Een gerandomiseerde vergelijking van EMDR, KIDNET en wachtlijst bij getraumatiseerde vluchtelingenkinderen.

Gepubliceerd: 17-02-2014 Laatst bijgewerkt: 19-03-2025

The study aims to answer the following research questions:1. How high/low are levels of symptomatology of depression and/or PTSD in traumatised refugee children in ASC?2. Do symptom levels decrease after a short-term trauma-focused intervention?3....

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestart
Type aandoening	Angststoornissen en -symptomen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON44793

Bron
ToetsingOnline

Verkorte titel
Effectiviteit van EMDR en KIDNET bij vluchtelingenkinderen

Aandoening

- Angststoornissen en -symptomen
- Levensstijlaangelegenheden

Synoniemen aandoening
angst, Posttraumatische stressstoornis

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Stichting Centrum 45 (Oegstgeest)
Overige ondersteuning: gedeeltelijke door subsidie van EMDR Europe en Vereniging EMDR Nederland (VEN)

Onderzoeksproduct en/of interventie

Trefwoord: gerandomiseerde vergelijkende studie, psychotrauma, traumagerichte interventie, vluchtelingenkinderen

Uitkomstmaten

Primaire uitkomstmaten

Key variables of this study are:

1. Posttraumatic stress symptoms (disorder)

2. Quality of life

3. General non-trauma specific stress reactions (such as bedwetting, eating

problems)

4. Behavioral and emotional symptoms

Secundaire uitkomstmaten

Drop-out, number of sessions, number of weeks, duration of intervention,

anxiety in parent(s).

Toelichting onderzoek

Achtergrond van het onderzoek

Traumatized refugee children present a complex constellation of symptoms. Many of them have been exposed to multiple stressful experiences, such as violence, separation and migration, and are facing difficult living circumstances. Few efficacy studies of treatments to this vulnerable group of children are available (Henley & Robinson, 2011). The evidence for the use of the psychotherapeutic intervention method EMDR in refugee children is still in its infancy (Oras, De Ezpeleta & Ahmad, 2004) and limited when it comes to KIDNET (Onyut, et al., 2005; Catani et al., 2009; Ruf et al., 2010). On the basis of meta-analytic results, it is recommended to further explore trauma focused interventions* incremental efficacy for refugee children in controlled studies (Rodenburg et al., 2009). This project is a collaborative effort to study the effects of EMDR and KIDNET as trauma-focused interventions for refugee children in a RCT. Its significance is related to the limited knowledge that exists in

this field, with the theoretical gain that is expected, and with the relevance because of a large and growing number of children in comparable circumstances worldwide.

This study combines expertise in applying EMDR and KIDNET, in children (Rodenburgh et al., 2009; De Roos et al., 2011; Neuner et al., 2008; Onyut et al., 2005; Wanders et al., 2008) with expertise in working with this vulnerable group. Effective interventions for mental health problems related to exposure to traumatic events in children is lagging behind in comparison to adults. Additionally, it is known that children may be burdened by psycho-traumatic symptoms and hampered in their development (Van Ee, Kleber & Mooren, 2012). Children of refugees and asylum-seekers offer an extra challenge for mental health services. While violence and loss have frequently disrupted their lives, they are also subjected to changing social surroundings due to flight, frequent allocations and an uncertain future. At the same time, they have caregivers undergoing similar levels or higher levels of stress causing various mental health problems, which are thought to intertwine with mental health problems of the child through limited parental availability and their rearing practices. Complex posttraumatic disturbances may follow cumulative and chronic disrupting life-events, such as war and subsequent migration and consist of severe chronic symptoms as well as changes within the personality (Herman, 1993). The impact on further development, including their ability to integrate, can be dramatic. Therefore, it is important to offer interventions timely, efficiently and effectively. Long-term consequences need to be prevented. This study aims at optimizing their chances for recovery.

The theoretical questions that will be answered in this project are related to the importance of traumatic memories and intrusions in children with more complex symptoms of PTSD following traumatic experiences. Is trauma-focused therapy (EMDR versus KIDNET) effective in alleviating and reducing PTSD? Is this true for different age-groups: 6-8 and 12-18 years? Which factors are predictive for treatment outcomes? Outcomes of this project will help us understand how traumatic stress symptoms can be reduced in a high-risk group of children. This project is a step towards disentangling these issues.
Lastly, the children included in this study are currently living in asylum centers and awaiting the decision on their asylum application. A growing number of refugees live in Western Countries, often in uncertainty of their future for longer periods of time. This study can contribute to the discussion in the mental health field if trauma focused therapy can be offered to this group as they experience this uncertainty and live in non-optimal circumstances. Ultimately, this study can open doors for a large group of children in need, too often *unseen* in mental health institutions because of the lack of understanding what trauma therapy can safely offer them in this period of their lives.

Doel van het onderzoek

The study aims to answer the following research questions:
1. How high/low are levels of symptomatology of depression and/or PTSD in traumatised refugee children in ASC?
2. Do symptom levels decrease after a short-term trauma-focused intervention?
3. Are EMDR and/or KIDNET effective in decreasing symptoms at the end of treatment and/or follow-up?
4. Are EMDR and/or KIDNET effective in improving quality of life at the end of treatment and/or follow-up?

The benefits of this project are several and related to implementation of trauma-focused methods, examining systematically effects of these types of interventions in high-risk groups and lastly dissemination of knowledge and expertise (by publication and presentation). This project will result in:
* starting clinical research expertise in the field of treatment of traumatized refugee children.
* disseminating of findings to scientific and clinical professionals (through publications, presentations).
* examining the merits of care as usual for this population and registration of specific type of interventions.

Onderzoeksopzet

The design of the study is a randomized controlled trial using standardized questionnaires as well as structured interviews and performance data (quality of life); children between 8 and 18 years of age will be randomly assigned to either EMDR, KIDNET or waitlist control (N=30-30-30). They will be stratified in order to obtain two equal sub-age-groups (8-12; 13-18 years). Sample size has been based on power calculations incorporating small to moderate effect sizes and risk of drop-out (software G*power (Faul, Erdfelder, Lang, Buchner, 2007).
Children will be assessed at intake (before first treatment session), after the last session (maximum of 8 sessions of 1 hour) and at follow-up (3 months after the last session). Moreover, participants will fill out the CRIES (Children*s Revised Impact of Event Scale) each session to monitor changes closely. In the period between the last treatment session and follow-up no prolonged treatment will be offered, unless really needed. The EMDR therapy will be performed by therapists who are trained at EMDR level-II and in providing KIDNET. They will receive monthly supervision by a registered supervisor. Treatment fidelity will be checked to assess treatment adherence in both conditions.

Onderzoeksproduct en/of interventie

Participants of the study will be informed about the study and then randomly assigned to one

of two interventions versus a (temporarily) wait-list condition: 1. Eye Movement Desensitization Reprocessing (EMDR), 2. Narrative Exposure Therapy (KIDNET), versus 3. Waiting list. Interventions Both research conditions will consist of 8 weekly sessions. The EMDR treatment condition starts with one preparatory session to establish a working alliance, conduct a case conceptualisation and to obtain agreement on treatment targets. (1) EMDR The trauma-focused EMDR condition continues with 7 sessions aimed at reducing disturbance associated with the most distressing traumatic memories, following the Dutch version of the EMDR protocol for children and adolescents (de Roos, Beer, De Jongh & ten Broeke; based on De Jongh & Ten Broeke, 2003; Shapiro, 2001). EMDR sessions last 75 minutes. (3) KIDNET The trauma-focused KIDNET condition continues with 7 sessions aimed at reducing disturbance associated with the most distressing traumatic memories, in chronological order (Neuner et al., 2008; Schauer et al., 2017). Kidney sessions last 75 minutes (same amount as EMDR). (3) Waiting list control condition (WL) Once trauma-focused treatment has been indicated, a child may be assigned to the waiting list. This implies that a child will have to wait 8 weeks before the start of EMDR or KIDNET (second randomization). Parental guidance In all conditions parent guidance will be offered > with a maximum of 4 sessions 1 hour, commonly with interpreter). There is consensus in the clinical field that parent guidance in the treatment of refugee children is needed. Psychoeducation is the dominant subject of the encounters with parents (e.g., information about the interventions; what kind of reactions can be expected in their children). The interventions (in terms of duration, kind and frequency) that parents receive will be registered. In the treatment of children there is great reluctance to prescribe medication; during this study it is therefore not to be expected that any medication will be needed as extra intervention. In the case of a crisis, a child-psychiatrist is available to be consulted > as is a normal procedure during treatment. Extra interventions will be noted (in the rare occasion medication will be prescribed, the child will be excluded from the study).

Inschatting van belasting en risico

No particular risks are being foreseen for participants. Data will be handled confidentially and stalled anonymously. A subject identification code will be used to link the research data to the subject. The key to the code will be kept separate by the investigator. The handling of personal data will be according to the Dutch Personal Data Protection Act (in Dutch: De Wet Bescherming Persoonsgegevens, Wbp).
Children will be compensated for their participation with a coupon (euro 10) per measurement after treatment (M2 and M3).

Contactpersonen

Publiek

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Oegstgeest 2342 AX
NL

Wetenschappelijk

Stichting Centrum 45 (Oegstgeest)

Rijnzichtweg 35
Oegstgeest 2342 AX
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Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Adolescenten (12-15 jaar)
Adolescenten (16-17 jaar)
Kinderen (2-11 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Zie D4a.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Zie D5a.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-01-2015
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	17-02-2014
Soort:	Eerste indiening
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)

Goedgekeurd WMO

Datum:	16-06-2017
Soort:	Amendement
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

ID: 22679
Bron: Nationaal Trial Register
Titel:

In overige registers

Register	ID
CCMO	NL40769.058.13
OMON	NL-OMON22679