Individual Psychotherapy for Cluster C Personality Disorders: A pragmatic RCT comparing time limited Psychodynamic, Affect Phobia and Schema Therapy

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

Summary

ID

NL-OMON52837

Source
ToetsingOnline

Brief title
I-FORCE

Condition

- Personality disorders and disturbances in behaviour

Synonym
Cluster C Personality Disorders, persoonlijkheidsproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)

Source(s) of monetary or material Support: Arkin/NPI

Intervention

Keyword: Cluster C PD, Individual, Psychotherapy, RCT

Outcome measures

Primary outcome

Personality change (ADP-IV) will be the main outcome measure.

Secondary outcome

Secondary outcome measures are psychiatric symptoms, quality of life and costs from a societal perspective. Assessments will take place at baseline (after signing the Informed Consent), at the start of the treatment and at 1, 3, 6, 9, 12, 18, 24 and 36 months after the start of the treatment.

Study description

Background summary

Cluster C personality disorders (PDs) are highly prevalent in clinical practice and are related to unfavorable outcome and chronicity of all common mental health disorders (e.g. depression and anxiety disorders). Although several forms of individual psychotherapy are commonly offered in clinical practice for this population, due to scarcity of well-designed studies evidence for differential efficacy, setting and format is lacking. Also, very little is known on working mechanisms of these psychotherapies. Finding evidence on the differential (cost)effectiveness for this group of patients and the working mechanisms of change is important to improve the quality of care for this vulnerable group of patients.

Study objective

In this study we will compare the differential (cost)- effectiveness of three individual psychotherapies: short-term psychodynamic supportive psychotherapy (SPSP), affect phobia therapy (APT) and schema therapy (ST). Although these psychotherapies are commonly used in clinical practice, evidence for the cluster C PDs is restricted to one RCT for ST (Bamelis et al., 2014) and one

for APT (Svartberg et al., 2004). Next we will investigate predictive factors, non-specific and therapy specific mediators.

Study design

A mono-center randomized clinical trial with three parallel groups 1) SPSP 2) APT 3) ST. Randomization on patient level will be pre-stratified according to type of personality disorders.

Intervention

SPSP, APT and ST (50 sessions per condition) are offered twice a week in sessions of 50 minutes for the first four to five months. After that, session frequency decreases to once a week. All conditions have a maximum duration of one year.

Study burden and risks

Patients will be invited to a clinical interview prior to start of treatment, 12 and 24 months after 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. Participators 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Primary diagnoses: DSM-5 diagnosis 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
- Dutch literacy
- The willingness and ability to participate in an individual treatment of 50 sessions in one year.

Exclusion criteria

- (Subthreshold) cluster A or B PD
- Having received SPSP, APT or ST in the previous year
- Immediate intensive treatment or hospitalization is needed, e.g. acute suicidality
- Severe psychiatric disorder requiring priority in treatment (autism spectrum disorder, psychotic symptoms/disorder, bipolar disorder)
- Severe substance use disorder
- IQ <80

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2020
Enrollment:	264
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2024
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	NL72823.029.20