The Treatment of PTSD in Children and Adolescents and the Relationship with Trauma-Related Cognitions

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Thesis Portfolio Abstract

Background: PTSD is a debilitating mental health condition that develops following trauma. It is now understood that for children who have experienced trauma, multiple trauma exposure is more common than exposure to an isolated event (Doba et al, 2022). Current treatment approaches for PTSD are largely based on trials that have recruited samples of children with single-incident PTSD (Meiser-Stedman et al, 2017). This thesis focuses on the treatment of children with multiple trauma PTSD. It examines the extent to which current psychological treatments for child PTSD target a key mechanism proposed by the cognitive model of PTSD (shifting trauma-related appraisals). Trauma-related appraisals tend to be stronger and more dysfunctional in children with multiple trauma PTSD (Kube et al, 2023).

Methods: This thesis presents a systematic review with meta-analysis (SRMA) investigating the extent to which current psychological treatments for child PTSD reduce negative trauma-related appraisals. The second paper is a case series study (n= 9) investigating the safety, feasibility, and acceptability of an existing treatment (cognitive therapy for PTSD; CT-PTSD) in children with multiple trauma PTSD. Preliminary outcomes demonstrated in this sample and putative cognitive mechanisms involved in treatment are also investigated.

Results: The case series indicates that CT-PTSD is a safe, acceptable, and feasible treatment for children with multiple trauma PTSD. Preliminary treatment outcomes were encouraging and demonstrated large shifts in the putative mechanisms held as key by the cognitive model (e.g trauma-related.appraisals , thought suppression). The SRMA identified a medium-large effect size of current psychological treatments for child PTSD on negative trauma-related appraisals.

Conclusions: The case series suggests that a larger randomized trial of the efficacy of CT-PTSD in children with multiple trauma PTSD is warranted. The preliminary outcomes suggest that an adapted form of an existing treatment approach (CT-PTSD) may be a suitable treatment option for this subgroup. The SRMA found that the current range of psychological treatments for child PTSD significantly reduce trauma-related appraisals. These findings provide additional support for the

cognitive model of PTSD and specifically, the cognitive-specificity hypothesis. They also provide support for the suitability of existing treatment approaches in treating children with more complex and severe forms of PTSD (e.g. multiple-trauma PTSD, complex PTSD)

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Terminology list of trauma-related terms

Complex PTSD*	A formal diagnostic category included within the ICD-11.
Complex trauma	Exposure to trauma that is more complex and comprehensive than a singular isolated traumatic event. (this includes exposure to multiple traumatic events).
Multiple trauma	Exposure to more than one type of trauma (e.g. sexual abuse and physical abuse) or multiple incidences of one type of trauma (e.g. ongoing domestic violence).
Multiple trauma PTSD	PTSD resulting from exposure to multiple traumatic events.
Single-incident PTSD	PTSD resulting from a singular traumatic event (e.g. a road traffic accident)

* Please note: *where the term 'complex PTSD' has been used and the word 'complex' has been asterisked, this denotes a complex PTSD presentation, likely to include aspects of the formal CPTSD symptom profile, rather than the formal complex PTSD diagnostic category.*

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Chapter 1: Systematic Review with Meta-analysis

Do Psychological Treatments for PTSD in Children and Young People Reduce Trauma-Related Appraisals? A Systematic Review with Meta-Analysis.

Short title: A review of trauma-related appraisal shifts in child PTSD treatments.

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Abstract

Research is increasingly highlighting the role of negative trauma-related appraisals in child PTSD (Brown et al, 2019). The cognitive model of PTSD (Ehlers & Clark, 2000) claims that an essential mechanism of treatment is a reduction in these appraisals. The current systematic review with meta-analysis investigated the extent to which psychological treatments for PTSD reduce negative trauma-related appraisals in children. Four databases (PsycINFO, Medline Complete, CINAHL Complete and PTSDpubs) were searched between the months of December 2022- January 2023. The risk of bias 2 (ROB-2) tool was used to assess for risk of bias linked to the randomization process. Thirteen studies were included in this review, including a total of 937 child participants. Using a random effects model to perform the meta-analysis, a medium pooled effect size of current treatments on trauma-related appraisals was found (g = 0.66, 95% CI [-0.85, -0.47]). There was only a moderate level of heterogeneity between studies (I^2= 42.57%), increasing the confidence with which these findings can be interpreted. These results indicate that psychological treatments for child PTSD significantly alter cognitive appraisals. This is consistent with the cognitive model of PTSD in children, and its claim that shifts in appraisals are a key mechanism of treatment (Brown et al, 2019).

Keywords: PTSD, child, appraisals, trauma, meta-analysis, systematic review

Introduction

Decades of research highlight the fundamental importance of negative trauma-related appraisals in PTSD (Brown et al, 2019). The extent of these appraisals is pivotal in determining whether, and to what extent, post-traumatic stress is experienced (Gomez de La Cuesta et al, 2019; Meiser-Stedman et al, 2019). Research indicates a predictive and mediational relationship between appraisals and subsequent PTSD-related pathology (see Brown et al, 2019; McLean et al, 2015; O'Donnell et al, 2007). Indeed, whether an individual forms these appraisals following trauma has been identified as more influential in terms of subsequent (PTSD-related) distress than other key characteristics, such as the nature of the trauma experienced (e.g., the number of traumatic events and whether these were interpersonal in nature; Kube et al, 2023; Martin et al, 2013, Srinivas et al, 2015). Trauma-related appraisals have also been proposed as key in preventing relapse following successful PTSD treatment (Scher et al, 2017).

Now considered fundamental to PTSD (Woud et al, 2019), trauma-related appraisals are incorporated within diagnostic criteria for PTSD (Woud et al, 2019). 'Negative alterations in cognitions and mood' are included in the diagnostic criteria for PTSD within the Diagnostic Statistical Manual for Mental Health Disorders (DSM-V; American Psychiatric Association, 2013) (Banz et al, 2022). Trauma-related appraisals have also been added to the ICD-11 criteria for complex PTSD (CPTSD) via the 'disturbances in self organisation' section (World Health Organisation, 2019) (Banz et al, 2022). The reason for this is that individuals with more severe and complex forms of PTSD (i.e., complex PTSD) demonstrate a higher degree of negative trauma-related appraisals than their single-incident PTSD counterparts (Karatzias et al, 2019; Ponnamperuma & Nicolson, 2015). This signifies an important development in the conceptualization of PTSD, extending the focus from the traditional three-symptom clusters (i.e. hyperarousal, avoidance, re-experiencing) to the

important cognitive and affective shifts in the perception of the world, self and future that occur in the condition (Brown et al, 2019).

The cognitive model of PTSD holds that trauma-related misappraisals are not only a symptom of PTSD but also the core mechanism through which PTSD develops and is maintained (Brown et al, 2019; Woud et al, 2019). It is proposed that this occurs in part through appraisals triggering the individual to feel unsafe, and therefore driving to them engage in a range of behaviours to reduce this perceived danger which unintentionally perpetuate the distress (Ehlers & Clark, 2000). It is held that PTSD-related treatment gains during therapy will occur in large part due to shifts in these negative trauma-related appraisals (Dunmore et al, 2001; Ehlers et al, 2005). Trauma-focused cognitive behavioural therapy (TF-CBT) in its various forms (e.g. Cognitive Therapy for PTSD [CT-PTSD]) privileges the process of identifying these appraisals, evaluating them, and revising them (Smith et al, 2014). A fundamental aim of this type of therapy is to develop cognitive appraisals of the trauma that are balanced, functional and flexible (Dalgleish et al, 2005). The cognitive model proposes that the successful treatment of PTSD is largely dependent upon the extent to which they shift appraisals (Ehlers & Clark, 2000).

The various forms of TF-CBT have indeed demonstrated successful outcomes in the treatment of both adults and children with PTSD (Ehlers et al, 2013; Meiser-Stedman et al, 2017; 2019; Woud et al, 2019). It is because of this that it is now considered the 'gold standard' treatment for PTSD worldwide (Bisson et al, 2019). Single studies have assessed changes in trauma-related cognitions throughout treatment, commonly using the child self-report post-traumatic cognitions inventory (CPTCI; Meiser-Stedman et al, 2009). They have shown that as therapy proceeds, children experience significant reductions in trauma-related appraisals (Woud et al, 2019). This suggests that cognitive-based treatments are targeting the fundamental cognitive mechanisms that they claim to work through. Researchers have further

demonstrated that this change in appraisals mediates recovery from PTSD-related distress (Jensen et al, 2018). A temporal link has been reported whereby a reduction in PTSD-related distress in one session is often preceded by a reduction on a measure of appraisals in the previous session (but not the other way round; McLean et al, 2015). This evidence provides further support to shifts in appraisals being a core active component of current treatments for PTSD.

If treatments are only effective to the extent that they shift negative trauma-related appraisals as claimed by the cognitive model (Ehlers & Clark, 2000) it would follow that all approaches found to treat PTSD effectively should affect change in trauma-related appraisals (Banz et al, 2022). Whilst some treatment approaches include an explicit focus on cognitions, others may still influence cognitive appraisals, possibly indirectly (Ehlers & Clark, 2000). Banz and colleagues (2022) conducted a meta-analytic review investigating whether PTSD treatments lead to shifts in negative self-cognitions in adults. They reported a medium-large pooled effect size for the effect of current psychological treatments on negative self-concept.

It remains largely unknown whether psychological treatments for PTSD affect change in negative appraisals in child and adolescent populations. However, the child literature on appraisals has advanced considerably in recent years and the number of studies examining this link has grown (see Brown et al, 2019). Multiple single trauma studies have indicated that existing treatments reduce negative appraisals in child samples (Woud et al, 2019). However, it is also important to acknowledge the existence of research that does not show this (e.g. Kangaslampi et al, 2016). To date, there has been no systematic and comprehensive review of the literature in this area to clarify whether, and to what extent, current treatments reduce appraisals in child PTSD treatment.

These findings would have theoretical and clinical implications. Firstly, if it were confirmed that current PTSD interventions reduced trauma-related appraisals in children, this

would support the cognitive-specificity hypothesis (Ehlers & Clark, 2000) and the suitability of this theoretical model for children with PTSD. If successful child PTSD interventions have little effect on appraisals, however, this would call into question claims of the cognitive model (Banz et al, 2022). Secondly, this finding would have potential treatment implications for children with more 'complex' PTSD presentations (e.g. PTSD resulting from multiple traumatic events and/ or those that fulfil criteria for CPTSD) and people with other psychiatric disorders in which negative cognitive appraisals related to the self, the world and others are implicated (e.g. depression; Dowd, 2004).

The present study aims to address this gap in research, by conducting a systematic review with meta-analysis to investigate whether, and to what extent, the current range of treatments for child PTSD reduce negative trauma-related appraisals in comparison to (active and passive) control conditions.

Methods

Protocol registration

This review was registered on the PROSPERO database on 9th December 2022 (CRD42022342743).

Primary outcome

The primary outcome was the pooled effect size of the comparison of post-treatment means on measures of negative trauma-related appraisals between psychological treatments for child PTSD and control conditions.

Eligibility Criteria

Studies were required to meet the following inclusion criteria to be included:

1. The mean age of the sample is equal to or under 18 years of age.

2. The sample have a clinical diagnosis of PTSD OR meet the cut off for full or partial PTSD on a PTSD questionnaire at the point of entry, or demonstrate symptoms in at least two of the ICD/ DSM PTSD symptom clusters.
3. The study includes a psychological treatment for PTSD.
4. The study involves a control condition: waiting list, no treatment, treatment as usual, an active or attentional control group (e.g. supportive counselling).
5. The study assesses trauma-related appraisals as one of its outcomes.
6. The study includes a quantitative measure of trauma-related appraisals on at least two occasions: baseline and post-intervention.
7. The study is a randomized controlled trial.
8. The study is published in a peer-reviewed journal article.

Search Strategy and Study Selection

Four electronic bibliographic databases (PsycINFO, Medline Complete, CINAHL Complete and PTSDpubs) were searched in December 2022 by the first author using the following search terms.

1. (child* OR adolescen* OR "young person" OR teen* OR "young adult" or "young-adult" OR juvenile* OR youth OR pediatric OR paediatric OR boy* OR girl* OR pupil* OR student*) AND
2. (PTSD or posttrauma* or "post- trauma*" OR "post trauma*" OR "traumatic stress") AND
3. (RCT OR "randomi* control* trial" OR "random* clinical trial" OR "random* trial" OR "controlled clinical trial" OR "random* allocated" OR "random* assign*" OR randomly OR randomized OR trial) AND

4. (treatment OR therap* OR intervention OR psychotherap* OR EMDR OR CBT OR TF-CT OR TFCT OR TFCBT OR TF-CBT OR "eye movement" OR "narrative exposure")

The first three were searched via one integrated search using the EBSCO platform. The PTSD pubs search was carried out separately. The results were limited to 'academic journals' (PTSD pubs) or 'peer-reviewed journals' (the integrated EBSCO search). No further limitations to the search results were applied. Additional records were identified from reviews of child PTSD research in the last 5 years and articles citing the paper documenting the development of the CPTCI (Meiser-Stedman et al, 2009) using the Google Scholar 'cited by' function.

A PRISMA flowchart of the review process is presented in Figure 1. After removing duplicates, article titles and abstracts of the articles were screened and articles that were clearly unsuitable/ ineligible were excluded. For the remaining articles, the full text was sourced and screened using the full eligibility criteria. For those papers that were ineligible, the reason for exclusion was recorded. Non-English papers were translated into English using Google Translate. This is considered an acceptable practice for the function of screening papers for literature reviews (Jackson et al, 2019).

During the review process, one paper was identified that met all eligibility criteria except for providing data on trauma-related appraisals (Rossouw et al, 2018). However, it was stated by the authors that data on appraisals were collected to be published in a subsequent article. The authors provided these data on request and the paper was therefore included in the review.

When screening articles, if there was uncertainty regarding whether a paper met eligibility criteria, the wider research team was consulted on this, and a shared decision was

made. Finally, all thirteen papers were reviewed for eligibility by a researcher independent of the research team. It was reconfirmed by this researcher that all 13 papers met criteria.

