are entitled in four sections: Home, Opportunity, People and Empowerment. The items must be rated on a 6-point Likert scale ranging from never to always. A high internal consistency and convergent validity have been found (Monger et al., 2013).

Quality of life is assessed by the Dutch Mental Health Quality of Life seven-dimensional (MHQol-7D; Van Krugten et al., 2019). The MHQol-7D is a self-administered measure of quality of life that has been developed for use in people with mental health problems. It consists of 7 items which highlights the most important quality of life domains in the context of mental health (self-image, independence, mood, relationships, daily activities, physical

health and hope). The items have four response levels ranging from very satisfied to very dissatisfied. The MHQol-7D index score can vary from 0 to 21, with higher scores indicating better quality of life. Internal consistency is high (Cronbach α 0.85). Convergent validity is supported (Van Krugten et al., 2019).

Study description

Background summary

Schema therapy (ST) has shown to be an effective therapy for personality disorders (PDs) in adults. Research on treatment for PD's has focused mainly on adults so far. Given the substantial increase of elderly people, including the group of older adults with PD, more research is needed that covers the full age-span. Preliminary results have shown that schema therapy is also applicable in older adults with PDs, more specifically cluster C PDs.
Suggestions were made to increase the efficacy of ST in older adults, including adjusting the case conceptualization, modifying the experiential techniques, making use of the patient's wisdom by placing their problems in a lifespan perspective and next asking them how they have coped with problems successfully earlier in life.

In (younger) adults a studyin which a combined protocol (groupschematherapy combined with individual sessions) has shown positieve effects. In older adults this protocol (combination group ST with individual sessions) has not been examined yet.

Study objective

The aim of this study is to investigate the effectiveness of a more intensive and longer protocol group ST (12-15 months) combined with individual sessions in older adults (aged 60 and older) diagnosed with Cluster B and/or C PDs.

Study design

We will use a multiple baseline design.

In this multiple baseline design, participants serve as their own control and the primary outcome, the credibility of the core beliefs, are measured

frequently (weekly). This may compensate for the potential loss of power. As an indication, it is possible to detect a large effect size (d >1.5; power >.80) with four participants with twenty measurements each (Ferron & Sentovic, 2002).

We chose for this design for several reasons. First, a multiple-baseline design offers experimental control over time compared to group comparisons in intervention effects. This is an important advantage over an open trial. A multiple-baseline design can, as a randomized control trial (RCT), demonstrate significant change. This change is the result of the intervention and not of time (Bulté & Onghena, 2009). Secondly, an advantage of this design over a RCT is that it requires fewer participants, because participants act as their own controls, and this increases power (Kazdin, 2010).

A multiple-baseline design requires a dependent variable that is frequently assessed and highly sensitive to change, in order to assess the effects of time and intervention (Bulté & Ongehna, 2009). This variable must represent a core aspect of the disorder (in this study the PD) that is addressed by the treatment. In this study, we choose the credibility of the core beliefs as the dependent variable because these beliefs are central in the PD problems.

The design of this study consists of four phases. The first phase is getting acquainted with one of the group therapists. The second phase is a baseline phase, randomly varying in length from 4 to 8 weeks. The third phase is the treatment phase and consists of ST (combination group with individual sessions). The fourth and final phase is a six months follow-up with monthly individual booster sessions.

During the first phase, participants will have two to five individual sessions with their therapist in which schema therapy and the schema mode model are explained. Also, the schema modes and their relationship to one another are identified, a treatment plan is drawn up and a case conceptualization is made. In these individual sessions two to five core beliefs (which are central to the PD problems) will be assessed. Additionally, participants will be asked to participate in the study after they are informed by their therapist. Further information is given by the researcher and the participants will be asked to fill in the informed consent. After signing the informed consent, the participants will be randomized to the length of the baseline phase.

The length of the baseline (second) phase will be randomized across participants to increase the internal validity. The baseline varies between 4 to 8 weeks and will be randomly assigned by an independent colleague using a lottery system which consists of five possible outcomes (4, 5, 6, 7, 8 weeks). During this phase no treatment is allowed but therapists and participants are allowed to plan sessions to stabilize the participant. Every other week the therapist plans an individual session with the participants. But they fill in the credibility of their core beliefs every week. Participants are allowed to

start with the group if there is place in the group, but only if they have completed the baseline phase.

The duration of the treatment (third) phase is 12 to 15 months. When participants start in the group, they attend the group weekly and they follow individual sessions with their therapist every other week. Every week, before the participants start with the group session, they will give a closed envelope with the credibility of their core beliefs to one of the group therapists, which they will pass on to the research team. This way we aim to reduce the influence of activated modes. In the individual sessions the therapist pays attention to the individual process of the participant, possible traumas can be treated, and the therapist also reminds the participant to fill in the credibility of their core beliefs.

The follow-up (fourth) phase lasts six months and includes monthly individual booster sessions. During this booster sessions it is the aim to maintain the acquired knowledge and skills of ST.

Intervention

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Study burden and risks

No risks are expected for participants in this study. In this study we treat older adults with PD with a treatment which is well-researched and the evidence for its efficacy is accumulating. Some adjustments, based on exploring research in how to adjust ST for better efficacy in older adults, are made. ST is, among others, the preferred treatment in PD's. All participants receive information regarding the study and they can be included only when informed consent is signed.

The SCID-S-PD and PID-5 (short form) are used standard in diagnosing PD in older adults, and are no extra burden for the client. The YSQ and SMI are standard in ST and therefore also no extra burden.

The extra measuremen at the eind of the group (SCID-5-P) is estimated to take 90 minutes. The Iroc, SQ48, MHQol-7D en SIPP-SF will be filled out every six months. It is estimated that this will take maximum of 30 minutes for patients. The YPSQ will be filled out at start and the eind of the group. It is estimated that this will take a maximum of 15 minutes for patients.

Negative core beliefs will be filled out weekly on a 100- point scale, and will take no more than one minute. The randomisation in baseline phase(4-8 weeks) is shorter than the waiting list for ST in older adults, so there is no disadvantage for participants. The extra burden for participants is low related to the recieved treatment (12-15 months weekly groupschematherapy combined with individual sessions every other week (45 minutes) followed by 6 monthly individual booster sessions).

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) age of 60 years or older;
2) willingness to participate in the study;
3) a primary diagnosis of a cluster B and/or C personality disorder according to the categorical model of the DSM-5 (assessed with the Structured Clinical Interview for DSM-5 Personality disorders (SCID-5-P) and according to the alternative model of personality disorders (assessed with the Personality Inventory of DSM-5 (PID-5) and the Severity Indices of Personality Problems short form (SIPP-SF)).

Exclusion criteria

1) a diagnosis of severe depression;
2) instable bipolar disorder; 3) acute psychotic disorder;
4) IQ under 80;
5) substance dependence that need detox;
6) autism spectrum disorder;
7) (moderate to severe) neurocognitive disorder (MOCA <25);
8) psychosocial circumstances that ask a lot of attention from the participant;
9) limited life expectancy due to severe somatic illness;

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL77840.028.21