Rewind and Fast Forward: Effectiveness of a high intensive trauma-focused, family based therapy for children exposed to family violence.

Published: 17-02-2021
Last updated: 09-04-2024

Primary Objective: 1. Is FITT more effective than ITT in terms of trauma reduction in children and improvement of structural emotional safety in families? Secondary Objective(s): 1. Is FITT more effective than TAU in terms of trauma reduction in...

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

Summary

ID

NL-OMON56260

Source
ToetsingOnline

Brief title
Rewind and Fast Forward: Effectiveness of FITT

Condition

- Anxiety disorders and symptoms
- Family issues

Synonym
posttraumatic stress, trauma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Domestic Violence, Randomized controlled trial, Structural emotional safety, Trauma

Outcome measures

Primary outcome

Child PTSD symptoms

The Clinician-administered-ptsd-scale-children-and-adolescents (CAPS-CA; Pynoos et al., 2015) is a standardized clinical interview, to assess PTSD conform the DSM-5 standards. A Dutch translation of the CAPS-CA (Van Meijel, Ensink, Verlinden, & Lindauer, 2019) is administered to children aged 8-18. The core traumatic event is chosen on the basis of the life-events checklist. If the core traumatic event is actually a sequence of events, which is often the case in family violence, a brief term is chosen to capture the core of these events. The CAPS-CA assesses the frequency and intensity in which each PTSD symptoms occur. A five-point severity rating scale is used for all symptoms, ranging from 0 (= absent) to 4 (= extreme/incapacitating). A total symptom severity score is calculated by summing severity scores for items 1-20. A total symptom score can also be calculated per cluster; re-experiencing (items 1-5), avoidance (items 6 and 7) negative alterations in cognitions and mood (items 8-17) and hyperarousal (items 15-20). A symptom cluster score may also be calculated for dissociation by summing items 29 and 30. To determine the PTSD diagnostic status individual symptoms should be dichotomized as *present* or

absent. A symptom is considered present only if the corresponding item severity score is rated 2 (=Moderate/ threshold or higher). Items 9 and 11-20 have the additional requirement of a trauma-relatedness rating of Definite or Probable. The DSM-5 diagnostic rule requires the presence of least one Criterion B symptom, one Criterion C symptom, two Criterion D symptoms, and two Criterion E symptoms. Also, Criteria F (disturbance at least one month) and G (disturbance cause either clinically significant distress or functional impairment) must be met.

The Children*s Revised Impact of Event Scale (CRIES-13; originally developed by Horowitz, Wilner, & Alvarez, 1979; translated to Dutch by Olff, 2005) is a questionnaire for assessment of traumatic impact across different types of trauma and life-threatening events. Children and parents will rate 13 items according to the frequency of their occurrence in the past 24 hours in relation to the traumatic experiences (1 = none, 2 = rarely, 3 = sometimes, ad 4 = often). Example items are: *Do you think about the **. even when you don*t mean to?*, and *Do you avoid talking about **?* We use the sum score as an indicator of traumatic impact (ranging from 0 to 65). A score of 30 and over has been suggested as the most efficient cut-off for discriminating heightened risk for PTSD. Within a semi-clinical study population Cronbach*s a was .89 for the 13-items child version. (Verlinden et al., 2014).

The Trauma Symptom Checklist for Children (TSCC; Briere, 1996) is a questionnaire to assess self-reported posttraumatic stress symptoms at children

(8-12 years). It consists of 54 items clustering in eight scales: two validity scales (underresponse, hyperresponse) and six clinical scales (anxiety, depression, post-traumatic stress disorder, dissociation, anger and sexual concerns). The response categories are the same as in the Trauma Symptom Checklist for Younger Children and reliability was high for the clinical total PTS score, with a Cronbach alpha*s ranging from 0.78 to 0.86 in a sample of sexually abused children (Briere, 1996).