[INSERT FIGURE 1]

Data extraction

The following data were extracted for each study: study characteristics (e.g. study authors, year of publication), sample characteristics (e.g. % female, mean age) and condition characteristics (e.g. the nature of the treatment and control groups, mean treatment length). Post-treatment means on measures of appraisals, standard deviations and sample sizes were extracted for each (control and treatment) condition. If multiple measures of appraisals were used, results for the most widely used measure across studies were extracted (an approach taken by Bhattacharya et al, 2023). Each study was coded for type of control (active or passive) and use of the full or short form of the CPTCI. When coding for the former, each condition was assessed on a case-by-case basis, considering the level of intervention provided.

When required statistics were not included in reports, they were calculated where possible (e.g. where standard error was reported, this was transformed into standard deviation, and where Pearson's *r* was provided this was transformed into Hedge's *g*). For one paper, where results were provided for only one of three subscales of the measure used the reported effect size was divided by three to provide a pooled (conservative) effect size. For papers that provided only subscale means, these were pooled to give an overall figure.

Risk of Bias

The ROB-2 tool (Sterne et al, 2019) was used to assess risk of bias. This assessment was completed independently by two researchers. The researchers then met to compare ratings. Where discrepancies in ratings were identified, these were discussed until a

consensus was reached. The tool focused on assessing for risk of bias resulting from the randomization process.

Analysis

Meta-analysis was conducted using metafor in R (Viechtbauer, 2010). The primary outcome of interest was the pooled between-groups effect size, calculated using hedges *g* (based on a random-effects model). Guidelines provided by Cohen were used to interpret the effect size (Cohen, 1977). On most measures a lower score signified a greater shift in (weakening of) negative trauma-related appraisals. One exception to this was the World Assumptions Scale used by Najavits and colleagues (2006). This was transformed to be consistent with the direction of the other measures.

The I^2 statistic was used to assess for heterogeneity and interpreted using the guidelines of Higgins and colleagues (2003). Prediction intervals were calculated with 95% confidence intervals to provide estimates of future effects that may be seen in subsequent studies. Publication bias was assessed using Egger's test for asymmetry, and by visual inspection of the funnel plot. The trim and fill method was used (Duval & Tweedie, 2000) to estimate the number of missing studies in this review, and provide an approximate adjustment of the results to account for these. This allows for an assessment of the extent to which possible missing studies may have biased the results.

One RCT included two treatment arms (eye movement desensitization therapy; EMDR and cognitive behavioural writing therapy; CBWT). The main meta-analysis was run using results from the EMDR treatment arm as this is the more widely used treatment approach in the field. A sensitivity analysis was run using results from the CBWT arm to confirm that this did not significantly impact the results. One RCT (McLean et al, 2015) reported only 3-month follow up data in the published article. The authors were not successful in retrieving the post-treatment means from this trial and so the 3-month post-

treatment data was used. A second sensitivity analysis was run, removing this result, to check that this factor did not significantly affect the overall result. A third sensitivity analysis was run to confirm that studies at high risk of bias did not significantly impact the results. Studies at high risk of bias were removed, to examine the effect of this on the overall result.

Two moderator analyses were run. The first examined whether there was a moderating effect for the type of control condition used (i.e. active or passive). The second examined whether there was a moderating effect for the type of appraisal measure used (i.e. full or short form of the CPTCI vs other).

Results

Included Studies

A PRISMA flowchart of the review process is provided in figure 1. In total, 3309 articles were screened for inclusion. The full text was sourced for 1535 of these. Thirteen studies were identified as meeting eligibility criteria and were included in this review.

[INSERT PRISMA FLOWCHART]

Study Characteristics

The characteristics of the 13 RCTs included in the review are shown in Table 1. Across studies, there were 14 treatment conditions and 13 control conditions (de Ross et al, 2017, included two treatment arms; CBWT and EMDR). In the main-meta-analysis, 937 children were included, with 479 in the treatment condition. The mean number of participants in each study is 72 (range= 23- 183). Based on the eleven studies that provided a mean age of the sample, the overall mean age was 14.1 (*SD*= 1.5). The sample was predominantly female (70% of the overall sample).

The most common treatment provided were forms of TF-CBT (e.g. prolonged exposure for adolescence; PE-A, CT-PTSD, TF-CBT) (8 studies). Eight studies used a passive control condition (e.g. waiting list), and five studies used an active control condition

(e.g. child-centred therapy, supportive counselling). Most studies assessed negative trauma-related appraisals using the CPTCI (8 studies) or the PTCI (2 studies). One study used the World Assumptions Scale, one study used the child post-trauma attitudes scale, and one study used the children's perceptions and attributions scale.

[INSERT TABLE 1]

Risk of Bias

Using the ROB-2 tool, seven studies were identified as having high risk of bias, with the six remaining studies being identified as raising some concerns (see table 2). Examining ratings within each domain, most studies (k= 9) were identified as having low risk of bias during the randomisation process and in terms of missing outcome data (also see the study rating forms in appendix B). Most studies (k= 7) were reported as having some concerns related to the risk of bias in the selection of the reported result. This was mostly because a pre-specified analytic plan could not be sourced for these studies. All studies were identified as raising some concerns regarding bias resulting from deviations from the intended intervention. This is primarily because, due to the nature of the studies, it was not possible to blind the participant nor the therapist to the condition they had received. This was paired with a lack of comment in the papers on whether any deviations from the treatment protocol had occurred in the RCT. All studies were also rated as having some concerns regarding bias related to the measurement of the outcome. This is primarily because appraisals were assessed using a subjective child self-report measure and therefore scores may have been influenced by knowledge of the assigned condition.

[INSERT TABLE 2]

The Impact of Child PTSD Interventions on Negative Trauma-Related Appraisals

Negative trauma-related appraisals were less strongly endorsed following treatment compared to control conditions, with a medium-sized effect (g= -0.66, 95% CI [-0.85, -0.47],

k= 13, p<.0001; see Table 2). A forest plot is provided in Figure 1. The I^2 statistic indicated a moderate level of heterogeneity (I^2= 42.6%). The prediction interval [PI -1.12 to -0.20] did not cross zero, suggesting that future trials should expect to observe an effect in favour of the treatment condition.

[INSERT TABLE 3]

[INSERT FIGURE 2]

Sensitivity Analyses

A sensitivity analysis was used to assess the impact on the results of including the 3-month post-treatment means provided by de Roos and colleagues (2017) (see Table 2). Removing this study from the analysis, had a minimal impact on the pooled effect size (*g* = -0.64, 95% CI [-0.84, -0.45], p <.0001) and the effect remained significant. A second sensitivity analysis assessed the impact of substituting the EMDR condition used in the main meta-analysis with the CBWT condition in the RCT conducted by de Roos and colleagues (2017). This also demonstrated minimal effect on the overall effect size (g= -0.65, 95% CI [-0.84, -0.45], p <.0001) and also remained significant. A third sensitivity analysis was run, removing the studies at high risk of bias. This had a minimal impact on the pooled effect size (*g* = -0.61, 95% CI [-0.91, -0.30], p <.0001).

Moderator and Subgroup analyses

No significant moderating effect was found for the nature of the control group (whether it was active or passive) or type of measure used (CPTCI or other; see Table 3).

Publication Bias

The funnel plot was visually inspected for asymmetry to assess publication bias and a degree of asymmetry was identified. The Egger's test was significant (k= 13, intercept (B0) = -.14, 95% CI [-.64, 0.36], p<.05), indicating the presence of publication bias. A trim and fill procedure (Duval & Tweedie, 2000) estimated that approximately four studies were missing

from the review. When estimates for these four missing studies were included (k= 17), the pooled effect size reduced to g = -.52 (95% CI [-0.74, -0.31], p<.001), i.e. a significant medium-sized effect remained.

Discussion

This meta-analysis found that psychological treatments for child PTSD reduced negative trauma-related appraisals, with an overall medium effect size reported. This closely parallels findings in the adult PTSD literature (Banz et al, 2022). Banz and colleagues reported a similar pooled effect size (g = -.67) in their meta-analysis investigating the impact of psychological treatments on negative self-cognitions in adults. Whilst the present findings were slightly affected by the nature of the control condition, showing a stronger effect when compared with passive controls, no significant moderating effect was found. These findings suggest that despite differences in treatments, all include a component or components which successfully target trauma-related appraisals. This component is present to a significantly larger degree in treatment conditions than both active (e.g. child-centred therapy) and passive control conditions. There was only a moderate level of heterogeneity between studies, which increases the confidence with which these results can be interpreted. Although a trim and fill test (Duval & Tweedie, 2000) estimated that four studies were missing from this review, when estimates for these were added, the pooled effect sized reduced only slightly and the effect remained significant.

These findings are consistent with the cognitive model of PTSD (Ehlers & Clark, 2000). They suggest that the maladaptive appraisals children may develop about themselves, the world, and their future following trauma can be reduced by treatments for child PTSD. To date, research has largely neglected the issue of active mechanisms in PTSD treatments (Nixon et al, 2012). This meta-analysis provides a contribution to this literature. Whilst it would not be appropriate to claim that this observed effect is *causally* responsible for the

good outcomes demonstrated by these treatments, it is encouraging and provides additional support for this being the case. A firm body of research already exists linking reductions in these appraisals with a reduction in PTSD-related symptoms in children (Jensen et al, 2018; Kleim et al, 2013; McLean et al, 2015; Pfeiffer et al, 2017; Smith et al., 2007).

It was not possible to conduct a moderator analysis exploring the potential moderating effect of therapy type on the outcome (i.e. cognitive-based vs. other treatment types). This is due to the lack of studies available, and subsequently, the small *k* that would be in each subgroup. It would prove useful to include this in future reviews, once more data is available.

These findings may have implications for treating related conditions. The finding that current psychological treatments for PTSD reduce trauma-related appraisals in children is promising for the treatment of children with more 'complex' PTSD (e.g. those that fulfil criteria for CPTSD or have experience multiple traumatic events). Negative trauma-related appraisals have been identified as particularly strong in this subgroup (Karatzias et al, 2019; Kube et al, 2023; Ponnamperuma & Nicolson, 2015). This meta-analysis adds further support for the potential appropriateness of existing treatments for this subgroup, as opposed to the effort, resources, and attention needed to develop new treatments. In addition, there are related psychiatric conditions in which negative cognitive appraisals are central (e.g. depression; Kokou-Kpolou et al, 2018; Zhang et al, 2022). Whilst depression can prove hard to treat (Gaynes et al, 2020) and shows a high level of comorbidity with child and adolescent PTSD (Thabet et al, 2004), cognitive-based treatments for PTSD have been found to target co-occurring depression effectively (Lenz & Hollenbaugh, 2015). This suggests that current treatments for PTSD which appear to successfully target negative cognitive appraisals pertaining to the self, world, the future and others may also inform the development of treatments for related conditions.

Strengths, Limitations, and Future Recommendations for Research

One strength of this review is the inclusive definition of negative trauma-related appraisals adopted, which permitted assessment of the impact of treatments on a wide range of appraisals, including those centred on the self, the world, others, and the future. This contrasts to the more restricted approach adopted by Banz and colleagues (2022), who limited their review to negative self-cognitions. The findings were therefore able to evidence the breadth of cognitive appraisals successfully targeted by current child PTSD treatments. Another strength is that we did not restrict included articles to those written in English. This does not seem to be standard practice in such reviews (e.g. see Brown et al, 2019). It is also worth noting that this meta-analysis, whilst being based on only 13 studies, included a large sample size of 937 children.

One limitation of this review is that the sample is largely biased towards adolescent females from Western countries. This reflects a general trend in the wider PTSD literature (Martin et al, 2013). Gender differences have been noted in research on appraisals, whereby females tend to form stronger negative trauma-related appraisals than males (de Haan et al, 2017; Martin et al, 2013) and this may have influenced the present results. This potential bias may have influenced results if the treatment and control conditions did not match participants on gender and so more females were included in the treatment condition. Bernandi and colleagues (2018) have also discussed at length the ways in which the formation of trauma-related appraisals are affected by culture and have questioned whether research on trauma-related appraisals conducted with Western samples can be applied to non-Western samples. In addition to this, young children were underrepresented in this review, with the youngest participant being eight years old. This may in large part reflect the methodological challenges involved in assessing trauma-related cognitions in very young children. However, it is important to note this as a limitation in terms of the generalizability of the findings. It

remains largely unknown whether current treatments for child PTSD reduce negative appraisals in very young children.

In terms of recommendations for future research, it became clear during the process of screening that the collection of data on trauma-related appraisals is not routine practice in treatment trials for child PTSD. To the extent that greater research into this area could lead to significant advances in understanding the active mechanisms of treatment (an area which is currently underdeveloped; Kindt et al, 2007), it is recommended that such measures be routinely incorporated into future trials.

Another recommendation is for future studies to include follow-up timepoints. There were insufficient data available to complete analyses on follow up data. This means that at present, it is uncertain whether the impact of treatment on trauma-related appraisals persists over the long term. Ascertaining whether this is the case would provide a further contribution to the validity of the cognitive model of PTSD; if it is found that at 6-month follow up the negative trauma-related appraisals resurface, but that people remain well, this would call into question the cognitive-specificity hypothesis. Another limitation, which reflects a wider limitation faced by the literature on trauma-appraisals, is that the results are based exclusively on subjective self-report measures of appraisals (Dalgleish et al, 2005; Shafran et al, 2015).

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Figure 1.

PRISMA Flowchart of the Review Process.

