

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Lotte Bamelis

Contact details

University Maastricht (UM)

DMKEP

P.O. Box 616

Maastricht

Netherlands

6200 MD

+31 (0)43 3881228

L.Bamelis@DMKEP.Unimaas.nl

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre randomised single blind active controlled parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration