# Efficacy and cost-effectiveness of Short-Term Inpatient Psychotherapy (STIP) as compared to outpatient psychotherapy: a randomized clinical trial among patients with personality disorders in the Netherlands.

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Ethische beoordeling Positief advies

**Status** Werving tijdelijk gestopt

Type aandoening -

Onderzoekstype Interventie onderzoek

# **Samenvatting**

#### ID

NL-OMON26392

#### **Bron**

Nationaal Trial Register

#### Verkorte titel

N/A

#### **Aandoening**

STIP is a 3-month inpatient program developed 25 years ago in De Viersprong. The program includes (a) group psychotherapy based on psychodynamic and transactional analysis principles; (b) sociotherapy (i.e. general group discussions on living conditions in hospital and at home during weekends); (c) nonverbal therapies (e.g. creative therapy, psychomotoric therapy). Key to the treatment is the integration of all therapeutic activities, including both structured and unstructured elements, in a therapeutic milieu serving to protect the preconditions of therapy (i.e. fostered with rules about being in time, following the program, no alcohol and drugs, respectfulness, openness and reliability). Also the common language of transactional analysis fosters integration. The professional staff consists of one psychiatrist,

one psychotherapist, two psychiatrists-in-training, five sociotherapists or psychosocial nurses, and two nonverbal therapists. Detailed attention is given to manifestations of transference and counter-transference, as well as to parallel processes between staff and patients. The inpatient program is followed by a modular aftercare program including optional occupational reintegration, system therapy, and pharmacotherapy modules. The average duration of the aftercare program is 9 months, so patients in the STIP condition finish treatment approximately 12 months after start.

The outpatient alternatives involve approximately 12-21 months of outpatient psychotherapy with a maximum of 75 one-hour weekly sessions. Two theoretical frames of reference are possible: (1) cognitive-behavioral therapy (CBT) or (2) transference-focused psychotherapy (TFP). These are both state-of-the-art manualized treatments that are widespread throughout the world.

## **Ondersteuning**

**Primaire sponsor:** Psychotherapeutic Centre De Viersprong

Overige ondersteuning: ZonMW

## Onderzoeksproduct en/of interventie

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

- 1. Symptomatic improvement;
- 2. Structural improvement;
- 3. Functional improvement;
- 4. Quality of life.

# **Toelichting onderzoek**

### Achtergrond van het onderzoek

Announcement d.d 23-jan-2007: Stop PSILO trial

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.

### Summary d.d. Jan-2006

Background: The effectiveness of Short-Term Inpatient Psychotherapy (STIP) for a wide range of personality disorders (PDs) has recently been shown by two naturalistic cohort studies. A conservative estimate for the effect size of this 3-month inpatient program ranges from 1.6 to 1.7, which can be considered (very) large as compared to effect sizes reported for alternative treatment programs. As to yet, the clinical utility and cost-effectiveness of STIP still requires to be established by comparison with less intensive (outpatient or day treatment) alternatives in a randomized study design.

Aims: To investigate the (cost)effectiveness of STIP as compared to alternative psychotherapeutic programs designed for the treatment of patients with PDs.

Method: Comparative Randomized Clinical Trial (RCT) among 80 patients with cluster B or C PDs and personality disorder not-otherwise-specified (PDNOS) who are able to cope with the high "pressure" exerted in the inpatient condition. The comparison (control) treatment is 12-month outpatient psychotherapy. The intake team is allowed to determine the theoretical frame of reference (either psychoanalytically or cognitive-behaviorally oriented) in the outpatient setting. Patients will be followed 24-36 months at multiple times of measurement (with intervals of 3-12 mo). The treatment outcome battery includes measures for symptom improvement, structural (personality) change, quality of life, social and occupational functioning, and care consumption. Cost-effectiveness will be computed as the ratio between quality of life improvement (a generic measure of effect), and direct and indirect medical costs.

Relevance: This study is the first to compare inpatient and outpatient alternatives to the treatment of cluster B and C personality disorders and PDNOS, and has relevance to both health care management and policy (cost-effectiveness) and clinical practice (efficacy).

#### Doel van het onderzoek

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 hypothesize that STIP shows a superior cost-benefit ratio as well.

#### Onderzoeksproduct en/of interventie

Short-term inpatient psychotherapy (STIP) and outpatient psychotherapy.

# Contactpersonen

### **Publiek**

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## Wetenschappelijk

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## **Deelname** eisen

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. DSM-IV diagnosis of one or more cluster B or C personality disorders or 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).

# Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 teratment history including one of the treatments in the current study AND a clear rationale why repetition of that treatment is contraindicated.

# **Onderzoeksopzet**

## **Opzet**

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Blindering: Open / niet geblindeerd

Controle: Actieve controle groep

## **Deelname**

Nederland

Status: Werving tijdelijk gestopt

(Verwachte) startdatum: 15-02-2006

Aantal proefpersonen: 80

Type: Verwachte startdatum

# **Ethische beoordeling**

Positief advies

Datum: 30-01-2006

Soort: Eerste indiening

# Registraties

# Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

# Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

# In overige registers

Register ID

NTR-new NL539
NTR-old NTR583
Ander register : N/A

ISRCTN ISRCTN99682667

# Resultaten

## Samenvatting resultaten

N/A