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# Which schemas and modes predict outcome of schematherapy?

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 04/08/2020 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 07/09/2020 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 19/01/2024 | Mental and Behavioural Disorders | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Schema therapy is a therapy for patients with longstanding mental health problems (e.g. depression, anxiety disorders and personality problems). It has been shown to be an effective treatment both as individual treatment and as group treatment. Little is known about what variables predict outcome of time-limited schema group therapy. This study aims to get a better understanding of what works for whom in time-limited schema group therapy.

Who can participate?
Patients aged 18-75 with a clinical syndrome or personality disorder according to the DSM-V

What does the study involve?
This study is based on analyzing (ROM) data of patients files of patients, who have given their consent and who have been in treatment at G-kracht mental health care institute in Delft in the Netherlands between 2016 and 2020. Patient records will be collected between June 2020 and March 2021.

What are the possible benefits and risks of participating?
The benefit for participants was that their progress will be systematically followed and used in evaluating their therapy process. By allowing their files to be opened for research, they will contribute to the accumulation of knowledge to predict what treatment works for whom.

Where is the study run from?
G-kracht Mental Health Care Institute (Netherlands)

When is the study starting and how long is it expected to run for?
June 2019 to March 2021

Who is funding the study?
Investigator initiated and funded with support from PsyQ (Netherlands)

Who is the main contact?
Michiel van Vreeswijk
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
OpenlabelST2020

# Study information

### Scientific Title
Predicting efficacy of time-limited schema group therapy

### Acronym
PETLSGT

### Study objectives
Patient characteristics (SES, clinical variables and schemas and modes) predict treatment outcome as measured with the BSI.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This study does not require ethics approval as the study is based on data in patient files which already have been treated and for whom certain self-reports were part of treatment as in Routine Outcome Monitoring (ROM). Patients were not subjected to any extra intervention which was not part of their regular treatment process.

## Study design
Open-label trial (patients files between the end of 2016 - June 2020) in a single-centre naturalistic clinical setting with a within-subject design with three measurement moments as part of ROM

## Primary study design
Observational

## Secondary study design
Ecological study

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Mental health care: patients with longstanding clinical syndromes and/or personality disorders

## Interventions
This is an observational study using historical data. Patient data will be collected from patient files of patients who had ST-group therapy between 2016 and the first half of 2020. These participants received time-limited schema group therapy of 18 group therapy sessions with either the focus on experiential schema therapy techniques, cognitive behavioural schema therapy techniques of a combination of the above.

## Intervention Type
Behavioural

## Primary outcome measure
Treatment outcome measured using the Brief symptom inventory (BSI) at baseline (start-of-treatment), 9 weeks (mid-treatment), and 18 weeks (end-of-treatment)

## Secondary outcome measures
Patient characteristics measured using the Young schema questionnaire (YSQ) and the Schema mode inventory (SMI) at the baseline, 9, and 18 weeks

## Overall study start date

01/06/2019

### Completion date
01/03/2021

## Eligibility

### Key inclusion criteria
1. Age 18-75 years
2. Having a clinical syndrome or personality disorder according to the DSM-5
3. Being fluent in writing/speaking Dutch

### Participant type(s)
Other

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
75 Years

### Sex
Both

### Target number of participants
90

### Total final enrolment
85

### Key exclusion criteria
1. Having a psychosis
2. Having a diagnosis of schizophrenia
3. Being in a crisis which needs admission to a mental health care hospital
4. Having very severe hearing problems which results in that working in a group therapy is not possible
5. Having very severe stuttering problems which results in that working in a group therapy is not possible

### Date of first enrolment
26/06/2020

### Date of final enrolment
01/03/2021

## Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**G-kracht Mental Health Care Institute**
Noordeinde 27A
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# Sponsor information

**Organisation**
G-kracht Mental Health Care Institute

**Sponsor details**
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.g-kracht.com

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Investigator initiated and funded

**Funder Name**
PsyQ

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed international journal

### Intention to publish date
01/01/2026

### Individual participant data (IPD) sharing plan
Requests for part of the data can be e-mailed to mf.vanvreeswijk@g-kracht.com. The data is collected from the files and put in an SPSS file. The data (outcome of self-report questionnaires YSQ, SMI, BSI and SES and clinical variables) will undergo an anonymization as is regular practice in research. The data will become available after publication of an article in an international scientific journal. The data will be available for 10 years after publication of the article. It will be accessible for other clinical psychology researchers having at least an academic title of PhD. It will be accessible for those who want to check the integrity of the outcome as is published and for those who want to use the data for a review of meta-analysis under the condition that the data set will be destroyed immediately after use and ownership will remain with us as a research group. It is preferred that only the minimum of data is shared which is really needed and not automatically the whole data set, because even though the data will have been anonymized the privacy laws are very strict on this.

### IPD sharing plan summary
Available on request