Structural emotional and physical safety

To assess the severity and intensity of the violence that children have been exposed to, we will use a combined measure including items from the Conflict Tactics Scale (Straus, 2001), the Conflict Tactics Scale parent child (Straus, 2001), the Parents Report of Traumatic Impact (Friedrich, 1997); and the Adverse Childhood Experience Questionnaire (Felitti et al, 2019). This combined questionnaire has been used in a previous study on the effectiveness of a psycho-educational prevention program for children exposed to IPV (Overbeek, Schipper, Lamers-Winkelman & Schuengel, 2012, see Publication list). The questionnaire covers the topics and duration of the violence, the nature of the arguments in the relationship with the (ex-partner), followed by items from the Conflict Tactics Scale parent child and Parents Report of Traumatic Impact about problems between parent and child, and traumatic events the child has experienced. The questionnaire also includes items about traumatic experiences in parents* own childhood. New IPV incidents: Parents and children are asked 8 questions if any new IPV incidents or other stressful events occurred.

To assess emotional security the Security in the Interparental Subsystem (Davies et al., 2002) will be used. The Security in the Interparental Subsystem consists of 43-items with a 4-point ordinal scale. Children are asked to answer questions about previous violence and conflicts between parents en current violence and conflicts between parent and partners. It has three scales and seven subscales: emotional reactivity (emotional reactivity, behavioral dysregulation), regulation of exposure to affect (avoidance, involvement) and internal representations (constructive family representations, destructive family representations and conflict spillover representations) . The subscales show satisfactory internal consistency and test-retest reliability and previous research supported the validity of the SIS scale (Davies et al, 2002). Children will be asked to answer the same questions with respect to past fights and arguments between their parents and current fights and arguments between their mother and partner at T1, T2, and T3. Children will be asked to answer the same questions with respect to past fights and arguments between their parents and current fights and arguments between their mother and partner at T1, T2, and T3.

The Security in the Family System scale (Forman & Davies, 2005) will be used to assess how much children perceive their families as a reliable source of protection, stability, and support. The subscale *Secure* will be used, which assesses a secure pattern of emotional security. Children indicate the extent to which they agree with 7 statements using a four-point scale ranging from *Complete disagree*(1) to *Complete agree*(4). Psychometric properties of this

security subscale are good, Cronbach*s a = 0.85 and test-retest reliability = 0.82 (Forman & Davies).

Caregivers report on children*s emotional security, including their emotional reactivity, behavioral involvement, and avoidance, after witnessing arguments between their parents using the Security in the Marital Subsystem Scale (SIMS; Davies, Forman, Rasi, and Stevens, 2002). Items are completed on a 5-point ordinal scale from 1 (not at all like him/her) to 5 (a whole lot like him/her) and include feeling sad, angry, afraid, and upset (e.g., *Still seems upset after we argue*). The SIMS has been found reliable and valid has demonstrated discriminante, convergente, and predictive validity (Davies, Harold, Goeke-Morey, & Cummings, 2002).

The Security Scales (Kerns, Klepac, and Cole, 1996) are 15-item self-report questionnaires for children between the ages of 8 and 18 and measures attachment security with their parents. Children and parents (independently) report on responsiveness and availability of the parent in the parent-child relationship (attachment figure). Each items is rated on a 5-point likert scale ranging from *strongly agree* (1) to *strongly disagree* (5) with a higher score indicating greater perceived attachment security. Several studies indicate adequate reliability and validity (Dwyner, 2005). Kerns, Tomich, Aspelmeir and Contreras (2000) reported high internal consistencies for 10 and 12 year olds (α=0.82,α=0.79). Test-retest reliability over a two-week period was high (r=0.75) (Kerns, Klepac, and Cole, 1996). The Security Scale is

related to other attachment measures (Kerns, Tomich, Aspelmeir and Contreras, 2000). In a Dutch sample, internal consistency was α= 0.77 for the mother version and α=0.85 for the father version (Willemen, 2008).

The Family Interaction Task (FIT; Weinfield, Ogawa, & Egeland, 2002) is an observational instrument that measures parent-child interaction and consists of four tasks in which parent and child are instructed to complete a series of interactive tasks together. The FIT consists of four structured tasks: (1) guessing words by getting clues, (2) getting marbles into the holes of a labyrinth, (3) discussing a topic, and (4) completing a difficult but solvable puzzle by untangling a fixed ring from a standard within 4 minutes. These tasks are designed to elicit variations in parental and adolescent autonomy-promoting behaviors and emotional affect. The tasks are originally developed for children in middle childhood, but the tasks have been adapted for adolescents. Rating scales range from 1 to 5 and a higher score indicates a greater presence of that particular construct. Ratings are based on the complete session. Each videotaped session is independently coded by two coders (research assistants).

