

Group Schema Therapy for Cluster-C Personality Disorders

No registrations found.

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

Summary

ID

NL-OMON19942

Source

Nationaal Trial Register

Brief title

GST-CLC

Health condition

Cluster-C Personality Disorder: Avoidant and/or Dependent and/or Obsessive-Compulsive Personality Disorder

Sponsors and support

Primary sponsor: ZonMW, participating mental health care institutes

Source(s) of monetary or material Support: ZonMW, participating mental health care institutes

Intervention

Outcome measures

Primary outcome

Avoidant Personality Disorder Severity Index OR Dependent Personality Disorder Severity Index OR Obsessive Compulsive Personality Disorder Severity Index

Secondary outcome

Personality (pathology): PD-beliefs (PDBQ); Self-Esteem (RSES); Self-Ideal Discrepancy (MSGO); Introversion (Introversion Inventory)

General psychopathology: BSI

Functioning: WHODAS

Quality of Life: EQ-5D-5L; MHQoL-7D; Happiness Question

ST-specific: schemas (YSQ-SR); schema modes (SMI)

Sleep quality: SLEEP-50

Study description

Background summary

BACKGROUND

Given the high prevalence of Cluster-C Personality Disorders (CI-C PDs) in clinical populations (>20%), disease burden, societal costs (48000–79000 € per year per person) and the consequences for the prognosis of comorbid mental disorders, a major efficiency gain in health care can be achieved if CI-C PDs are recognized and treated in time. Cost-effectiveness research of their treatment is scarce. The only controlled cost-effectiveness study published so far found Individual Schema Therapy (IST) superior to Treatment as Usual (TAU). Group treatment is an attractive solution for improving quality and efficiency of health care as larger numbers can be treated in (>50%) less time compared to individual therapy. Group schema therapy (GST) is delivered in a protocolled manner, which facilitates training and implementation, making GST easily accessible for large patients groups. GST might deliver a cost-effective solution for unnecessary long treatments and chronicity of CI-C PDs. However, up to date there is no RCT supporting its (cost-)effectiveness. Costs other than related to direct application are unknown. Documenting the (cost-)effectiveness of GST is therefore an urgent issue. Moreover, it is unlikely that GST fits all – some might do better with IST, for instance clients with specific diversity characteristics, introverted, sleep disordered or highly traumatized clients.

AIMS

The overall aim of the project is to assess the evidence for GST for CI-C PDs and to improve treatment allocation for individual clients. Three main questions are addressed:

1. Is GST for CI-C PDs (cost-)effective compared to TAU?
2. How does GST compare to IST as treatment for CI-C PDs in (cost-)effectiveness?
3. What client-characteristics predict better response to GST, IST, or TAU?

In addition, we aim to improve our understanding of what is essential in treatment to further

ameliorate treatment protocols and meet clients' needs better.

METHOD

In a multicenter Randomized Controlled Trial (RCT) GST, IST and TAU are compared in 378 CI-C PD clients in effectiveness

and cost-effectiveness. Ten sites are planned to participate. GST and IST are based on protocols and completed within 1 year.

TAU is the optimal treatment available at the site for the particular patient according to regular procedures, ST excluded.

GST is based on a protocol that has been piloted in N=140 clients of 6 sites, and found to have high treatment retention and a large pre-post effect size. In collaboration with experience experts, the protocol has been further improved.

Severity of the primary CI-C PD is the primary outcome, assessed with clinical interviews by independent raters blind for

treatment. Functioning (including social & societal) and wellbeing are important secondary outcomes. For the economic

evaluation, a societal perspective is used. Assessments take place at week 0 (baseline), week 17 (mid GST), week 34 (post

GST), week 51 (post booster sessions of GST), and 2 years (FU). The 2-year follow-up is important as assessment of

long-term effects is essential to study whether effects are maintained or lost, or further increase. This follow-up is also important for the cost-effectiveness, as it will clarify what the (societal and health-care) costs are after treatment.

