ISRCTN17262253 https://doi.org/10.1186/ISRCTN17262253

Who benefits from time-limited schema group therapy for outpatients with personality problems?

Submission date
07/09/2017

Recruitment status
No longer recruiting

Registration date
20/09/2017

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with personality disorders or long lasting Axis-I disorders (e.g. anxiety disorders, depression) often have specific ways of perceiving themselves and others. Events (in the past), temperament, biological make-up, environment of upbringing makes people who they are and how they respond. People develop pitfalls and in most cases patients with personality problems and long lasting Axis-I disorders suffer more than healthy people from their pitfalls. Most often these patients have had several treatments already, but still experience problems where they seek treatment for. Schema therapy is an evidence based psychotherapy which specifically aims at changing/reducing the pitfalls. In this therapy, patients become more aware of their pitfalls and how these interfere with their psychological wellbeing and functioning in daily life with other people. They learn to make more healthy choices and to understand more and act upon their healthy needs. As this therapy is given in a group format, patients learn from others and can practice with each other what they learn in the safety of a group setting with two schema therapists as group therapists guiding the group processes. The aim of this study is to investigate if Schema therapy can improve psychological symptoms in patients with personality problems.

Who can participate?
Adults aged 18-65 years who have personality problems and are treatable in an outpatient setting

What does the study involve?
This study reviews files of patients who have been participating in schema group therapy. Patients who participate in schema group therapy are indicated for this therapy because of longstanding psychological problems, mostly personality problems. In this therapy, patients become more aware of their pitfalls and how these interfere with their psychological wellbeing and functioning in daily life with other people. The researchers collect data about patients using their patient files to measure their duration of treatment, the amount of therapy time, whether they got more than five therapy sessions and the amount of patients who participating in the therapy who longer are in the therapy.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

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?
January 2015 to December 2021

Who is funding the study?
1. Investigator initiated and funded (Netherlands)
2. G-kracht Mental Health Care Institute (Netherlands)

Who is the main contact?
Mr M.F. van Vreeswijk

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

Scientific Title
Predictors, mediators and moderators of outcome of time-limited schema group therapy for outpatients with personality disorders: An open-label trial

Study objectives

1. Schemas and modes as measured at pre-treatment predict therapy outcome in time-limited schema group therapy
2. Changes in schemas and modes co-occur with changes in psychological problems

Ethics approval required
Old ethics approval format

Ethics approval(s)
As this is an open-label trial in which only the files were checked of 137 patients who have had schema group therapy and who did not have to do any additional work for the study (so no additional questionnaires or interviews had to be filled in by the patients) according to the Medical Ethical Committee no formal request had to be made. Everything is according to the Helsinki agreement/WHO guidelines which allow research based on patients files solely. A request to the ethics board has not been done based on the Dutch law (WMO) with regard to retrospective patient file studies. The WMO incorporates WHO and Helsinki regulations and can be found via http://www.ccmo.nl/en/your-research-does-it-fall-under-the-wmo.

Study design
This study is a case-file study of patients with personality problems who have been treated with time-limited schema group therapy between 2007-2017 as an outpatient at a mental health care institute.

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Personality disorders

Interventions
Patients who are in treatment at G-kracht Mental Health Care Institute and who are taking part of Schema group therapy (ST-g) for their personality problems as a part of their standard treatment package do have to fill in the BSI, YSQ, SMI as a standard evaluation measure at the beginning of the ST-g, in the middle of the ST-g and before the final ST-g session (the last follow up session). The outcome of this Routine Outcome Monitoring (ROM) is used in individual evaluation sessions with the patients as discussion material on the amount of change and whether or not more therapy is necessary. The ROM data is part of the Electronic Patient File (EPF) as it is standard part of the treatment. ST-g’s take around 10 months including the follow ups.

A research assistant collects all the data (SES, duration of treatment before ST-g, the amount of therapy time before ST-g, during ST-g and whether or not a patient got more than 5 therapy sessions after ST-g, BSI, YSQ, SMI; which were collected based on a preset of data which had to be included in the study) of the patients who had participated in ST-g during 2007-2017 and who are no longer in ST-g. The data collected was anonymized before it was entered in SPSS.

Intervention Type
Behavioural

Primary outcome measure
1. Psychological symptoms are measured using the Brief Symptom Inventory (BSI) at baseline, in the middle of ST-g and two months after the last therapy session but before the last follow up session.
2. Schemas are measured using the Young Schema Questionnaire (YSQ) at baseline, in the middle of ST-g and two months after the last therapy session but before the last follow up session.
3. Modes are measured using the Schema Mode Inventory (SMI) at baseline, in the middle of ST-g and two months after the last therapy session but before the last follow up session.

NOTE: as some ST-g as there was a differentiation in amount of sessions of the ST-g's the wording "in the middle" is used instead of 10, 12 weeks.

Secondary outcome measures
1. Socio Economic Status is measured using the records in the patient files at baseline
2. Total amount of treatment before and after the time-limited ST-g is measured using the records in the patient files at the end of this study

Overall study start date
01/01/2015

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Male/ female
2. Aged between 18-65
3. Personality problems
4. Treatable as an outpatient at a mental health care institute

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
280 patients

Total final enrolment
253

Key exclusion criteria
1. Patients whose Axis-I diagnosis has not been treated yet by the more appropriate therapy forms for the particular Axis-I disorder
2. Patients who need constantly to be in a crisis unit
3. Patients with severe drug abuse
4. Patients whose psychological problems will interfere with group therapy processes (e.g. moderate-severe narcissism, moderate-severe autism, moderate-severe anti-social personality problems)

Date of first enrolment
03/02/2015

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
G-kracht Mental Health Care Institute
Delft
Netherlands
2611 KG

Sponsor information

Organisation
G-kracht Mental Health Care Institute

Sponsor details

Noordeinde 27A
Delft
Netherlands
2611 KG

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
G-kracht Mental Health Care Institute

Results and Publications

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

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from M. F. van Vreeswijk (mf.vanvreeswijk@g-kracht.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/07/2024	19/07/2024	Yes	No