The effects of parental components in a trauma-focused cognitive behavioral based therapy for children exposed to interparental violence

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Primary Objectives1. The primary objective of Study 1 is to evaluate the relationship of IPV and children*s symptoms and adjustment within a clinical sample of 75 families exposed to IPV and 50 comparison families, and to test whether this...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39267

Source
ToetsingOnline

Brief title
TF-CBT based therapy for children exposed to IPV

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
emotional and behavioral problems, post-traumatic stress disorder (PTSD)

Health condition

emotionele en gedragsproblemen bij kinderen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: children, domestic violence, parental availability, TF-CBT

Outcome measures

Primary outcome

To address the main study aim, the main parameters are the reductions in trauma symptoms, internalizing and externalizing problems and improvements in adjustment in children from baseline to post-test and 6-month follow-up. To address our other study aims, the main parameters are observational, interview and questionnaire measures of parental availability, parent-child relationship variables, physiological assessment and children*s responses to IPV.

Secondary outcome

Not applicable

Study description

Background summary

Exposure to interparental violence (IPV) can be a traumatic experience for children and is associated with poor developmental and adjustment outcomes. Trauma focused-cognitive behavioral therapy (TF-CBT) has shown to be effective for treating children*s psychological trauma in general, but appears to be less effective for IPV. Given that IPV affects the whole family unit, a promising direction is extending trauma-focused cognitive behavioral therapy with components involving parents. Different ideas exist regarding the manner in which parents can be effectively involved, and the mechanisms that explain the

effects of multi-component treatments. At present, it is unclear which components can contribute to treatment effectiveness in TF-CBT based therapies for children who have experienced IPV.

Study objective

Primary Objectives

1.
The primary objective of Study 1 is to evaluate the relationship of IPV and children*s symptoms and adjustment within a clinical sample of 75 families exposed to IPV and 50 comparison families, and to test whether this relationship can be explained by the following factors
i) children*s emotional, cognitive, behavioral and physiological responses
ii) parental availability
iii) quality of the parent-child relationship and parenting

Research question 1:

A. Which factors mediate or moderate the effects of IPV on children*s symptoms and adjustment and how are they inter-related?

Additionally, this study will compare children exposed to IPV and 50 matched comparison families to identify differences in emotional, cognitive, behavioral, and physiological functioning between these two groups.

B. Does the quality of the parent-child relationship, parental availability and children*s emotional, cognitive, behavioral and physiological responses to conflicts and violence differ between families who have been exposed to IPV vs. those who have not been exposed?

Families in the comparison group will be matched with IPV-exposed families on demographic variables, such as gender, SES, family structure and ethnicity.

2.
The primary objective of the Study 2 is to evaluate the effects of (i) the parent preparatory program and (ii) the parent-child interaction component as additions to the Horizon, a TF-CBT-based group therapy for parents and children who have experienced IPV on child symptoms and adjustment.

Research question 2:

A. Is Horizon TF-CBT more effective when a 6 session preparatory program for parents is offered?
B. Is Horizon TF-CBT more effective when a parent-child interaction component is offered at the end of each therapy session?
C. Is Horizon TF-CBT more effective when both a preparatory program for parents

and a parent-child interaction component are offered?

Secondary objectives

A secondary goal within our RCT study (Study 2) is to investigate associated changes between: 1) child symptoms and child adjustment, 2) child emotional, behavioral, and cognitive responses, 3) parental availability and 4) parent-child interaction.

Research question 3:

A. Are changes in child symptoms and adjustment after treatment associated with changes in emotional, behavioral, and cognitive responses in children?
B. Are changes in child symptoms and adjustment after treatment associated with changes in:
1. parental availability
2. parent-child interaction
C. Are changes in parental availability and parent-child interaction after treatment associated with changes in children*s emotional, behavioral, and cognitive responses?

Third, the goal is to examine whether the preparatory program and the parent-child interaction component sessions achieved what they aimed to change and whether these changes mediate child symptoms and adjustment, specifically:

Research question 4:
A. Does the preparatory program lead to increased parental availability, and does this mediate reduction in symptoms and improvement in child adjustment after treatment?
B. Does the parent-child interaction component lead to improved parenting behavior to support the child, and does this mediate reduction in symptoms and improvement in child adjustment after treatment?
C. If these changes in parental availability and improved parenting behavior occur, the explorative question is whether these changes lead to a reduction in symptoms and improvement in child adjustment after treatment by changing emotional, behavioral and cognitive child responses.

Finally, we will control for variables that have been shown to potentially affect the relations that are at the heart of our project: duration and severity of the IPV (Kitzmann et al., 2003), parental psychopathology (Levendosky et al., 2003) and new incidents of IPV.

