Schema Therapy for Couples (ST-C) with (one or both having) a Personality Disorder: a pilot study.

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Hypothesis 1. The slopes of improvement are significantly stronger during ST than during control conditions (baseline, ST-preparation, communication training, follow-up). Hypothesis 2. The slopes of improvement in the sequence ST - Communication...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24101

Bron
NTR

Verkorte titel
ST-I/C

Aandoening

Not applicable

Ondersteuning

Primaire sponsor: PsyQ Amsterdam (Parnassia Group)
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome will be measured with the Visual Analog Scale (VAS). With the VAS negative (core) beliefs partners have about themselves and each other will be measured on a weekly basis. This will lead to two scores: the average score on negative self beliefs and an average score on negative beliefs about the other.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a first pilot of the addition of schema therapy (ST) based couples therapy to individual ST for patients with personality disorder (PD) according to DSM-5 criteria. The prevalence of severe relationship problems with the partner is common in PD, and although addressing such problems as part of the treatment package for PD seems obvious, no research has documented the feasibility and effects of such an approach. Models have been proposed, but never formally put to the test. The current study tests the effects of adding a ST-based couples module to a regular course of individual ST for PD. By using a multiple baseline case series design, with a crossover of two types of couples therapy, and comparing the short-term effects of the module to those of non-ST based usual couples therapy (communication training), baseline (wait), and ST-preparation, the following questions are addressed: 1. Does the experimental module have stronger effects than baseline, ST-preparation, and communication training on outcomes related to partner-relationship problems and individual problems? 2. Is the order couples-ST-communication training superior to the opposite order?
The primary outcome are idiosyncratic beliefs about (i) the partner and (ii) the self, weekly rated by both partners on visual analogue scales VAS). The secondary outcomes include: The ARE (measuring the security of the attachment bond with the partner); the Daily Coordination Scale (measuring the degree to which partners experience their daily interactions as smooth or as difficult).
Effects on PD-pathology will be documented with the ADP-IV but this instrument is not used for testing the hypotheses, as it is not suitable for assessing short-term changes. SMI-2 and the YSQ-3SF will be used for the patient for the case conceptualisation, as part of the ST-I. Sessions will be video recorded and a random selection will be checked for adherence by an independent rater. Tapes will be stored according to the rules of the AVG and research.Twelve non-borderline PD patients and their partners will participate, recruited from the regular stream of patients at the PsyQ site. N=12 yields 80% power to detect a large effect size of Cohen's d = .89 at 5% significance level. There will be two primary outcomes as a result of the measurement of two kinds of beliefs.1. The idiosyncratic dysfunctional beliefs partners have about themselves (the core beliefs) and 2. The dysfunctional beliefs they have about each other. Both groups of beliefs will be assessed with Visual Analog Scales (VAS) to be measured during the whole period of research. The 1-10 beliefs will be collected in a pre-interview by the researcher. Partners will be asked to rate their beliefs weekly. The VAS will range from 0-100. The scores on the VAS for corebeliefs will be averaged as will be the scores for beliefs about the partner. These averaged scores will be separately analyzed by mixed regression separately for PD-patients and for their partners. The covariance structure for the

repeated part will be determined on the basis of the best fitting structure of AR1, ARMA11 or CS models. The fixed part will contain dummies for treatment condition (baseline, ST preparation, ST, communication training, booster sessions). Time will be modeled by (i) a general linear effect of time, and (ii) a (centered) linear time within treatment condition effect. Non-significant time-effects will be deleted backwards. For the test of effect of order on communication training effects, order and its interactions will be added to the model. In case the distributions are not normal, appropriate distributions will be chosen.
A similar approach will be used for the secondary outcomes, except that time within treatment condition is not modelled given the lack of repeated assessments of these during these periods.
Participants have the right to leave the study at any time, without losing the possibility to continue their treatment at PsyQ. Participants will be asked to rapport to the researcher the start of using or changing psychopharmacological treatment during the study. Inclusion criteria: Primary diagnosis of Cluster-C, Paranoid, Narcissistic, Histrionic Personality Disorder or OSPD, according to the criteria of DSM-5, assessed with the SCID-5-P (patient); Age 18+ (both); Ability to understand, read, write and speak Dutch(both). Exclusion criteria : DSM-5 substance use disorder, severity level moderate or severe (defined by 4 or more symptoms). (After 6 weeks of abstinence participation is possible(both); Comorbid psychotic disorder (both); DSM-5 Bipolar disorder, type 1 (current or in the last year;both); Comorbid Schizotypal-, Schizoid-, Borderline, or Anti-social PD(both); Acute relationship crisis with acute threat of divorce or splitting up (both); Acute suicide risk (both); Severe brain damage or degenerative cognitive disturbances like Alzheimer, Parkinson etc.or IQ < 80 (both); ST of any kind in the past year (both); Patients or their partners should not start, or plan to start, any form of psychological treatment or medication during screening or during the study's waitlist or treatment period. Medication should be on a stable level for 3 months, if not stopped. (In case patient and her or his partner receives non-PD focused supportive treatment, this can be continued during the waiting period, but not during the study treatment) (both); Not being able to plan therapy sessions of 60 minutes (ST-C, booster and communicationtraining sessions) and/or 45 minutes (ST-I) within the treatment period (both); Travel time to treatment location > 1 hour (both); Partner has PD and wants only to participate in ST-C, refuses to participate in ST-I (both). The results of this pilot study will be disseminated in the scientific community by publication of an article. Time Schedule: Sept/Oct. 2020-Dec. 2024.

