Group Schema Therapy for Cluster-C Personality Disorders

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19942

Bron
Nationaal Trial Register

Verkorte titel
GST-CLC

Aandoening

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

Ondersteuning

Primaire sponsor: ZonMW, participating mental health care institutes
Overige ondersteuning: ZonMW, participating mental health care institutes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND
Given the high prevalence of Cluster-C Personality Disorders (Cl-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 Cl-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 Cl-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 Cl-C PDs and to improve treatment allocation for individual
clients. Three main questions are addressed:
1. Is GST for Cl-C PDs (cost-)effective compared to TAU?
2. How does GST compare to IST as treatment for Cl-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 Cl-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 Cl-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 Cl-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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-03-2021
Aantal proefpersonen:	378
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
will follow

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9209
Ander register	Ethical Committee FMG UvA : 2020-CP-12948

Resultaten