Change in Post-traumatic Cognitions Mediates Treatment Effects for Traumatized Youth
A Randomized Controlled Trial

Abstract

Objective: Post-traumatic stress symptoms (PTSS) are associated with serious impairments in psychological, social, and academic functioning in youth. The aim of this study is to investigate whether changes in post-traumatic cognitions mediate treatment effects. Methods: Participants were multi- traumatized youth (N = 156, mean age 15.1 years, range 10-18; 79.5% girls) randomly assigned to receive trauma-focused cognitive behavioral therapy (TF-CBT) or therapy as usual (TAU). Mixed effects models were applied to investigate the impact of treatment conditions on post-traumatic cognitions. Mediation analyses were applied to examine whether changes in post-traumatic cognitions mediated the relationship between treatment conditions and outcome in post-traumatic stress symptoms, depressive symptoms and general mental health. Results: Participants receiving TF-CBT reported significantly lower levels of negative post-traumatic cognitions at the end of treatment compared to participants in TAU. Change in post-traumatic cognitions mediated the treatment effect difference found for PTSS; indirect effect estimate = 5.63, 95% CI [1.48, 11.02]. When the overall change in cognition was divided into early and late change, it was only the late change that significantly mediated the PTSS treatment effect; indirect effect estimate = 5.30, 95% CI [2.15, 10.28]. A mediation effect of post-traumatic cognitions was also found for the treatment effect difference in depressive symptoms; indirect effect estimate = 3.82, 95% CI [1.08, 7.09], and in general mental health symptoms; indirect effect estimate = 1.37 [0.32, 2.78]. Conclusions: Traumatized youth report having many negative posttraumatic cognitions and changes in negative cognitions plays a key role for treatment outcome.

Post-traumatic cognitions mediates treatment effects

Keywords: maladaptive appraisals, Trauma Focused-Cognitive Behavioral Therapy (TF-CBT), child trauma, post-traumatic stress, Children's Post-Traumatic Cognitions Inventory.

Impact Statements

Many traumatized youth develop negative thoughts about the world and themselves that are associated with the development and maintenance of post-traumatic stress symptoms. This study shows that youth receiving trauma-focused cognitive behavioral therapy (TF-CBT) report fewer negative thoughts at the end of treatment compared to youth receiving standard therapy, and that this difference mediates the treatment outcome on posttraumatic stress symptoms and on symptoms of depression and general mental health problems as well. Addressing and altering these negative thoughts may be crucial to successful treatment.

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The psychotherapy development of the last years has generated several evidence-based therapies (EBT) for youth, including treatments for youth exposed to potentially traumatizing events. Trauma-focused cognitive behavioral therapy (TF-CBT) is currently one of the most studied trauma treatments for youth (Dorsey et al., 2017; Morina, Koerssen, & Pollet, 2016). There is, however, a lack of studies investigating potential treatment mechanisms in TF-CBT. Exposure to potentially traumatizing events is common in youth (Costello, Erkanli, Fairbank, & Angold, 2002; McLaughlin, et al., 2013). Although many recover, a substantial number of youth will be at risk of developing posttraumatic stress symptoms (PTSS) that can severely impact emotional, academic, social, and later adult functioning (Alisic, et al., 2014; Trickey, Siddaway, Meiser-Stedman, Serpell, & Field, 2012). Understanding how treatment may help these youth is therefore essential. No doubt understanding complex interpersonal processes and therapeutic change is never-ending. Research on therapy processes has none the less identified characteristics of the client, the therapist and their relationship, as well as specific therapeutic interventions to predict outcome (see e.g., Norcross & Lambert, 2011). The relative importance of these aspects is, however, debated.

One concern in the psychotherapy research field has been that studies have not had comparable control groups, so that the role specific interventions may play in treatment effects is not easily determined (Wampold et al., 1997). Many control conditions are not intended to be therapeutic (i.e., they are not bona fide treatments), making direct comparisons difficult and potentially overestimating effects. Furthermore, in some study designs the specific ingredients thought to be important to the active condition is purposely left out, at disadvantage to the control condition (Wampold & Imel, 2015). One consequence is that one

may be asking the therapist to deliver a therapy s(he) does not believe in, producing negative allegiance effects (Miller, Wampold, Varhely, 2008; Wampold et al., 2000; Wampold & Imel, 2015;). It may be reasonable to assume that a therapist who does not believe in the therapy s(he) is asked to provide will be less invested in treatment delivery and may express less positive expectations for outcome, thus inadvertently influencing outcome negatively. Consequently, in order to study the relative importance of specific therapeutic ingredients over common ingredients, interventions compared should be bona fide treatments and allegiance factors should be taken into account.

In a meta-analysis on treatments for PTSD in adults, Benish, Wampold & Imel (2008) concluded that when trauma-focused therapies are compared to bona fide treatments the efficacy of the trauma-focused treatments is diminished (see also Wampold et al., 2010 for a discussion). Although this claim has been challenged (Ehlers et al. 2010), Benish et al.'s (2008) meta-analysis lends support to the importance of the factors that are common across treatments, such as a strong therapeutic alliance. A comparable meta-analysis for youth trauma treatments is lacking. However, Spielmans, Gatlin, and McFall (2010) compared EBTs with bona fide usual care for youth suffering from a wide range of symptoms and concluded that when controlling for an array of confounding variables, the advantage of EBTs was small. In line with this, a current meta-analysis of youth studies showed that EBTs had the lowest effect sizes across studies when compared to usual care that included active treatment ingredients (Weisz et al., 2017). Also Miller, Wampold & Varhely, 2008) found that effect sizes in youth studies varied, providing evidence that some treatments may be more helpful than others, but this difference diminished when allegiance was controlled for. However, the number of studies comparing any two bona fide treatment approaches intended for children and adolescents are few, making firm conclusions premature (Weisz et al., 2017).

