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Psychological and psychosocial interventions for trauma-related psychological distress in adults living in ongoing conflict (Protocol)

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[Intervention Protocol]

Psychological and psychosocial interventions for trauma-related psychological distress in adults living in ongoing conflict

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the relative benefit and harms of different psychotherapeutic or psychosocial interventions for trauma-related psychological distress in adults affected by ongoing conflict.

BACKGROUND

Description of the condition

International law states that civilians should be protected from war unless they take part in hostilities [1]. Research suggests that civilians living in ongoing conflict experience traumatic events (TE) including loss of family or friends, starvation, displacement, destruction of infrastructure, physical injuries (including severe burns, traumatic brain injury [2], and limb injuries [3]), and violence [4, 5, 6, 7]. Data from the Civil War in South Sudan indicate that conflict-related TE are associated with depression, anxiety, and post-traumatic stress disorder (PTSD).

Continuous traumatic stress (CTS) occurs as a consequence of ongoing violence, displacement, and loss [8, 9], including destruction of healthcare infrastructure [10, 11]. It is the psychological and physiological effects (fear structures) [12] of individuals who remain under persistent threat, such as sustained political violence [13, 14, 15], systemic oppression, or poverty, where the danger is current and ongoing rather than past [16]. Unlike PTSD, which arises from a TE that may be no longer occurring, CTS is characterised by sustained hypervigilance and emotional dysregulation in response to an environment where future trauma remains a real and present possibility [17]. While this review will focus on individuals exposed to ongoing conflict, we acknowledge that prior TE may contribute to existing PTSD symptomatology as well as other possible trauma-related pathologies such as bipolar disorder [18, 19] and schizophrenia [19, 20, 21, 22, 23]. Where reported, we will consider the influence of prior TE in the interpretation of findings.

Existing research on PTSD interventions has included diverse samples such as veterans, children, refugees, and civilians, with systematic reviews reporting significant reductions in PTSD and related symptoms following psychological treatments. Recent reviews suggest that trauma-focused cognitive-behavioural therapy (TF-CBT), eye movement desensitisation reprocessing (EMDR), multidisciplinary treatments, and non–trauma-focused interventions are associated with reduced PTSD symptoms, particularly among children [24, 25].

This review will build on previous evidence by examining psychotherapeutic and psychosocial interventions used to address trauma-related pathology among civilians, particularly internally displaced individuals in low- and middle-income countries (LMIC) affected by ongoing political conflict. It will identify which interventions are most effective in contexts where post-trauma care is limited [26, 27, 28, 29, 30]. We will not include children and adolescents (< 18 years of age) in this review. All data referred to in this Background apply to adult civilian populations.

Description of the intervention and how it might work

Description of the intervention

Interventions are predominantly structured, brief to moderate-length psychological ('talking') therapies delivered in conflict-affected settings, frequently through task-shifting to trained lay or paraprofessional providers and/or low-intensity formats (group delivery or internet delivery) [31, 32, 33, 34]. The interventions typically combine cognitive-behavioural elements (e.g. psychoeducation, coping skills, cognitive restructuring, behavioural activation, and trauma processing/exposure) tailored to the local context [33, 34, 35]. Outcomes include PTSD symptoms, depression/anxiety symptoms, and functional impairment [36].

The effectiveness and adaptability of these interventions in conflict settings remain underexplored, with existing studies yielding conflicting outcomes [11]. Common psychotherapeutic interventions that have been used in war zones include TF-CBT [37], narrative exposure therapy (NET) [38], and EMDR, among others [39, 40].

TF-CBT combines cognitive restructuring with exposure techniques to help individuals process traumatic memories and develop adaptive coping skills [41]. Extensively applied in low-resource and conflict-affected settings, NET enables individuals to construct a coherent narrative of their life, integrating TE in a structured, chronological manner, and has shown strong evidence for reducing PTSD symptoms among refugees [42]. EMDR facilitates trauma processing through guided eye movements, and has been adapted for use in humanitarian emergencies, offering rapid symptom reduction for individuals suffering from acute stress and PTSD [43].