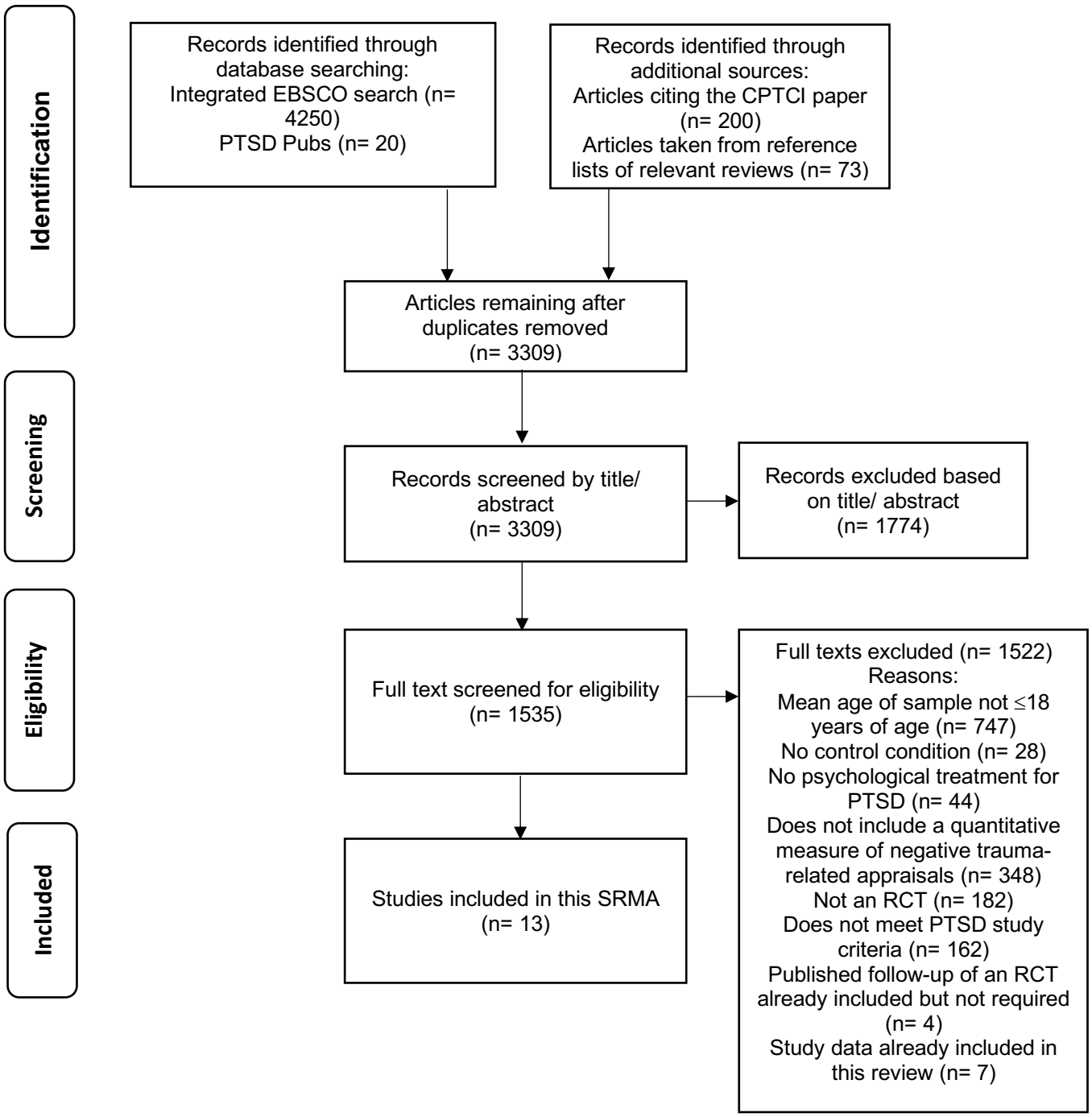


Table 1

Study Characteristics of the 13 Included Trials.

Study ID	Location	N	Treatment	Control	Appraisal measure	Mean Age (SD, range where available)*	% Female	Majority Ethnicity
Cohen (2004)	USA	229	TF-CBT	CCT	CAPS	10.76 (8-14 years 11 months)	79	60% Caucasian
de Roos (2017)	Netherlands	103	EMDR, CBWT	WL	CPTCI	13.06 (2.92, 8- 18)	57.30	28.20% immigrant
Dildar (2019)	India	60	TRT	WL	CPTCI	14.27 (.98)	100	Not provided
Ford (2012)	America	59	TARGET	ETAU	PTCI	14.70 (1.2, 13-17)	100	59% Latino or mixed race
Goldbeck (2016)	Germany	159	TF-CBT	WL	CPTCI	13.03 (2.8)	71	89.9% German native
Jensen (2018)	Norway	156	TF-CBT	TAU	CPTCI	15.1 (10-18)	79.50	73.70% Norwegian
Khubsing (2020)	India	23	Group EMDR	WL	CPTCI	EMDR 13.55 (2.42) WL 14.50 (2.61)	0	Not provided
McLean (2015)	America	61	PE-A	CCT	C-PTAS	15.30 (1.5, 13-18)	100	55.74% Black
Meiser-Stedman (2017)	UK	29	CT-PTSD	WL	CPTCI	13.3 (2.5, 8-17)	72.40	86.20% White British
Najavits (2006)	America	32	Seeking safety	TAU	WAS	16.06 (1.22)	100	78.80 % Caucasian
Pfeiffer (2018)	Germany	99	Mein Weg	UC	CPTCI-S	Mein Weg 17.00 (1.11) UC 16.92 (.76)	7.07	45.5% from Afghanistan
Rossouw (2018)	South Africa	63	PE-A	Supportive counselling	PTCI	15.35 (13-18)	87.30	69.84% mixed parentage
Smith (2007)	London	24	CBT	WL	CPTCI	13.89	50	45.83% White British

Note: TF-CBT= trauma-focused cognitive-behavioural therapy, CCT= child-centred therapy, CAPS= Children's attributions and perceptions scale, EMDR= eye movement desensitization and reprocessing therapy, CBWT= cognitive behavioural writing therapy, WL= wait list control, CPTCI= CPTCI= child posttraumatic cognitions inventory, TRT= teaching recovery techniques, ETAU= enhanced treatment as usual, TAU= treatment as usual, PE-A= prolonged exposure therapy for adolescents, US= usual care, CBT= cognitive behavioural therapy, WAS= world assumptions scale, PTCI= post-traumatic cognitions inventory, C-PTAS= child post-trauma attitudes scale, *where pooled age was not provided, statistics are provided for each condition.

Table 2.

Risk of Bias 2 Ratings for Each Study and Each Domain

Study ID	Randomisation process	Deviations from the intended intervention	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall risk
Cohen (2004)	Some	Some	Some	Some	Some	High
de Roos (2017)	Low	Some	Low	Some	Some	Some
Dildar (2019)	Some	Some	Low	Some	Some	High
Ford (2012)	Low	Some	Some	Some	Some	High
Goldbeck (2016)	Low	Some	Low	Some	Low	Some
Jensen (2018)	Some	Some	Some	Some	Some	High
Khubsing (2020)	Some	Some	Low	Some	Some	High
McLean (2015)	Low	Some	Low	Some	High	High
Meiser-Stedman (2017)	Low	Some	Low	Some	Low	Some
Najavits (2006)	Low	Some	Low	Some	High	High
Pfeiffer (2018)	Low	Some	Low	Some	Low	Some
Rossouw (2018)	Low	Some	Some	Some	Low	Some
Smith (2007)	Low	Some	Low	Some	Some	Some

Note: Studies that had at four or five domains that were considered as having 'some' concerns regarding bias were judged as having an overall high risk of bias

Table 3

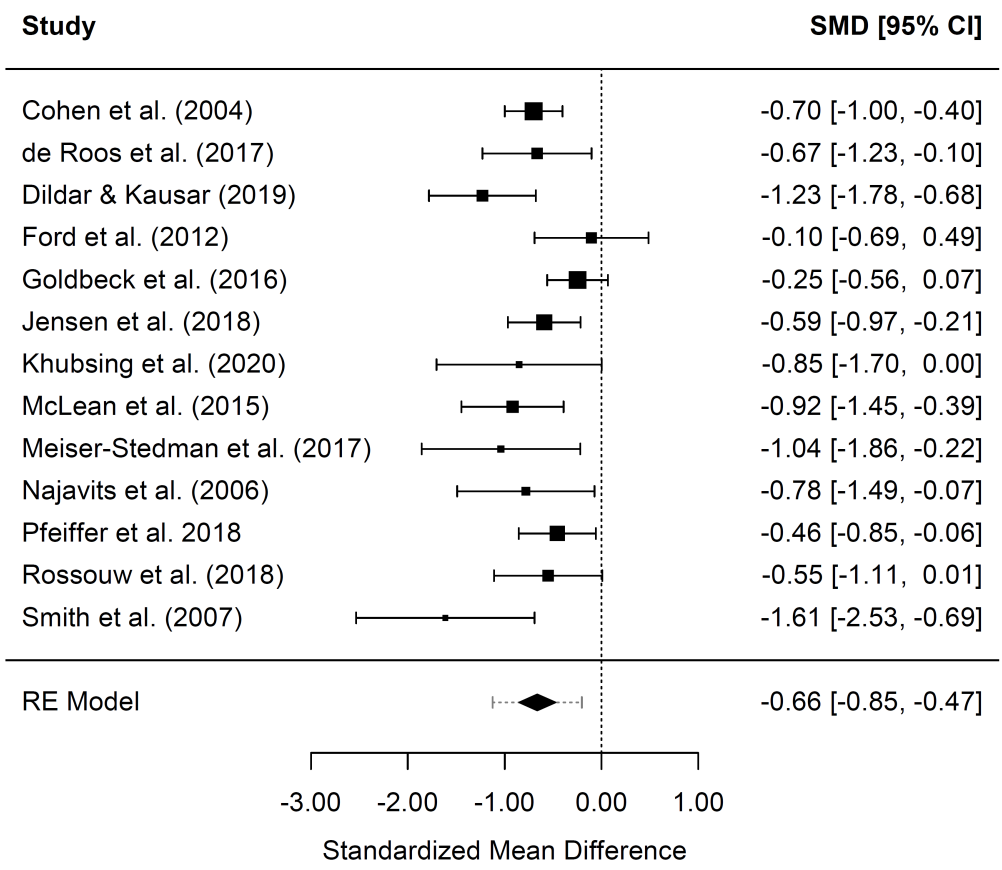
Results of the Meta-analysis, Moderator/ Subgroup Analyses and Sensitivity Analyses.

Analysis	k	g	95% CI	p	I^2	$P_{subgroup}$
Main meta-analysis						
Main results*	13	-0.66	-0.85, -0.47	<.0001	42.57	
Moderator and subgroup analyses						
Active vs. passive conditions						.51
Active arms only	5	-0.62	-0.81, -0.43	<.0001	0	
Passive arms only	8	-0.76	-1.08, -0.45	<.0001	57.35	
CPTCI vs. other						.70
CPTCI only	8	-0.73	-1.02, -0.43	<.0001	58.84	
Non-CPTCI only	5	-0.65	-0.85, -0.44	<.0001	0	
Sensitivity analyses						
de Roos 2017 CBWT condition included	13	-0.65	-0.84, -0.46	<.0001	41.68	
McClean 2015 removed	12	-0.64	-0.84, -0.45	<.0001	43.35	
High risk of bias studies removed	6	-0.61	-0.91, -0.30	<.0001	48.30	

Note: *de Roos 2017 EMDR treatment condition included

Figure 2.

Forest Plot Showing the Post-Treatment Effect Sizes and 95% Confidence Intervals for the 13 Included Studies.



Chapter 2: Primary Research Study

Cognitive Therapy for PTSD following Multiple Trauma Exposure in Children and Adolescents - A Feasibility Case Series

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This chapter has been written for submission to Behavioural and Cognitive Psychotherapy. See Appendix C for a summary of author guidelines for manuscript preparation.

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Conflicts of interest

None of the authors have identified a conflict of interest in this study.

Data availability statement

The data for this study are available from Professor Meiser-Stedman

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Abstract

Background: Cognitive-therapy for PTSD (CT-PTSD) is an efficacious treatment for children with PTSD following single incident trauma, but there is a lack of evidence-based treatment options for those with PTSD following exposure to multiple traumatic experiences.

Aims: The aims of the current study were to assess the safety, acceptability, and feasibility of CT-PTSD for children following multiple incident trauma.

Method: Nine children and adolescents with multiple trauma PTSD were recruited to a single arm feasibility case series of CT-PTSD. Participants completed a structured interview and PTSD-specific and non-PTSD related mental health questionnaires at pre-treatment, post-treatment and 6-month follow up.

Results: All nine participants tolerated treatment well, and there was no study drop out. No safety concerns or adverse effects were recorded. Suicidal ideation markedly reduced following treatment. CT-PTSD was rated highly credible by the sample, and participants reported strong working alliances with their therapists. All nine children met developmentally adjusted criteria for PTSD at baseline, but only two continued to meet criteria following treatment. A large treatment effect was observed post-treatment and at 6-month follow up on measures of PTSD severity (CRIES-13 and CPSS) and general functioning (CGAS). Participants also showed reduced psychiatric comorbidity at post-treatment and 6-month follow up (RCADS-C).

Discussion: These findings suggest that CT-PTSD is a safe, feasible and acceptable treatment for children with multiple-trauma PTSD. Preliminary outcomes suggest that CT-PTSD is a promising treatment for this complex population. Our results suggest a randomized controlled trial of CT-PTSD with children with multiple trauma PTSD is warranted and could be used to guide the design of a full-scale trial.

Keywords: PTSD, CT-PTSD, children, case-series, intervention

Introduction

Trauma exposure is common in children and young people (CYP); epidemiological surveys indicate that by the time a child reaches 16 years of age, they are more likely to have been exposed to trauma than not (Copeland et al, 2007; McLaughlin et al, 2013). Whilst for some children this involves a single, isolated traumatic event (e.g., a road traffic accident: RTA) a significant proportion of children experience multiple traumatic events early in life (Doba et al, 2022). This includes children who experience repeated physical, emotional and sexual abuse within the home by a relative. In a recent study by Radford and colleagues (2013), the reported rate of exposure to abuse or neglect in their UK-based sample of 11-17-year-olds was over one in five children. Meltzer and colleagues (2009) reported that 4.3% of their UK-based sample of children had been exposed to 'severe' domestic violence. This figure is based on parental reports, however, and may underestimate the scale of children's exposure. Cohort studies suggest children with experience of trauma are more likely to have experienced multiple traumas rather than an isolated event (e.g. Doba et al, 2022).

Around 15-25% of children exposed to trauma develop trauma-related symptoms warranting a diagnosis of PTSD (Alisic et al., 2014; Danese et al, 2020). Children who have experienced multiple traumas are at increased risk of PTSD compared to those who have experienced single-incident trauma (Doba et al., 2022; Maercker et al, 2022). They are also more likely to receive a diagnosis of complex PTSD (Hyland et al, 2017). Complex PTSD involves the presence of three additional symptom clusters: negative cognitions about the self, interpersonal difficulties, and difficulties with affect regulation (World Health Organisation, 2018). Some estimates suggest that CPTSD is twice as prevalent as PTSD (Karatzias et al, 2019).