Another concern in the psychotherapy field is related to the large number of studies

showing that EBTs often do not outperform therapy as usual (TAU) when delivered in regular clinical practice. This has been demonstrated in several youth meta-analysis (See Kazdin, 2015; Spielmans et al., 2009; Weisz et al., 2013). In the prototypic randomized clinical trial, carefully selected therapists who receive extensive training and supervision deliver the treatment. They are often specialists in one treatment condition. The clients are often highly selected with low comorbidity, recruited through advertisements or to specialty clinics associated with a university or medical institution (Kazdin, 2015; Wampold & Imel, 2015; Weisz et al., 2013). In order to bring the field forward we need to document that evidence based treatments also are useful when applied in regular clinical settings.

In this paper, we aim to understand more of what may lead to reductions in trauma-related symptoms in traumatized youth by comparing youth receiving Traumafocused cognitive behavior therapy (TF-CBT) with youth receiving bona fide therapy as usual (TAU) in regular mental health clinics. The analysis builds on results from a randomized controlled trial (RCT) showing that youth who received TF-CBT experienced significantly larger reductions on the primary outcome measure, PTSS, compared to the TAU group. Also on the secondary outcome measures, depression, and general mental health problems, participants in TF-CBT had larger symptom reductions than participants in TAU, albeit both groups experienced improvements (Jensen, et al., 2013). A strong alliance was predictive of reductions in PTSS for the TF-CBT group but not for the TAU group, although both groups reported similar alliance scores (Ormhaug, Jensen, Wentzel-Larsen, & Shirk, 2014). These results lend support to the claim that it may be the combination of a good alliance (i.e., a common factor) and specific interventions (i.e., specific factors) that leads to symptom reduction. Another study has documented that constructing a trauma narrative may be one important specific ingredient (Deblinger, Mannarino, Cohen, Runyon, & Steer, 2011). However, when analyzing the effect of narrative change in TF-CBT, we found that while

youth in TF-CBT developed narratives that were more coherent and organized compared to baseline, these changes were not associated with changes in PTSS (Knutsen & Jensen, 2017).

In the current paper we wish to further untangle which factors may be important change mechanisms by studying whether changes in maladaptive cognitions mediate the effect of TF-CBT. We focus on changes in maladaptive cognitions since these are considered essential to the development and maintenance of posttraumatic stress in several information- and emotional-processing models (e.g., Ehlers & Clark, 2000; Foa & Kozak, 1986; Meiser-Stedman, 2002). According to these models, it is the person's appraisals of the trauma itself and its' sequelae that maintain the PTSS. Misappraisals may be over-generalizations of danger, exaggerated fear of recurrence of a new traumatic event, and/or mistaken thoughts about the causes of the trauma and the way the person reacted, often leading to feelings of guilt and shame. Regarding the sequelae of trauma, misinterpretations of trauma symptoms can lead people to believe they are crazy, weak, helpless, or damaged. These negative cognitions may cause a range of unhelpful coping strategies such as avoidance and scanning the environment for possible danger, causing hypervigilance, rumination, and safety behaviors. In line with this, a recent study is published showing that changes in traumarelated cognitions precedes changes in PTSS in an adult population, giving support to the claim that changes in cognitions may be the driving force in changing PTSS (Kleim et al., 2013).

Although the emotional and cognitive processing models are mostly tested in traumatized adults, there is increasing evidence that unhelpful post-trauma coping strategies contribute to the maintenance of PTSS also in youth (Bryant, Salmon, Sinclair, & Davidson, 2007; Ehlers, Mayou, & Bryant, 2003; Hitchcock, Ellis, Williamson, & Nixon, 2015; McLean, Yea, Rosenfield, & Foa, 2015, Meiser-Stedman, Dagleish, Glucksman, Yule, & Smith, 2009; Stallard, 2003; Stallard & Smith, 2007; Udwin, Boyle, Yule, Bolton, & O'Ryan,

2000). A growing body of evidence indicates that traumatized youth experience more negative cognitions compared to non-traumatized youth. This has been found in sexually abused (Mannarino & Cohen, 1996) and maltreated (Münzer, Ganser, & Goldbeck, 2017) youth, physically injured youth (Ehlers, et al., 2003; Nixon et al., 2010), physically abused children (Kolko, Brown, & Berliner, 2002), youth injured from motor vehicle accidents (Meiser-Stedman, Dalgleish, et al., 2009), and youth subjected to psychological maltreatment (Leeson & Nixon, 2011). Thus, many trauma-focused interventions recommend addressing negative and maladaptive cognitions in their protocols.

Although studies are limited in number, according to a meta-analysis, trauma focused cognitive therapies do effectively reduce trauma-related cognitions more so than non-trauma focused control conditions in adults (Diehle, Schmitt, Daams, Boer, & Lindauer, 2014).). Since nearly all studies are with adult populations we currently have little knowledge about how trauma related cognitions change in trauma therapy for youth, and whether these changes are related to reductions in PTSS. To our knowledge, only two studies have examined whether changes in post-traumatic cognitions mediate treatment effects for youth with PTSS (McLean et al., 2015; Smith et al., 2007). Smith et al., (2007) showed the effects of CBT were partially mediated by changes in post-traumatic cognitions in children who had experienced motor vehicle accidents, interpersonal violence, or witnessed violence, while McLean et al., (2015) found the same for a group of adolescent female sexual assault survivors receiving client centered therapy or prolonged exposure therapy.

After several studies have shown that exposure to traumatic events is associated with changes in cognitive appraisals and beliefs, the fifth edition of the DSM (DSM-5; American Psychiatric Association, 2013) incorporated trauma-related cognitions as part of the posttraumatic stress disorder (PTSD) diagnosis. Until recently, the diagnostic criteria for this diagnosis included three symptom clusters, namely re-experiencing the trauma, avoidance of

trauma-reminders, and hypervigilance. Negative changes in thoughts and mood are now included as a fourth symptom cluster. It becomes therefore even more pertinent to know more about whether interventions may contribute to reducing post-traumatic cognitions.

