# Group Psychotherapy for Cluster C Personality Disorders: Effect study.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23623

**Source**
Nationaal Trial Register

**Brief title**
G-FORCE

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Arkin
**Source(s) of monetary or material Support:** Arkin

### Intervention

### Outcome measures

**Primary outcome**

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

**Secondary outcome**

Avoidant personality disorder severity index (AVPDSI), Dependent personality disorder severity index (DEPDSI), Compulsive personality disorder severity index (OCPDSI).
Structural Clinical Interview for DSM-5 personality disorders (SCID-5-P-NL)
Inventory of Personality Organisation Short Form (IPO-16-NL)
Brief Symptom Inventory (BSI)
EQ-5D
Happiness Questionnaire
TiC-P

# Study description

**Background summary**

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.

### Study objective

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.

### Study design

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

### Intervention

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

## Contacts

**Public**
Arkin NPI
Birre Van den Heuvel

0205904700
**Scientific**
Arkin NPI
Birre Van den Heuvel

0205904700

# Eligibility criteria

## 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

- 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

# Study design

## Design

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

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| Control: | Active |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2020 |
| Enrollment: | 214 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 11-05-2020 |
| Application type: | First submission |

## 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 | NL8607 |
| Other | VU METC : 2020.066 |

# Study results