Doel van het onderzoek

Hypothesis 1. The slopes of improvement are significantly stronger during ST than during control conditions (baseline, ST-preparation, communication training, follow-up).
Hypothesis 2. The slopes of improvement in the sequence ST - Communication Training are significantly stronger than in the opposite sequence.

Onderzoeksopzet

In order A the assessments will be: at 1. at start of wait (week 6-11); 2. at start of the preparatory ST sessions (week 0); 3. at start of the 12 weeks ST-C/-I treatment period (week 6); 4. halfway the ST-C/-I treatment period (week 12); 5. at start of the communication skills

training (week 18); 6. at start of the 5 monthly booster sessions (week 24); 7. at the end of the booster sessions/ start of the therapy less period of 1 year (week 46); and 8. at 1 year follow-up (1 year after week 46).

In order B the assessments will be: at 1. at start of wait (week 6-11); 2. at start of the communication skills training (week 0); 3. at start of the preparatory ST-period (week 6); 4. at start of the 12 weeks ST-C/-I treatment period (week 12); 5. halfway the 12 weeks ST-C/-I treatment period (week 18); 6. at start of the 5 monthly booster sessions (week 24); 7. at the end of the booster sessions/ start of the therapy less period of 1 year (week 46); and 8. at 1 year follow-up (1 year after week 46).

At the start of the wait period, start of the preparatory-period, end of the booster session period and end of the whole treatment trajectory, the ADP-IV will be used for the patient to assess changes in personality characteristics.

Preliminary to gathering all data at the start of 2022, the research data, collected so far, will be analyzed. The results of the interim analysis won't be shared with third parties. The influx of patients, after the interim analysis, will be continued until N=12 is reached, i.e. the aim remains to finish the research.

Onderzoeksproduct en/of interventie

The study is a Multiple Baseline Case Series Study with N = 12 couples. The study has six different baseline lengths: 6, 7, 8, 9, 10 and 11 weeks. In each baseline length there will be 2 couples to be assigned at random, for each of the two treatment orders, one couple. After finishing the baseline condition, patients will be randomly allocated to two different treatment orders.
Order A starts with 6 weeks of preparatory (prep) sessions ST. Of these 6 sessions, 3 will be for the patient and 3 for the couple, together. After the preparatory sessions the therapy continues with 12 weeks of Schema Therapy for Couples (ST-C). During the period of 12 weeks in which the patient and his or her partner gets ST-C, the patient also follows individual Schema Therapy (ST-I) on a weekly basis with the same therapist as the one who provides the ST-C. The therapy continues with 6 sessions of communication training for the couple following the communication training protocol. After having finished this, a period of 5 booster sessions, one session monthly, follows for the couple. This brings the amount of sessions for the patient at 41 (6 prep, 12 ST-C,12 ST-I, 6 communication, 5 booster).
Order B starts with the 6 weeks communication skills training protocol, followed by 6 sessions in 6 weeks of preparation sessions ST (prep-sessions; same set up as in condition A), 12 weeks ST-C protocol (including 12 sessions ST-I for the patient, as in condition A), 5 booster sessions (same set up as in condition A).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Personality Disorder according to the criteria of the DSM-5 and as measured using the SCID-5-P
- Age 18+
- Ability to understand, read, write and speak Dutch or English

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- DSM-5 alcohol or drug dependence. (After 3 months of abstinence participation is possible).
- Comorbid psychotic disorder
- DSM-5 Bipolar disorder, type 1 (current or past)
- Schizo-typical-, Schizoid-, Anti-social PD
- Borderline personality disorder patient and or partner
- Autism Spectre Disturbance (ASD)
- Acute relationship crisis with acute threat of divorce or splitting up
- Acute suicide risk
- Born with brain damage
- Degenerative cognitive disturbances like Alzheimer, Parkinson etc.
- IQ < 80
- Schema Therapy of any kind (e.g., individual, group, inpatient, outpatient, day treatment) in the past year.
- Patients or their partners should not start with any form of psychological treatment or medication during screening or during the study’s treatment, waitinglist period or till a year

after end of last boostersession. Medication should be on a stable level for 3 months, if not stopped. (in case patient and or his partner receives non-PD focused supportive treatment, this can be continued during the waiting period, but not during the study treatment).
- Not being able to plan therapy sessions of 60 minutes (ST-C, boostersessions and communication training sessions) and/or 45 minutes (ST-I) within the treatment period.
- Moving house plans to outside the agglomeration of Amsterdam.
- Partner has PD and wants only to participate in ST-C, refuses to participate in ST-I.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8906
Ander register	Local Ethics Review Board University of Amsterdam : 2020-CP-12331

Resultaten