So far, the literature has focused mainly on the relationship between cognitions and PTSS, and less on other symptom groups. Since many traumatized youth not only develop PTSS but also severe symptoms of depression and a range of general mental health problems as well, examining whether changes in negative cognitions also mediates changes in these symptoms may be helpful to understand mechanisms of change. If changes in negative cognitions mediate changes in a range of mental health problems and not only PTSS, then this may indicate that changing negative cognitions is a general change mechanism for TF-CBT.

The aims of the current study are twofold. The first aim is to examine the impact of TF-CBT on post-traumatic cognitions relative to a bona fide control condition (i.e., TAU). Since TF-CBT specifically targets post-trauma cognitions we hypothesize that TF-CBT will yield greater reductions in post-traumatic cognitions than TAU. The second aim is to investigate whether post-traumatic cognitions mediate the relationship between treatment condition and PTSS, depressive symptoms and symptoms of general mental health. For the primary outcome, PTSS, we also examine whether a potential mediator effect occurs early or late in treatment. Since studies suggest that trauma-focused CBT interventions lead to larger reductions in trauma-related cognitions than non-trauma focused control conditions (Diehle et al., 2014; Smith et al., 2007), we hypothesize that the superior performance of TF-CBT to TAU will be mediated (i.e., explained by) differences in cognitive change.

Method

The difference in post-traumatic cognitions between TF-CBT and TAU over time were investigated with mixed effects analyses. Mediation models (Preacher & Hayes, 2008) were

tested to investigate the mediating effect of post-traumatic cognitions on changes in PTSS, depressive symptoms, and general mental health symptoms. In the mixed effects analyses, we accounted for nesting of therapist level. Also, since the ability to form internal and stable cognitions has been found to increase with age (Salmon & Bryant, 2002) we controlled for the youth' age in all analytic models. All results in the study draws upon data from a randomized controlled trial conducted in community mental health clinics comparing TF-CBT with TAU. Previously published results showed TF-CBT to be more effective in reducing PTSS than TAU among youth with diverse traumatic experiences (d = 0.51, t = 0.01) (Jensen, et al., 2013).

Participants

The sample comprised 156 youth aged between 10 and 18 years ($M_{age} = 15.1$ years, SD = 2.2; 79.5% girls), referred to one of eight community clinics. The majority of the children were ethnic Norwegian (73.7 %, n = 115). Around half the sample lived most of the time or only with their mother (51.9%), and 22.4% lived with both parents. On average, participants reported having been exposed to 3.6 different types of traumatic events in their lifetime (SD = 1.8, range = 1.10). The most frequently reported traumatic events were sudden death or severe illness of a close person (60.9%), violence or threats of violence outside the family context (59.0%), physical abuse within the family (45.5%), witnessing violence within the family (42.9%), witnessing violence outside the family (27.6%), and sexual abuse outside the family (27.6%). For a more detailed description of the sample, see Jensen, et al. 2013.

Procedures

A total of 454 youth were screened for eligibility in the RCT using the Child Post-Traumatic Symptom Scale (CPSS; Foa, Johnson, Feeny, & Treadwell, 2001). To be eligible, the youth must had experienced at least one potentially traumatizing event that had occurred ≥ four weeks before study inclusion, and have PTSS scores above cutoff (i.e., CPSS scores ≥ 15). The cut-off score of 15 was chosen as this has been suggested an optimal indicator for clinically elevated PTSS (Kassam-Adams, Marsac, & Cirilli, 2010). Exclusion criteria were acute psychosis, acute suicidal behavior, or need of an interpreter. Two hundred youth scored above the established cut-off, of whom 156 agreed to participate. Youth were randomly assigned to either TF-CBT or TAU (see Figure 1). At each clinic, a computer-generated randomization procedure allocated participants into random blocks of four or six in random order with an equal probability of four or six with half (i.e., two or three) assigned to TF-CBT and half to the control group. The randomization was not stratified by any variables. Computer-assisted assessments were conducted by two clinicians naïve to treatment condition at pre-treatment (T1), after six sessions (T2), and after 15 sessions (T3). The clinical diagnostic interviews for PTSS (CAPS) and assessment of youth general mental health symptoms (SDQ) were only conducted at T1 and T3. Written informed consent was provided by youth and parents. The study was approved by the Norwegian Regional Ethical Committee.

(Insert Figure 1 here)

Treatment Conditions

The TF-CBT treatment model addresses possible problem domains such as Cognitive, Relationship, Affective, Family, Traumatic behavior, and Somatic problems, summarized by the acronym CRAFTS. The treatment comprises 12-15 sessions and involves individual child and caregiver sessions and conjoint sessions (see Cohen, Mannarino, & Deblinger, 2017).

The treatment consists of three phases. The first one is stabilization and skill building which encompass teaching *psychoeducation* to normalize the youth's and caregivers' reactions to the trauma and to support accurate cognition about what has happened; improving *parenting skills* to maintain normal daily routines and expectations; teaching *relaxation skills* to reduce physiological stress and arousal; *identifying feelings* so that the

youth can learn to regulate these and not feel overwhelmed and vulnerable; teaching cognitive coping skills so that the youth can explore and correct thoughts that are unhelpful. The next phase is trauma narration and processing which includes creating a trauma narrative to desensitize the youth to trauma reminders and minimize avoidance and hyperarousal, and to identify and modify trauma-related cognitions to reduce possible self-blame, shame, and fear through cognitive reprocessing. The final phase is consolidation and closure in which the therapist may use in vivo exposure to help the youth cope with generalized avoidant behavior and enhance feelings of mastery and work to enhance future safety and development so the youth can recognize and respond to future threats.