Secondary outcome

Child functioning

The Strengths and Difficulties Questionnaire (SDQ; Van Widenfelt, Goedhart, Treffers & Goodman, 2003) is a 25-item questionnaire to measure a) conduct problems, b) emotional functioning, c) hyperactivity/inattention, d) Peer problems, e) prosocial behaviour. There is a self-report, parent and teacher version. The internal consistency of the teacher version is good. The parent

and self-report version have an internal consistency that is generally acceptable (Van Widenfelt et al., 2003).

The Children*s Depression Inventory (CDI; Kovacs, 1982). is a 28-item self-rated questionnaire that measures symptoms of depression in children (7-18 years): mood disturbances; capacity for enjoyment; depressed self-evaluation; disturbances in behavior toward other people; and vegetative symptoms, which include fatigue, oversleeping, having difficulty with activities requiring effort, and other symptoms of passivity or inactivity. Per item the child is asked to choose one of three sentences that best fits his/her feelings and thoughts in the past two weeks. The answers are calculated in a total score (ranging from 0 to 54). The internal consistency in a Dutch sample was high (a = 0.79), just as the test-retest reliability (r = 0.79) (Timbremont, Braet, & Roelofs, 2008). The CDI has high criterion validity and scores on the CDI correlate high with scores on other measures for depression (Timbremont et al., 2008).

The Child Dissociation Checklist (CDC; Putnam, Helmers, & Trickett, 1993) is a 20-item parent-rated questionnaire with a 3-point Likert scale answering format ranging from *not true*(0), *somewhat or somehow true*(1) and *very true*(2). The child dissociation checklist is a screening device and gives an indication for dissociative problems in children (5-18 years). It shows good test-retest reliability (r = 0.69) and internal consistency (Cronbach*s a = 0.86) (Hartveld & Janssen, 1992). Good convergent and discriminant validity have been indicated

(Hartveld & Janssen, 1992).

Parent functioning

To asses parental stress, the Nijmegen Parental Stress Index*short version (NOSI-K; De Brock et al., 1992) will be used. The NOSI-K is a short version of the NOSI (full parental stress index) and a 25-item parent-rated questionnaire. The NOSI-K consists of ten subscales: Competence, attachment, depression, health, adjustment, mood, distractibility, fussiness, positive ratification and acceptance. Cronbach*s alpha for mothers and fathers are .90 and .91 respectively (De Cock et al., 2017).

To measure caregivers* trauma knowledge, we will use a short self-report questionnaire developed for the training *Caring for Traumatized Children* (Coppens & Van Kregten, 2018). The questionnaire comprises 6 items that reflect the six primary training goals, rated at a 10-point scale (1 = not accomplished, 10 = totally accomplished). Higher scores indicate higher trauma knowledge.

To assess trauma symptoms in caregivers, we will use the Impact of Events Scale - Revised (IES-R; Weiss & Marmar, 1997). The Dutch version *Schokverwerkingslijst (SVL-22)* was developed by Kleber & De Jong (1998). This questionnaire consists of 22 items measuring symptoms of PTSD during the last week. The SVL-22 measures three dimensions: intrusion, avoidance and hyper-arousal. Parents rate the items on a 5-point Likert-scale ranging from

not at all to *extremely*. Internal consistency was high (alpha = .88) (Olde, Kleber, van der Hart, & Pop, 2006).

Further, we will use the Young Adult Self-Report (Aachenbach, 1997). The Young Adult Self-Report will be used to assess psychopathology symptoms in parents. The short version of 29 items will be used in this study to limit the amount of time needed to fill in the questionnaire. Items are rated on a 3-point scale ranging from *not true*(0), *somewhat or sometimes true*(1) and *very true or often true*(2). Reliability and validity of the Dutch version are good (Wiznitzer et al., 1992).