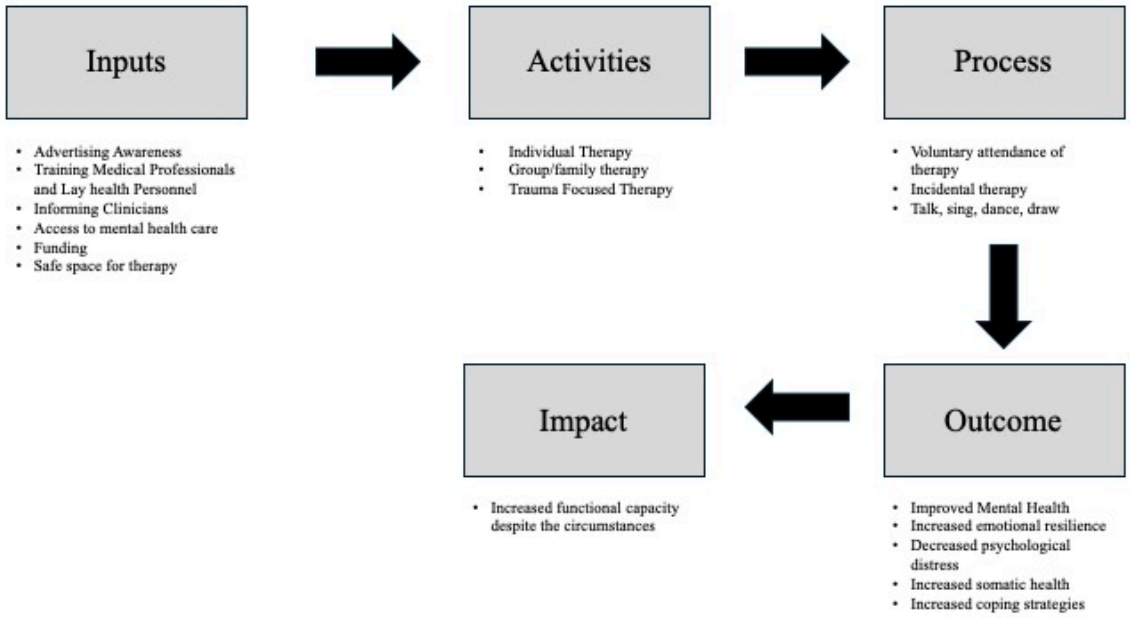
These programmes promote resilience and social cohesion [44]. Evidence indicates that such interventions can reduce trauma-related pathologies as described above and enhance coping capacity, emotional awareness, and functional recovery [45, 46, 47, 48]. These interventions draw on cognitive-behavioural, emotional-processing, and adaptive information-processing theories, alongside ecological and community resilience frameworks that emphasise the link between individual well-being and broader social systems [30, 49, 50, 51, 52, 53, 54, 55].

How the interventions might work

The dominant hypothesised pathway is that skills-based psychological treatments reduce distress by targeting modifiable proximal processes (e.g. trauma-related avoidance, maladaptive appraisals, emotion dysregulation, and impaired coping) and by improving daily functioning through behavioural re-engagement and problem management [31, 33, 34]. Cultural adaptation and delivery supports (training, supervision, structured materials) are expected to improve acceptability, comprehension, engagement, and fidelity, thereby increasing effective exposure to therapeutic components [32, 35]. Consistent with these mechanisms, there are pooled improvements for CBT-oriented programmes across trauma-related pathology in humanitarian LMIC contexts, though evidence is limited and heterogeneous [36].

Psychotherapeutic and psychosocial interventions in conflict-affected settings can be conceptualised through a logic model linking resources, therapeutic processes, and outcomes [56, 57]. Evidence-based therapies address trauma-related symptoms, while community-based psychosocial approaches restore safety and social cohesion in disrupted contexts. Together, these complementary strategies provide a tailored system of care for conflict-affected populations (see Figure 1).

Figure 1. Figure 1: Logic Model outlining mental health interventions designed to support individuals living in areas of ongoing conflict.



This logic model describes mental health interventions for individuals living amid ongoing war and conflict [58, 59]. It begins with key inputs such as mental health awareness, clinician training, accessible services, funding, and the creation of safe, therapeutic spaces despite insecurity [60]. These inputs support activities including individual, group, and family-based therapy, as well as trauma-focused approaches tailored to conflict-affected populations. Participants engage through formal or informal therapies. Together, these processes aim to reduce psychological distress and sustain functional capacity in highly destabilised environments.

Why it is important to do this review

A literature search indicates that important gaps remain regarding the effectiveness and methodological quality of psychological interventions delivered in settings of ongoing conflict [11, 61, 62, 63, 64]. While isolated studies have been identified – including an online EMDR intervention for forcibly displaced Syrian women and a quasi-experimental evaluation of social-bonding interventions in Rwanda – key questions remain for the field [39, 65]. To our knowledge, little systematic attention has been given to interventions implemented during active conflict, and there is limited synthesis.

While psychological interventions cannot resolve the consequences of conflict, they may offer affected populations coping mechanisms. Adults exposed to chronic TE frequently experience illness and persistent psychological distress [66]. Despite this, mental health research in conflict settings has disproportionately focused on PTSD, with less attention given to other common trauma-related pathologies [58].