All therapy sessions were audio-recorded to control for treatment fidelity using the TF-CBT Fidelity Checklist (Deblinger, Cohen, Mannarino, Murray, & Epstein, 2008). Fidelity was satisfactory in the TF-CBT group except for five cases. These cases were omitted from the per-protocol analyses. On average, the TF-CBT participants received 13.1 sessions (SD = 3.1, range 4 - 17) before completing the post treatment assessment, and the two assessment points were on average 33.2 weeks (SD = 11.4, range 17 - 73) apart.

The TAU group received a bona fide treatment. The TAU- therapists were informed that their client was traumatized and was suffering from severe PTSS, in addition to any other comorbid conditions. They were specifically asked to give their treatment of choice i.e. the therapy that they believed to be the best for their client, thus reducing possible bias for allegiance affects. The TAU-therapists were not instructed to omit any certain interventions (i.e. talking about the trauma), and the children in TAU reported a strong therapeutic alliance with their therapist (Ormhaug, Jensen, Wentzel-Larsen, & Shirk, 2014). These are all considered important criteria for an intervention to be a bona fide treatment, allowing us to examine possible mediators of outcome (Flückiger et al., 2014; Wampold et al., 2010).

All TAU sessions were audiotaped, and five sessions from each therapy were coded according to the TF-CBT Fidelity Checklist. None of the TAU-cases met the adherence criteria for TF-CBT. In addition, three sessions from each of the TAU therapist (n = 81 sessions) were coded using the Therapy Process Observational Coding System – Strategies Scale (TPOCS-S; McLeod & Weisz, 2010). The following frequency and thoroughness (combined as intensity, possible range: 1 - 7) of 31 items across the five TPOCS-S domains were identified: Client-Centered (observed in 92.6% of sessions; $M_{intensity} = 3.0$, SD = 0.8), Psychodynamic (observed in 45.7% of sessions; $M_{intensity} = 2.5$, SD = 0.6), Family (observed in 35.8% of sessions; $M_{intensity} = 2.4$, SD = 0.6), Cognitive (observed in 30.9% of sessions; $M_{intensity} = 2.8$, SD = 0.8), and Behavioral (observed in 19.8% of sessions; $M_{intensity} = 2.6$, SD = 1.0). Post-traumatic cognitions were explicitly addressed in 8.6% of the coded TAU sessions. On average, participants in the TAU condition had 13.4 sessions (SD = 4.1, range 4 – 21) before completing the post treatment assessment, and the two assessment points were 36.4 weeks (SD = 11.7, range 17 – 63) apart.

Therapists

All therapists volunteered to participate in the study. The TF-CBT therapists (n=26) received training in TF-CBT that included a two-days training session and weekly supervision for the first two cases. Each TF-CBT therapist treated an average of 3.0 participants (SD=1.4, range: 1-6), and included 21 psychologists, two psychiatrists, two educational therapists, and one social worker. The TF-CBT therapists had on average 10.2 years of clinical experience (SD=6.4, range: 3-28). The TAU therapists (n=45) treated on average 1.7 participants (SD=1.3, range: 1-9), and included 23 psychologists, 12 social workers, eight educational therapists, and two psychiatrists. The majority reported that their theoretical background was psychodynamic (n=35), but TAU-therapists were also trained in cognitive behavioral therapy (n=16) and systemic family therapy (n=15). On average,

TAU-therapists had 12.5 years of clinical experience (SD = 10.3, range: 1-40). Fifteen of the TAU therapists reported receiving supervision on their work with the study case (mean hours of supervision: 6.3, SD = 10.2, range 1 – 40).

Measures

Measure to determine eligibility: Child PTSD Symptom Scale (CPSS; Foa et al., 2001). The CPSS is a 17-item self-report questionnaire developed to measure PTSS in children between 8 and 18 years, according to the DSM-IV. Symptoms are scored on a 4-point Likert scale ranging from 0 to 3. Higher scores indicate a higher level of PTSS. The CPSS has shown satisfactory internal consistency, test-retest reliability, and convergent validity (Foa, et al., 2001; Nixon et al., 2013). In the current sample of 454 screened youth, the total scale showed internal consistency of $\alpha = .91$.

Post-Traumatic Cognitions Inventory – Child Version (CPTCI; Meiser-Stedman, Smith et al., 2009). The CPTCI is a 25 item self-report measure of posttraumatic cognitions in youth aged 10 to 18 years. The scale is adapted from the Post-Traumatic Cognitions Inventory, a measurement of dysfunctional trauma-related appraisals in adults (Foa, Ehlers, Clark, Tolin, & Orsillo, 1999), and comprises two subscales. These are "Disturbing and permanent change" (i.e., I feel like I am a different person since the frightening event; I will never be able to have normal feelings again) and "Feeble person in a scary world" (i.e., Anyone could hurt me; I can't stop bad things from happening to me). Responses range from 1 to 4, where higher scores indicate more post-traumatic cognitions. A recent study has shown that the CPTCI has excellent psychometric properties and is a useful tool for clinicians to assess changes in cognitions (McKinnon et al., 2016). In this sample, the two subscales were highly correlated (r = .74, p < .001), and were therefore not separated in the analyses.

The total scale showed good internal consistency (α = .92). The CPTCI was collected at three time points (T1, T2 and T3).

The Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA; Nader et al., 1996; Nader et al., 2004). The CAPS-CA is a structured clinical interview used to assess the frequency and intensity of the 17 DSM-IV defined symptoms of PTSD (Nader et al., 1996; Nader et al., 2004). Items are scored based on symptom severity during the last month, and the items are scored based on both the youth's answers and clinical judgment during the interview (range: 0-136). In this sample, the total sum score showed satisfactory internal consistency (α = .90). In the present study, the CAPS-CA was included as an outcome measure instead of CPSS because a clinical diagnostic instrument with a clinical judgment of intensity was considered to be the most thorough measure of PTSS. In the current study, the CAPS was used at T1 and T3.

