The Effectiveness of Group Psychotherapy for Cluster C Personality Disorders: A pragmatic RCT comparing Psychodynamic and Two Forms of Schema Group Therapy

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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)...

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

Summary

ID

NL-OMON52525

Source
ToetsingOnline

Brief title
G-FORCE

Condition

- Personality disorders and disturbances in behaviour

Synonym
1. Cluster C Personality Disorders 2.angstige/geremde persoonlijkheidsproblematiek

Research involving
Human

Sponsors and support

Intervention

Keyword: Cluster C, Group Therapy, Personality Disorder, RCT

Outcome measures

Primary outcome

Change in severity of cluster C personality disorder (APD-IV) will be the main

outcome measure.

Secondary outcome

Secondary outcome measures are psychiatric symptoms, structural personality

pathology, recovery of personality disorder, quality of life and costs from a

societal perspective. Assessments will take place at baseline (after signing

informed consent en before randomization) and at start of treatment and 1, 3,

6, 9, 12, 18, 24 and 36 months after the start of the treatment.

Study description

Background summary

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 optimal treat-ment 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
psy-chotherapy for these patients is not established. Important questions to be
answered concern the optimal duration of group therapy and influence of
theoretical framework. Also, very little is known on the mechanisms of change
in these psychotherapies. Finding evidence on the differential effectiveness of
group therapy and the mechanisms of change is important to improve the quality

of care for cluster C patients.

Study 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 cluster C personality disorder.

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.

Study burden and risks

Patients will be invited to a clinical screening interview prior to the start of treatment and at 12 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.

Contacts

Public
Arkin (Amsterdam)

Domselaerstraat 128
Amsterdam 1093 MB
NL
Scientific
Arkin (Amsterdam)

Domselaerstraat 128
Amsterdam 1093 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 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.

Exclusion criteria

-(Sub threshold) Cluster A or B PD
- 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
- No fixed home address

- Estimated IQ <80
- Pregnancy or other practical reasons why trial demands can*t be met

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	290
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	22-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	31-03-2023

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL72826.029.20