Daily Psychological Availability Scale (Danner-Vlaardingerbroek, Kluwer, Van Steenbergen, and Van der Lippe, 2013). To assess parental availability for the child we will use eight adapted items of the Daily Psychological Availability Scale. Items were measured using 7-point scales from 1 (totally disagree) to 7 (totally agree). Cronbach*s α was 0.78 for both fathers and mothers (Danner-Vlaardingerbroek, Kluwer, Van Steenbergen, and Van der Lippe, 2013). A higher score on this scale represents more psychological availability for the child.

Participants* experiences with intensive trauma treatment

In order to understand experiences of participating children regarding outcomes, key elements of (F)ITT and barriers for treatment success , we use a qualitative interview with adolescents who have participated in FITT or ITT.

The interview takes approximately one hour, and - according to the participants* possibilities and preferences will be face-to-face or online. The interview is administered by two primary researchers (V.F. and C.S.J.). Open, exploratory questions are asked regarding the overall experience with (F)ITT, the perceived outcomes, proposed key elements as facilitator and perceived barriers to treatment success. Interviews are audio recorded and anonymously transcribed. Topics in the interview are based on our systematic literature search and rationale and elements of the intensive treatments: traumafocused therapy, therapist rotation, psycho-education/knowledge of trauma and family violence, parent-child relationship, parenting, social support/resources and safety within the family.

Study description

Background summary

Family violence is a common problem and affects children and their families. Family violence refers to any violence between other family members, e.g. interparental violence - with or without child (sexual, physical) maltreatment. 5,5% of the Dutch population aged 18 and older have experienced some incident of family violence over the 5 years prior to the study (Van Eijkern et al., 2018). Based on self-report research, interparental partner violence co-occurred with child maltreatment in 2,5% of the Dutch youth population aged 12-17 (Schellingerhout & Ramakers, 2017). Also, 48% of maltreated children witnessed violence between parents concurrently (Alink et al., 2018). Family violence shows strong adverse impact, both immediately and in the long term, across somatic and psychological domains (Alink et al., 2012). The effects of family violence are direct, in the form of posttraumatic stress symptoms, anxiety and depressive symptoms (Janssen et al., 2019; Tierolf et al., 2014) and indirect, through the association of family violence with parenting and the parent-child interaction (Visser et al, 2015; Visser et al., 2016). When treating childhood trauma effect sizes of *golden standard*- trauma treatments are generally lower than for children who have suffered other forms of trauma (Ehring et al., 2014). Also, in 85% of the families referred to mental health

care after family violence, violence was found to have continued 7 years later (Lünnemann et al., 2020).

Direct effects of family violence

One out of every three children exposed to family violence develops trauma-related symptoms, such as posttraumatic stress symptoms, anxiety, and depressive symptoms (Janssen et al., 2019; Tierolf et al., 2014). The Cognitive Context Theory states the violence is a stressor and children try to understand and cope with this stressor. Contextual, cognitive and developmental factors determine the child*s understanding and therefor response to family violence (Grych & Fincham, 1990). According to Emotional Security Theory (Davies & Martin, 2013), witnessing family violence directly triggers affective, behavioral, and cognitive responses to the perceived threat to the integrity of the family system. Sustained exposure to destructive family conflict may lead to cascading developmental adaptations that underlie mental health risks. Children may become hypervigilant and easily distressed (affective response) (Katz el. al, 2007), take a distancing or domineering approach to the family conflict (behavioral response) (Deborad-Lucas et al., 2011; Koss et al., 2011), or devalue their family relationships (cognitive response) (Fosco et al, 2007). In the aftermath of family violence children*s responses may no longer be adaptive, increasing vulnerability for psychological problems.

Indirect effects of family violence

In addition to direct effects, family violence may also indirectly cause symptoms in children because of the association of family violence with diminished parental availability (Visser et al., 2015) and disturbed parent-child interaction (Visser, 2016). Parents may experience a broad range of mental health problems, such as depression (Renner, 2009) and post-traumatic stress disorder (Dutton et al., 2006) after exposure to family violence. These mental health problems can be assumed to affect their parenting and quality of parent-child relationships. For example, the spillover hypothesis predicts that distressing experiences in interparental relationships, like violence, carry over to parenting behavior (Krishnakumar & Buehler, 2000) and to the parent-child interaction (Floyd et al, 1998). Consequently, family violence has been linked to more negative and less positive parenting compared to non-violent families, to harsh discipline towards their children (Osofsky, 2003), less supportive and less effective parenting (Levendosky & Graham-Bermann, 2001), and more emotional unavailability and psychological control (Fauber et al., 1990; Gonzales et al, 2000).