Mood and Feelings Questionnaire (**MFQ**). The MFQ is a 34 item self-report questionnaire measuring depressive symptoms in children and adolescents between 8-18 years (Angol et al, 1995). The symptoms cover the DSM-IV diagnostic criteria for depressive disorders and are assessed on a 3-point Likert scale ranging from 0 to 2. Higher scores indicate more depressive symptoms. The scale showed an internal consistency of α = .91 in the current sample. The MFQ was collected at three time points (T1, T2 and T3), but only information from T1 and T3 was used in the current study.

Strengths and Difficulties Questionnaire (SDQ). The SDQ is a 25 item self-report questionnaire developed to measure general psychological adjustment in children and adolescents (Goodman, 2001). The questionnaire is divided into different sub scales, and the four problem oriented sub scales, the hyperactivity/inattention-scale, the emotional symptom-scale, the conduct problem-scale and the peer relation problem-scale are used in the current study. The questions are scored on a 3-point Likert scale ranging from 0 to 2. Higher scores

indicate more problems. The total scale showed an internal consistency of α =.73 in the current sample. The children and adolescents answered the SDQ-items on T1 and T3.

Data Analyses

Characteristics of the sample were investigated with descriptive statistics, and differences between the attrition group and retention group were investigated with independent samples t-tests and Pearson's chi square test. To investigate the main research questions, two analytical approaches were applied. Mixed effects models were used to examine the difference in post-traumatic cognitions between the conditions as well as the cognitions within each treatment condition across time and mediation analyses investigated the mediating effect of post-traumatic cognitions on treatment outcome.

A dependency among subsets of cases within the same dataset is referred to as clustered or nested datasets. Such dependency arose in the current dataset because we had repeated measures on single individuals over time and because the therapists provided treatments to more than one participant. The advantage of mixed effects models is that they take into account the nested nature of the data by estimating a measure of random variation both between and within participants (Fairclough, 2010; Pinheiro & Bates, 2000). The models handle missing data under the missing at random assumption (MAR). Given the longitudinal design of the study, we included participants as the second level in the analysis, and given the nested data at the therapist level, therapists were included as a third level in the analysis. The level of child post-traumatic cognitions was used as dependent variable, and the independent variables were treatment condition and time, including a condition by time interaction. The mixed effects models were based on intention-to-treat (ITT) analyses, meaning that all participants who completed the T3-assessments, including dropouts, were analyzed in the condition in which they were originally randomized. The age of the youth was entered as a covariate in the analyses.

The second analytic approach was mediation analyses. For a mediation process to be present in psychotherapy, particularly two conditions have been outlined as necessary (Kazdin, 2009). First, there has to be an intervention that leads to change in the outcome. Secondly, a mediator should account for the relationship between the dependent and independent variables. The terms mediator and mechanism should be distinguished (Kazdin, 2009). As the mediator accounts for the relationship between the treatment and the outcome, the mechanism reveals the reasons why the change occurs. In the current study, we only investigated an analytic model that took into account the mediator, not the change mechanism.

We attempted estimation of multilevel mediation models, as these models allow clustered variables to be entered as new levels in the analyses (Preacher, Zyphur & Zhang, 2010). More specifically, we attempted to enter therapists as a second level. Unfortunately, the models came out unstable, probably because of the large number of therapists relative to the few clients nested within each. Subsequently, the mediation analyses were conducted as single level mediation analyses. The mediation modeling according to Preacher and Hayes was applied (Preacher & Hayes, 2008). The main reason for choosing this mediation approach was that we were able to investigate the indirect effect specifically of change in post-traumatic cognition on child outcome. The approach allows a significant indirect effect to be present although the relationships in the individual paths are not significant. The bootstrap resampling method was applied using 5000 re-samples of the data. This mediation modeling framework comprises two regression models; one model for the mediator which indicates the relationship between the independent variable (IV) and the mediator (M) – the a-path, and one model for the outcome, which estimates the relationship between the M and the dependent variable (DV) – the b-path, and the c'-path, which shows the relationship between the IV and DV while controlling for the M.

The mediation models were conducted separately for three different outcomes, PTSS (CAPS), depression (MFQ) and general mental health symptoms (SDQ), respectively. As PTSS was the primary outcome in the study, the PTSS-model was further divided into three different versions. In the first PTSS-model (Model 1A), the mediator was the overall change in appraisals from pre- to post-treatment (T1 to T3). In the second PTSS-model (Model 1B)) the mediator comprised the change in cognitive appraisals from pre- to mid-treatment (T1 to T2, early change), and the third PTSS-model (Model 1C) consisted of the mediator measured as the change in cognitive appraisals from mid- to post-treatment (T2 to T3, late change). All variables were treated as continuous measures. The age of the youth was entered as a covariate in the mediation analyses.

In the mediation analyses ITT-analyses were conducted. In addition, all data were analyzed following a *per-protocol* (PP) approach, meaning that the five participants from the TF-CBT group that did not receive TF-CBT were removed, and participants were analyzed with regard to the treatment they actually received. The PP analyses were performed to examine whether they yielded similar results as the ITT-analyses.

We estimated intraclass correlations (ICC) based on mixed effects models with intercept only, with therapists as a clustering variable, for the three outcome variables PTSS, depressive symptoms and general mental health symptoms. Significance of including the therapist level variance was computed by likelihood ratio tests from a comparison of the mixed effects models with linear regressions, both estimated by maximum likelihood.

