

# The (cost-)effectiveness of generalist (GIT-PD) versus specialist treatment (MBT/ST) for severe personality disorders (the P-DAET study): a pragmatic randomized controlled non-inferiority trial

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To compare the effectiveness of a generalist approach (GIT-PD) to specialized psychotherapy for personality disorders (PD) and to predict for which individual patient generalist treatment is not inferior to specialist treatment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Personality disorders and disturbances in behaviour
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56791

### Source

ToetsingOnline

### Brief title

P-DAET

### Condition

- Personality disorders and disturbances in behaviour

### Synonym

character pathology, personality problems

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Arkin (Amsterdam)

**Source(s) of monetary or material Support:** Stichting VCVGZ

## Intervention

**Keyword:** generalist treatment, personality disorders, personalized treatment, treatment capacity

## Outcome measures

### Primary outcome

The level of personality functioning after 1.5 years of therapy and the difference between both conditions in terms of personality functioning

### Secondary outcome

- Drop-out after randomization
- Severity of symptoms
- Psychosocial functioning
- Costs
- What works for whom? Determining different treatment effects between specialized treatments and generalist treatments (GIT-PD) by combining multiple predictors in an algorithm (the Personalized Advantage Index) and building a model to generate individual treatment recommendations. See research protocol for the specific predictors that will be measured.

## Study description

### Background summary

There are long waiting lists for the treatment of personality disorders. This is partly due to the fact that there are too few specialized psychotherapies available and that the training courses for these psychotherapies are quite long and expensive. That is why the GIT-PD, Guideline-Informed Treatment for Personality Disorders (GIT-PD), was developed. GIT-PD is a generalized approach that is based upon functional components from other forms of treatment. GIT-PD can be easily applied by many practitioners. There is clear evidence that this works as well as specialized psychotherapies for many patients, but this has not yet been properly investigated in a direct comparison. Nevertheless, GIT-PD is already being used in many institutions.

## **Study objective**

To compare the effectiveness of a generalist approach (GIT-PD) to specialized psychotherapy for personality disorders (PD) and to predict for which individual patient generalist treatment is not inferior to specialist treatment.

## **Study design**

This is a pragmatic randomized controlled non-inferiority trial in which people with severe personality pathology receive either general treatment or a highly specialized form of psychotherapy (Schema Focused Therapy or Mentalization Based Treatment).

The main outcome measure is level of personality functioning after 1.5 years of therapy. In addition, an effect is expected on the severity of the symptoms, quality of life and social and professional functioning. This is determined after 3, 6, 12, 18, 24 months of treatment and one year after the end of treatment.

Participants will be recruited from the following mental health institutes: Altrecht, Arkin, Dimence, GGZ Oost-Brabant, and de Viersprong. Patients meeting the inclusion criteria will be informed about the study by the clinician at intake phase. They will be handed out a brochure with information about the study and an informed consent form. Then, they will be given a week to consider participation in the study. After signing informed consent, a baseline measure will take place (see Flowchart and Table 1). The baseline measure will be conducted by research assistants and will take about 1.5 hours to complete. Then, randomization takes place by an independent statistician. The research assistant receives the information on the allocation from the independent statistician and informs the patient about which treatment has been assigned. Participants will undergo either GIT-PD treatment or SFT/MBT treatment. During treatment, there will be five follow-up measurements (see Flowchart). The follow-up measures at 3, 6, 12, and 24 months will take about half an hour, while the measures at 18 months and at one year after completing treatment will take about 1.5 hours.

## **Intervention**

There are 2 conditions in this study:

- 1) Participants receive a generalist treatment for personality problems, namely GIT-PD
- 2) Participants receive specialist treatment for personality problems, namely SFT or MBT

Both conditions do not deviate from regular care.

## **Study burden and risks**

There are no risks associated with participating in this study. Much experience has already been gained with the treatments provided, which shows that people benefit from the treatment and that there are no special risks associated with it. The treatments are also part of the institution's standard treatment program. Therefore, no additional risks are associated with participating in the study.

During the research there are several moments when participants have to complete questionnaires. An interview is also conducted. It is estimated that the starting measurement will take approximately 1,5 hours. The follow-up measures at 3, 6, 12 and 24 months will take about half an hour, while the measures at 18 months and at one year after completing treatment will take about 1.5 hours.

## **Contacts**

### **Public**

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NL

### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients (age 18 or older) who meet DSM-5 criteria for *\*severe\** or *\*extreme\** PD according to the alternative model for PDs, as assessed by the Semi-Structured Interview for Personality Functioning DSM-5 (STiP-5.1)

### Exclusion criteria

- Autism Spectrum Disorder
- Chronic psychotic disorder
- IQ < 75 or legal incapacity
- Any mental state disorder that requires prior treatment (e.g. severe eating or substance abuse disorder).

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	358
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	23-05-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	05-08-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	27-03-2025
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## 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	NL86263.028.24