Trauma treatment

The current Dutch guidelines for treatment of PTSD in adults (Trimbos, 2013), as well as international guidelines for children (AACAP, 2010; NICE, 2018), recommend individual trauma-focused cognitive behavioral therapy (TF-CBT) and Eye Movement Desensitization and Reprocessing (EMDR). Also, Dutch studies just recently showed that an intensive trauma-focused treatment with three to five treatment days per week can be effective for adults (Woudenberg et al., 2018)

and adolescents (Hendriks et al, 2017) with PTSD. However, as TF-CBT and EMDR on average are effective in addressing PTSD symptoms of children (Mavranezouli et al., 2019), treatment effect sizes were generally lower for different forms of childhood maltreatment like family violence, than for other forms of trauma (Ehring et al., 2014). Moreover, little is known about the reciprocal effects of TF-CBT and EMDR on family relationships and emotional family safety. Individual trauma treatments may be enhanced by adding a parental and systemic component. Evidence that adding a parental component to individual trauma treatment increases treatment success is promising, yet inconclusive (Mavranezouli et al., 2019). Minor studies have systematically reviewed and/or meta-analytically examined effectiveness trials towards an intervention focusing on parenting factors in situations of family violence. Our systematic literature search only found four publications (Johnsen et al., 2018; Hacket et al., 2016; Rizo et al., 2011, and Austin et al.,2019), which included the following parenting factors 1) knowledge of trauma and family violence, 2) trauma sensitive parenting, 3) resilience of the parent, 4) social support/resources, 5) the parent-child relationship, 6) safety within the family and 7) parental stress and competence. The review of Johnson et al. (2018) showed that a parent-child or parent intervention positively affects positive parenting behavior (effect size Cohen*s d=0.72, C.I. 0.43-1.00) and child*s functioning (effect size internalizing problems d=0.59, C.I. 0.43-0.74; externalizing problems d=0.48, C.I. 0.34-0.62; trauma symptoms d=0.56, C.I. 0.36-0.76). Interventions focusing on family violence produce greater improvements in parenting behavior in comparison to interventions focusing on child maltreatment, while interventions for child maltreatment produce greater improvements in PTSD-symptoms. From this review there is limited evidence for the value of combining parent and child interventions, except for a few studies. One study suggests this combination leads to a decrease in PTSD symptoms for the child and this decrease is mediated by improved parent mental health (not by parenting or decreased parental stress). The review of Johnson et al. (2018) also indicated that the type of intervention, that is parent intervention versus parent-child intervention, did not account for a significant variability in effect sizes. In the other three reviews no distinction was made between child intervention, parent-child intervention or parent intervention when discussing the effects of these interventions. Evidence for these different approaches is combined. For example, the review of Hacket et al. (2016) states that interventions focused on the parent, child and/or the parent-child interaction in general are effective (effect size, d=0.76, C.I. 0.58-0.93). Effects differed depending on the informant. Mothers as informants delivered a medium effect; for children as informants there was a medium to large effect, measured to external stress, psychological adjustment, self-concept, social adjustment and family relationships. Mothers also reported a decrease in maltreatment effects within the family (large effect). The review of Rizo et al. (2011) discussed the effects of interventions on parent, child and parent-child or a combination of these interventions in a narrative manner. Rizo et al. (2011) concluded that adolescents showed least improvements, that children with outside support fared better on behavior problems and that there

is more improvement when offering more

than five contacts to the family. Furthermore, they stated that changes in parenting behavior and psychiatric symptoms are largely responsible for the treatment effects on children*s conduct problems. Unfortunately, because of the great variation in interventions studied in these reviews, it is not possible to draw unambiguous conclusions about the effects of parent and family-focused interventions on parent functioning, child functioning, and the parent-child relationship because of different limitations of the reviewed studies. It is not possible to draw conclusions about the association between specific interventions and improvement in child and family functioning. There is a need towards greater sample sizes, controlled study designs, protocolized treatments, and assessment of treatment fidelity, to understand which parent factors are most important in the treatment of children with PTSD symptoms after family violence (Austin et al., 2019). Engagement of maltreated children in the research process can further enhance study quality (Head, 2011), such as more honest findings (Racine et al., 2023) and increased insight in outcomes of interventions that are important to children themselves (Cuijpers, 2019). At the same time this engagement can empower children (Racine et al., 2023; Head, 2011). Besides these positive outcomes, children have the right to be involved in research that concerns themselves and their voices need to be heard (Head, 2011).