One established psychological treatment for PTSD is trauma-focused cognitive behavioural therapy (TF-CBT). TF-CBT has received worldwide recognition as an effective

treatment for individuals with PTSD (Bisson et al, 2019). The PRACTICE (Cohen & Mannarino, 2008) protocol is an example of TF-CBT. In the PRACTICE approach, children and their families are guided through a phase-based programme (Cohen & Mannarino, 2008). This programme includes psychoeducation, parenting support, relaxation training, affect regulation, exposure, and trauma processing (Cohen & Mannarino, 2008). The treatment combines multiple approaches (e.g., cognitive, behavioural, and systemic) into one treatment plan (de Arellano et al, 2014).

An alternative approach to treatment is cognitive therapy for PTSD (CT-PTSD; Smith et al, 2014). The cognitive model underpinning this approach proposes that three cognitive processes are responsible for the development and maintenance of PTSD. These are trauma-related cognitive misappraisals; unhelpful cognitive coping strategies such as cognitive and behavioural avoidance, rumination and use of safety-seeking behaviours; and inadequate processing of the trauma memory (Ehlers & Clark, 2000). The strong focus on cognitive aspects of PTSD in CT-PTSD is pertinent, given that researchers are increasingly finding evidence for the crucial role of cognitions in understanding the development and maintenance of this condition (Brown et al, 2019; Gomez de la Cuesta et al., 2019). This research provides strong support for the involvement of each of these three cognitive processes in the development and maintenance of PTSD in children (e.g. Meiser-Stedman et al, 2019; Meiser-Stedman et al, 2017; Woud et al, 2019).

CT-PTSD has several features that lend themselves to working with children and young people with PTSD following multiple trauma exposure. Firstly, it stresses the importance of addressing cognitive processes that have been found to underpin PTSD and CPTSD symptoms in this population (Hiller et al., 2021; Karatzias et al, 2019; Ponnamperuma & Nicolson, 2015). Moreover, CT-PTSD is a formulation-driven approach (Ehlers & Wild, 2015). This means that treatment is tailored to the individual, including the

extent to which each cognitive-based factor is contributing towards maintaining their distress (Ehlers et al, 2005). The flexibility of this formulation-driven approach may be particularly beneficial in the treatment of children with more complex PTSD profiles (including those with multiple trauma PTSD). CT-PTSD has been used successfully with adults with complex PTSD presentations (Ehlers & Murray 2020), though clinical trials evidence is lacking.

It is possible to treat CYP with single-incident PTSD effectively using CT-PTSD (Hoppen et al, in press). Whilst there are differences in the presentation of PTSD between CYP with single-incident and multiple traumas (Maercker et al, 2022), it is possible that with adaptations, CT-PTSD could prove an appropriate treatment for CYP with multiple trauma (Smith et al, 2014). At present, however, the feasibility and acceptability of CT-PTSD in this population have not been established.

We therefore aimed to investigate the feasibility and acceptability of CT-PTSD for CYP who have PTSD following multiple trauma exposure. CT-PTSD was the chosen intervention for this investigation because of its commitment to developing individual case formulations to guide tailored treatment plans (Ehlers & Wild, 2015), and its more exclusive focus on the cognitive aspects of PTSD (compared to other forms of treatment such as TF-CBT). In particular, we aimed to identify whether CT-PTSD is a safe, feasible and acceptable treatment for CYP who have PTSD following multiple trauma exposure, investigate preliminary outcomes following CT-PTSD for this subgroup and explore whether CT-PTSD influences the specific cognitive processes through which it is purported to work. To address these questions, we used a feasibility case-series design to monitor the impact of CT-PTSD on a small sample of CYP with PTSD following multiple traumatic events. This enabled us to determine if a larger scale trial is warranted and, if so, inform the design of a trial by providing estimated effect sizes, adaptations to the treatment protocol, and acceptable recruitment strategies.

Methods

Design

A single-arm feasibility case-series design was used, with outcome measures completed at baseline, post-treatment and 6-month follow up.

Participants

The study inclusion criteria were: age 8-17 years old with PTSD following multiple trauma exposure. Multiple trauma exposure was assessed using information provided by the referrer, and was confirmed during the parent interview. PTSD diagnosis was confirmed in the study using the Children's PTSD Inventory (CPTSD-I; Saigh et al, 2000). A developmentally adjusted alternative algorithm was applied (Meiser-Stedman et al, 2008). Multiple trauma exposure was defined in terms of a child experiencing either multiple trauma types, or multiple incidents of a single trauma type (e.g. chronic domestic violence). The exclusion criteria were diagnoses of autism or learning disability, a primary mental health diagnosis other than PTSD, the family of the CYP not speaking English, living in an unsafe environment (e.g., with a known abuser) or brain damage. A recruitment target was set to consent one CYP to the study per month. In the absence of data on the prevalence of this subgroup in general, and specifically within mental health services, and ability to recruit to research, this was considered a conservative estimate.

Ethical Considerations

This study received ethical approval by the NHS Health Research Authority (NRES Committee East of England – Cambridge South, 13/EE/0262

Procedure

Recruitment was supported by healthcare professionals in two child and adolescent mental health teams and one specialist service situated across two mental health NHS Trusts. Healthcare professionals identified potential participants within their services, introduced

them to the study and sought consent for their details to be passed to the research team. Those who consented for their details to be shared were sent an information sheet and contacted by the research team for eligibility screening and if eligible, to arrange an assessment meeting. Written consent was obtained from parents, and assent was obtained from the child, during this first face-to-face meeting. Participant PTSD diagnosis was also reconfirmed at this stage, applying a developmentally adjusted algorithm (AA; i.e. at least one reexperiencing symptom, at least one avoidance symptom, at least two hyperarousal symptoms, and impaired functioning, using symptoms from the DSM-IV PTSD diagnosis; Meiser-Stedman et al, 2008).

Intervention

CT-PTSD was delivered by three Clinical Psychologists (study authors) who have specialist training in the treatment of child PTSD. They received regular supervision throughout the treatment phase by the developer of CT-PTSD (Patrick Smith). Details of this intervention can be found elsewhere (Smith et al, 2014). Treatment was delivered in up to 15 weekly sessions, more than the original 10-session treatment package (Meiser-Stedman et al., 2017; Smith et al., 2007). Treatment ceased once the clinician and young person agreed that PTSD symptoms had reduced sufficiently.

Specific therapy techniques in CT-PTSD include psychoeducation about PTSD, graduated exposure to the trauma through imagination, drawings and in vivo work, the development of a coherent trauma narrative, the identification and reappraisal of erroneous trauma-related beliefs, the incorporation of new corrective information into trauma memories, reduction in the use of maladaptive behaviours (e.g., safety behaviours, rumination) and safety planning. The CT-PTSD manual provides some guidance on adaptations to treat CYP with multiple trauma PTSD (Smith et al, 2014). Several of these adaptations were applied in the current study. Firstly, treatment duration was lengthened because multiple trauma

memories were present. Secondly, clinicians worked collaboratively with each child to plan the order in which the traumatic memories would be processed, supported by the development of a timeline. Thirdly, special attention was given to the individual's overarching narrative to ensure that a coherent account of the trauma in the wider context of the person's life had been formed. Fourthly, an initial 'stabilisation' phase was provided, if needed. This provided the child and clinician with an opportunity to address any pressing, acute issues (e.g., self-harm) before beginning trauma processing. The mode of stabilisation was tailored to the individual's presenting difficulties (e.g., a focus on behavioural activation if suffering from low mood, anger management skills etc).

Measures

Data were collected from parents on their child's sociodemographic background and trauma history. A series of child-administered questionnaires were completed at baseline, post-treatment and at 6-month follow up. Scoring and psychometric properties of each of the questionnaires used in this study are provided in Supplementary Table 1.

Safety, Feasibility, and Acceptability of CT-PTSD

The safety of CT-PTSD was assessed by monitoring serious adverse events, treatment discontinuation, symptom exacerbation, and level of suicidality across the study. To assess suicidality, participants were asked to complete the suicidal ideation subscale of the mood and feelings questionnaire (MFQ-SI; Hammerton et al, 2014). This self-report measure was administered at baseline, after treatment and at 6-month follow up. Feasibility was assessed in terms of the ability to meet the recruitment target and retain participants to treatment completion. Data were collected on the recruitment process, recruitment timeline, referral routes and reasons for exclusion and drop-out (if applicable). The acceptability of the intervention was assessed via reported credibility ratings of treatment (using a 4-item

questionnaire taken from Ehlers et al, 2003) and a measure of therapeutic alliance (the short-form working alliance inventory: WAI-S; Tracey & Kokotovic, 1989).

Mental Health Outcomes

Treatment outcomes were assessed using PTSD-specific and broader, non-PTSD related mental-health measures. DSM-IV PTSD and AA PTSD were assessed using the CPTSD-I (Saigh et al, 2000). This is a structured interview administered to the child by a member of the research team.

PTSD symptom count and severity were assessed at baseline, post-treatment and 6-month follow up using the CRIES (the 13-item versions, with data for the abbreviated 8-item version also reported; Perrin et al, 2005) and Child PTSD Symptom Scale (CPSS; Foa et al, 2001). The extent to which the sample experienced difficulties in emotion regulation, which is a main feature of CPTSD, was also assessed using the Difficulties in Emotion Regulation Scale (DERS- child version; Gratz & Roemer, 2004). The DERS provides scores for six 'domains' of emotion regulation: i) non-acceptance of emotional responses, ii) difficulty engaging in goal-directed behaviour, iii) impulse control difficulties, iv) lack of emotional awareness, v) limited access to emotion regulation strategies and vi) lack of emotional clarity. The general mental health status and overall functioning of participants were assessed using the (child-administered) Revised Child Anxiety and Depression Scale (RCADS; Chorpita, Moffitt & Gray, 2005) and children's Global Assessment Scale (CGAS; Shaffer et al, 1983) respectively. The RCADS provides scores on 6 subscales: social anxiety, panic, depression, separation anxiety, generalized anxiety and obsessions and compulsions. The CGAS is completed by the researcher and provides an overall functional score. Voice hearing was assessed using items from the voice hearing questionnaire (Anilmis et al, 2015).

Cognitive Processes

Seven potential cognitive and psychosocial mechanisms of treatment were assessed pre- and post-treatment using a range of child self-report questionnaires. These questionnaires assessed: trauma-related appraisals [CPTCI]; Meiser-Stedman et al. 2009), trauma-related memory quality (the Trauma Memory Quality Questionnaire [TMQQ]; Meiser-Stedman et al. 2007), perceived social support (the Multidimensional Scale of Perceived Social Support [MSPSS]; Zimet et al, 1988), the use of safety behaviours (the Child Safety Behaviour Scale [CSBS] Alberici et al, 2018), self-blame, trauma-related rumination, and trauma-related thought suppression. The latter three were assessed using a questionnaire developed for use in a previous study (Meiser-Stedman et al, 2017).

Analysis

Analysis involved descriptive statistics and visual analytic methods consistent with other intervention case series (Brand et al, 2020; Maddox et al, 2013). Within-subjects effect sizes were calculated for pre-post and pre- 6-month changes independently using SPSS. The adjusted (Hedges *g*) effect size statistic was used as a conservative option that takes account of the small sample size. For the CRIES-8 and the RCADS, reliable change was assessed using published reliable change index scores (see Wolpert et al, 2016).

Results

Recruitment and Retention

Recruitment took place over a five-month period, between January-July, 2014. A consort diagram of the recruitment and study process is provided in Figure 1. All participants who consented onto the study completed treatment.

[INSERT FIGURE 1 HERE]

Average Number of Treatment Sessions Needed

The average number of therapy sessions required for participants was 11.2 (*SD*= 1.3). Treatment ceased once the clinician and young person agreed that PTSD symptoms had abated sufficiently.

Sociodemographic Characteristics

Nine young people were recruited aged between 9.5 years to 17.0 years old (mean = 14.1, *SD* = 3.2). Seven were female. Only one participant identified as belonging to a minoritized racial group. Three participants had parents who were married; in three cases their parents cohabiting; one participant lived with a separated/divorced parent; one participant lived with a single parent; in one case these data were not available. Household incomes were as follows: less than £10,000 per year, n = 1; £10-20,000, n = 1; £20-30,000, n = 2; £30-40,000, n = 2; missing, n = 3.

Trauma History

The participants had experienced an average of two different trauma types (range= 1-4). The most common type of trauma experienced by the sample was domestic violence within the home environment (n=5) followed by sexual assault/ abuse (n=4) and road traffic accidents (n=3). Other traumas experienced were attempted murder (n=1), bullying (n=1), witnessing the near death of a relative (n=1), torture (n=1), being accused of a serious criminal act (n=1), and physical abuse (n=1).

Voice Hearing

At baseline, six out of the eight participants for whom there are data, reported hearing voices. Three of these reported hearing the voices of people who attacked them, and voices that were part of their intrusive thoughts or flashbacks. The other three children reported that their voices involved neither of these. Of this group of voice hearers, only one reported hearing voices in the previous two weeks (n= 5 due to one missing data point).

Treatment Safety, Acceptability, and Feasibility

No adverse events were recorded throughout the six-month trial. No evidence of PTSD symptom exacerbation was found at post-treatment. At no point did treatment have to be discontinued for any participants. The overall mean score across the four suicidal ideation items was 1.03 (i.e., everyone endorsed) (n= 8) at pre-treatment, .31 (n= 8) at post-treatment and .33 (n= 6) at 6-month follow up. On average participants shifted from experiencing suicidal ideation 'sometimes' at baseline (corresponding to a score of 1), to 'never' at post-treatment and 6-month follow up (corresponding to a score of 0). Mean differences and effect sizes for participant total suicidal ideation score across the study are provided in Table 1. A medium effect size of treatment was found for post-treatment suicidal ideation.

[INSERT TABLE 1 HERE]

Treatment Credibility

The mean score for treatment credibility across all four items at post-treatment was 8.9 (maximum score 10, n= 8; range= 4.8- 10.0). Four of the eight children for whom we have data on this measure gave a score of 10 for every credibility item.

Therapeutic Alliance

The mean score for therapeutic alliance at post-treatment was 6.2 (maximum possible seven; n = 6, range = 5.8-7.0).

Primary Outcome: PTSD Caseness Post-Treatment

PTSD caseness was assessed at baseline and post-treatment according to DSM-IV criteria and the developmentally adjusted AA (Meiser-Stedman et al., 2008). At baseline, all nine participants met the AA criteria for PTSD, and eight also met full DSM-IV criteria for PTSD. At post-treatment one participant met DSM-IV criteria for PTSD, and another participant met AA criteria for PTSD. At 6-month follow up, none of the seven participants for whom there are data met the DSM-IV or AA criteria for PTSD.

