Treatment of Multiple traumatized Adolescents

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26367

Bron
Nationaal Trial Register

Verkorte titel
The MARS-study

Aandoening

PTSD, Complex PTSS, child abuse, adverse childhood experiences

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of Post Traumatic Stress Disorder (PTSD) symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Because child abuse often has devastating effects on many aspects of a child's life, treatment to deal with the consequences such as Post Traumatic Stress Disorder (PTSD) is extremely important. But, there are two problems with regard to the psychological treatment. Firstly, little is known about the effectiveness of treatment of adolescents with child abuse related PTSD. Secondly, recommendations of (international) guidelines on treating child abuse related PTSD proves contradictory.

One group of colleagues advocates that a stabilization phase is necessary to work on improving emotion regulation and interpersonal skills, which are hypothesized to be underdeveloped as a result of chronic stress in childhood.

The second group has doubts about these assumptions. The underlying empirical evidence is weak. Based upon recent treatment efficiency research in adults with PTSD due to childhood abuse, it has been suggested that emotion regulation and interpersonal regulation skills will automatically improve as a result of successful trauma-focused treatment. Adding a specific skills training (or 'stabilization') phase would, in their view, lead to unnecessarily long, expensive and unstructured treatment pathways, with less focus on the core problem, namely processing of the traumatic memories, thereby reducing post traumatic stress symptoms.

Objective: The randomized controlled trial (RCT) will be performed at Karakter Child and Adolescent's Psychiatric Hospital and will be implemented at all locations, spread out over three provinces in The Netherlands. The project aims:

1. To explore the necessity and efficacy of a preparatory skills training in the treatment of patients suffering from PTSD due to multiple interpersonal traumatization. The main objective is to demonstrate that the new therapy (EMDR-only) is non-inferior to the standard phase-based therapy (STAIR-EMDR) based on the change of the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA). If EMDR proves to be as effective as EMDR preceded by STAIR-A, it opens the way to a significantly reduced treatment duration.

Secondary, this project aims

1.2. To investigate whether a phase-based treatment approach will lead to a significantly better outcome than the direct trauma-focused condition in terms of symptoms of Complex PTSD (emotion regulation, interpersonal problems and self-esteem), comorbid symptoms and drop-out rate. An additional aim is to investigate potential moderators and predictors of drop-out or treatment (non-)response. To this end, we hypothesize that signs of affect dysregulation and having interpersonal problems at the start of therapy will be related to

worse outcome in the direct traumafocused condition (e.g., Cloitre, Petkova, Su, & Weiss, 2016; Dorrepaal et al., 2014).

2.3. To explorer gender differences related to treatment response. We know that there are significant differences in the ways that female and male adolescents think, act, and relate. Furthermore, treatment results may very well depend on the gender of the patient. In all analyses, we will take a close look at the results with regard to gender differences.

3.4. To investigate whether reduction of posttraumatic stress symptoms in the adolescent is related to reduction in self-reported parental/caretaker stress, since one common clinical assumption states that therapists should focus on managing parental stress before starting PTSD treatment with adolescents.

Study design: This study entails a randomized controlled trial with two arms; a phase-based treatment condition (STAIR-A followed by EMDR) versus a trauma-focused treatment condition (EMDR only).

Study population: Participants are individuals between 12 and 18 years, meeting the criteria for the diagnosis PTSD (according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition; APA, 2013), and who are victims of repeated sexual and/or physical abuse in childhood. Patients will be recruited from different departments of Karakter, a large mental health organization for children in the Netherlands.

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Intervention: In the STAIR-EMDR condition, patients receive twelve sessions of skills training (STAIR-A), followed by twelve sessions of EMDR therapy. In the other condition, patients receive twelve sessions of EMDR therapy. All sessions take 75 minutes and are provided by the same therapist for every patient. v

Main study parameters/endpoints: In this trial, the objective is to demonstrate that participants receiving EMDR-only is non-inferior to the standard therapy (STAIR-EMDR). The main study parameter is based on the CAPS-CA, the largest clinically acceptable effect to be able to declare non-inferiority is a change on the CAPS-CA of 1.6 points

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants and their parents/caregivers in both treatment groups are expected to highly benefit from their treatment. The risks associated with participating in the study are considered negligible and the burden associated with participation is estimated to be low.