Study objective

Primary Objective:
1. Is FITT more effective than ITT in terms of trauma reduction in children and improvement of structural emotional safety in families?

Secondary Objective(s):
1. Is FITT more effective than TAU in terms of trauma reduction in children and improvement structural emotional safety in families, based on the intermediate measurement?
2. To what extent do we find differences between FITT and ITT in trauma informed parenting at the end-of-treatment measurement?
3. Is trauma reduction in children and improvement of structural emotional safety in families equivalent between FITT and TAU, based on the end-of-treatment measurement?
4. What do participants identify as improved outcomes as a result of (F)ITT? What key elements of (F)ITT do the participants perceive as important for treatment success and what do they perceive as barriers?

Study design

This multi-center study examines the addition of a parenting training and family-sessions to an intensive trauma-focused therapy for children exposed to family violence, which results in a randomized controlled trial. Participating families are divided over three trauma treatment arms, intensive trauma treatment, family-based intensive treatment, and treatment as usual. The effectiveness trial comprises a pre-treatment, during treatment, end of treatment, and follow-up design.

Intervention

FITT is a four-week family-based intensive trauma treatment program, containing a preparation phase in week 1, an intensive phase in week 2 and 3 and an integration phase in week 4. Research indicates intensive trauma therapy for adults (Van Woudenberg al., 2018) and adolescents (Hendriks et al. 2017) results in lower levels of PTSD symptoms. In different studies no adverse events occurred and the dropout rate is low (Van Woudenberg et al., 2018).

Preparation phase
The preparation phase consists of two treatment days. On the first treatment day the adolescent, parents and the support system will receive a 90-minute session of psycho-education about trauma, the impact of trauma and the treatment program. They receive psycho-education about trauma, sensitive parenting and how they can support the adolescent during and after treatment. On the second treatment day the adolescent is offered a 90-minute session in which the different traumatic memories are clustered. The adolescent and the therapist choose the six most traumatic memories, ordered by their level of disturbance (SUD, subjective units of disturbance) and these memories will be reprocessed in the exposure and EMDR sessions.

Intensive phase
In the intensive phase the adolescent and parents have 6 treatment days. The first six treatment days the adolescent has a fixed program each day, consisting of a:
• 90-minute session Exposure
• 60-minute session Physical Activity
• 90- minute session EMDR
On the correspondent days the parents have a:
• 60-minute session Parent training

Exposure and EMDR
The exposure and EMDR in the program will be given by different therapists. Hypotheses are that this therapist rotation can decrease fear and avoidance behavior of the therapist (Van Minnen et al., 2018). The exposure and EMDR sessions will be given by therapists with at least two years of experience in

treating adolescents with trauma and advanced training in exposure and EMDR therapy. One traumatic memory each day will be treated with exposure and EMDR. The exposure therapy is based on the protocol from Minnen and Arntz (2007). Prolonged exposure therapy is a form of cognitive behavioral therapy in which the adolescent repeatedly describes the traumatic event in detail and in present tense, focusing on the anxiety-provoking parts of the traumatic event. Every 5 to 10 minutes the therapist checks the level of disturbance experienced by the adolescent. The adolescent learns fearful expectations stay away when being exposed to the trauma and there is no need for avoidance behavior. For the EMDR session we will use the Dutch EMDR protocol for children and youth (2019). During EMDR therapy the adolescent is asked to focus on the most disturbing image of the traumatic memory and the therapist asks questions about the thought and feelings associated with the traumatic image and the level of disturbance. The therapist will ask the adolescent to focus on the image and the associated thoughts and feelings and at the same time focus on a distracting stimulus. This will bring a stream of associations in the form of thoughts, feelings, images and bodily sensations and helps to reprocess the traumatic memory. The therapist will then ask what the adolescent notices and repeat the distracting stimulus. After a while the adolescent will notice the level of disturbance will lower until the traumatic memory is desensitized. If necessary, the therapist
can add cognitive interweaves during the desensitization phase to elicit new associations.