PTSD Severity

A large pre-post effect size was observed for PTSD severity using the CPSS and the CRIES (both the CRIES-8 and CRIES-13) at post-treatment and 6-month follow up (see Table 1). At post-treatment all eight children for whom there were data demonstrated reliable clinical change on the CRIES-8. At 6-month follow up, five children demonstrated reliable clinical change on the CRIES-8 (see Supplementary table 2).

Session-by-session mean total CPSS scores are presented in Figure 2. Across the intervention phase, PTSD severity reduced markedly. There were no apparent increases in severity at any point during treatment, and at no stage did scores approach baseline levels. PTSD severity reduced at a steady pace until session seven, when scores plateaued.

[INSERT FIGURE 2 HERE]

Session-by-session mean impairment scores (CPSS) are presented in Figure 3. PTSD-related level of impairment can be clearly seen to reduce throughout intervention, with the biggest treatment gains occurring soon after treatment commenced (week 1-3). There is a slight increase in impairment between weeks three and four of treatment, which does not reach pre-treatment level, and reduces in subsequent sessions.

[INSERT FIGURE 3 HERE]

General Functioning

A large effect size was observed for overall functioning of the sample (CGAS) at post-treatment and 6-month follow up (see Table 1).

Psychiatric Comorbidity

As shown in Table 1, large effect sizes were observed for each of the psychiatric comorbidities assessed at post-treatment. Medium-large effect sizes were observed for each of the psychiatric comorbidities assessed at 6-month follow up.

Supplementary Table 3 presents case-by-case data on psychiatric comorbidity assessed using the clinical cut off (T< 70) for the six subscales of the RCADS-C at baseline,

post-intervention and six-month follow up. Seven of eight cases presented with comorbidities at baseline but these persisted post-treatment for only one participant. At six-month follow up, only case one met the clinical cut-off for the comorbid issue they had initially presented with. Panic was the most common issue to present alongside the PTSD in this subgroup at baseline (n=5), followed by depression (n=3) and separation anxiety (n=3).

The extent to which the children demonstrated reliable clinical change at post-treatment and six-month follow up varied by subscale (see Supplementary Table 2). All eight participants for whom there were data demonstrated reliable change post-treatment on the obsessions and compulsions and panic disorder subscales. The percentage of participants demonstrating reliable change on other post-treatment subscales varied between 25-75%. At six-month follow-up, half of the participants demonstrated reliable clinical change on five of the six subscales. The lowest frequency of reliable changes was observed for the separation anxiety subscale, where only 25% of the sample demonstrated reliable change. However, this increased to 50% of the sample at 6-month follow up.

Difficulties with Affect Regulation

As shown in Table 1, a large effect size was observed post-treatment for the DERS subscales of 'difficulty engaging in directed behaviour', 'impulse control difficulties' and 'limited access to emotion regulation strategies'. A medium-large effect size was observed for the 'lack of emotional clarity' subscale. A small-medium effect size was observed for the 'non-acceptance of emotional responses' subscale.

Putative Cognitive Treatment Mechanisms

Table 2 provides effect size findings for each cognitive process through which CT-PTSD is purported to work. Large effect sizes were observed for all cognitive factors assessed, with the exception of self-blame and perceived social support which yielded medium and small effect sizes, respectively.

[INSERT TABLE 2 HERE]

Discussion

This case-series is the first investigation of the suitability of CT-PTSD for CYP with multiple trauma PTSD. The results suggest that CT-PTSD is a safe, acceptable and feasible treatment for this subgroup. Participants regarded CT-PTSD as a highly credible form of treatment and reported experiencing strong working alliance with clinicians. As treatment requires children to engage directly and intensively with numerous distressing memories, it is encouraging that strong working alliances were maintained throughout. Notably, all nine participants engaged with treatment, with no participants withdrawing from treatment.

In terms of the safety of CT-PTSD, it was found that children with multiple trauma PTSD tolerated the treatment well. No adverse events were reported throughout the duration of the study and treatment did not have to be discontinued for any reason. There was no evidence of PTSD symptom exacerbation. Findings showed that level of risk, as indicated by a measure of suicidal ideation, reduced during treatment.

The preliminary treatment outcomes are encouraging. All nine young people demonstrated significant improvements in PTSD symptoms, overall functioning, and psychiatric comorbidities. The primary outcome, caseness, showed treatment benefit for all but two participants. In line with this, PTSD severity and symptom count decreased post-treatment, and scores for both remained low at six-month follow up, with large treatment effect sizes observed. This preliminary evidence suggests that CT-PTSD may be an effective PTSD treatment for children with multiple trauma PTSD. The large effect sizes observed for PTSD severity and symptom count are similar to those reported for single-incident PTSD (Meiser-Stedman et al, 2017). Moreover, significant treatment gains were obtained within an average of only 11 sessions despite a history of exposure to multiple, severe traumas.

We observed a large shift in the core cognitive mechanisms through which treatment is purported to work. This suggests that treatment was effective by altering cognitive-specific mechanisms proposed by the cognitive model of PTSD (Ehlers & Clark, 2000). Specifically, large treatment effect sizes were found for trauma-related misappraisals, trauma memory quality, rumination, safety behaviours and thought suppression, all of which reduced following treatment. This replicates findings from research on single-incident PTSD (Meiser-Stedman et al, 2017; Smith et al., 2007) and consistent with the cognitive model (Ehlers & Clark, 2000), suggests that these factors are more proximal in the treatment process. Overall, this suggests that CT-PTSD may be a suitable treatment approach for this group, as the same mechanisms are being targeted in both single and multiple incident PTSD.

Limitations

The primary limitation of this research is that by definition, the case series involves a very small sample. Indeed, for a case series our sample size is considered sufficient. A review of 586 case series studies reported that 63% of these had equal or less than 10 participants (Abu-Zidan et al, 2012). Similar intervention case series in clinical psychology research have recruited between 4-15 participants (e.g., Glover et al, 2007; Maddox et al, 2013). This study provides a 'proof of concept' for CT-PTSD in multiple-trauma exposed children. However, it will be important for research to progress to full randomised controlled trials of CT-PTSD in this population, to test efficacy. It is important to acknowledge that the findings are based on an unrepresentative sample. Participants in this UK study were predominantly white, adolescent females. This sample bias is not unique to this study, with many studies finding this trend in their research on trauma therapy (e.g., Martin et al, 2013). Over three-quarters of the present sample were female, and some evidence suggests that PTSD treatment is more successful for females (Stefanovics & Rosenheck, 2020) so gender may have led to an over-inflation of treatment effect size. In addition, the youngest child to take part in this study was

9.5 years old, so it remains unclear whether this treatment is acceptable and feasible for younger children.

The findings predominantly rely on self-report measures completed by CYP. This was considered appropriate based on research suggesting that children's self-reports of their PTSD symptoms are more accurate than reports provided by their parents, and that parental report of a child's PTSD symptoms is impacted by their own PTSD-related pathology (Shemesh et al, 2005).

Future Research

The findings provide a strong argument for the feasibility, necessity and appropriateness of conducting a randomised controlled trial of the efficacy of CT-PTSD in children with multi-trauma PTSD. The findings of this feasibility case-series would inform the development of such a trial. They suggest that within the UK this subgroup is relatively easy to recruit to research trials and a timescale of recruiting one person per month is feasible. Recruiting via local NHS mental health Trusts appears feasible. As our sample was skewed towards white female adolescents, it is worth considering how a more representative, culturally diverse sample could be reached in a full trial. It is also worth considering the option of mental health professionals other than clinical psychologists delivering CT-PTSD within a full trial. A systematic review has shown that the delivery of TF-CBT by other therapy professionals does not necessarily compromise on outcome (Granger et al, 2022) and this will have clear economic impacts. Our case-series provides effect sizes that can inform power calculations for intervention trials. As all participants of this case series tolerated treatment well and demonstrated good treatments outcomes, the minor adaptations made to the CT-PTSD appear feasible, appropriate and sufficient for use in a full efficacy trial.

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Figure 1. *A Consort Diagram of the Recruitment and Study Process*

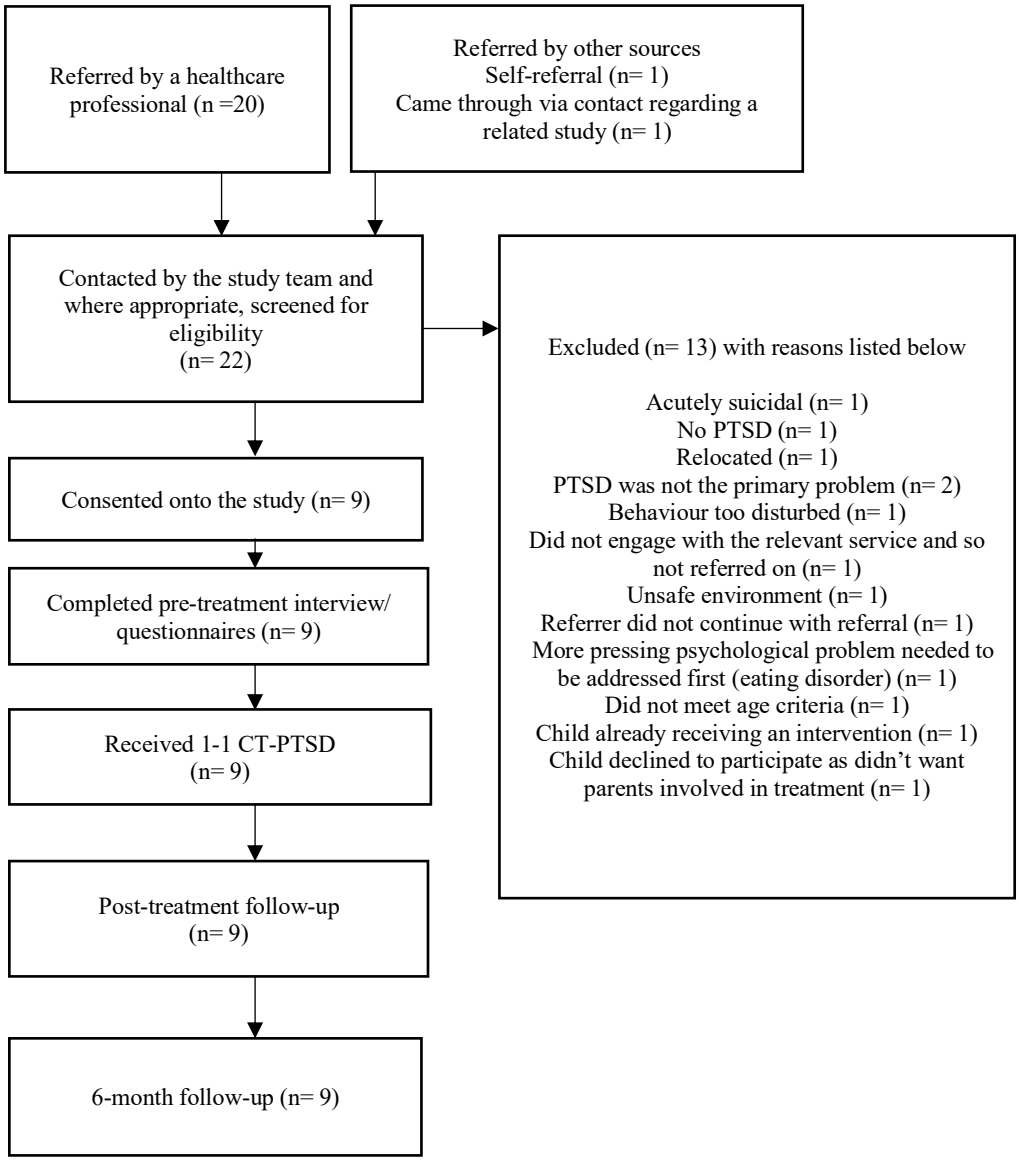


Table 1.

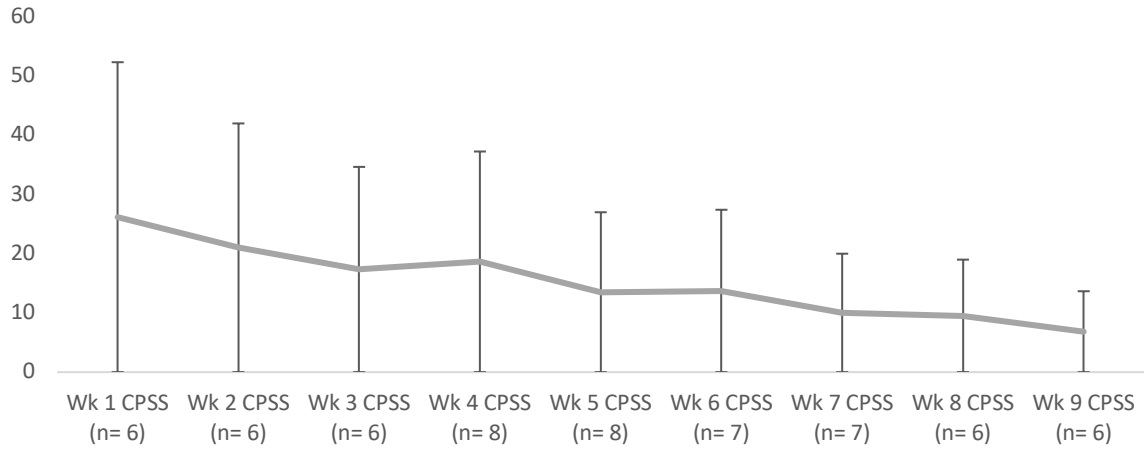
Mean, Standard Deviations and Effect Sizes for Quantitative Measures.

