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.

No registrations found.

Ethical review Positive opinion **Status** Suspended

Health condition type -

Study type Interventional

Summary

ID

NL-OMON26392

Source

Nationaal Trial Register

Brief title

N/A

Health condition

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.

Sponsors and support

Primary sponsor: Psychotherapeutic Centre De Viersprong **Source(s) of monetary or material Support:** ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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).

Study objective

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.

Intervention

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

Contacts

Public

3 - Efficacy and cost-effectiveness of Short-Term Inpatient Psychotherapy (STIP) as ... 13-05-2025

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Eligibility criteria

Inclusion criteria

- 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).

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

Study design

Design

Study type: Interventional

Intervention model: Parallel

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Suspended Start date (anticipated): 15-02-2006

Enrollment: 80

Type: Anticipated

Ethics review

Positive opinion

Date: 30-01-2006

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

RegisterIDNTR-newNL539NTR-oldNTR583

Register ID

Other : N/A

ISRCTN ISRCTN99682667

Study results

Summary results

N/A