Implementation of out-patient schema-focused therapy for borderline personality disorder in regular mental healthcare.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22039

Source
NTR

Brief title
N/A

Health condition

Out-patient Schema Therapy for patients with a borderline personality disorder.
Ambulante schematherapie voor patiënten met een borderline persoonlijkheidsstoornis.

Sponsors and support

Primary sponsor: ZonMw Grant application 945-16-313asand GGZinGeest
Source(s) of monetary or material Support: ZonMw Grant application 945-16-313asand GGZinGeest

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the score on the BPDSI-IV, a DSM-IV BPD criteria- based semi structured interview: this 70- item index represents the current severity and frequency of the DSM-IV BPD manifestations. This instrument shows excellent psychometric features (Cronbach's alpha = 0.85, interrater reliability, 0.99; validity and sensitivity to change; Arntz, van den Hoorn, et al., 2003; Giesen-Bloo, Wachters, et al., 2006). Previous research (Arntz, van den Hoorn, et al., 2003; Giesen-Bloo, Wachters, et al., 2006) found a cut-off score (Jacobson & Truax, 1991) of 15 between patients with BPD and controls, with a specificity of 0.97 and a sensitivity of 1.00.

Recovery criterion:

The recovery criterion is, therefore, defined as achieving a BPDSI-IV score of less than 15 and maintaining this score until the last assessment.

Reliable change:

A second criterion is reliable change (Jacobson & Truax, 1991), which reflects individual clinically significant improvement. For the BPDSI-IV, reliable change is achieved when improvement is at least 11.70 points at the last assessment (Giesen-Bloo et al., 2009).

Secondary outcome

Information on demographic factors (age, gender, marital status, education and employment status) will be collected at baseline.

A secondary outcome measure is quality of life, which will be assessed by means of two widely used and psychometrically sound self-report questionnaires: the EuroQol-thermometer and EQ-5D and the World Health Organisation Quality of Life Questionnaire (EuroQol Group, 1990; Dolan, 1997; Brooks, 1996; WHOQOL Group, 1998). The vertical EuroQol-thermometer rating indicates one's experienced level between best (100) and worst (0) imaginable health status. The EQ-5D contains 5 dimensions: mobility, self care, daily activities, pain/discomfort and depression/anxiety. Each dimension is rated at three levels: no problems, some problems and major problems. EQ-5D health states can be converted into utility scores. The WHOQOL is a 100-item self-report questionnaire, and through the domains of physical health, psychological health, environment, personal convictions, social relationships and extent of independency, the WHO concept of quality of life is assessed.
BPD-47, SCL-90, Young Schema Questionnaire.
Other secondary outcome measures are general psychopathologic measures and measures of ST personality concepts, all in self-report format and with robust psychometric properties. These measures include the BPD Checklist on the burden of BPD-specific symptoms (Giesen-Bloo, Arntz, et al., 2006) and the Symptom Checklist-90 for subjective experience of general psychopathology (Derogatis, Lipman, et al., 1973, Arrindell and Ettema (1986). A theory specific instrument is the Young Schema Questionnaire on schemas underlying Young's

theory (Rijkeboer, 2005, Rijkeboer, van den Bergh, et al., 2005; Schmidt, Joiner, et al., 1995; Sterk and Rijkeboer, 1997).

Economic evaluation:

In addition to the clinical evaluation, an economic evaluation will be performed to assess the cost-effectiveness of ST with versus ST without extra phone support outside office hours. In the cost-effectiveness analysis of ST with versus ST without phone support, the difference in costs will be related tot the difference in effectiveness, resulting in an Incremental Cost Effectiveness Ratio (ICER). The base-case cost-effectiveness analysis will be based on two different effectiveness outcomes. First, cost effectiveness will be based on the proportion of patients recovered according to the BPDSI-IV, this reflecting the investment needed to cure one patient. Secondly, cost-effectiveness will be based on Quality Adjusted Life Years (QALY), resulting in costs per QALY. The cost-effectiveness analysis will be based on the principles of a societal perspective using a time horizon of three years. The costs of patients will be monitored by means of a cost-interview that will take place during the patient interview alongside the other measurements. The cost-interview contains items about paid and unpaid work, study, daily activities, family burden, paid help, use of healthcare and social services, use of medication, consumption of alcohol and drugs and out-of-pocket expenses. Also the number of face-to-face and telephone contacts with the study therapists will be registered.

Therapeutic Alliance:

This study will also investigate the quality and the development of the therapeutic alliance as a mediator of change in ST. In the RCT [1] scores for the therapeutic alliance were higher in ST than in TFP. Negative ratings of therapists and patients at early treatment were predictive of dropout, while increasingly positive ratings of patient in the first half of treatment predicted subsequent clinical improvement.(Spinhoven, P., Giesen-Bloo, J. et al., 2007). Working Alliance Inventory (WAI). The WAI (Horvath & Greenberg, 1989) is one of the most commonly used and extensively validated measure of the alliance. It has been found to predict therapy outcome in numerous studies (Martin et al., 2000; Orlinsky et al., 2004). The Dutch version of the WAI consists of three subscales of 12 items each, rated on a 5-point in stead of 7-point Likert-type scale ranging from 1 (“never”) to 5 (“always”). The subscales based on Bordin’s (1979) working alliance theory address agreement about the goals of therapy, agreement about the tasks of therapy, and the bond between the client and therapist. Patients completed the patient form (WAI-P) measuring the contribution of the therapist to the alliance as perceived by the patient and therapists completed the therapist form (WAI-T) in which they rated the contribution of the patient to the alliance. Because of the high intercorrelations among subscales (WAI-P range: .69 - .88; WAI-T range: .67 - .89) subscale mean scores were added together to derive a global score. A higher score on the WAI indicates a higher quality of the working alliance. The internal consistency of the WAI-P was .94 and of the WAI-T .95.
Difficult Doctor-Patient Relationship Questionnaire – Ten Item Version (DDPRQ-10). The

