The Lucy Trial: Legitimizing Using Childhood memory rescripting early in the first Year

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

Samenvatting

ID

NL-OMON29642

Bron
NTR

Verkorte titel
LUCY

Aandoening

The present study focuses on the treatment of patients with borderline personality disorder.

Ondersteuning

Primaire sponsor: No external funding. This study is supported by the participating mental health institutes and the Department of Clinical Psychology, University of Amsterdam
Overige ondersteuning: Initiators (No external funding).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is change in the severity and frequency of the DSM-5 BPD manifestations (BPDSI-IV, total score; Arntz et al., 2003; Giesen-Bloo, Wachters, Schouten, & Arntz, 2010). This outcome measure is frequently used in other studies of ST: Giesen-Bloo et al. (2006), Van Asselt et al. (2008), Nadort et al. (2009), and Wetzelaer et al. (2014). This interview yields dimensional total severity scores, as well as dimensional scores per criterion, and diagnostic status.

Toelichting onderzoek

Achtergrond van het onderzoek

Schema Therapy (ST) is an effective treatment for Borderline Personality Disorder (BPD). In ST Imagery Rescripting (ImRs) is a technique for the treatment of adverse childhood experiences such as emotional abuse and neglect, abandonment, social exclusion, physical abuse, sexual abuse, and bullying. Current ST protocols prescribe trauma treatment to be done in the middle of treatment (Arntz & van Genderen, 2011).

By doing ImRs, the therapist makes the patient experience that his /her needs are met, in contrast to what patients experienced in the past. We hypothesize that recovery benefits from these positive corrective experiences. In addition to a direct effect of ImRs on schemas underlying BPD, we expect that the working alliance with the therapist who meets the patient's needs during ImRs will improve, which could possibly lead to secure attachment. When this technique is applied early on in therapy, it may therefore lead to a faster decrease of the borderline manifestations.

The central subject of this study is therefore to test whether the effect of trauma treatment (by imagery rescripting) early in therapy positively impacts the course of BPD manifestations during ST. When early application of ImRs leads to a faster decrease of BPD manifestations, the treatment of BPD patients might be shortened. Early ST-protocols prescribed a duration of 3 years, which has already been decreased to 2 years, and perhaps this can be even further shortened.

An important reason to postpone trauma processing to the middle phase of ST is that the therapeutic relationship is not yet strong enough and the patient not yet ready (Arntz & van Genderen, 2011). If correct, starting trauma processing early in treatment would lead to increased dropout from treatment. A second objective of the current study is therefore to investigate whether trauma processing early in treatment leads to increased dropout from treatment.

A third question is about the working relation with the therapist, reported by patient. Does early application of ImRs positively affects the therapeutic relationship? Clinical observations suggest that by doing ImRs patients get a feeling of being seen and listened to. With ImRs therapists meet the patients' needs, so the expectation is that early application of ImRs leads to patients reporting a better working relationship compared to late application.

A fourth question that will be examined in this research is about the decrease of the disconnection and rejection domain: abandonment/instability, mistrust/abuse, emotional deprivation, defectiveness/shame, social isolation/alienation after the ImRs phase. During ImRs, therapist meets the needs of the patient. Feeling this early in therapy might help them with their emotional deprivation schema. The expectation is that early application of ImRs will lead to a faster decrease in emotional deprivation schema than later application.

Lastly, the effects of ImRs on a set of secondary outcomes will be explored. These include general functioning, PTSD-symptoms, general psychopathological complaints, quality of life, happiness, schemas and schema modes.

Study design: The study design is a randomized controlled intervention study.

Study population: The target group consists of adult patients (18-65) with a primary diagnosis of BPD.

Intervention: treatment will consist of a combination of individual sessions and group sessions with nine patients and will have a maximun duration of 25 months. In the individual therapy there are 2 conditions, which participants are randomly assigned to. Condition A: patients will start with ImRs only in months 2-4. Condition B: patients have schema therapy as usual (no ImRs allowed during months 2-4).

Main study parameters: The primary outcome measure is change in the severity and frequency of the DSM-5 BPD manifestations (BPDSI-IV, total score; Arntz et al., 2003; Giesen-Bloo, Wachters, Schouten, & Arntz, 2010).