The CPTCI was completed electronically, and the computer program did not allow for missing items. However, the clinical diagnostic interview CAPS had a few missing single items, and we allowed 10% missing values in computing the sum scores of CAPS. Scale scores were computed based on the mean of valid items. In Mplus, the treatment of missing

data is applied by full information likelihood (FIML) under the MAR assumption (Muthén & Muthén, 2010)

All analyses were conducted using SPSS version 17.0 (IBM SPSS Statistics, 2011), and the R (The R Foundation for Statistical Computing, Vienna, Austria) packages nlme, multcomp and car, and the mediation analyses were conducted in Mplus (Muthén & Muthén, 2010).

Results

Attrition, Baseline Comparisons and ICC-values

All symptom scores at pre-, mid- and post-treatment are presented in Table 1.

(Insert Table 1 here)

Of the 156 youth who completed the intake assessments, 116 (74.3%) participated in the post-treatment assessment (T3). The attrition rate was not significantly different between the two treatment conditions, and no significant differences between the retention group and the attrition group on basic characteristics such as gender, and/or outcome variables were found ($p \ge .170$). However, participants in the attrition group were significantly older than participants in the retention group (15.7 years compared to 14.8 years, p = .039), and they reported exposure to a significantly higher number of different traumatic events (4.3 in the attrition group compared to 3.4 in the retention group, p = .007).

Intraclass correlations were 0.038, 0.122 and 0.032 for PTSS, depressive symptoms and general mental health symptoms, respectively. The corresponding p-values for therapist level variances were 0.791, 0.357 and 0.783, respectively.

Change in Post-traumatic Cognitions (Mixed Effects Analyses)

The interaction between time and group was significant, indicating that the treatment slopes were significantly different from one another (p = .002). Furthermore, participants in

TF-CBT changed significantly more in their cognitions from pre to post therapy compared to participants in the TAU-condition (p = .002). There was also a significant reduction in post-traumatic cognitions from T1 to T2 both in TF-CBT (p < .001) and in TAU (p < .001). The change in post-traumatic cognitions from T2 to T3 was significant in the TF-CBT condition (p < .001), but not in the TAU condition (p = .198). For details, see Table 2.

(Insert Table 2 here)

Mediation Analyses (Intention to Treat Analyses).

In the three first models (Model 1A, 1B and 1C), the child posttraumatic symptoms (measured by the CAPS-CA) constituted the outcome variable. Model 1A, that investigated the overall change in cognitive appraisals as a mediator and PTSS as dependent variable, had a significant indirect effect via the mediator (CPTCI T3 - CPTCI T1, p = .018). By investigating this model further, the c'-path showed that the total relationship between therapy condition and outcome was not statistically significant when controlling for the mediator (p = .263). The second PTSS-model (Model 1B), using early change in cognitive appraisals as a mediator variable and PTSS as dependent variable did not reveal a significant indirect effect via the mediator (CPTCI T2 - CPTCI T1, p = .724). The total effect of therapy condition on outcome was still statistically significant after controlling for the early change in cognitions (p = .023). In the third PTSS-model (Model 1C), however, a significant indirect effect was found when using the late cognitive appraisals change score (CPTCI T3 – CPTCI T2) as a mediator variable and PTSS as dependent variable (p = .009). In line with this, there was no total significant relationship between condition and outcome after controlling for the late change in cognitions (p = .241). For details, see Table 3.

(Insert Table 3 here)

In the next mediation models, child depressive symptoms (Model 2) and child general mental health symptoms (Model 3) constituted the outcome variables. Both models showed that

there was a significant indirect effect via the mediator (the overall change in cognitive appraisals), p = .011 for the depression model and p = 0.027 for the general mental health model. For more details, see Table 4.

(Insert Table 4 here)

Per-protocol Analyses.

Per-protocol analyses were conducted in which the five cases that did not receive TF-CBT were taken out of the analyses. These analyses yielded similar results as the intention to treat analyses (data not shown).

Discussion

In this study we aimed to understand more of what may contribute to reductions in trauma-related symptoms for severely traumatized youth. The study builds on results from a randomized controlled study showing that participants receiving TF-CBT reported lower levels of PTSS, depression and general mental health problems compared to participants in the TAU condition. This result does not in itself tell us how the change occurred or by which mechanisms. In order to examine this, mediator analyses are necessary (Kazdin, 2009). Understanding how therapy leads to change is an important step towards optimizing and individualizing therapy.

Many RCT studies have been criticized for using control groups that are biased either because they are not bona fide treatments or because specific ingredients are left out (Wampold & Imel, 2015). In the current study we examined mediators of therapy by comparing two bona fide treatments. We built on previous results showing that the therapeutic alliance (typically a common factor) in interaction with the specific trauma treatment predicts outcome (Ormhaug, Jensen, Wentzel-Larsen, & Shirk, 2014). Since post-trauma cognitions are believed to be crucial in maintaining PTSS after trauma, one next step in entangling possible change mechanisms is to examine whether change in post-trauma

cognitions mediates treatment outcome both for PTSS, which are typically targeted in trauma-focused treatments, and for non-targeted symptoms such as depression and general mental health problems.

Our first hypothesis, that TF-CBT would yield greater change in post-traumatic cognitions relative to TAU, was supported. This was not surprising given that cognitive restructuring is a core component of TF-CBT, while cognitive interventions were observed in less than a third of TAU cases. The finding is also in line with previous studies of adults with PTSD (Diehle et al., 2014). Furthermore, post-traumatic cognitions changed significantly both from pre to mid treatment and from mid to post treatment in TF-CBT. In TAU, however, the cognitions did only change significantly from pre to mid treatment. Thus, while post-traumatic cognitions continue to change throughout TF-CBT, this effect seems to wear off as TAU progresses.

