REWIND AND FAST FORWARD: EFFECTIVENESS OF A HIGH INTENSIVE TRAUMA-FOCUSED, FAMILY BASED THERAPY (FITT) FOR CHILDREN EXPOSED TO FAMILY VIOLENCE

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24707

Source
NTR

Brief title
TBA

Health condition

Posttraumatic stress disorder (PTSD)

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: 70-74900-98-002

Intervention

Outcome measures

Primary outcome

PTSD and structural emotional security

Secondary outcome

parent functioning and child functioning

Study description

Background summary

This proposal concerns Family based Intensive Trauma Treatment (FITT) for children exposed to family violence. In addition to direct harm from posttraumatic stress symptoms (Tierolf, Lünnemann & Steketee, 2014, see Publication list; Janssen, Lünnemann, D'haese & Groenen, 2019), children exposed to family violence are also bound to suffer from family dysfunctioning and emotional and physical insecurity (Cummings & Davies, 2010; Visser, Schoemaker, de Schipper, Lamers-Winkelman, & Finkenauer, 2015, see Publication list; Visser, 2016, see Publication list). In 85% of the families who were referred to youth mental health care after family violence, violence was found to have continued 7 years later (Lünneman, van der Horst, Prinzie, Luijk & Steketee, under review, see Publication list). EMDR and TF-CBT on average are effective in reducing children's PTSD symptoms (Mavranezouli et al., 2019). However, for maltreated children effect sizes are generally lower than for children who have suffered other forms of trauma (Ehring et al., 2014). EMDR and TF-CBT in themselves do not restore family functioning. Adverse parenting, apart from parental violence, may impede recovery from trauma (Visser et al., 2015, see Publication list). Evidence that adding a parental component to individual trauma treatment increases treatment success is promising, but inconclusive (Mavranezouli et al., 2019). Furthermore, the underlying social behavioral and psychophysiological mechanisms remain speculative. Integrating measurement of social and physiological processes with clinical efficacy research is a growing and powerful scientific paradigm for understanding how to ameliorate the effects of childhood adversity (Purewal Boparai et al., 2018). In FITT, trauma-focused therapy is combined with a component focusing on parenting and parent-child interaction. Enhancement of parent-child relationships and emotional and psychical security is expected to facilitate recovery from trauma treatment. FITT consists of an individual part focusing on reducing PTSD symptoms (6 sessions EMDR and 6 sessions exposure) and has a parental component addressing parenting and family relationships as developed in the Horizon-method (Platje et al, under review, see Publication list). Parents have 6 sessions of skills training, focusing on trauma-sensitive and supportive parenting. The program ends with a parent-child interaction session wherein the child shares its trauma narrative. While it is plausible that adding parent-child intervention elements enhances effects of individual trauma treatment for children, the expected benefits await empirical testing. The proposal for this randomized controlled trial addresses two separate goals. First to isolate the adjuvant effects of the parental and systemic components on 1) child PTSD symptoms, 2) parenting functioning, 3) family-safety casu quod the parent-child relationship, and 4) child internalizing and externalizing behavior. The second goal is to explore whether adjuvant effects are

manifested in children’s immune system functioning and epigenetic changes. The RCT will be conducted by a consortium of mental health centers for traumatized children in The Netherlands. Eligible families will be randomly assigned to Intensive Trauma Treatment with or without the parental component. In Phase 1 theoretical and practice-based insights will be collected and integrated to enhance the design of FITT, design viable versions of FITT with and without the parental components, and address conditions for their implementation and sustainability. First, the results of a literature search will be combined with the results of an expert-meeting to enhance our understanding how the parenting training may lead to change in parenting behavior, in the parent-child relationship and especially in structural family safety, and how to measure these changes. Secondly, based on the findings in the expert-meeting a plan will be constructed with the conditions needed to integrate, implement and sustain FITT in the existing health care system. Furthermore, in Phase 1 the Consortium of clinical trauma treatment partners for youth will plan and prepare for the trial in Phase 2. With the results of Phase 1 and Phase 2 FITT can contribute to the ambition of the Dutch program ‘Geweld hoort nergens thuis’ that has the task to stop, reduce, and limit the impact of family violence and create emotional and psychical safety for children in a sustainable way.

Study objective

Treatment succes increases when a parental component is added upon individual trauma treatment

Study design

In total 14

T0 = before start
T1-12 = each treatment day
T13 = end of treatment
T14 = 3 months follow-up

Intervention

FITT and ITT (Family-based] Intensive Trauma Treatment)

Contacts

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Eligibility criteria

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 biological parent(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 drug addictions are excluded for this treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2020
Enrollment:	96
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8592
Other	METC VuMC : Not yet submitted

Study results