Study design

There are two studies. Both studies use a multi-method approach combining both

observational and quantitative data collection within a cross-sectional design (Study 1) and a randomized 2 by 2 factorial experimental design (Study 2). In this multi center RCT study the workings of two parental compnents added to TF-CBT will be tested. The resulting design is a 2 (preparatory program present versus absent) x 2 (parent-child interaction present versus absent) factorial randomized experimental design with a pre- and post-test and follow-up after six months in which one-hundred children and their custodial parents will participate.

Intervention

Horizon, a trauma-focused cognitive behavioral based therapy (TF-CBT) consisting of 15 sessions of group therapy for children and a parallel parenting program is offered to 100 children. In a factorial design, this group will be randomly divided in 50 dyads with and 50 dyads without the preparatory parent component (6 extra sessions) and in 50 dyads with and 50 dyads without the parent-child interaction component.

The HORIZON 3 & 4 (Leeuwenburgh, Visser, & Lamers-Winkelman, 2006b; Visser et al., 2006b) is a group intervention for children and their parent(s) for children who have been exposed to IPV. The aim of the intervention is to help children process the traumatic experiences of having been exposed to IPV. The aim of the parent group is to guide parents to help their traumatized children by processing the traumatic experiences and by adjusting to the IPV. Both children and parents have a therapy book (Leeuwenburgh, Visser, & Lamers-Winkelman, 2006a; Visser, Leeuwenburgh, & Lamers-Winkelman, 2006a). This book is used weekly during the therapy sessions for information about the topic, assignments, and drawings.

For the description of the intervention we distinguish three parts:
1. The Preparatory Program (PP) is for the parents and consists of six sessions. The preparatory program aims to increase parental availability and insightfulness in their children*s needs. Parents are coached to accurately read the behavioral and emotional signals of their children*s needs and to adequately respond to these signals. To enable them to do so, the therapists coach parents to better differentiate between their own and their children*s needs, to differentiate between their own violence history and the children*s violence history, to differentiate between their own posttraumatic stress responses and those of the children, to gain insight into the developmental tasks appropriate to the age of the children, and to gain insight in the developmental consequences of IPV on children.
2. The second part is the parallel parents and children groups and consists of fifteen weekly sessions. Because the intervention is trauma-focused and based on cognitive behavioral therapy principles, it includes the same components as the TF-CBT that was described and studied by Cohen and Mannarino (2008). Components of this intervention method are psycho-education, relaxation,

affective expression and modulation, cognitive coping and processing, trauma narrative and parenting skills. These components are covered by the following themes: psycho-education about therapy, violence and conflicts, and posttraumatic stress; training of emotion regulation skills; addressing incorrect attributions about conflict and violence; expressing and sharing the IPV experiences; managing anger, guilt and shame handling nightmares; good and bad sides of mother and father; and future safety. These weekly sessions have a duration of 60 minutes.
3. The Parent Child Interaction Component (PCIC) takes place adjacent to the parallel parent and child group. The parent group joins the children*s group after one hour. During 30 minutes, parents and children are given the opportunity to work on the way in which they interact with each other. The aim of the PCIC for the parents is to learn to show more emotional supportive behavior, more involvement (e.g., talking together), more praise, less harsh discipline, and increased parental presence (e.g., time spent together). This parenting behavior can be practiced and trained by the parents in exercises during the parent-child interaction component. Parents will receive feedback on their interaction behavior during the next session in the parallel parent group. Children will receive feedback on their interaction behavior directly during the session.

All children and parents in all four conditions will receive therapy as described in part two of the above mentioned three components. This part of the treatment was developed first by the authors. (The preparatory program and the parent child interaction component were added later to the HORIZON therapy). There is no waitlist or control intervention. After each session, the therapists of both the parent program and the child program will evaluate the session and share information about children*s as well as parent's progress.

Study burden and risks

The risk associated with our study is considered small. Our study focuses on the effectiveness of parental components in the TF-CBT-based *Horizon* therapy for children who have experienced IPV. TF-CBT is known to be effective in reducing emotional and behavioural problems and PTSD symptoms in children who have experienced trauma (Cohen et al., 2010; Cohen & Mannarino, 2008; Cohen, Mannarino, & Murray, 2011). For more than 10 years, the TF-CBT-based group therapy *Horizon* has been used to treat children who have experienced IPV. The therapy is administered in several children and youth treatment centers in the Netherlands and does not seem to involve risks for participants. The Horizon therapy has the status 'theoretically sound' by the NJI (http://www.nji.nl/eCache/DEF/1/22/611.html). The intervention will be delivered by trained and supervised clinicians using a published treatment manual (Leeuwenburg, Visser, & Lamers-Winkelman, 2006). Children and parents who can participate in the current study are already referred to the respective

treatment centers (KJTC Haarlem, Fier Fryslan, De Rivierduinen) to participate in the Horizon group therapy. For this study, the families will be randomly assigned to one of four treatment conditions within this therapy. As a consequence of the 2 by 2 factorial design, children and parents that participate in the current study will always receive therapy. There are no waitinglist or placebo control conditions. Further, previous research has not provided evidence that the addition of a preparatory program or parent-child interaction component makes TF-CBT more effective for children. Based on theoretical considerations, we expect that the addition of the two components could be beneficial for children, but our study has yet to confirm this hypothesis. Given the potential deleterious outcomes of experiencing IPV for children and their families and the scarcity of available treatments for this group, the development and refinement of evidence-based therapies that address IPV-related trauma is clearly warranted.