DDPRQ (Hahn, Thompson, Stern, Budner, & Wills, 1990) is a self-report questionnaire, which aims to measure the extent to which patients are experienced as frustrating or difficult in the therapeutic relationship by their doctor or therapist and provoke levels of distress that transcend the expected and accepted level of difficulty. Of the DDPRQ-10 five items are about the therapist's subjective experience (e.g., "Do you find yourself secretly hoping that this patient will not return?"), four are quasi-objective questions about the patient's behavior (e.g., "How time consuming is caring for this patient?"), and one item about symptoms combines elements of the patient's behavior and the therapist's subjective response (i.e. "To what extent are you frustrated by this patient's vague complaints?"). The items are answered on a 6-point Likert-type scale ranging from 1 ("not at all") to 6 ("a great deal"). The total score of the DDPRQ equals the mean of the 10 items. A higher score indicates a higher level of therapist frustration. The internal consistency of the DDPRQ in the current study was .79.

Study description

Background summary

Background:

Schema Therapy (ST) is an integrative psychotherapy based upon a cognitive schema model and aims at identifying and changing dysfunctional schemas and modes through cognitive, experiential and behavioral pathways. It is specifically developed for patients with personality disorders. Its (cost) effectiveness has been demonstrated in a randomized controlled trial [1,2]. However, no other studies have as yet replicated these findings and ST has not been tested in regular mental healthcare settings. This protocol describes a randomized clinical trial on the implementation of ST in the Netherlands.

Methods/Design:

The purpose of this paper is to report the study protocol of a multisite randomized 2-group design, testing the implementation of outpatient schema therapy for borderline patients in regular mental healthcare and determining the added value of therapist telephone availability outside office hours in case of crisis. Patients outcome measures will be assessed with a semi-structured interview and self-report measures on BPD, quality of life and general psychopathology at baseline, 6, 12 and 18 months. Intention-to-treat analyses will be executed with survival analysis for dichotomous variables, and one-sample t-tests and ANCOVAs for continuous variables with baseline as covariate and condition as between group factor. All tests will be two-tailed with a significance level of 5%.

Discussion:

The study will provide an answer to the question whether ST can be effectively implemented and whether phone support by the therapist has an additional value.

Study objective

1. To investigate the implementation of Schema Therapy (ST) in regular mental healthcare and investigate whether its effectiveness and cost-effectiveness is comparable to the original RCT (Outpatient Psychotherapy for Borderline Personality Disorder: A randomized trial of Schema Focused Therapy versus Transference Focused Therapy (Giesen-Bloo et al., (2006).Archives of General Psychiatry, 63, 649-58);

2. To investigate the added value of telelphone support outside office hours, provided by the therapist.

Study design

BPDSI-IV: baseline, 6 months, 12 months, 18 months, follow-up three years, BPD-47, SCL-90, Young Schema Questionnaire, EuroQol, WHO Qol, Cost interview, WAI-T, WAI-P, idem all measures at baseline, 6 months, 12 months, 18 months and follow-up at three years.

Intervention

Schema Therapy with two sessions a week in the first year and one session a week in the second year. 50% of the patients will receive Schema Therapy with extra phone support outside office hours and 50% without extra phone support outside office hours.

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Eligibility criteria

Inclusion criteria

Patients (aged 18-60) are eligible to participate if their main diagnosis is a Borderline Personality Disorder according to the DSM-IV criteria. The Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (SCID-II) (First, Gibbon, et al., 1997; Weertman, Arntz, et al., 2000) will be used for assessing the diagnosis BPD. In addition, the level of symptom severity should be > 20 on the Borderline Personality Disorder Severity Index (BPDSI-IV). (Arntz, van den Hoorn, et al., 2003; Giesen-Bloo, Wachters, et al., 2006). Co morbid axis-I and axis-II disorders are allowed as is medication use.

Exclusion criteria

Patients are excluded from the study if they suffer from one or more of the following disorders: a psychotic disorder (except short, reactive psychotic episodes), bipolar disorder, dissociative identity disorder, antisocial personality disorder, attention deficit hyperactivity disorder, addiction of such severity that clinical detoxification is indicated (after which entering treatment is possible), psychiatric disorders secondary to medical conditions and mental retardation or if they do not have sufficient command of the Dutch language necessary to participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	62
Type:	Actual

Ethics review

Positive opinion

Date:	29-04-2009
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

Register	ID
NTR-new	NL1680
NTR-old	NTR1781
Other	ZonMw : 945-16-313
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Nadort, M., Dyck, R. van, Smit, J. H., Giesen-Bloo, J., Eikelenboom, M., Wensing, M., Spinhoven, P., Dirksen, C., Bleecke, J., Milligen, B. van, Vreeswijk, M. van & Arntz, A. (2009). Three Preparatory Studies for Promoting Implementation of Outpatient Schema Therapy for Borderline Personality Disorder in general mental health care. Submitted Behaviour Research and Therapy.