Group Psychotherapy for Cluster C Personality Disorders: Effect study.

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Primary hypothesis: We expect a difference between PG, SFGT and GST in (cost-) effectiveness in reducing severity of cluster C PDs and psychiatric complaints. We hypothesize to find a mediating effect of common group processes i.e. cohesion,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23623

Bron
Nationaal Trial Register

Verkorte titel
G-FORCE

Aandoening

Personality disorders cluster C (avoidant, dependent, obsessive-compulsive personality disorder)

Ondersteuning

Primaire sponsor: Arkin
Overige ondersteuning: Arkin

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Assessment of DSM-IV Personality Disorders questionnaire (ADP-IV)

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY
Rationale: Cluster C personality disorders are highly prevalent and related to unfavourable outcome and chronicity of all common mental health disorders. Until now evidence for the op-timal treatment for these patients is lacking. For patients with a cluster C personality disorder group psychotherapy is commonly offered in clinical practice, but the effectiveness of group psychotherapy for these patients is not established. Important questions to be answered con-cern the optimal duration and influence of theoretical framework. Also, very little is known on the mechanisms of change in these psychotherapies. Finding evidence on the differential (cost)effectiveness of group therapy and the mechanisms of change is important to improve the quality of care for cluster C patients.
Objective: In this study we will compare the (cost)- effectiveness of psychodynamic group therapy (PG) with schema-focused group therapy (SFGT) and group schema therapy (GST). The group formats differ both in amount of sessions (resp. 80, 60 and 30 sessions) and theoretical background. The main hypothesis is that the three formats differ in (cost-) effectiveness in changing personality functioning and reducing psychiatric symptoms in the treatment of cluster C personality disorders. Next, we will investigate predictive factors and non-specific and therapy specific mediators.

Study design: A mono-centre pragmatic randomized clinical trial with three conditions: 1) PG, 2) SFGT and 3) GST. Randomization on patient level will be pre-stratified on type of personality disorder.

Study population: 214 patients with cluster C personality disorder(s) or other specified personality disorder with predominantly cluster C traits, aged 18-65 years, seeking treatment at NPI, a Dutch mental health care institute specialized in the treatment of personality disorders.

Intervention: The three interventions differ in duration. PG is offered in weekly sessions of 90 minutes for the duration of 2 years (80 sessions). SFGT combines elements of schema therapy with unstructured group dynamic therapy and is offered in weekly sessions of 120 minutes (60 sessions). The total dose in minutes is equal for PG and SFGT. GST is considerably shorter, consisting of 30 weekly sessions of 90 minutes, combined with a total of 300 minutes of additional individual sessions.

Main study parameters/endpoints: Change in severity of personality disorder (APD-IV and SCID-5-P) will be the main outcome measure. Secondary outcome measures are psychiatric symptoms, quality of life and costs from a societal perspective. Assessments will take place at baseline and at 1, 3, 6, 9, 12, 18, 24 and 36 months after the start of the treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be invited to a clinical screening interview prior to the start of treatment and 24 months after the start of treatment. Other measurements can be done

either online or on paper-and-pencil. Although the burden includes a time-investment of the patient (by filling in questionnaires) no risks are associated with participation in the study. Participants in all conditions will receive specialized treatment for personality disorders, their treatment and measurements will be well monitored and checked on adherence and additional treatment is provided if necessary.

Doel van het onderzoek

Primary hypothesis: We expect a difference between PG, SFGT and GST in (cost-) effectiveness in reducing severity of cluster C PDs and psychiatric complaints.

We hypothesize to find a mediating effect of common group processes i.e. cohesion, group climate, working alliance in all groups, a mediating effect of therapy specific processes i.e. change in schema modes in the two forms of schema group therapy and a mediating effect of insight, level of defense functioning and affect processing in psychodynamic group therapy.

Onderzoeksopzet

Assessments will occur before randomization, baseline and 1, 3, 6, 9, 12, 18, 24 and 36 months after the start of the treatment.

Onderzoeksproduct en/of interventie

1) Psychodynamic Group Therapy (PG): 80 sessions in 2 years
2) Schema Focused Group Therapy (SFGT): 60 sessions in 1,5 year
3) Group Schematherapy (GST): 30 sessions + limited number individual sessions in 1 year

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Primary diagnosis: DSM-5 diagnosis of a cluster C PD or otherwise specified PD with predominantly cluster C traits, operationalized as a minimum of 5 cluster C traits.
- Age 18-65 years
- A written informed consent
- The willingness and ability to participate in a group treatment of 1 - 2 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Non-Dutch speakers/readers
- Immediate intensive treatment or hospitalization is needed, e.g. acute suicidality
- Severe psychiatric disorder requiring priority in treatment (autism spectrum disorder, psychotic symptoms, bipolar disorder)
- Severe substance use disorder
- (Sub threshold) Cluster A or B PD
- No fixed home address
- Estimated IQ <80
- Pregnancy or other practical reasons why trial demands can’t be met

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	214
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-05-2020
Soort:	Eerste indiening

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	NL8607
Ander register	VU METC : 2020.066

Resultaten