In addition to the therapy itself, we ask children and parents to fill out questionnaires on three occasions and to participate in 2 observational tasks, which will be combined with physiological assessments. There is also an interview with the primary caregiver. The total assessment will take approximately 2 hours and 45 minutes for parents and 2 hours for children at T1. At T2 and T3 the assessment time will be around 1 hour. Observational tasks simulate frequently occurring interactions between parent and children and were not associated with burden for participants in previous research (Oppenheim et al., 2007). The family interaction task has previously been approved for research with children in youth mental health care (CCMO P04.0817c). Physiological assessment using the VU-AMS has been used often with children (Oosterman & Schuengel, 2007) and the assessment tools are non-invasive.

The potential burden of the participation in the research could be that questionnaires probe into the children*s and parent*s experience of IPV. However, the topic of IPV will also be addressed extensively in the therapy itself. Questionnaires and observation tasks are therefore always administered by research psychologists and research assistants, assisted by graduate students who have at least an undergraduate degree in psychology, education or a related discipline. However, the majority of the questionnaires (e.g. Emotional Awareness Questionnaire, Cognitive Emotional Regulation Questionnaire, Self Control Scale, Chaos, Hubbub and Order Scale, Fundamental Needs, Security Scale, Children*s Generalized Trust Beliefs, Capitalization, Protective Factors Survey, Inclusion of the Other in the Self Scale, Attitudes about family violence) proposed in the current study were tested in a pilot study by our group. In this pilot study, both parents and children reported that these questions were relatively easy to answer and did not cause distress. Moreover, the observational tasks (AEED and FIT) and part of the questionnaires * including the questionnaire about severity and duration of IPV - of this study are approved by the METC for the research project of Prof. Dr. F. Lamers-Winkelman (protocol ID 80-82435-98-8010/3) on the effectiveness of a psycho-educational prevention program for children who have experienced IPV.

Finally, assessments take place in clinical settings in close liaison with therapists. Therefore, the risk with participating in this project is considered small. Nevertheless, should a child or a parent seem adversely affected by the questionnaires or observational tasks as observed by the researchers or therapist, it may be decided to (temporarily) discontinue participation in the project.

With respect to the study procedure, the intermediate assessment (session 1, 9 and 5) will take 10 minutes for parent and child. The administration of observational tasks, questionnaires, and physiological assessment will take place on a separate day before the treatment starts. The administration of questionnaires will take place after the last treatment session to prevent it from affecting the therapy and to minimally burden parents and children.

The study has not been done before and cannot be carried out with adults, but only with children who have experienced IPV. The study is therefore group-related.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Study 1: Mediators and moderators of the effects of IPV on child adjustment study;IPV sample;* The child has been exposed to IPV (or violence between a parent and a cohabitant).
* The child is no longer exposed to IPV (or violence between a parent and a cohabitant).
* The child is between the age of 4 and 12.
* Both custodial parents gave written informed consent.;Comparison group
* The child has not experienced IPV or any other type of child abuse
* The child is between the age of 4 and 12
* Custodial parents gave written informed consent;Matching criteria:
* Child*s age
* Child*s gender
* SES
* Family structure (single-parent families and two-parent families)
* Ethnicity;Study 2: The effects of parental components in HORIZON treatment study;* The child has been referred to the HORIZON group therapy.
* The child has been exposed to IPV (or violence between a parent and a cohabitant).
* The child is no longer exposed to IPV (or violence between a parent and a cohabitant).
* The child is between the age of 4 and 12.
* Both custodial parents gave written informed consent.

Exclusion criteria

Study 1: Mediators and moderators of the effects of IPV on child adjustment study;* The child has an intellectual disability (approximately under IQ 80).
* The parent has an intellectual disability (approximately under IQ 80).
* The child and/or parent do not speak sufficient Dutch.

* One of the custodial parents or the child aged 12 or older does not give written informed consent to participate in the study.;Study 2: The effects of parental components in HORIZON treatment study
* The child has an intellectual disability (approximately under IQ 80).
* The child has serious behavioral problems that prevent him or her to function in a group.
* The parent has an intellectual disability (approximately under IQ 80).
* The child and/or parent do not speak sufficient Dutch.

* One of the custodial parents or the child aged 12 does not give written informed consent to

participate in the study.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2012
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO Date:	14-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL39277.029.12