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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

Registration date
14/02/2006

Overall study status
Completed

Last Edited
18/08/2009

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] 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

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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
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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