The STAP-study: Skills training and traumafocused treatment in multiple interpersonal traumatized adolescents with PTSD.

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON44346

Source
ToetsingOnline

Brief title
The STAP-study

Condition

- Anxiety disorders and symptoms

Synonym
PTSD and trauma

Research involving
Human

Sponsors and support

Primary sponsor: Karakter kinder- en jeugdpsychiatrie

Source(s) of monetary or material Support: ZonMw praktijkfellowship GGZ

Intervention

Keyword: Child abuse, EMDR, PTSD, Randomized Controlled Trials

Outcome measures

Primary outcome

Score on the clinical PTSD interview: CAPS-CA.

Secondary outcome

Vragenlijsten: RCADS, RSES, ECR-RC, DERS, CPTCI, CBCL, Y-OQ-30, OBVL.

Study description

Background summary

Epidemiological research shows that 34 out of 1000 Dutch children are victims of child abuse (Alink et al., 2012). This number implies that annually more than 100.000 children deal with chronic stress due to domestic violence, physical abuse, emotional neglect and/or sexual abuse. As a result, these children face an increased risk of developing medical problems later in life such as obesitas, diabetes, cardiovascular problems, sexually transmitted diseases, and COPD (Dube et al., 2003). They also more often face psychiatric problems such as mood and anxiety disorders, psychosis, personality disorders, posttraumatic stress-disorder (PTSD), somatic disorders, and developmental disorders such as ADHD (Fergusson, McLeod & Horwood, 2013). In addition, several studies show that children who are a victim of child abuse show a higher rate of drop out at school (Porche et al., 2011). They also develop more often problems with substance use abuse (Fergusson, McLeod & Horwood, 2013) and face difficulties in participating in society. The distress that results from child abuse is proven to be harmful for the child*s development, and therefore, ending these situations and treating the impact of chronic trauma is pivotal.

Child abuse related PTSD is prevalent in youth utilizing inpatient and outpatient mental health services (Mueser & Taub, 2008). As described, child abuse is also associated with increased rates of major depression, anxiety disorder, suicidal ideation, suicide attempts, alcohol dependence, and drug dependence later in life (Fergusson, McLeod & Horwood, 2013). It has been found that trauma-related problems are not identified and addressed well in early adolescence; changing cognitive, behavioral and emotional patterns become

increasingly difficult later in life (Ford, 2009). Furthermore, the adverse childhood experiences-studies (Felliti et al., 1998) found the higher the Adverse Childhood Experiences (ACE) score, defined as the amount of ACE*s, the greater the risk of experiencing poor physical and mental health, and negative social consequences later in life. On top of this, child abuse victims are at increased risk for revictimization (Benjet et al., 2015). Theory and research suggest that PTSD may mediate the relationship between child abuse and later interpersonal violence. Revictimization is one of the most troubling outcomes associated with child abuse, because later victimization is likely to compound or exacerbate the effects of prior abuse experiences (see Classen, Palesh, & Aggarwal, 2005, for a review). To help break the cycle, PTSD should be treated as early as possible with the most effective methods available.

Recent RCT*s show that both EMDR Therapy and Trauma-focused Cognitive Behavioral Therapy (TF-CBT) are effective in the treatment of children and adolescents with PTSD (Diehle et al., 2014). Both interventions are included in the National Guidelines of Anxiety Disorders (Nationale Richtlijn Angststoornissen, Balkom et al., 2013). Nevertheless, in practice, direct trauma treatment with a primary focus on reducing PTSD symptoms, for child abuse victims is indicated in a highly restrained order (Bicanic, de Roos, Beer, & Struik, 2016) for various reasons such as fear of therapists to possibly dysregulate their patients when exposing them to traumatic memories. This has recently led to the development of several phase-based treatment models. Meaning that patients are first taught to stabilize themselves through skills training before focusing on reprocessing the trauma (Cloitre et al., 2012; Gudino et al., 2014, Dorrepaal e.a., 2015) which is in line with several international guidelines, such as the International Society for Traumatic Stress Studies (2012) and the European Society for Trauma and Dissociation (2015). However, convincing evidence for there is lacking (Bicanic et al., 2015; De Jongh et al., 2016).

Stabilizing patients through skills training may have some disadvantages. For example, this may entail an elevated risk that patients suffer longer than necessary from symptoms that could have been treated effectively with a traditional evidence-based trauma-focused therapy (see De Jongh et al., 2016). Furthermore, if the first phase of the phase-based treatment protocol is indeed redundant, incorporation of a skills training would unnecessarily lengthen therapy, thereby increasing the likelihood of dropping-out, particularly if this, in the patient*s view, no longer contributes to the intended treatment results. In addition, patients may get the impression that the therapist is unwilling or unable to listen to the patient*s story for fear of being exposed to details of patients* traumatic memories, which may adversely affect the therapeutic relationship and self-confidence of the patient.

Moreover, some assumptions in favor of phase-based trauma treatment do not match with recent findings from research in adult trauma treatment. For example, there is evidence to suggest that adults with abuse related PTSD in

combination with a psychotic disorder (van den Berg et al., 2015), a personality disorder (Raabe et al., 2015) or dissociative symptoms (Van Minnen et al., 2016) can be treated effectively and safely by trauma-focused interventions without a preparatory period of skills training. These findings resulted in a discussion about the validity of the international guidelines for treating complex PTSD (see De Jongh et al., 2016).

With the urge to 1) break the cycle of revictimization in traumatized adolescents and having knowledge that 2) intervening as early as possible will prevent further damage to quality of life due to the effects of chronic stress on somatic and psychological functioning and the predicted 3) difficulties of changing cognitive, behavioral and emotional patterns later in life, the three most important aspects to write the proposal are described. With these aspects in mind the search for effective treatments to reduce posttraumatic stress symptoms in adolescents with child abuse related PTSD (as early as possible) makes sense. Therefore, the debate as to whether or not to offer adolescents a 12-session skills training before encountering trauma-focused treatment is worthwhile researching.

In conclusion, there is a lack of knowledge concerning the safety and efficacy of treatment for adolescents with PTSD as a result of child abuse. Therefore, the aim of the proposed project is to compare a phase-based treatment (skills training followed by trauma-focused therapy) with a trauma-focused therapy (without prior skills training), to evaluate their relative effectiveness.

Study 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.
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).
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.
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 followed by EMDR) versus a trauma-focused treatment condition (EMDR only). In the STAIR-EMDR condition, patients receive 12 sessions of skills training (STAIR-A), followed by 12 sessions of EMDR therapy. In the other condition, patients receive 12 sessions of EMDR therapy. All sessions take 90 minutes and are provided by the same therapist for every patient. The two groups will be compared on a number of outcome variables before treatment, after six sessions, post-treatment and three months and six months post-treatment (follow up).

Intervention

Participants in condition 1 will receive 12 sessions of STAIR-A followed by 12 sessions EMDR. Participants in condition 2 will receive 12 sessions of EMDR.

Study burden and risks

The risks for children and parents are minimal, since both groups recieve treatment as usual.
Regading the burden for patients: assessment of psychopathology is common in a pretreatment phase. Measuring therapeutic effects after CBT/EMDR treatment is also common. However, the burden in participating in this study is somewhat more intensive due to multiple (and repeated) measurements, which aren't common in clinical pratices.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

12 - 18 years old, PTSD due to child abuse

Exclusion criteria

Cognitive disorders and disabilities

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2018
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26367
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62839.091.17

Register	ID
OMON	NL-OMON26367