Outcome	Baseline, M (SD), n=9	Post-Treatment, M (SD), n=9	6m Follow up, M (SD), n=7	Effect size, baseline-post (Cohen's d), n=9	Effect size, baseline-6MFU (Cohen's d), n=7
PTSD severity					
CPSS	22.00 (11.96)	3.56 (5.90)	4.29 (4.11) (n= 7)	1.98	4.08 (n=7)
CRIES-13	45.75 (10.59) (n= 8)[a]	5.25 (7.07) (n= 8)	8.67 (9.85) (n= 6)	4.25 (n= 8)	1.65 (n=6)
CRIES-8	28.75 (7.32) (n= 8)	1.75 (2.55) (n= 8)	2.50 (5.65) (n= 6)	2.99 (n= 8)	1.82 (n=6)
General functioning					
CGAS	57.00 (10.78) (n= 8)	78.25 (14.85) (n= 8)	78.86 (13.93) (n= 7)	-1.23 (n=8)	-1.41 (n=7)
Suicidality (MFQ-SI)	4.13 (4.39) (n= 8)	1.25 (1.75) (n= 8)	1.33 (3.27) (n= 6)	.59 (n= 8)	.35 (n= 6)
Psychiatric comorbidity (RCADS-c)	(n= 8)	(n= 8)	(n= 6)	(n= 8)	
Social phobia	14.50 (7.84)	4.88 (5.94)	6.00 (4.34)	1.07	.77
Panic	11.25 (7.82)	4.38 (6.37)	4.00 (4.82)	1.32	.57
Depression	16.00 (8.30)	3.93 (4.84)	5.67 (6.56)	1.42	.87
Obsessions and compulsions	7.75 (4.33)	2.00 (2.45)	1.83 (2.14)	1.43	1.00
Generalised anxiety	9.25 (6.56)	2.50 (3.96)	3.33 (2.34)	1.14	.70
Separation anxiety	7.63 (5.13)	2.75 (4.30)	3.00 (2.83)	.95	.66
Difficulties in emotion regulation scale (DERS) (n= 8)					
Non-acceptance of emotional responses	14.00 (8.09)	9.25 (5.23)	N/A	.44	N/A

Difficulty engaging in goal directed behaviour	19.5 (3.42)	12.00 (5.45)	N/A	.92	N/A
Impulse control difficulties	18.88 (6.88)	11.88 (5.22)	N/A	.81	N/A
Lack of emotional awareness	19.25 (6.76)	21.50 (6.85)	N/A	-.19	N/A
Limited access to emotion regulation strategies	25.00 (5.45)	14.75 (7.42)	N/A	1.02	N/A
Lack of emotional clarity	16.00 (3.25)	11.25 (5.09)	N/A	.66	N/A

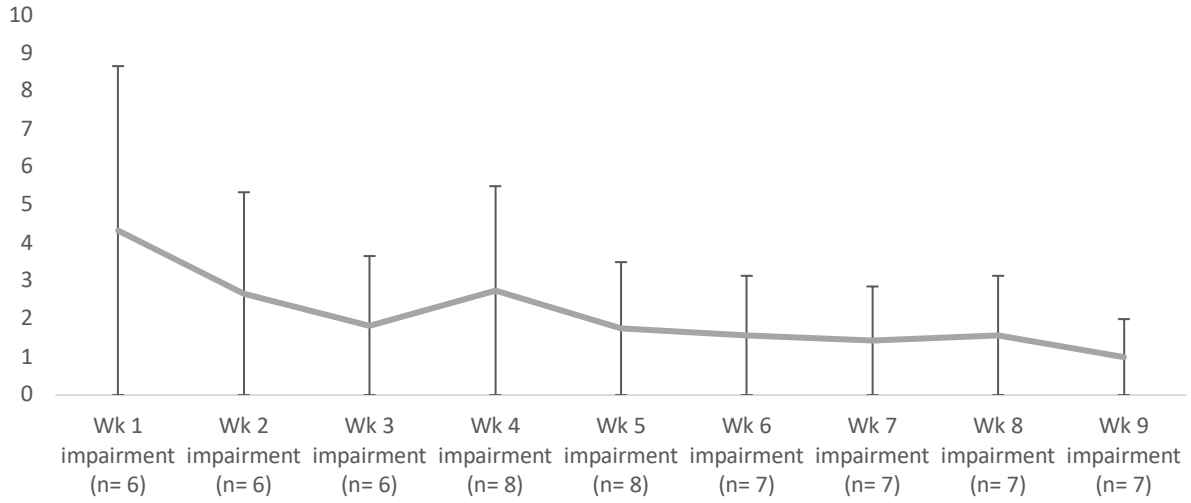
Note. [a] $n = 8$; [b] $n = 7$; [c] $n = 6$. MFQ = mood and feelings questionnaire- suicidal ideation subscale. CPSS = Child PTSD symptom scale. CRIES = child revised impact of events scale. CGAS = children's global assessment scale. RCADS- c = Revised child anxiety and depression scale (child administered version). DERS = difficulties in emotion regulation scale. N/A = not applicable.

Figure 2. *Average Total Score on the CPSS Session-By-Session with 95% Confidence Intervals*.



Note: Case 6 was removed as there were no session-by-session data available for this participant.

Figure 3. *Average Total Impairment Score on the CPSS Session-By-Session with 95% Confidence Intervals*.



Note: Case 6 was removed as there were no session-by-session data available for this participant.

Table 2. *Means, Standard Deviations, Mean Differences and Effect Sizes for Each Cognitive or Psychological Mechanism Assessed*

	Baseline		Post-intervention		
Cognitive or psychosocial mechanism	M	SD	M	SD	ES
Trauma-related misappraisals (CPTCI)	61.55	24.94	31.75	12.78	1.39
Memory quality (TMQQ)	30.24	6.49	16.50	6.57	1.70
Rumination	8.88	3.04	5.13	3.68	.90
Safety behaviours (CSBS)	34.63	18.91	9.16	13.15	1.72
Self-blame	3.75	2.25	2.13	.35	.68
Thought suppression	16.13	3.68	6.38	3.89	1.40
Social support (MSPSS)	57.11	17.70	66.50	16.65	-.34

Note. ES= effect size using Hedges' g. CPTCI= child's posttraumatic cognitions inventory. TMQQ= trauma memory quality questionnaire. CSBS= child safety behaviour scale. MPSS= multidimensional scale of perceived social support.

Supplementary Table 1.

Psychometric Properties of the Quantitative Measures Used in this Study (Where Available)

Questionnaire used	Number of items	Scoring information	Score range (where relevant)	Internal consistency (Cronbach's alpha coefficient)	Test-retest reliability
Voice hearing questionnaire (Anilmis et al, 2015)	4	Questions 1-3 scored 0, 1 or 2 ('not true', 'somewhat true' or 'certainly true' Question 4 scored 0 or 1 (yes or no)	Questions 1-3 coded 0= no, 1 or 2= yes	NA	NA
MFQ-SI (Hammerton et al, 2014)	4	0, 1, 2 or 3 ('never' to 'always')	0-12 for total; 0-3 for individual items	.87- .91 for child self-report (Hammerton et al, 2014)	NA
Treatment credibility measure (Ehlers et al, 2003)	4	1-10, ('definitely do not agree' to 'definitely agree')	1-10 for individual items	NA	NA
WAI-S (Tracey & Kokotovic, 1989)	12	1-7, ('never' to 'always')	1-7 for individual items	NA	NA
Children's PTSD Inventory (CPTSD-I) (Saigh et al, 2000)	25	'yes' or 'no'	Not applicable	.95 for diagnosis (Strand, 2005)	97.6% agreement for diagnosis (Yasik et al, 2001)
CRIES-13 (Perrin et al, 2005)	13	0, 1, 3 or 5 ('not at all' to 'often')	0-65 (total score)	.89 (total score; Giannopoulou et al, 2006)	.85 (total score; Verlinden et al, 2014)
CRIES-8 (Perrin et al, 2005)	8	0, 1, 3 or 5 ('not at all' to 'often')	0-40 (total score)	.86 (total score; Verlinden et al, 2014)	.78 (total score; Verlinden et al, 2014)

Child PTSD Symptom Scale (CPSS; Foa et al, 2001)	17 + 6	Symptom items: 0, 1, 2 or 3, ('not at all or only one time' to '5 or more times a week/ almost always'); Impairment items: yes (1) or no (0)	0-51 (symptom total); 0-6 for impairment	.89 for symptom severity scale (Strand, 2005)	.84 for symptom severity scale (Strand, 2005)
Difficulties in Emotion Regulation Scale: child version (Gratz & Roemer, 2004	36	1-5 ('almost never (0-10%)' to 'almost always (91-100%)')	5-25 (goal-directed; emotional clarity); 6-30 (nonacceptance; impulse control; emotional awareness); 8-40 (emotion regulation)	.93 (total score); >.80 (each subscale)	ϱ*I* = .88 for total score ϱ*I s;* = .57- .89 for subscales
Interviewer scored Children's Global Assessment Scale (CGAS; Shaffer et al, 1983)	1	1-100 ('extremely impaired' to 'doing very well')	1-100	NA	NA
Child administered Revised Child Anxiety and Depression Scale (RCADS-c; Chorpita et al 2005).	47	0, 1, 2 or 3 ('never' to 'always')	0-27 (social phobia; panic disorder); 0-30 (depression); 0-21 (separation anxiety); 0-18 (generalized anxiety; obsessions & compulsions)	.79-.88 (de Ross et al, 2002)	.66-.90 (de Ross et al, 2002)
Trauma Memory Quality Questionnaire (TMQQ; Meiser-Stedman et al, 2007)	11	1-4 ('disagree a lot' to 'agree a lot')	4-44 (total score)	.82	NA
Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al, 1988)	12	1-7 ('very strongly disagree' to 'very strongly agree')	7-84 (total score)	.88 (total score)	.85 (total score)
Self-blame (Meiser-Stedman et al, 2017)	2	1-4 ('disagree a lot' to 'agree a lot')	2-8 (total score)	.94	NA

Trauma-related rumination (Meiser-Stedman et al, 2017)	3	1-4 ('disagree a lot' to 'agree a lot')	3-12 (total score)	NA	NA
Thought suppression (Meiser-Stedman et al, 2017)	5	1-4 ('disagree a lot' to 'agree a lot')	5-20 (total score)	NA	NA
Children's Posttraumatic Cognitions Inventory (CPTCI; Meiser-Stedman et al, 2009)	25	1-4 ('don't agree at all' to 'agree a lot')	25-100	.93 and .88 (two sub-scales)	.78 and .72 (two-subscales)
Child safety behaviour scale (CSBS; Alberici et al, 2018).	22	0-3 ('never' to 'always')	0-66 (total score)	= .90	.64

Note. NA=Not available.

Supplementary Table 2.
Evaluation of Reliable Change on CRIES-8 and RCADS Subscales

Case	CRIES-8 reliable change		Social phobia (RCADS) reliable change		Major depressive disorder (RCADS) reliable change		Generalised anxiety (RCADS) reliable change		Obsessions and compulsions (RACDS) reliable change		Panic disorder (RCADS) reliable change		Separation anxiety (RCADS) reliable change	
	Pre-post	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**	**Pre-post**	**Pre-6MFU**
1	yes	no	yes	no	yes	no	no	no	yes	no	no	yes*	no	no
2	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
3	yes	yes	no	no	no	no	yes	no	yes	no	yes	yes	no	yes
4	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	no
5	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	no	yes	yes	yes
6	yes	missing	no	missing	no	missing	no	missing	yes	missing	no	missing	no	missing
7	yes	yes	yes	no	yes	no	yes	no	yes	yes	no	yes	no	no
9	yes	missing	no	missing	yes	missing	yes	missing	yes	missing	yes	missing	no	missing
% sample reliable change (total n)	100 (n= 8)	83.33 (n= 6)	62.50 (n= 8)	50 (n= 6)	75 (n= 8)	50 (n= 6)	75 (n= 8)	50 (n= 6)	100 (n= 8)	50 (n= 6)	50 (n= 8)	100 (n= 6)	25 (n= 8)	50 (n= 6)

Note: *reliable change occurred in the other direction, case 8 removed due to missing data, RCADS= revised children's anxiety and depression scale (child administered), CRIES= child revised impact of events scale, reliable change index scores taken from figures published by Wolpert et al, 2016

Supplementary Table 3. *Psychiatric Comorbidities Presenting in Each Participant at Baseline, and its Trajectory Across the Intervention.*

	Above clinical cut off at baseline*	Remaining above clinical cut off post-intervention	Remaining above clinical cut off post-intervention at six month follow up
Case 1	D (T= 78)	No	D (T= 75)
Case 2	SA (T= 75); GA (T> 80); P (T> 80) SOC (T= 77); OC (T> 80); D (T> 80)	No	No
Case 3	P (T= 72)	No	No
Case 4	P (T= 72); OC (T> 80)	No	No
Case 5	SA (T= 76)	No	No
Case 6	None	N/A	N/A
Case 7	P (T= 75)	No	No
Case 9	SA (T> 80); GA (T= 76); P (T> 80); D (T> 80)	SA (T> 80); P (T= 80)	No data

Note: Results excluded total anxiety and total anxiety and depression, no data available for case 8, N/A= not applicable, D=Depression; SA=Separation anxiety; GA= Generalised anxiety; P=panic; OC=Obsessions and compulsions.

Chapter 3: Discussion and Reflection

The aim of this thesis was to investigate the treatment of PTSD in children and the role of trauma-related cognitions within this. This final chapter aims to provide an overall discussion of the research included in this thesis. Firstly, brief summaries of the systematic review with meta-analysis (SRMA) and the primary research study will be provided. Secondly, their methodological limitations and implications for clinical practice and theory will be discussed. The chapter will end with some reflections on the research process.

Summary of Systematic Review with Meta-Analysis Findings

The SRMA investigated whether the current range of psychological treatments for child PTSD reduce negative trauma-related appraisals. Adopting a random effects model, a medium-large pooled effect size was reported between treatment and (active and passive) control groups. Only a moderate level of heterogeneity was reported. A moderator analysis revealed that the effect was reduced when comparing treatment groups with active controls, but not substantially so and the link remained significant. It was concluded from these findings that the current range of psychological treatments for child PTSD shift negative trauma-related cognitions.

Summary of Primary Study Findings

The feasibility case series aimed to investigate the safety, feasibility and acceptability of cognitive therapy for PTSD (CT-PTSD; Smith et al, 2014) in children with multiple trauma PTSD. Secondary aims included assessing preliminary outcomes demonstrated by the sample and exploring potential cognitive mechanisms of treatment in this subgroup. It was found that CT-PTSD was a safe, feasible, and acceptable form of treatment for the sample (n= 9). All children completed treatment, with no drop out. No adverse events were reported, and suicidal ideation decreased after treatment. Furthermore, CT-PTSD showed large effect sizes on a range of PTSD-related and non-PTSD related outcome measures at post-treatment

and 6-month follow up. Importantly, most children no longer met developmentally adjusted criteria for PTSD after treatment. Psychiatric comorbidity decreased, and general functioning increased post-treatment. An investigation into potential cognitive mechanisms of treatment revealed large effect sizes for those (cognitive) factors regarded as key in the cognitive model of PTSD (e.g. appraisals) (Ehlers & Clark, 2000). Factors held to be less important in the treatment process by the cognitive model (Ehlers & Clark, 2000) were less affected by treatment (e.g. social support). This suggests that treatment successfully targeted the cognitive processes that it aims to work through. This replicates findings reported from samples of children with single-incident PTSD (e,g, Meiser-Stedman et al, 2017).