Doel van het onderzoek

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Onderzoeksopzet

EMDR-only condition:

Baseline (T1), after 12 sessions (T3), follow-up after 6 months (T4)

STAIR + EMDR Condition:

baseline (T1), after 12 sessions STAIR (T2), after 12 sessions EMDR (T3), follow-up after 6 months (T4).

Onderzoeksproduct en/of interventie

Skills Training in Affective and Interpersonal Regulation (STAIR-A):

In Phase I of the phase-based treatment we will use an adapted version of the Skills Training in Affective and Interpersonal Regulation for Adolescents (Cloitre et al., 2014; Dutch version Bijen et al., 2017). The goals of this treatment are to address problems in affect and interpersonal regulation as they negatively impact on daily life, and to prepare the patient for the effective and successful use of trauma-focused treatment. The program exists of twelve 75-minutes-sessions, with different topics (e.g., distress tolerance, different kind of role-plays, labelling and identifying feeling, enhance adequate coping strategies, train self-soothing skills, etc.). All STAIR-A sessions have an identical format and structure: psycho-education about the rationale and goals of interventions, skills acquisition, skills application and practice.

EMDR therapy:

EMDR therapy is a protocolled evidence-based trauma treatment, aimed to resolve symptoms resulting from disturbing or unprocessed life experiences (Shapiro, 2001). The treatment starts with recalling the traumatic memory and selecting the most disturbing part of this memory with the associated dysfunctional thoughts and feelings about oneself. While concentrating on the traumatic memory, the patient’s working memory is taxed by employing eye movements for about 30 seconds. The therapist will ask the patient to follow his fingers, while encouraging to go with every association that comes up in his or her mind. Repeatedly the patient is asked to report what comes to mind, which may be cognitive, emotional, somatic or imagistic experiences. After some sets of eye movements, the patient is asked to report a SUD (Subjective Unit of Disturbances) between 0 and 10, until the disturbance related to the memory reaches a SUD of zero and positive beliefs are rated strong on a VoC (Validity of Cognition, between 1 and 7). A wide array of studies supports the working memory account as a mechanism explaining the treatment effects. Recalling a traumatic episode depends on working memory resources, which are limited. If a second task, taxing the working memory, is executed during recall of the traumatic memory, less resources will be available for recalling the traumatic episode. Because performing both tasks at the same time, the memory becomes less vivid and emotional, and is stored in this new way, the negative cognitions lose believability and opposed to this, positive cognitions become increasingly believable (De Jongh & ten Broeke, 2011).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Meeting the criteria for PTSD, assessed with the Clinical-Administered PTSD Scale for Children and Adolescents (CAPS-CA)

2. Reporting a history of repeated physical and/or sexual abuse and/or domestic violence by a caretaker, family member, or person in authority

3. Availability of a non-offending adult caregiver for the treatment, as the inclusion of a caregiver is part of the treatment design

4. Motivation and ability of the patient and the caregiver to attend weekly treatment sessions

5. Safe living circumstances to minimize the risk of retraumatization during the study

6. Patients' and caregivers' have sufficient command of the Dutch language to participate in the treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute suicidal behavior or suicidal ideations requiring immediate hospitalization

2. Severe head trauma indicated by a score <9 on the Glasgow Coma Scale [17] as known from the patient’s medical history, to avoid brain dysfunction or retrograde amnesia of the traumatic event due to head injury

3. Concurrent psychotherapy during the study

4. Current severe mental disorder in the patient’s main caregiver (as evaluated by the responsible clinician), such as psychosis, severe episode of depression, or severe substance abuse, to assure the ability of the caregiver to participate in the treatment

5. A sibling of the patient already participating in the study (to avoid the transference of treatment effects if siblings are randomized in different conditions)

6. Intellectual disabilities (IQ < 70)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2018
Aantal proefpersonen:	136
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-02-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44346
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6846
NTR-old	NTR7024
CCMO	NL62839.091.17
OMON	NL-OMON44346

Resultaten

Samenvatting resultaten
Not Applicable.