

# Samen stap voor stap vooruit

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25861

### Source

Nationaal Trial Register

### Health condition

Domestic violence and trauma

## Sponsors and support

**Primary sponsor:** None

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

The main parameters of this study are the change in disrupted parenting behaviors, the change in sensitive parenting behaviors, and the change in PTSD symptoms of the mother.

### Secondary outcome

The secondary parameters for this study 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 for developing 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.

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 young children after domestic violence (phase 1). Next, we will evaluate the additional effectiveness of individual trauma therapy for the victimized mother (EMDR) (phase 2). The primary goals of this study are:

- To test whether mothers who receive NIKA will show less disrupted parenting than mothers in the waitlist usual care group.
- To test whether mothers who receive NIKA will show more sensitive parenting than mothers in the waitlist usual care group.
- For mothers who report clinically significant PTSD symptoms after phase 1: To test whether mothers who receive EMDR will show fewer PTSD symptoms than mothers in the waitlist usual care group.
- To explore the additive effect of EMDR for mothers with clinical PTSD symptoms on their parenting behavior.

The hypotheses will be tested using a randomized controlled trial (RCT). Families who are residing at a women shelter location 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 the severity of 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 trauma treatment, a post-test of phase 2 will be conducted for all families. This study will include 150 mother-child dyads who are residing at a women shelter location in the Netherlands after experiencing severe domestic violence. Mothers with children aged between 6 months and 6 years old will be included.

## Study objective

The goal of this study is to test the effectiveness of a short-term, attachment-based

parenting intervention (NIKA) for victimized mothers and their children after domestic violence. In addition, we will evaluate the additional effectiveness of individual trauma therapy for the victimized mother (EMDR). We will conduct an RCT with a waitlist usual care group. The study will include a sample of mother-child dyads (children aged 6 months-6 years) who have experienced severe and chronic domestic violence and are currently residing at a number of women shelters in the Netherlands.

#### Phase 1

##### Primary Objectives:

- To test whether mothers who receive NIKA will show less disrupted parenting than mothers in the waitlist usual care group.
- To test whether mothers who receive NIKA will show more sensitive parenting than mothers in the waitlist usual care group.

##### Secondary Objectives:

- To test whether children whose mothers receive NIKA will show fewer PTSD symptoms than children in the waitlist usual care group.
- To test whether children whose mothers receive NIKA will show fewer emotional and behavioral problems than children in the waitlist usual care group.

#### Phase 2

##### Primary Objective:

- 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.

##### Exploratory Objective:

- For mothers who report clinical PTSD symptoms in phase 2 after receiving NIKA (upper part of Figure 2), we will explore whether mothers who receive NIKA combined with EMDR will show (1) less disrupted parenting and (2) more sensitive parenting than mothers who only receive NIKA. In addition, we will explore whether children whose mothers receive NIKA combined with EMDR will show fewer PTSD symptoms than children whose mothers only receive NIKA.

### **Study design**

- 1) Baseline measure
- 2) Post-test measure phase 1 (week 7)
- 3) Post-test measure phase 2 (week 13)

### **Intervention**

- 1) NIKA (Nederlandse Interventie Kortdurend op Atypisch opvoedgedrag) is a short-term, attachment-based video-feedback intervention for parents and their children aged between 0 and 6 years old. The intervention specifically targets high-risk families, for instance families where child maltreatment or domestic violence has occurred. The goal of NIKA is to prevent or reduce disorganized attachment and related psychopathology in children by reducing

disrupted parenting behavior and increasing sensitive parenting. The intervention uses elements from cognitive behavior therapy and is based on attachment theory. 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.

2) EMDR is a brief 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.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- The mother and child are residing in a women shelter because of severe domestic violence between the mother and her (ex-)partner
- The child is aged between 6 months-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 require 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 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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	07-01-2021
Enrollment:	150
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	07-01-2021
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 52893  
Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL9179
CCMO	NL74114.058.20
OMON	NL-OMON52893

## Study results