Prior to randomization, patients will be assessed at baseline. After the baseline assessment, patients will complete at 4, 8, 12, 18, 24, and 36 months after the start of the treatment (group sessions) a battery of questionnaires and interviews. Each assessment will take approximately 2.5 hours to complete. There are no direct risks involved for patients involved in this study. Patients will receive an evidence-based treatment. In addition, patients will receive a treatment they probably would receive even if they did not participate in the study. Participating in interviews and filling out questionnaires is often part of centers’ regular practice and does not involve specific risks.

Doel van het onderzoek

The primary aim of the study is to examine the effects of trauma treatment early on in schema therapy for patients with BPD on the decrease of BPD manifestations. Hypothesis:

1. The scores of the BPDSI of patients in condition A (starting with ImRs during months 2-4) will have a steeper early decrease compared to the patients in condition B (ST as usual).

The secondary aims of the study include to test whether or not early ImRs leads to increased dropout from treatment, whether early ImRs causes an improvement in the therapeutic alliance, and whether early ImRs leads to an accelerated reduction of the emotional deprivation schema.

Hypotheses:

2. There will be more drop out with early application of ImRs than with usual ST.

3. Patients in the condition with early ImRs will report a better working alliance compared to those in usual ST.

4. Patients in the condition with early ImRs will have a faster decrease of schemas of the disconnection and rejection domain: abandonment/instability, mistrust/abuse, emotional

deprivation, defectiveness/shame, social isolation/alienation measured by the YSQ than those in usual ST.

Lastly, it will be explored whether early ImRs has a positive effect on a range of secondary outcomes, compared to usual ST.

Onderzoeksopzet

The first assessment will occur after inclusion and before randomization. The subsequent six assessments will occur at 4, 8, 12, 18, 24 and 36 months after the start of the treatment (group sessions).

Onderzoeksproduct en/of interventie

-ST is based on an integrative cognitive model, combining cognitive behavior therapy with attachment theory, psychodynamic concepts, and experiential therapies (Jacob & Arntz, 2013). Central concepts are early maladaptive schemas and schema modes. Early maladaptive schemas can be defined as broad, pervasive patterns of thoughts, emotions, memories, and cognitions regarding oneself and relationships with others, developed during childhood (Young et al., 2003). A schema mode refers to an activated set of schemas and the associated coping response (i.e., overcompensation, avoidance, and surrender), and describes the momentary emotional, cognitive, and behavioral state of the patient. ST aims to replace the maladaptive schemas of patients with BPD by more healthy schemas.

Treatment will consist of a combination of individual sessions and group sessions with nine patients. ST has a maximum duration of 25 months and starts with a pretreatment program of four weeks consisting of several (approximately three) individual sessions. The main treatment consists of a treatment phase and a maintenance phase. The treatment phase has a maximum duration of 18 months and consists of weekly group (90 minutes) and individual (45 minutes) psychotherapy for a period of 12 months, continued by weekly group psychotherapy and biweekly individual psychotherapy for a period of six months. The maintenance phase consists of biweekly individual psychotherapy for a period of three months, continued by three months of one individual session each month.Randomization will take place in the individual process which participants are randomly assigned to. Condition A (starting with only ImRs during months 2-4) compared to condition B (patients will get ST as usual, ImRs not allowed in months 2-4).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Borderline PD based on the DSM-5 as primary diagnosis (assessed with SCID-II or SCID-5-P) and a score of 20 or above on the Borderline Personality Disorder Severity index (BPDSI).

- Age 18-65

- Ability to understand, read, write and speak Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Alcohol or drug dependence needing clinical detox. (After 3 months of abstinence participation is possible).

- Comorbid psychotic disorder (when > 1 year in full remission inclusion is possible).

- Antisocial personality disorder with a history of physical interpersonal violence in the last two years.

- DSM-5 Bipolar disorder, type 1 (current or past) . If there has been no manic episode the last year patients will be included.

- Acute suicide risk

- IQ < 80

- Schema Therapy of any kind (e.g., individual, group, inpatient, outpatient, day treatment) in the past year.

- Patients should not start with any form of psychological treatment or medication during screening or during the study's treatment or waitlist period. Medication should be on a stable level for 3 months, if not stopped. (Non-PD focused supportive treatment may be continued during wait and screening, but not during the study treatment and study 1-year follow-up period)

- Not able to plan (group) therapy sessions of 90 minutes and individual sessions of 45-60 minutes once a week during 2 years within the treatment period.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-08-2019
Aantal proefpersonen:	73
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

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	NL7965
Ander register	Ethics Review Board (FMG-UvA) University of Amsterdam Source ID 2019-CP-10845 : 2019-CP-10845

Resultaten

Samenvatting resultaten
N/A