These findings indicate that a larger, randomized trial to explore the efficacy of this treatment in this subgroup is warranted. The findings reported in this thesis can be drawn on to inform the design of such trial (e.g., recruitment strategy and timeline, and expected effect sizes). The findings provide tentative support for the suitability of the cognitive approach as an appropriate theoretical framework and treatment model for children with multiple trauma PTSD. They also suggest that the cognitive mechanisms targeted in this subgroup during CT-PTSD are identical to those targeted in children with single-incident PTSD (see Meiser Stedman et al, 2017).

Integrating findings

The findings from this thesis suggest that a treatment approach (CT-PTSD) that is successful in treating children with single-incident PTSD (Meiser-Stedman et al, 2017), is potentially appropriate, acceptable and effective in treating children with multiple trauma PTSD. The case series indicated that identical cognitive-specific mechanisms are targeted in this subgroup of children (compared to those with single-incident PTSD; Meiser-Stedman, 2017), suggesting that fundamentally, the cognitive factors involved in the treatment of both groups is the same regardless of the differences in trauma exposure. The SRMA established

that the wide range of treatment approaches for child PTSD significantly reduce negative trauma-related appraisals. This review included both samples of children with single-incident PTSD, and samples of children with multiple-trauma PTSD. Given that children in the latter group demonstrate more dysfunctional trauma-related appraisals compared to the former (Karatzias et al, 2019; Kube et al, 2023), it is highly possible that the existing range of treatments will effectively target appraisals in more complex cases of PTSD (i.e. those with complex PTSD and those who have experienced multiple traumas). The case series further supports this by demonstrating a large effect for traumatic appraisals in the nine children that received CT-PTSD.

Hoppen and colleagues recently established in their systematic review that the effectiveness of current treatments for child PTSD is not impacted by the degree of traumatic exposure (i.e., one event vs. more than one). Research is beginning to suggest that the extent to which an individual appraises their trauma negatively is more influential (Srinivas et al, 2015). This is in line with the recent movement towards an introduction of 'complex PTSD' as a separate diagnostic category (Cloitre, 2020). The emphasis of this diagnosis is not on the objective features of the traumas itself (including the number of traumas experienced) but the subsequent impact that these experiences have on the individuals view of the world, themselves and others (i.e., their cognitive appraisals) (Srinivas et al, 2015). Whilst there is a link between increased exposure and severer and more complex PTSD symptoms (Hyland et al, 2017), it is possible that this can be explained by an increasing risk of the child forming dysfunctional appraisals with each trauma (Srinivas et al, 2015).

Limitations and Recommendations for Future Research

One limitation of the systematic review with meta-analysis and the case series is that their findings are predominantly based on female adolescents from the Western world. This is a common limitation of research studies investigating PTSD (e.g., Martin et al, 2013). The

main issue is that it is currently uncertain whether the present findings can be generalised to very young children and those from non-Western cultures.

Another limitation of both papers is that their findings are largely based on child subjective self-report data collected after receiving treatment for their PTSD. This is standard practice in the child PTSD field, in the absence of established, validated objective measures of PTSD-related symptoms (including trauma-related appraisals). Child-reporting of symptoms is preferred over parent-reporting because some research suggests that parent reports are influenced by their own trauma-related distress (Shemesh et al, 2005). Although, it is important to acknowledge that the findings may nonetheless be biased. For example, children may rate favourably post-treatment due to their desire to appear grateful and/ or favourable to their clinician/ researcher leading to overinflated treatment effect sizes (see Brunet et al, 1996).

Turning to the findings of the SRMA, it is important to consider that whilst a link was established between treatment and reduced appraisals, causality cannot be claimed. It remains possible that reduction in appraisals occurs as a coincidental by-product of effective therapy, rather than being a driving factor of it. Although, considering this review in the context of the wider literature, which demonstrates a predictive, mediational and temporal relationship between appraisal change and reduction in PTSD symptoms (Brown et al, 2019; McLean et al, 2015; O'Donnell, 2007), makes this link more likely. However, further research is needed. Specifically, longer-term follow-up research is needed to investigate whether the shift in trauma-related cognitions persists over a longer period. If it is identified that a long-term maintenance of this reduction occurs alongside a continued absence of PTSD symptoms, this would suggest that appraisal change is at the root of successful treatment as the cognitive model claims. If it is indeed found that a reduction in appraisals does not persist longer term

(e.g. 6 months), but children remain symptom free, then this would refute the cognitive model of PTSD.

As the literature develops further and more studies become available in this area, it would be valuable to investigate single vs. multiple, chronic and early trauma as a moderator of effect size. It is possible that existing treatments are more effective at shifting appraisals in children with single-incident PTSD because they are potentially less engrained. If this is found to be the case, potential adaptations may be needed to increase the efficacy with which existing treatments shift these appraisals in those with multiple trauma. Some of the studies included in the present review included children predominantly affected by multiple trauma (e.g., Jensen et al, 2018), and the effect sizes reported in these studies is similar to those with single-incident PTSD (e.g. Meiser-Stedman et al, 2017), decreasing the chance that this is the case. However, the research would benefit from a systematic examination into this in time.

The main limitation of the case series is the small sample size on which the findings are based (n= 9). Whilst this is considered an appropriate sample size for a case series design and for the study aims to be sufficiently addressed, the results from this small-scale study must be interpreted with caution and require replication in a larger, randomized trial.

Clinical and Theoretical Implications of these Findings

The findings from these studies have several clinical and theoretical implications. The findings provide support for the applicability of the cognitive model of PTSD to children (Ehlers & Clark, 2000), including those who present with more complexity (e.g., a history of multiple traumas). Both papers provide tentative support for the potential cognitive treatment mechanisms held by the cognitive model as fundamental in the successful treatment of PTSD (see Ehlers & Clark, 2000). The primary research paper demonstrated large effect sizes occurring in these core cognitive processes, whilst smaller effect sizes were reported for factors that are held by the cognitive model as less important (e.g., social support). The

SRMA demonstrated that the range of current successful treatments available today effectively target appraisals. This includes those that do not include an explicit focus on cognitive change (e.g., EMDR).

The findings from this thesis have implications for the treatment of children with PTSD. At present, there are no evidence-based treatment options available to treat children with more 'complex' PTSD presentations (i.e., those who have experienced multiple, repeated traumas and who possess strong, dysfunctional trauma-related cognitions). In clinical practice, this means that child and adolescent mental health services across the UK are required to rely on treatment manuals that have been developed with single-incident PTSD in mind. Two of the main treatment protocols currently drawn on in services are the TF-CBT manual by Cohen and colleagues (2016) and CT-PTSD manual by Smith and colleagues (2009). However, the fact that these manuals have not been researched specifically with children with multiple trauma PTSD paired with the lack of evidence on the specific adaptations needed for this subgroup mean that Clinicians face a certain degree of uncertainty when delivering treatment to this more complex subgroup.

This lack of evidence-based is also alarming, when considering the research demonstrating that this subgroup typically presents with higher levels of self-harm and risk, and increased suicidality (Layne et al, 2014). The preliminary evidence provided by the primary paper is encouraging in terms of the potential treatability of multiple-trauma PTSD within a relatively short time frame (11 sessions on average) and by drawing on an existing treatment approach (CT-PTSD). Whilst it could be hypothesised that this group would have proved harder to treat, given the early and engrained nature of their trauma and its sequalae, the preliminary evidence from this paper provides a more optimistic account. It is essential that these positive outcomes be replicated in a full-scale RCT. If these results are replicated,

this has the potential to significantly advance the treatment of this subgroup within healthcare services worldwide.

Both papers speak to the significant advances that have been made in the research into child PTSD treatment in the last several decades. The SRMA demonstrated that the current range of treatments successfully shift negative trauma-related appraisals. It is possible that these treatments can be drawn on to inform the treatment of other psychiatric conditions in which negative cognitive appraisals are implicated (e.g., depression). Current understanding of the aetiology of depression is that it is rooted in negative appraisals related to the self, the world and others (Dowd, 2004). It is reasonable to suggest that drawing on aspects of PTSD treatments may enable these to be more effectively targeted in therapy.

The findings from this thesis make a further contribution to the growing literature suggesting that existing treatment approaches for child PTSD are suitable for more complex cases (e.g., children with CPTSD and/ or multiple trauma exposure) (Hoppen et al, in press). The present findings suggest that the cognitive mechanisms targeted in treatments for children with multiple-incident trauma are potentially identical to those with single-incident trauma. This being the case, this has implications for the conceptualisation of PTSD and its classification. Resick and colleagues (2012) stated that 'the clinical utility of CPTSD rests on demonstrating that the diagnosis would make a difference for treatment outcomes'. It is likely that at least some of the children in the case series also met criteria for CPTSD, given their trauma history. If it is the case that identical treatment mechanisms are involved in samples with PTSD and CPTSD, and therefore that the same treatments can be applied across both conditions, then this calls into question the need for an additional category. CPTSD is not without controversy (Resick et al, 2012), and it may indeed be more appropriate to consider PTSD on a 'spectrum' (Goodman, 2012).

It is also worth acknowledging here that the data for the primary paper were collected some years ago and a subsequent follow-up trial of CT-PTSD for multiple trauma PTSD has been conducted. However, this in no way diminishes the contribution of this current article. The dearth of literature available on the treatment of this subgroup of children means that these findings provide a unique, valuable standalone contribution to the literature, alongside other related studies (e.g. including results from full scale trials published in time). The preliminary case-series design uniquely provides valuable data to inform future grant applications and study proposals for future trials in this area (by providing information on the safety and acceptability of CT-PTSD, recruitment strategies and expected effect sizes etc.). The case-series also provides additional standalone evidence of the potential suitability of CT-PTSD for this subgroup of children.

Reflection on the Research Process of the Primary Study

The process of completing this thesis has been an extensive learning journey. During my first year of training, I selected to complete a qualitative study within clinical health psychology. However, this project fell through due to reasons related to the Covid-19 global pandemic. At this point, I was provided with the opportunity to complete my primary research on an MRC-funded single-case series study in child PTSD. This study was led by a team of world-leading researchers in the field of child PTSD. As the data had already been collected for this study, my role would be to take it forward from this point and conduct a primary analysis of the data (as it was yet to be analysed). This was an incredible opportunity that I was keen to take up. I was aware that it would allow me to build on the research knowledge and skills that I'd developed to date.

Whilst a key advantage of this project was that the earlier phases had already been completed (e.g., study design, ethics, data collection), this project came with its own unique challenges that needed to be overcome. I received the relevant paperwork for the study (e.g.,

the protocol, ethics form) and the dataset and was required to develop a thesis proposal. I was required to rapidly familiarise myself with the child PTSD literature, case series methodology, the specific study and the database. Whilst data had been collected from only nine participants, there was a large breadth of data collected from these children, including neurocognitive data and parent self-report data to complement the main dataset. During the data analytic phase, I was required to learn and become proficient in SPSS syntax and case-series data analytic methods. It became a great learning experience and something that I would not have experienced if my initial project had worked. It has given me a realistic view of how research occurs in the 'real world', outside of educational-based qualification research and in a 'real' research team of collaborators. It has increased my confidence in and passion for working in research post-qualification, and I believe, it has prepared me for pursuing this.

At one point during the thesis, I was completing this research whilst simultaneously completing my placement within an NHS child and adolescent mental health service (CAMHS). My experience on this placement underscored the importance of such research into child PTSD, and in particular the treatment of children with multiple trauma PTSD in healthcare services. My experience was that a substantial proportion of children that were accepted into the service had reported experiencing multiple traumas, usually beginning early and sometimes perpetrated by a member of the family. I experienced first-hand the challenges in treating this group of children in the absence of evidence-based treatments for this specific subgroup. This acted to further increase my commitment to this research and allowed me to recognise the significance of it.