Client characteristics predicting better response to a specific treatment are studied, four a priori formulated: childhood trauma (CTQ), autistic features (ASS), sleep problems (SLEEP-50), and introversion (II). A tool supporting clients and clinicians in matching treatment to client will be developed. A qualitative study explores experiences of participants: what is helpful for recovery and creating a fulfilling life; how can treatments be improved.

Diagnostic assessments: DSM-5 diagnoses will be made on the basis of the Dutch SCID-5-CV and SCID-5-P interviews. Intelligence will be estimated with the Dutch Adult Reading Test (DART). The cost interview is an adaptation of the TIC-P, suitable for this population. Influence of diversity on effects is explored by testing prediction and moderation by diversity indicators (age, gender, sexual orientation, social-economic status, education, cultural background).

Statistical analysis: Primary and secondary outcomes are analyzed with Linear Mixed Models (LMM), with random effect of site. As data of group members are not independent because group members might influence each other, this dependency needs to be taken into account. With the semi-closed group format, groups change in composition every 10 sessions, and participants will share different amounts of time in sessions with group peers: from all group sessions to 10 group sessions. It seems then natural to model covariances as a function of the amount of time (i.e. sessions) patients have spent together in a group. This can be achieved in a multilevel model with repeated measures by specifying a Toeplitz covariance

structure to model this dependency on the group level. For the repeated part at the individual level, the best fitting covariance structure will be chosen (e.g., AR1, ARMA11, Unstructured). If residuals deviate from normal distribution, Generalized LMM (GLMM) will be used with an appropriate distribution (e.g., negative binomial or gamma in case of skewed distributions). Analyses are intent-to-treat and will be controlled for primary PD-diagnosis. Dropout from treatment will be analyzed with GLMM survival analysis with site as random effect. Tests of predictors and moderators will be done by similar (G)LMM analyses, with the predictor, predictor x time, predictor x treatment, and predictor x time x treatment interactions added to the model.

An app will be developed that can inform future users about the potentially optimal treatment for the specific patient. The app will be based on the large set of baseline variables available. The field of treatment selection is rapidly developing, hence the exact statistical method will be decided at the end of the project.

Economic analysis: both a cost-effectiveness and a cost-utility analysis will be performed, primarily from a societal perspective (the health care perspective is secondary). The time window is 2 years. Costs will be assessed with an interview (at each assessment). Clinical effectiveness is the primary outcome (severity of the primary PD, assessed with interviews) at 2 years, utilities are based on a Dutch algorithm for the EQ5D. If available, the cost-utility analysis is also done with utilities derived from the MHQoL-7D. The utilities at the 5 time points are used to compute QALY scores by means of the area under the curve method. Sensitivity analyses will be done. For the primary research question, GST is compared to TAU. For the secondary research question, GST is compared to IST.

EXPECTED RESULTS

Superiority of GST vs TAU is expected given a study in which IST for CI-C was superior to TAU in effectiveness and cost-effectiveness, and GST for Borderline PD was superior to TAU. The effects of a recent pilot study further support this expectation. However, we also expect that for some clients GST is suboptimal. Therefore we will create a tool that informs client and clinician which treatment is presumed to be optimal (personalized care). Results will be disseminated by publications, presentations and trainings. If GST is found to be (cost-)effective for many patients, supply of effective treatment can be easily increased. The allocation tool will help to improve treatment outcomes and efficiency. Results of the qualitative study will help to improve the studied treatments.

Study objective

Group Schema Therapy is more effective and more cost-effective than Individual Schema Therapy and than Treatment-as-Usual

Study design

baseline, week 17, week 34, week 51, 2 years

Intervention

Group Schema Therapy, Individual Schema Therapy, Treatment-as-Usual (i.e., the optimal treatment (not schema therapy) available for the participant at the site)

Contacts

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Eligibility criteria

Inclusion criteria

1. primary diagnosis CI-C PD (assessed with the SCID-5-P)
2. age > 17

Exclusion criteria

1. acute suicidality
2. insufficient Dutch language skills to participate in assessments
3. received ST last year
4. not available or not motivated for a treatment of 1 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-03-2021
Enrollment:	378
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
will follow

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	NL9209
Other	Ethical Committee FMG UvA : 2020-CP-12948

Study results