Group Schema Therapy for Borderline Personality Disorder.

No registrations found.

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

Summary

ID

NL-OMON25917

Source
NTR

Health condition

Borderline Personality Disorder
Borderline Persoonlijkheidsstoornis

Sponsors and support

Primary sponsor: Maastricht University, PO Box 616, 6200 MD Maastricht, the Netherlands.

Source(s) of monetary or material Support: Grants / financial support from: Dutch National Fund of Mental Health (the Netherlands); Else-Kröner Fresenius Stiftung (Germany); Rotary Mental Health (Australia); Netherlands Organization for Health Research and Development (ZonMW) (Netherlands); Bradford District Care NHS Foundation Trust (UK); Institut für Verhaltenstherapie Ausbildung Hamburg (IVAH) (Germany/Greece); South London and Maudsley NHS Foundation Trust (UK); Research Center Experimental Psychopathology (EPP), Maastricht University (the Netherlands, UK).

Central study costs paid by performer.
Local patient care costs covered by mental health care institutes.

Intervention

Outcome measures

Primary outcome

Borderline Personality Disorder Severity Index, mean score.

Secondary outcome

1. BPD-checklist, BSI, GAF, Work;

2. Social Adjustment Scale, Social Occupational Functioning Assessment Scale, Social Adjustment Scale-Self Report;

3. WHOQOL, EuroQol, Happiness Rating;

4. Schema questionnaire, Schema Mode Inventory, Group Climate Questionnaire (GCQ-S).

Study description

Background summary

In an international multicenter RCT two forms of group Schema Therapy for Borderline Personality Disorder will be compared to the usual treatment provided to these patients. Effectiveness, cost-effectivenss (with full economic analysis, incl cost-utility and cost-effectiveness), and stakeholders'opnions will be assessed. A secondary aim is to find out what format of group Schema Therapy is to be preferred: mainly group treatment, or the combination of group and individual treatment. the study will take place in at least 14 centers in the Netherlands, Germany, USA, UK, Sweden, Ireland and Australia. At each center min. 32 participants will be recruited, and randomized over the two forms of group Schema Therapy and treatment as usual. Experimental treatment will be provided for 2 years, and a last follow-up assessment will be done at year 3.

Study objective

Group Schema Therapy is more effective and more cost-effective than treatment as usual for Borderline Personality Disorder.

Two subforms of group Schema Therapy (with different ratio of group and individual sessions) will also be compared, and stakeholders' opinions will be investigated (patients, therapists).

Study design

Baseline, 6,12,18, 24 months and 36 months.

Intervention

Experimental A: 118 group Schema Therapy sessions over 2 years with max. 17 individual sessions.

Experimental B: 63 group Schema Therapy over 2 years with max. 61 individual sessions.

Control: Treatment as usual - the standard treatment given for that patient at the treatment center.

Contacts

Public
University of Amsterdam
Arnoud Arntz
Maastricht 6200 MD
The Netherlands
+31 20 525 6810
Scientific
University of Amsterdam
Arnoud Arntz
Maastricht 6200 MD
The Netherlands
+31 20 525 6810

Eligibility criteria

Inclusion criteria

1. Age 18-65 year;

2. Primary DSM-IV diagnosis of BPD (assessed with the SCID-II interview);

3. BPD severity above 20 on the BPDSI interview;

4. Willingness to participate in the study (informed consent procedure);

5. Ability to participate in (group) treatment and research for 2 years (e.g., no plans to move to other city).

Exclusion criteria

1. Lifetime psychotic disorder (short stress-related episodes are allowed, as described in DSM-IV BPD criterion 9);

2. IQ < 80 (in case of suspicion of low IQ, to be assessed with full intelligence test);

3. Unable to read, speak, or write the language used at the site (in case of suspicion an official language test is to
be used);

4. ADHD (when suspected on basis of self-report for the KID-SCID is used to assess ADHD);

5. Bipolar disorder type 1 (SCID-1);

6. Dissociative Identity Disorder (confirmed by senior investigators);

7. Full or sub-threshold (defined as one less than the number of criteria to qualify for the diagnosis) narcissistic or antisocial personality disorder (SCID-2);

8. Substance dependence needing clinical detox (after detox and 2 months sobriety can be included);

9. Serious and/or unstable medical illness;

10. Previous schema therapy of more than 3 months duration.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2010
Enrollment:	448
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Pseudonymised individual participant data that underlie the results may be made available for researchers upon reasonable request, which must include a protocol and statistical analysis plan and not be in conflict our prespecified publication plan. The request should include a guarantee of compliance with the EU and participating countries' General Data Protection
Regulations given the privacy sensitive character of the data. Data and a data dictionary will be made available after publication, for at least 5 years. Requests for data sharing will be considered by the study board. Requests should be directed to a.r.arntz@uva.nl; requestors will need to sign a data access agreement.

Ethics review

Positive opinion

Date:	25-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43782
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2266
NTR-old	NTR2392
CCMO	NL28016.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43782

Study results

Summary results

Wetzelaer, P., Farrell, J., Evers, S.M.M.A., Jacob, G., Lee, C.W., Brand, O., van Breukelen, G., Fassbinder, E., Fretwell, H., Harper, R.P., Lavender, A., Lockwood, G., Malogiannis, I.A., Schweiger, U., Startup, H., Stevenson, T., Zarbock, G., & Arntz, A. (2014). Design of an international multicentre RCT on group schema therapy for borderline personality disorder. BMC Psychiatry, 14:319. DOI: 10.1186/s12888-014-0319-3