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Appendix A

Author Guidelines for Journal of Traumatic Stress

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- The title page of the manuscript, including:
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        - Procedure
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        - Data Analysis
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- References
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Brief Report	Preliminary findings of research in progress or a case	4,500 words, including abstract, reference	Yes	Data Availability Statement IRB Statement

	report of particular interest	s, tables, and figures		
Review Article	Overview of developments in the field or current lines of thought; synthesizes multiple sources of information and has long list of references	7,500 words, including abstract, references, tables, and figures	Yes	Data Availability Statement IRB Statement
Commentary	Evidence-based opinion piece on a recently published *JTS*article	1,000 words, including references, tables, and figures	No	N/A

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Appendix B
Individual Study Ratings on the Risk of Bias-2 Measure

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Cohen, J.A., Deblinger, E., Mannarino, A.P., & Steer, R. (2004). A multisite randomized controlled trial for children with abuse-related PTSD. *Journal of American Academy of Adolescent Psychiatry, 43*(4), 393-402. doi: 10.1097/00004583-200404000-00005

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: TF-CBT Comparator: Client centred therapy

Specify which outcome is being assessed for risk of bias	Post treatment CAPS means for both conditions (4 subscales)
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Cohen et al (2004) Page 13 CAPS subscales data

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	See page 12 of manual- credible journal, established authors.	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	TF-CBT: 114 randomized, data for 92- >95% missing CCT: 115 randomized, data for 91- >95% missing	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Not for the CAPS statistics	N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	No information to suggest otherwise	Y
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	No information to suggest that it's likely, none of the 5 points discussed in the guidance booklet apply (e.g. equal N missing in 2 groups)	N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Cannot locate any information on planned analysis	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	No pre-specified planned analysis documents could be sourced	NI
5.3 ... multiple eligible analyses of the data?	Reports in main way- overall post-treatment subscores	PN
Risk-of-bias judgement		Some
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	de Roos, C., van der Oord, S., Ziljstra, B., Lucassen, S., Perrin, S., Emmelkamp, P., & de Jongh, A. (2017). Comparison of eye movement desensitization and reprocessing therapy, cognitive behavioural writing therapy, and wait-list in pediatric posttraumatic stress disorder following single-incident trauma: a multicenter randomized clinical trial. *Journal of Child Psychology and Psychiatry, 58*(11), 1219-1228. doi: 10.1111/jcpp.12768

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: EMDR/ CBWT Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI post-treatment means, SD, N for all conditions
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 4

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Ratio of 2: 2: 1 43: 42: 18 participants No clear difference in pre-treatment outcomes/ baseline using visual inspection	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement on this in the paper	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	CPTCI EMDR= 43 (total in condition) CBWT= 42 (total in condition) WL= 18 (total in condition)	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	A pre-specified analysis plan could not be sourced	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Reported on PTCI, a main measure, did not only report certain subscales	PN
5.3 ... multiple eligible analyses of the data?	Reported overall mean as would be expected so no evidence of this	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Dildar, S., & Kausar, R. (2019). Efficacy of teaching recovery techniques on psychological functioning of flood affected girls in pakistan. *International Journal of Research in Informative Science Application and Techniques, 3*(3), 193348-193357. doi: 10.46828/ijrisat.v3i3.70

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: TRT Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI post treatment means, SD and N for both groups
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

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Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	No further information other than that random- cannot go by other trials published by authors	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No information in relation to this i.e. participant characteristics by group But no large disparity in N allocation between groups, when visually inspecting the baseline outcome measures of group no visible differences	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No comment on this in paper	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	60 children randomized, data for 60 children available	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Pre-specified analysis plan could not be sourced	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Used a main measure	PN
5.3 ... multiple eligible analyses of the data?	Reported on post-treatment subscales	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Ford, J.D., Steinberg, K.L., Hawke, J., Levine, J., & Zhang, W. (2012). Randomized trial comparison of emotion regulation and relational psychotherapies for PTSD with girls involved in delinquency. *Journal of Clinical Child & Adolescent Psychology, 41*(1), 27-37. doi: 10.1080/15374416.2012.632343

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: TARGET Comparator: ETAU

Specify which outcome is being assessed for risk of bias	PTCI, post-treatment means for each group, SD, N
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Used SPSS 15.0 random number generator by admin staff unconnected to study	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Assigned after baseline assessment interview	Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Only one baseline difference found on baseline demographics/ outcome measures 33- TARGET, 26- ETAU	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement of this in paper	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	TARGET= 33 randomized, ETAU= 26 randomized PTCI data for 25 & 20 respectively	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No adjustment made for PTCI mean scores reported	N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		Y
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No pre-specified analysis plan available	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Used a main measure- PTCI	PN
5.3 ... multiple eligible analyses of the data?	Total PTCI	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Goldbeck, L., Muche, R., Sachser, C., Tutus, D., & Rosner, R. (2016). Effectiveness of trauma-focused cognitive behavioural therapy for children and adolescents: a randomized controlled trial in eight german mental health clinics. *Psychotherapy and Psychosomatics, 85*, 159-170. doi: 10.1159/000442824

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: TF-CBT Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI post-treatment means for each condition, SD, N
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 2

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐	occurrence of non-protocol interventions
☐	failures in implementing the intervention that could have affected the outcome
☐	non-adherence to their assigned intervention by trial participants
Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)	
☐	Journal article(s) with results of the trial
x	Trial ~~protocol~~ TRIALS REGISTER
☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	"Grey literature" (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Intervention= 76, WL= 83 See page 164/ 165 of paper	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement of this included in paper	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Intervention= 76 children, WL= 83 Data available for 75, 82 children respectively	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	See trials register CPTCI change (pre-post)	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	CPTCI- trials register	N
5.3 ... multiple eligible analyses of the data?	Total CPTCI	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Jensen, T.K., Holt, T., Ormhaug, S.M., Fjermestad, K.W. (2018). Change in post-traumatic cognitions mediates treatment effects for traumatized youth- a randomized controlled trial. *Journal of Consulting Psychology, 65*(2), 166-177. doi: 10.1037/cou0000258

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: TF-CBT Comparator: TAU

Specify which outcome is being assessed for risk of bias	CPTCI post-treatment means, SD, N for each group
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Computer- generated randomization procedure No information on how/ who/ when exposed	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	TF-CBT= 79, TAU= 77 See table 1- no clear differences between groups on outcome/ characteristics	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement on this in the paper	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	TF-CBT= 79 children, TAU= 77 children CPTCI data for 54/ 60 respectively 68% of intervention data available post-treatment	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		Y
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Could not locate a pre-specified plan of analysis	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	CPTCI- a main measure	PN
5.3 ... multiple eligible analyses of the data?	Overall total	PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Khubsing, R.S.I., Daemen, I.K.S., Hendricks, L., van Emmerik, A.A.P., Shapiro, E., & Dekker, J.J.M. (2020). An EMDR group therapy for traumatized former child slaves in India: a pilot randomized controlled trial. *The International Journal of Indian Psychology, 8*(3), 722- 731. doi: 10.25215/0803.082

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: EMDR Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI post-treatment means, SD, N for each group
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1

Is the review team's aim for this result…?

- x to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Only states random allocation No information on concealment, method	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Experimental = 11 children WL= 12 children No other information	NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Data available for all randomized children	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	No pre-specified analysis plan could be sourced	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		PN
5.3 ... multiple eligible analyses of the data?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	McLean, C. P., Yeh, R., Rosenfield, D., & Foa, E. B. (2015). Changes in negative cognitions mediate PTSD symptom reductions during client-centered therapy and prolonged exposure for adolescents. *Behaviour Research and Therapy*, *68*, 64-69. doi: 10.1016/j.brat.2015.03.008

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: PE Comparator: Supportive counseling

Specify which outcome is being assessed for risk of bias	CPTAS, b, t, p, 3-month post-treatment between groups
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Page 67

Is the review team's aim for this result…?

- x to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Only mentions random and block design Doesn't mention how sequence was generated but published in JAMA- prestigious journal and established authors (see guidelines) Condition shared after consented onto study	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	31 and 30 children in each condition Page 2653, no differences Visual inspection of baseline data- no visible differences	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement in paper on this	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Page 67 in the paper	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Could not source pre-specified analysis plan	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	CPTAS	NI
5.3 ... multiple eligible analyses of the data?	Reported 3 month post-treatment out of multiple options	PY
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Meiser-Stedman. R., Smith, P., McKinnon, A., Dixon, C., Trickey, D., Elhers, A., Clark, D.M., Boyle, A., Watson, P., Goodyer, I., & Dalgeish, T. (2017). Cognitive therapy as an early treatment for post-traumatic stress disorder in children and adolescents: a randomized controlled trial addressing preliminary efficacy and mechanisms of action. *The Journal of Child Psychology and Psychiatry, 58*(5), 623-633. doi: 10.1111/jcpp.12673

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: CT-PTSD Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI post treatment means, SD, N
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	See supplementary table

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Randomized Well established author/ good journal	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Used minimisation- based on participant characteristics	Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No significant baseline differences	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	No statement included on this	NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	CT-PTSD= 14, WL= 15 Data for 13 children in each condition More than 5% missing but using subjective judgement here- see page 41 of full guidance, 5% rule but depends on proportion	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	See study protocol/ trials registry Use CPTCI- pre and post for outcome measures including secondary outcome measures	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Protocol states CPTCI	N
5.3 ... multiple eligible analyses of the data?	Total post-treatment	PN
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Najavits, L. M., Gallop, R. J., & Weiss, R. D. (2006). Seeking safety therapy for adolescent girls with PTSD and substance use disorder: A randomized controlled trial. *The Journal of Behavioral Health Services & Research*, *33*, 453-463.

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: SS Comparator: TAU

Specify which outcome is being assessed for risk of bias	WAS effect size, between groups post-treatment
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 1

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Just states randomly assigned 'assignment occurred immediately after intake completion, with staff blind to their assignment until informed by the PI'	NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	18 SS, 15 TAU No clear differences in baseline characteristics No clear differences in pre-treatment scores on outcome measures in visual inspection	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	SS= 18, TAU= 15 WAS data for 18, 15 children	Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Report only significant subscales	PY
5.3 ... multiple eligible analyses of the data?		PN
Risk-of-bias judgement		High
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		High
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Pfeiffer, E., Sachser, C., Rohlmann, F., & Goldbeck, L. (2018). Effectiveness of a trauma-focused group intervention for young refugees: A randomized controlled trial. *Journal of Child Psychology and Psychiatry*, *59*(11), 1171-1179. doi: 10.1111/jcpp.12908

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: Mein weg Comparator: UC

Specify which outcome is being assessed for risk of bias	CPTCI-S post-treatment means, SD, N, for each group
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 3

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Used randomization software	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Based on authors comments, no baseline differences	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	See trials register- CPTCI-S as secondary outcome	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple eligible analyses of the data?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Rossouw, J., Yadin, E., Alexander, D., & Seedat, S. (2018). Prolonged exposure therapy and supportive counselling for post-traumatic stress disorder in adolescents: task-shifting randomised controlled trial. *The British Journal of Psychiatry*, *213*(4), 587-594. doi: 10.1192/bjp.2018.130

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: PE-A Comparator: Supportive counseling

Specify which outcome is being assessed for risk of bias	CPTCI post-treatment
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Raw data was shared with the author- not yet been published

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	PE-A data for 25/31 SC- data for 26/32	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		Y
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		N
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Study protocol	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple eligible analyses of the data?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.

Study details

Reference	Smith, P., Yule, W., Perrin, S., Tranah, T., Dalgeish, T., & Clark, D.M. (2007). Cognitive-behavioural therapy for PTSD in children and adolescents: A preliminary randomized controlled trial. Journal of American Academy of Child and Adolescent Psychiatry, 46, 1051-1061. doi: 10.1097/CHI.0b013e318067e288

Study design

- X Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental: CT-PTSD Comparator: WL

Specify which outcome is being assessed for risk of bias	CPTCI r, p
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Page 1058 in text

Is the review team's aim for this result…?

- X to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☐ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

☐ occurrence of non-protocol interventions
☐ failures in implementing the intervention that could have affected the outcome
☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

☐ Journal article(s) with results of the trial
☐ Trial protocol
☐ Statistical analysis plan (SAP)
☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐ "Grey literature" (e.g. unpublished thesis)
☐ Conference abstract(s) about the trial
☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐ Research ethics application
☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐ Personal communication with trialist
☐ Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Consented, completed intial assessment to confirm PTSD status then randomized	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		PN
5.3 ... multiple eligible analyses of the data?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Overall risk of bias

Risk-of-bias judgement		Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Appendix C:

Author guidelines for Behavioural and Cognitive Psychotherapy

Preparing Your Manuscript

Articles must be under 5,000 words at the point of submission, excluding references, tables and figures. Manuscripts describing more than one study may exceed no more than 6000 words but please make this clear in your cover letter.

Brief Clinical Reports should be no more than 1800 words (see more information below).

Please note that we currently do not usually accept studies carried out on student samples unless there is a clear indication of generalisability to clinical populations.

The journal strongly encourages blind review. Authors who want a blind review should indicate this at the point of submission of their article, omitting details of authorship and other identifying information from the main manuscript. Authors who do not omit this information will be assumed as submitting a non-blinded manuscript.

All submissions should be submitted via this portal: http://mc.manuscriptcentral.com/babcp

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Article Types

Main*

Reports of original research employing experimental or correlational methods and using within or between subject designs. Review or discussion articles that are based on empirical data and that have important new theoretical, conceptual or applied implications.

Empirically Grounded Clinical Interventions*

This section is intended for reviews of the present status of treatment approaches for specific psychological problems. It is intended that such articles will draw upon a combination of treatment trials, experimental evidence and other research, and be firmly founded in phenomenology. It should take account of, but also go beyond, treatment outcome data.

Brief Clinical Reports*

Material suitable for this section includes unusual case reports and accounts of potentially important techniques, phenomena or observations; for example, descriptions of previously unreported techniques, outlines of available treatment manuals, descriptions of innovative variations of existing procedures, details of self-help or training packages, and accounts of the application of existing techniques in novel settings. The BCR section is intended to extend the scope of the clinical section. **Submissions to this section should be no longer than 1800 words and should include no more than six references, one table or figure, and an extended report that contains fuller details. There are no restrictions on the size or format of the extended report as it will be published online only.** It may, for instance, be a treatment manual, a fully detailed case report, or a therapy transcript. If a submission is accepted for publication as a Brief Clinical Report, the author(s) must be prepared to send the fuller document to those requesting it, free of charge. The extended document will also be mounted on the journal's website as a PDF format (the document will not be copyedited).

Study Protocols*
Protocols of proposed and ongoing trials in behavioural and cognitive therapies will be considered. Your study must be registered and have ethical approval, and proof of this will be required. The abstract should be structured under the following four headings; Background, Aims, Method, Discussion.
Please use the Standard Protocol Items: Recommendations for Interventional Trail (SPIRIT) checklist for protocols of randomised controlled trials (see the reporting standards section below). Manuscripts should be under 2000 words at the point of first submission, and include no more than 15 references, and no more than three tables/figures in total. A PDF with additional, unlimited text, figures and tables may be included designated for online only publication.
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The following statements should be included on the title page:
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Please provide details of the sources of financial support for all authors, including grant numbers. For example, "This work was supported by the Medical research Council (grant number XXXXXXX)". Multiple grant numbers should be separated by a comma and space, and where research was funded by more than one agency the different agencies should be separated by a semi-colon, with "and" before the final funder. Grants held by different authors should be identified as belonging to individual authors by the authors' initials. For example, "This work was supported by the Wellcome Trust (A.B., grant numbers XXXX, YYYY), (C.D., grant number ZZZZ); the Natural Environment Research Council (E.F., grant number FFFF); and the National Institutes of Health (A.B., grant number GGGG), (E.F., grant number HHHH)". Where no specific funding has been provided for research, please provide the following statement: "This research received no specific grant from any funding agency, commercial or not-for-profit sectors."

Main Text (anonymised with no author information)

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Abstract

Should consist of no more than 250 words and structured under the following five headings: Background, Aims, Method, Results, and Conclusions. Include up to six key words that describes the article.

Main Text

This should contain the sections **Introduction** (including overview and theoretical background), **Method**(participants, design, data analyses and Ethical Statement- see below), **Results** (described in detail with summary figures and tables), **Discussion** (including conclusions and limitations).

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Use text anchors to show their intended position within the paper within the manuscript.

Numbered figure captions should be provided.

Tables should be provided in editable Word format. They should be numbered and given explanatory titles

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