ISRCTN17131709 https://doi.org/10.1186/ISRCTN17131709

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design
Observational

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

Study type(s)
Treatment

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

Key secondary outcome(s)
Patient characteristics measured using the Young schema questionnaire (YSQ) and the Schema mode inventory (SMI) at the baseline, 9, and 18 weeks

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

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
Delft
Netherlands
2611 KG

Sponsor information

Organisation
G-kracht Mental Health Care Institute

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded

Funder Name
PsyQ

Results and Publications

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