

Group Schema Therapy for Borderline Personality Disorder.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25917

Bron

NTR

Aandoening

Borderline Personality Disorder
Borderline Persoonlijkheidsstoornis

Ondersteuning

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

Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Borderline Personality Disorder Severity Index, mean score.

Toelichting onderzoek

Achtergrond van het onderzoek

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-effectiveness (with full economic analysis, incl cost-utility and cost-effectiveness), and stakeholders' opinions 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.

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	29-06-2010
Aantal proefpersonen:	448
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

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.

Ethische beoordeling

Positief advies	
Datum:	25-06-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43782
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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