Physical activity
Physical activity is a standard component of intensive trauma treatment, because trauma
therapy combined with physical activity results in lower PTSD symptoms (Rosenbaum et
al.,2015). The sessions psychical activity consists of exercises focusing on activation,
relaxation, and recognizing and controlling bodily sensations.

Parent training
The aim of the parent training and parent-child interaction session is to increase parental skills, parental availability and insightfulness in children*s needs and strengthen the parent-child relationship and therefor the emotional safety in the family. The parent training is given by a family therapist or family worker with at least two years of experience in counseling parents of children with complex trauma. In the parent training parents learn:
1. The difference between their own trauma history and children*s trauma history,
2. The difference between their own trauma-related symptoms and children*s symptoms,
3. About the consequences of exposure to family violence on the individual and relational level for children and their families,
4. How to practice parenting skills in a trauma-sensitive way.

5. Recognizing destructive family patterns.

Integration phase
The integration phase consists of three family sessions in the final week. These sessions focus on sharing thoughts and feelings about the traumatic events, recognizing and breaking destructive patterns, and finding solutions for recurring problems.

Study burden and risks

Family violence has a devastating effects on children and families. Current trauma treatments show lower effect on trauma reduction in children exposed to family violence, they do not (intent to) restore family functioning. In 85% of the families referred to youth mental health care after family violence, violence was found to have continued 7 years later (Lünnemann et al., 2019). Family based intervening added upon trauma treatment may impede recovery from trauma, and the expected benefits await empirical testing. It is in the best interest of the children to make sure that there comes a family based intensive trauma treatment available, that is able to reduce trauma in children and increases structural emotional and physical safety in families. If FITT performs according to the expectations than the mental health professional has a tool to help children structurally recover from family violence, which improves their wellbeing.

Questionnaires and interviews will always be administered by research psychologists, and research assistants (assisted by graduate students, with at least a bachelor*s degree in psychology, education or a related discipline). The majority of the instruments is already part of the routine outcome monitoring of (some of the) participating trauma centers or are used in previous research. Based on previous experiences we estimate that completion of the questionnaire at T0, T12-T14 takes about one hour for child and caregivers. Questionnaires at T1-T11 take about 10 minutes to complete by child and caregivers. The interview at T0 and T13 takes about 1 hour. The observational task at T12 takes about half an hour. The adolescents who participated in ITT or FITT will be asked to participate in an interview about their experience with intensive trauma treatment.

Considering the expected benefits of this study, we find the emotional burden acceptable. Especially because there is no scientific prove that symptoms increase when children are asked about traumatic experiences, nor is there scientific prove that trauma-related research has a more negative impact than not-trauma related research (Van der Velden, Bosmans, Scherpenzeel, 2013). However, traumatic incidences inflicts feelings of shame, quilt and embarrassment, which has severe and long-lasting consequences when left untreated (Felliti et al., 1998).

The risk for participating in this project is considered moderate. Therefor an

monitoring board will be installed, and researcher will receive supervision from clinical trauma experts (e.g. Margreet Visser & Valerie Fictorie). When a child seems adversely affected by the questionnaires, interview, or observational tasks it may be decided to (temporarily) discontinue participation in the project.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1) the child has been exposed to child abuse/family violence;
2) the acute safety in the family has been established in the short time;
3) the child is between 12 and 20 years old;
4) the child lives at home with its caregiver(s);

5) caregivers, living with the child are able to participate in the systemic components;
6) the child has trauma symptoms, at least intrusions and avoidance;
7) both custodial parents gave written informed consent consistent with the Dutch legislation;
8) caregivers and children master the Dutch language

Exclusion criteria

Children and parents with acute psychotic symptoms or severe alcohol and/or drug addictions. Children with a suicide attempt in the past 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2021
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2023
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	NL74172.029.20
Other	Trial NL8592