# Time-Limited Experiential Versus Long Term Schema Therapy: Non-Inferiority Trial for Groups of Outpatients with Personality Disorders

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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-OMON57009

**Source**
ToetsingOnline

**Brief title**
TEN-GO!

### Condition

- Personality disorders and disturbances in behaviour

**Synonym**
Personality disorders, personality problems

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Parnassia (Den Haag)

**Source(s) of monetary or material Support:** Ministerie van OC&W,Subsidie vanuit Stichting tot steun VCVGZ

## Intervention

**Keyword:** Personality disorders, Randomised controlled trial, Schema therapy, Time-Limited

## Outcome measures

### Primary outcome

The main study parameter is the level of personality functioning as measured by the Level of Personality Functioning Scale - Brief Form (LPFS-BF). It is tested whether TE-ST is non-inferior to long term group schema therapy.

### Secondary outcome

Secondary objectives to the study are: to explore the effect on decreasing the severity of general psychiatric complaints (Brief Symptom Inventory), personality disorder symptoms (PID-5-BF) of time-limited compared to long-term group schema therapy; to understand the effect of increasing emotion regulation ability (DERS), and improving functioning (WHODAS-2) and quality of life (MHQOL) of time-limited compared to long-term group schema therapy; to understand the effectiveness of therapy from the patient*s perspective using patient derived goals in time-limited compared to long-term group schema therapy; to estimate the cost-effectiveness (TIC-P/EQ-5D-5L) of time-limited compared to long-term group schema therapy; to understand what factors are predictive in therapy outcome (CTQ, YSQ, SMI, DES-T).

# Study description

### Background summary

Personality disorders are prevalent and can be successfully treated using psychotherapy. However, while the burden for patients is high, access to treatment is limited due to wait lists. There is a need to study the effectiveness of brief interventions. Specifically, time-limited schema group therapy has shown promising results. Therefore, this study seeks to investigate whether time-limited experiential group schema therapy (TE-ST) is equally effective to long-term group schema therapy.

## Study objective

The primary objective of this study is to investigate the effectiveness of TE-ST in enhancing personality functioning as compared to long-term schema group therapy. Secondary objectives to the study are: to explore the effect on reducing general psychiatric symptoms and decreasing the severity of personality disorder symptoms of time-limited compared to long-term group schema therapy; to understand the effect of increasing emotion regulation ability, and improving functioning and quality of life of time-limited compared to long-term group schema therapy; to understand the effectiveness of therapy from the patient*s perspective using patient derived goals in time-limited compared to long-term group schema therapy; to estimate the cost-effectiveness of time-limited compared to long-term group schema therapy; to understand what factors are predictive in therapy outcome.

## Study design

The study is a multi-centre randomised controlled non-inferiority trial with two arms comparing TE-ST to long-term group schema therapy.

## Intervention

Within the experimental condition TE-ST is provided consisting of 18 90-minute group sessions and two 60 minute follow up sessions. Experiential techniques like imagery, imagery with rescripting, historical roleplay and chair techniques will be included. In the control condition, experiential group schema therapy is provided consisting of 36 90-minute group sessions and two 60-minute follow up sessions.

## Study burden and risks

The present study consists of completing questionnaires, with no additional risks involved. There is a burden for the participant in terms of time to complete the questionnaires. We expect that both arms of the study will be equally effective in reducing psychiatric distress. Therefore, we do not expect any adverse effects of the experiential group schema therapy. However, there is a risk that the time-limited treatment will be less effective in reducing personality functioning than the longer treatment. Benefits may be an

improvement of functioning and a decline of psychiatric complaints.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

### Inclusion criteria

1. DSM-5 classification of a personality disorder preferably assessed with the aid of the Structured Clinical Interview of DSM-5 Disorders (SCID-5-P, Arntz, Kamphuis & Derks, 2017). The SCID-5-P is part of the standard admission procedure for specialised care. A different standardised assessment may be used.
2. Age at least 18 years,
3. Eligibility for group therapy based on;
a. symptoms of personality disorders are the reason for seeking help,
b. the patient is motivated to follow psychotherapy in a group, and
c. the clinical judgement of the group therapists.

The latter is based on the patient ability to attend group meetings, the patient openness within a group and the patient reflective ability given the input of other patients.

### Exclusion criteria

1. Acute crisis (such as suicidality) for which a patient needs inpatient treatment,
2. Acute psychotic episode or psychotic disorder, autism spectrum disorder or alcohol or drugs-related disorders as primary diagnosis,
3. Limited knowledge of the Dutch language,
4. Severe auditory problems that interfere with participation in a group, or severe stuttering,
5. Estimated IQ below 70.

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-11-2024 |
| Enrollment: | 342 |
| Type: | Actual |

### Medical products/devices used

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| Registration: | No |

# Ethics review

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| Approved WMO Date: | 12-09-2024 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL86131.078.24 |