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Efficacy and cost-effectiveness of short-term inpatient psychotherapy (STIP) as compared to outpatient psychotherapy: a randomised clinical trial among patients with personality disorders in the Netherlands

Submission date 08/03/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/03/2006	**Overall study status** Stopped	
Last Edited 05/11/2008	**Condition category** Mental and Behavioural Disorders	

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
NTR583

Study information

Scientific Title

Study objectives
It is expected that STIP shows superior efficacy in terms of faster improvement in the first 12 months of the trial and a higher recovery rate at 24 months of follow-up. In addition, it is expected that the higher direct medical costs of STIP are compensated by higher reduction of indirect medical costs and productivity losses. Therefore, we hypothesise that STIP shows a superior cost-benefit ratio as well.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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

Interventions
Short-term inpatient psychotherapy (STIP) versus 12-month outpatient psychotherapy

This trial was terminated in October 2006:

We aimed to compare Short-Term Inpatient Psychotherapy (STIP) with long-term outpatient Schema-Focused Therapy (SFT). Unfortunately, this trial has failed to succeed due to slow

patient recruitment, a large refusal rate and several methodological reasons. After five months of patient recruitment, we had only been able to include one patient in the study. Eight other patients refused participation in the randomised trial, but were included in a parallel preference trial in which they received the treatment of their choice (either SFT or STIP). An important implication of this research failure may be that a randomised design is not feasible for all scientific studies. Patient preferences play an important role in this matter, especially when huge differences between the treatment conditions exist (for example in treatment length and setting) as in our study. Alternative designs should then be considered.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Symptomatic improvement
2. Structural improvement
3. Functional improvement
4. Quality of life

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/02/2006

Completion date
15/02/2009

Reason abandoned (if study stopped)
We aimed to compare short-term inpatient psychotherapy (STIP) with long-term outpatient schema-focused therapy (SFT). Unfortunately, this trial has failed to succeed due to slow patient recruition, a large refusal rate and several methodological reasons. After five months of patient recruition, we had only been able to include one patient in the study. Eight other patients refused participation in the randomised trial, but were included in a parallel preference trial in which they received the treatment of their choice (either SFT or STIP). An important implication of this research failure may be that a randomised design is not feasible for all scientific studies. Patient preferences play an important role in this matter, especially when huge differences between the treatment conditions exist (for example in treatment length and setting) as in our study. Alternative designs should then be considered.

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of one or more cluster B or C personality disorders or personality disorder not otherwise specified (PDNOS) (as evidenced by a semi-structured interview)
2. Personality pathology as focus of treatment
3. Age at least 18

4. Residing within a 30-mile circle around Centre of Psychotherapy De Viersprong in Halsteren (i. e. Rotterdam, Dordrecht, Breda, Antwerpen, Zeeland)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Insufficient command of Dutch language
2. Severe cognitive impairments
3. Mental retardation or borderline intellectual functioning
4. Severe Axis I comorbidity as indicated by the presence of chronic psychotic disorder, bipolar disorder or substance dependence
5. A history of psychosis
6. Past year treatment history including one of the treatments in the current study AND a clear rationale why repetition of that treatment is contraindicated

Date of first enrolment
15/02/2006

Date of final enrolment
15/02/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Viersprong Institute for Studies on Personality Disorders (VISPD)
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Sponsor information

Organisation
Viersprong Institute for Studies on Personality Disorders (VISPD) (The Netherlands)

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/048jnwk41

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The 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