Our second hypothesis was that the overall PTSS effect difference found between TF-CBT and TAU would be explained by change in post-traumatic cognitions, and this was supported. Overall change in post-traumatic cognitions significantly mediated the treatment effect. Investigation of the timing of the mediation effect of cognitions on PTSS indicated that the change in cognitions occurring late in therapy (from mid treatment to post treatment) significantly mediated the treatment effect, whereas early change (from pretreatment to mid treatment) did not. Thus, the main finding of the present study is that change in post-traumatic cognitions is a driving force for the difference in treatment effects found between TF-CBT and TAU. As such, change in post-traumatic cognitions seems to be a key component to recovery for traumatized youth receiving TF-CBT. This finding is in line with Kleim et al., (2013), in which changes in maladaptive cognitions preceded changes in PTSD symptoms for adults receiving TF-CBT. This lends support to cognitive theories of PTSD,

claiming that reductions in PTSS occur as a result of changing maladaptive cognitions, and that maladaptive cognitions maintain and exuberate PTSS.

The analysis also showed that changes in post-traumatic cognitions mediated the treatment effect for depression and general mental health problems. This provides further support for the notion that change in appraisals may be a key mechanism for multiple outcomes in TF-CBT. Since many traumatized youth have co-morbid symptoms this finding is clinically significant for treatment providers and suggests that negative cognitions may be pivotal in maintaining mental health problems.

However, even though the significant difference between the treatment conditions occurred late in treatment, we cannot necessarily infer from this study which components in TF-CBT contribute to changes in post-traumatic cognitions. A mediator does not necessarily explain the process of how a change occurs (Kazdin, 2009; 2014; Wampold et al., 2010). The cognitive restructuring component in TF-CBT explicitly aims to help youth to identify and modify unhelpful trauma-related cognitions. However, several other components in the protocol may contribute to these changes, and behavioral, emotional, and cognitive oriented techniques may play a role in reducing post-traumatic cognitions. For instance, psychoeducation may help to normalize youth and caregiver reactions to the trauma and to support accurate thoughts about what has happened and why. Improving parenting skills may help to maintain normal daily routines and help the child to feel that things are not permanently changed. Also including caregivers in therapy may improve their ability to help with their child's emotional distress and management of related behavior problems. Learning relaxation skills to reduce physiological stress and arousal and helping the child identify feelings may help the child not feel so overwhelmed and vulnerable. The creating of the trauma narrative is thought to help desensitize the youth to trauma reminders and minimize avoidance behaviors. This in turn may help the youth to regain a sense of control and that (s)he is not permanently

damaged by what happened. In vivo exposure may help the youth cope with generalized avoidance behavior and enhance feelings of mastery. Finally, enhancing future safety and development may help youth regain hope that they can recognize and respond to danger and thus minimize feelings of future threat. All these changes may be related to alleviating PTSS, depression and general mental health problems in multiple ways, and future research should examine these pathways.

For the PTSS-model, there are more potential explanations of why the mediation effect is significantly applied to late change in post-traumatic cognitions, and not to early change. Changing post-traumatic cognitions takes time and entails a broad range of techniques that are likely to work together to produce change. It may be that it is the cognitive restructuring component, which typically takes place later in the therapy process that contributes most to changes in post-traumatic cognitions. However, it may also be that the integration and sensitive interplay between the different components contribute to changes in post-trauma cognitions. It is important to note that content analysis of the TAU condition showed that there was little direct therapeutic work addressing post-trauma cognitions, and overall, cognitive processing was only present in a third of coded sessions. Importantly, negative cognitive appraisals were also significantly reduced in TAU. However, the effects of TAU may have improved further with a stronger focus on cognitions. It may also be the ongoing exposure work that contributes to changes in cognitions, a claim proposed by Foa and Rauch (Foa & Rauch, 2004). In line with this, a meta-analysis did not find that including cognitive restructuring in trauma-focused interventions led to significantly larger reductions in trauma related cognitions than interventions that only include exposure work (Diehle et al., 2014).

The understanding of the mechanisms of change in youth trauma therapy is only commencing and lagging behind adult studies. Several therapy models have proven to be

helpful in reducing trauma related symptoms (Gillies, Taylor, Gray, O'Brien, & D'Abrew, 2012). Future research should examine more closely whether there are specific techniques that help youth alter post-trauma cognitions and regain their sense of safety and hope for recovery.

The present study has limitations. First, in terms of generalizability, as the majority of our participants were Caucasian girls, questions can be raised as to whether our findings apply to clients who are boys and/or of other ethnicities. Second, we had missing data on T3 as some of the participants dropped out of treatment or did not complete the post-treatment assessments. We do not know whether this may have biased the results; however, the analytic strategies allowed us to include all the recruited participants in the analyses. Third, the nesting of therapists is a limitation, since several therapists treated more than one participant. However, when attempting estimation of multilevel mediation models, these models did not converge without problems. It is unclear exactly how much the nesting of therapists might have influenced the results. However, the ICC-values in the current study was relatively low. The ICC expresses the variability due to the therapists to the total variability in outcome among participants. A high value indicates that the outcomes of two participants who have been treated by the same therapist are more similar than the outcomes of two participants who have been treated by two different therapists (Wampold & Imel, 2015). Low ICC-values in the current study thus indicate that the therapist nesting did not influence the results too much. Fourth, when interpreting the beneficial effect of TF-CBT over TAU one has to take into account that the TF-CBT therapists received more supervision than the TAU therapists. Although the TF-CBT therapists were all novices in the model, and regular supervision was considered necessary in order to help them provide the method with fidelity, we do not know how much the supervision influenced the result. Also, this may limit the generalizability of the findings to regular clinical practice where therapists typically do not have continuous

case-by-case supervision. Fifth, we did not conduct separate analyses with different age groups because the sample was too small. However, we did include age as a covariate in all analyses, and this step did not change original results. Future studies should have a more specific focus on cognitions in different developmental stages.

