

Group Schema Therapy for the Other Specified Personality Disorder: a pilot study.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20495

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Other Specified Personality Disorder

Sponsors and support

Primary sponsor: Universiteit van Amsterdam and PsyQ Amsterdam

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The main outcome variable is change in severity of manifestations of OSPD, measured with ADP-IV (Schotte & De Donker, 1996)

Secondary outcome

1. PD-related beliefs will be assessed with the PDBQ-69 (Arntz et al., 2004). Beliefs related to the six most common PDs are represented in this instrument. The participants will probably most frequently have PD-traits of these six PDs (avoidant, dependent, obsessive-compulsive, paranoid, histrionic, and borderline PD).
2. Self-esteem will be assessed with the 10-item version of Rosenberg's Self-Esteem Scale (RSES; Rosenberg, 1965; Franck et al., 2008).
3. Self-Ideal Discrepancy will be assessed by calculating the difference between the Self and Goal scales of the Miskimins Self-Goal-Other Discrepancy Scale (MSGO; Miskimins et al., 1971).
4. General, social and societal functioning will be assessed with the WHODAS, taken by the research assistant (Üstün, 2010).
5. Happiness will be assessed with the 1-item happiness question validated in more than 30 countries (Veenhoven, 2011).
6. Quality of Life will be assessed with the EuroQol EQ-5D-5L (Herdman et al., 2011; Rabin & Charro, 2001).
7. Schema Modes will be assessed with the Schema Mode Inventory-2 (SMI-2; Bamelis et al., 2011), which assesses the frequency of Schema Mode activation for the modes most relevant for the pertinent PDs.
8. Early Maladaptive Schemas will be assessed with the YSQ-Revised, a shortened version of the YSQ (YSQ-R; Rijkeboer, 2013).
9. General psychopathological symptoms as an index of severity of syndromal disorders will be assessed with the Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983).
10. Medication and mental health care use will be monitored at each assessment.
11. New variables will be composed to measure mistrust, avoidance and lack of selfdiscipline.

Study description

Background summary

Group Schema Therapy (GST) for Personality Disorders is getting increasingly popular in clinical practice. In particular the model developed by Farrell & Shaw (Farrell et al., 2015) has become popular for the more severe PD patients. Whilst there is some evidence for its effectiveness for Borderline PD (Farrell et al., 2009), a large group of patients currently receiving GST has an "Other Specified PD" (OSPD) as primary diagnosis (in DSM-IV labelled "PD Not Otherwise Specified"). This group consist of patients with PD traits, usually from different PDs, not meeting the threshold for a specific DSM-5 PD diagnosis, and is in many mental health care institutes a relatively large group. The evidence for the Farrell & Shaw GST model as a treatment for OSPDs is limited to a speculative generalization of findings in BPD and Cluster-C PDs (Farrell et al., 2009; Skewes et al., 2015). Apart from the problem that there is limited evidence for the effectiveness of GST for this specific group of patients, there is the problem that variations of GST are applied under the same label, which creates a

barrier for quality maintenance and training of new therapist: what exactly is the protocol that should be used? It is therefore important that a well-defined protocol is tested in this specific patient population, with appropriate outcome measures, that assess the severity of manifestations of the pertinent PDs. As a first step an open trial is proposed to document effects of GST for OSPD. If successful, the next step will be a multicentre RCT comparing the protocol to a comparison condition, e.g. waitlist or Treatment as Usual (TAU).

Study objective

The hypothesis is that patients who complete the 30-weeks group schema therapy will benefit from this treatment (i.e., a significant drop in severity in the manifestation of OSPD, as measured with ADP-IV, and secondary outcomes) at Post-Booster and Follow-up two years after starting the treatment program.

Study design

The outcome instruments will be assessed at Pretreatment (just before treatment starts, this moment will be counted as 0 months), at Mid-treatment (after 15 sessions of GST; this moment will be at 4 months approximately), at Post-treatment (after patients completed the 30 sessions GST; this will be at 8 months approximately), at Post-booster sessions (this will be around 12 months after start of therapy), and a Follow-up (two years after start of treatment).

Intervention

Group Schema Therapy

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Eligibility criteria

Inclusion criteria

- Patients with Other Specified PD based on the DSM-5 as primary diagnosis (assessed with SCID-5-P).
- Age 18-70
- Ability to understand, read, write and speak Dutch.

Exclusion criteria

- DSM-5 alcohol or drug dependence. (After 3 months of abstinence participation is possible).
- Comorbid psychotic disorder
- DSM-5 Bipolar disorder, type 1 (current or past)
- (Sub)threshold Borderline PD
- Acute suicide risk
- IQ<80
- Schema Therapy of any kind (e.g., individual, group, inpatient, outpatient, day treatment) in the past year.
- patients should not start with any form of psychological treatment or medication during screening or during the study's treatment or waitlist period. Medication should be on a stable level for 3 months, if not stopped. (Non-PD focused supportive treatment may be continued during wait and screening, but not during the study treatment and study 1-year follow-up period)
- Not able to plan (group) therapy sessions of 90 minutes within the treatment period.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017

Enrollment: 50
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Not applicable

Application type: Not applicable

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

NTR-new NL9521

Other Ethische commissie Faculteit Maatschappij en Gedragwetenschappen (FMG) van de UvA : 2017-CP-7563

Study results

Summary results

N/A