

Group schema-focused therapy enriched with psychomotor therapy for older adults with personality disorders in specialized mental health care: a (cost-) effectiveness study

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To study the (cost-)effectiveness of group schema-focused therapy (SFT) enriched with psychomotor therapy (PMT) in specialized mental health care for older adults. It is hypothesized that group SFT+PMT is cost-effective and superior to treatment as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON47231

Source

ToetsingOnline

Brief title

Cost-effectiveness of group schema-focused therapy in geriatric psychiatry

Condition

- Personality disorders and disturbances in behaviour

Synonym

Personality disorder; character traits

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMw;Health Care Efficiency Research programme

Intervention

Keyword: Cost-effectiveness, Geriatric psychiatry, Personality disorder, Psychotherapy

Outcome measures

Primary outcome

Primary outcome is general psychological distress (Brief Symptom Inventory; BSI-53). Cost-effectiveness analysis will be performed from a societal perspective (based on EQ-5D-5L and structured cost-interviews).

Secondary outcome

Secondary outcome measures are: quality of life and psychotropic drug use.

Study description

Background summary

The disease burden due to personality disorders is high for patients (lowered quality of life, high levels of psychological distress) and society (increased medical consumption and informal care). A personality disorder is found in more than one third of geriatric psychiatric outpatients, and presence of a comorbid personality disorder worsens treatment outcome for affective disorders. For long, personality disorders were considered treatment resistant, but the past decades several psychological therapies - including schema-focused therapy - have been proven successful. However, personality disorders often remain undiagnosed in geriatric psychiatry, and specific treatment for personality disorders is often not available. Patients are therefore commonly offered treatment for symptoms of depression, anxiety or somatization, leaving their underlying personality pathology untreated.

Study objective

To study the (cost-)effectiveness of group schema-focused therapy (SFT)

enriched with psychomotor therapy (PMT) in specialized mental health care for older adults. It is hypothesized that group SFT+PMT is cost-effective and superior to treatment as usual (TAU) in reducing psychological distress and improving quality of life.

Study design

A multicenter, randomized trial, with one-year follow-up, comparing the treatment effect of group SFT+PMT to that of TAU.

Intervention

Twenty sessions of group SFT+PMT delivered in groups of 4 through 8 older patients over a 6-month period.

Study burden and risks

Before patients can participate in the study, eligibility is checked in a 90 minutes diagnostic interview with a local researcher (psychologist), and baseline characteristics are assessed by questionnaire (estimated to take 49 minutes) and interview (20 minutes).

Group SFT+PMT treatment consists of 20 three-hour sessions (2 hours psychotherapy and 1 hour PMT) over a 6-month period. As part of treatment, patients in the intervention group will score the severity of their schemas and modes on a weekly basis (taking two minutes each time). Outcome assessment in both study groups consists of questionnaires (taking 52 minutes), telephone interviews (one week after the questionnaires, taking 30 minutes) and an experience sampling measure by smartphone (3 times a day, during one week, taking 42 minutes in total). These assessments are administered at the start and end of treatment, and 6 and 12 months post-treatment.

Group SFT is a specific form of psychotherapy, aimed at reducing current and future psychological distress, and PMT is added to enhance treatment effect by experiential - bodily - techniques. PMT will be adapted to the physical abilities of individual participants. We do not expect any risk associated with participation in the study, and therefore applied for exemption from the compulsory insurance for study participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age: 60 years or older
- Cluster B or C personality disorder
- Mentally able to adhere to the group schema-focused treatment schedule and to fill out the schema (-mode) questionnaires
- Informed consent for the study

Exclusion criteria

- Severe mental illness, including current bipolar disorder or psychosis, or substance abuse disorder needing clinical detoxification.
- An established neurodegenerative disorder or cognitive impairment defined as a Montreal Cognitive Assessment (MoCA) sum score below 24 points.
- Prior schema-focused therapy, received in the previous year or during the present episode of illness.
- Immediate suicide risk interfering with adequate treatment delivery.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2017
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO	
Date:	12-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	24-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	28-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL59382.042.16