The main implication of the current study is that changing post-traumatic cognitions seems to be essential to recovery from a range of trauma-related symptoms. In this study, post-traumatic cognitions were conceptualized as the youth's sense that the trauma has led to permanent and disturbing change, and a sense of being a fragile person in a scary world (Meiser-Stedman, Smith et al., 2009). It is encouraging that such negative post-traumatic cognitions can be targeted and modified in therapy. Particularly for youth, having persistent negative and maladaptive views of continuing threat and personal vulnerability may lead to negative developmental pathways. Our results indicate clinicians should address appraisals of the experienced trauma when working with youth. Furthermore, it may be particularly important to address this throughout treatment, and not only in the early stage of treatment. Late change in post-traumatic cognitions may be particularly beneficial for recovery.

In conclusion, this study provides further support for the key role of change in post-traumatic cognitions for treatment outcome with traumatized youth. It is important to note, however, that this study only points to changes in cognitions as a mediator of outcome. Again, a mediator may point to possible mechanisms of change but cannot tell us how the change came about (Kazdin 2009, 2014). Further investigations into the pathways of change may help us understand more of change processes and which specific and common ingredients may be needed to help traumatized youth cope with trauma-related symptoms. In the future. This may focus and refine our interventions to help clinicians tailor treatments to the individual needs of their clients.

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Table 1.

Description of CAPS and CPTCI from T1 (Pretreatment) to T3 (Posttreatment) in Each

Treatment Condition

Variable	Condition	n	Mean (SD)
CPTCI T1	TF-CBT	77	62.5 (14.6)
CPTCI T1	TAU	76	63.4 (15.3)
CPTCI T2	TF-CBT	62	55.0 (17.8)
CPTCI T2	TAU	60	56.5 (19.6)
CPTCI T3	TF-CBT	54	42.7 (16.6)
CPTCI T3	TAU	60	53.2 (18.6)
CAPS-CA T1	TF-CBT	79	60.2 (19.9)
CAPS-CA T1	TAU	77	60.7 (21.2)
CAPS-CA T3	TF-CBT	55	30.6 (25.3)
CAPS-CA T3	TAU	61	42.1 (26.6)
MFQ T1	TF-CBT	79	35.4 (11.8)
MFQ T1	TAU	77	35.3 (13.3)
MFQ T3	TF-CBT	57	14.4 (13.7)
MFQ T3	TAU	62	22.7 (16.2)
SDQ T1	TF-CBT	78	18.92 (4.9)
SDQ T1	TAU	76	19.1 (5.5)
SDQ T3	TF-CBT	56	12.0 (6.5)
SDQ T3	TAU	59	14.5 (6.1)

Table 2.

Treatment Effects Within and Between Treatment Conditions

Outcome CPTCI	Estimate	95% CI	p	t (df)
TF-CBT vs TAU T2	0.95	-5.24 to 7.14	.761	0.31 (84)
TF-CBT vs. TAU T3	10.07	3.76 to 16.38	.002	3.18 (84)
T1 vs T2 TF-CBT	-7.41	-11.03 to -3.79	<.001	-4.04 (231)
T2 vs T3 TF-CBT	-11.64	- 15.56 to -7.72	<.001	-5.85 (231)
T1 vs T2 TAU	-8.14	-11.81 to -4.47	<.001	-4.37 (231)
T2 vs T3 TAU	-2.52	-6.37 to 1.33	.198	-1.29 (231)

Table 3.

Results from Three Mediation Models for CPTCI Mediation on Child PTSS

Model 1A: Overall mediation model for CPTCI mediation on child PTS. The mediator is the overall						
change in CPTCI-scores between T1 and T3.						
Effect	Estimate	SE	95% CI Bootstrap percentile	p		
a	7.83	3.02	1.87 to 13.45	.009		

a	7.83	3.02	1.87 to 13.45	.009
b	0.72	0.13	0.48 to 0.99	<.001
c'	5.15	4.60	-4.28 to 13.88	.263
Indirect effect (a x b)	5.63	2.38	1.48 to 11.02	.018

Model 1B: Early mediation model for CPTCI mediation on child PTS. The mediator is the change
in CPTCI-scores between T1 and T2.

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Effect	Estimate	SE	95% CI Bootstrap percentile	P
a	-1.05	2.68	-6.49 to 4.05	.695
b	0.34	0.15	0.05 to 0.66	.023
c'	11.49	4.63	2.35 to 20.52	.013
Indirect effect (a x b)	-0.36	1.01	-2.88 to 1.38	.724

Model 1C: Late mediation model using bootstrap method for CPTCI mediation on child PTS. The mediator is the change in CPTCI-scores between T2 and T3.

mediator is the change in Cr 1C1-scores between 12 and 13.						
Effect	Estimate	SE	95% CI Bootstrap percentile	Р		
a	9.57	2.70	4.42 to 14.97	.001		
b	0.55	0.15	0.27 to 0.85	.001		
c'	5.74	4.90	-4.72 to 14.81	.241		
Indirect effect (a x b)	5.30	2.03	2.15 to 10.28	.009		

Table 4.

Results from Mediation Models for CPTCI Mediation on Child Depression and General Mental Health

Model 2: Overall mediation model for CPTCI mediation on child depression. The mediator is the overall change in CPTCI-scores between T1 and T3.					
Effect	Estimate	SE	95% CI Bootstrap percentile	p	
a	7.86	3.01	2.10 to 14.02	.009	
b	0.49	0.07	0.35 to 0.62	<.001	
c'	4.17	2.52	-0.76 to 8.99	.100	
Indirect effect (a x b)	3.82	1.15	1.08 to 7.09	.011	

Model 3: Overall mediation model for CPTCI mediation on child general mental health (SDQ). The mediator is the overall change in CPTCI-scores between T1 and T3. 95% CI Bootstrap percentile Effect Estimate SE p 7.28 3.04 1.42 to 13.34 .017 a b 0.19 0.03 0.13 to 0.26 <.001 c' 1.17 1.07 -0.93 to 3.13 .260 Indirect effect (a x b) 1.37 0.62 0.32 to 2.78 .027