Psychological treatment of Personality Disorders: A multi-centered randomised controlled trial on the (cost-)effectiveness of Schema-Focused Therapy

Submission date	Recruitment status	[X] Prospectively registered
14/02/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
14/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
18/08/2009	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR566; 3353 (ZonMW DO)

Study information

Scientific Title

Study objectives

To assess the (cost-)effectiveness of Schema-Focused Therapy (SFT) compared to Treatment as Usual (TAU) as treatment for six Personality Disorders (PDs).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised single blind active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Personality Disorder

Interventions

Schema-Focused Therapy (SFT) versus Treatment as Usual (TAU).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Presence versus absence of Personality Disorder(s) (assessed with SCID-2 and ADP-IV [intermediate]).

Secondary outcome measures

- 1. Axis-1 diagnoses (assessed with the SCID-1)
- 2. General psychopathological symptoms (assessed with the SCL-90)
- 3. PD-related schemas and beliefs (assessed with the Young Schema Questionnaire [YSQ] and the PD-Belief Questionnaire [PDBQ, Arntz et al., 2004])
- 4. Social functioning will be assessed with the WSAS
- 5. Independent raters will assess global functioning with the GAF Scale (DSM-IV)
- 6. Quality of Life will be assessed with the WHOQOL and the EuroQol

Overall study start date

01/04/2006

Completion date

01/04/2010

Eligibility

Key inclusion criteria

250 outpatients of mental health institutes in the Netherlands with a cluster-C PD, a narcissistic, histrionic or paranoid PD as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria as first diagnosis.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

250

Key exclusion criteria

- 1. IQ less than 80
- 2. Problems with Dutch language (talking, reading, writing)
- 3. Borderline, antisocial, schizoid, schizotypal personality disorder
- 4. Psychotic or bipolar disorder on axis-I, DSM-IV
- 5. Substance dependence needing clinical detoxification (after detoxification this is no longer an exclusion criterion)
- 6. Immediate suicide risk

Date of first enrolment

01/04/2006

Date of final enrolment

01/04/2010

Locations

Countries of recruitment

Netherlands

Study participating centre University Maastricht (UM)

Maastricht Netherlands 6200 MD

Sponsor information

Organisation

University Maastricht (UM) (Netherlands)

Sponsor details

P.O. Box 616 Maastricht Netherlands 6200 MD

Sponsor type

University/education

ROR

https://ror.org/02jz4aj89

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration