Effectively intervening in traumatized parents and children after structural domestic violence

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Ethical reviewApproved WMOStatusCompletedHealth condition typeOther conditionStudy typeInterventional

Summary

ID

NL-OMON52893

Source

ToetsingOnline

Brief title

Moving forward together

Condition

• Other condition

Synonym

domestic violence / trauma

Health condition

tekortkomingen in opvoedvaardigheden en PTSS-klachten bij ouders en kinderen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: attachment, domestic violence, trauma

Outcome measures

Primary outcome

Primary study outcomes are the change in disrupted parenting behavior, the change in sensitive parenting behavior, and the change in PTSD symptoms of the parent.

Secondary outcome

The secondary study outcomes are the change in PTSD symptoms of the child and the change in emotional and behavioral problems of the child.

Study description

Background summary

While the adverse effects of domestic violence on victimized parents and children have been extensively documented, there is still little knowledge on effective intervention approaches for these families. Even more scarce are intervention studies that target young children including infants and toddlers, even though these children are particularly vulnerable for the long-term effects of domestic violence. Their risk to develop trauma-related psychopathology is exacerbated because victimized parents are likely to show disrupted parenting due to their own traumatization (resulting from domestic violence and often also from their own traumatic childhood). This increases the risk on a disturbed attachment relationship. It is therefore crucial that the parent-child relationship is targeted in an intervention for these families. In addition, treatment should focus on reducing individual post-traumatic stress symptoms (PTSD symptoms) of the parent.

Study objective

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The goal of this study is first to test the effectiveness of a short-term, attachment-based parenting intervention (NIKA) for victimized mothers and their children after domestic violence (phase 1). Next, we will evaluate the additional effectiveness of an intervention focused on individual trauma therapy for the mother (EMDR) (phase 2). The goals of this study are:

- 1. To test whether mothers who receive NIKA will show less disrupted parenting than mothers in the waitlist usual care group.
- 2. To test whether mothers who receive NIKA will show more sensitive parenting than mothers in the waitlist usual care group.
- 3. For mothers who report clinically significant PTSD symptoms in phase 2: To test whether mothers who receive EMDR will show fewer PTSD symptoms than mothers in the waitlist usual care group.

Furthermore, we will explore the additive effects of NIKA and EMDR for mothers with clinical PTSD symptoms on their parenting behavior.

Study design

The hypotheses will be tested using a randomized controlled trial (RCT). Families who are residing in or receive care from one of the included women shelters will be randomly assigned to either NIKA or a waitlist usual care group (phase 1). A pre-test will be conducted prior to the treatment period and a post-test will be conducted directly afterwards (six weeks later). During the post-test of phase 1, all mothers will be screened for clinical PTSD symptoms. Those mothers who do not report clinical PTSD symptoms will not participate in the randomization for EMDR, whereas those mothers who do report clinical PTSD symptoms will be randomly assigned to either EMDR or a waitlist usual care group. Six weeks later, directly after the treatment period, a post-test of phase 2 will be conducted for all families.

NB: Even though we refer to *clinical PTSD symptoms* in our study protocol, the mothers who will be included in this study will not be classified with posttraumatic stress disorder by a psychiatrist. Selection of mothers for EMDR will occur based on a validated self-report questionnaire that measures PTSD symptoms consistent with the DSM-V. Only those mothers with self-reported clinical PTSD symptoms will receive EMDR.

Intervention

NIKA consists of 5 sessions during which mother and child are videotaped by a trained therapist. The therapist will provide personalized feedback to the mother, which is focused on reducing disrupted parenting behavior and increasing sensitive parenting behavior. EMDR is a short trauma therapy (in this trial a maximum of 6 90-min sessions) aimed at reducing the negative load of the memories of traumatic events. The parent is asked to bring the traumatic event to mind while the therapist provides a distracting task. Mother-child dyads in the waitlist usual care group will only receive care as usual at the

women shelter during the study.

Study burden and risks

The families will be asked to fill out questionnaires and to participate in observational tasks that are not intrusive or dangerous. The researchers and therapists will make sure participants can ask questions and everything will be explained carefully. The pre- and post-tests will take 1 hr and will take place at the women shelter where the families are staying. The 5 NIKA sessions will take approximately 1 hr each in a time span of 5 weeks. The 6 EMDR sessions will take approximately 1.5 hr each. If the mothers encounter difficult themes or feelings, they will be supported by the therapist or social worker if needed. Therapists who encounter difficulties are able to share these issues in supervision meetings which will be organized frequently by highly experienced therapists. Other studies that investigated similar interventions show no negative consequences of the intervention (Bernard et al., 2012; Moss et al., 2011; De Jongh et al., 2019). There is still a big gap in the current knowledge regarding effective treatment approaches for young children who are traumatized after domestic violence. In these families, there is a high risk of co-occurring child maltreatment and often both mother and child suffer from PTSD symptoms. How these families can be best supported is still unknown. If NIKA and EMDR are effective in improving the quality of parent-child interactions and decreasing both parents* and children*s PTSD symptoms, the wellbeing of these children will improve.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Children (2-11 years) Babies and toddlers (28 days-23 months)

Inclusion criteria

- -(1) The mother and child are residing in a women*s shelter because of severe domestic violence between the mother and her (ex-)partner, or (2) the family receives ambulatory care from the women*s shelter after the safety in the family situation has been classified as highly unsafe (*çode red*) and specific safety measures (a restraining order or an AWARE system) are taken in the family, or (3) the family receives ambulatory care from the women*s shelter, after being transferred from a women*s shelter in another part of the country, due to safety restraints in the region where the family resided in the women*s shelter.
- -The child is aged between 6 months and 6 years old (if there is more than 1 child in this age range in the family, we will select the youngest child between 1.5 and 6 years old as the target child for the study)
- -The mother speaks sufficiently Dutch to be engaged in the treatment program, or a translator is available.

Exclusion criteria

- Mothers with extreme mental health problems (e.g., psychosis) that directly affect their ability to participate in an intervention and requires immediate intervention for the parent
- Mothers who hardly speak Dutch or not at all (NB: only if no translator is available)
- The mother and child are residing in or receive hep from a women shelter because of severe domestic violence between the mother and someone else than her (ex-)partner

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Primary purpose: Other

Recruitment

NL

Recruitment status: Completed
Start date (anticipated): 10-05-2021

Enrollment: 150

Type: Actual

Ethics review

Approved WMO

Date: 21-12-2020

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 27-10-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 11-11-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 10-03-2023

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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: 25861 Source: NTR

Title:

In other registers

Register ID

CCMO NL74114.058.20

Other NL9179