Furthermore, prior reviews have often focused narrowly on treatment effects without adequately distinguishing between interventions aimed at promotion, prevention, and treatment of mental disorders [11].

We therefore aim to evaluate the effects of psychotherapeutic and psychosocial interventions for adults living in ongoing conflict. The public health significance of synthesising such evidence is that we may inform effective interventions [67], and the findings of the review will help guide the rebuilding of conflict-affected mental health systems.

OBJECTIVES

To evaluate the relative benefit and harms of different psychotherapeutic or psychosocial interventions for trauma-related psychological distress in adults affected by ongoing conflict.

METHODS

We will follow the *Cochrane Handbook for Systematic Reviews of Interventions* [68] and Methodological Expectations of Cochrane Intervention Reviews (MECIR) [69] for the conduct of the review, and PRISMA 2020 [70] for the reporting.

Criteria for considering studies for this review

Types of studies

We will include studies that incorporate interventional measures, including randomised and non-randomised designs in line with Cochrane Effective Practice and Organisation of Care (EPOC) [71].

We will include the following study designs.

- Randomised controlled trials (RCTs), including cluster-randomised trials.
- Controlled before-after (CBA) studies, provided there are at least two intervention sites and two control sites, or at least two intervention groups for each intervention type. Outcomes in two groups of participants before and after the implementation of an intervention are measured with one group receiving the intervention and the other not receiving the intervention [72].
- Interrupted time series (ITS) studies with a clearly defined intervention point and a minimum of three data points before and after the intervention [73].
- Non-randomised trials, including quasi-experimental study designs.

Types of participants

We will include civilian adults (≥ 18 years) residing in LMIC affected by ongoing conflict who are exposed to CTS and receive a psychological intervention delivered by trained or non-specialist providers. Eligible participants must demonstrate clinically significant trauma-related pathology, identified through diagnostic interviews or validated self-report measures using established clinical cut-offs; studies including mixed-age samples will be included if adult civilian data can be extracted separately.

We will exclude individuals no longer residing in active conflict settings (e.g. refugees resettled in high-income countries), as well as healthcare workers, who are not the focus of this review.

Types of interventions

We will include in-person and/or remotely delivered psychotherapeutic and psychosocial interventions implemented during ongoing conflict and designed to treat trauma-related pathology in adults presenting with symptoms of trauma-related pathology. Eligible interventions include TF-CBT, NET, EMDR, group psychoeducation and support, community-based social support programmes, and lay- or non-specialist-delivered interventions.

We will include interventions delivered as stand-alone treatments or alongside other services (e.g. housing or vocational support) if the therapeutic component can be isolated for analysis. Group-only interventions will be eligible if baseline symptom data are reported at the group level. We will include preventive programmes only where participants were screened and demonstrated psychological symptoms prior to the intervention. We will include studies investigating pharmacological treatment only if they incorporate a psychotherapeutic or psychosocial component that can be separately analysed.

We will exclude studies that examine pharmacological treatment alone, lack baseline assessment, or evaluate interventions delivered to combatants rather than civilians.

Standard of care

We will define standard of care according to the IASC Guidelines on Mental Health and Psychosocial Support in Emergency Settings, including basic services and security, community and family supports, focused non-specialised supports, and specialised clinical care. The implementation of these services are expected to vary widely across conflict-affected settings [74].

Outcome measures

We will prespecify outcome measures and strategies to minimise bias. These outcomes will be examined using validated instruments [31, 32, 33, 34, 35, 75]. We will prioritise outcome measures based on the most commonly reported validated instruments. These are noted in the critical and important outcomes below.

Critical outcomes

Critical outcomes will be aligned with those specified in the summary of findings tables, and are listed below.

- Reduction in depression symptoms, measured using the Hopkins Symptom Checklist (HSCL).
- Reduction in anxiety symptoms, measured using the Generalised Anxiety Disorder-7 or the HSCL.
- Reduction in trauma-related symptoms, including post-traumatic stress symptoms and trauma exposure, measured using the Harvard Trauma Questionnaire (HTQ).
- Worsening of trauma-related symptoms following the intervention, measured using the HTQ.
- Quality of life outcomes, including physical, psychological, social, and environmental domains of quality of life, measured using the EUROHIS-QOL 8-item index.
- Emotional distress, functioning, and transdiagnostic mental health symptoms, measured using the Transdiagnostic Mental Health Scale (TMHS).

We will extract outcome data at prespecified time points, namely baseline, ≥ 1 month post-trauma exposure (reflecting the clinically relevant window for PTSD symptom change) [76, 77], and approximately 12 months follow-up to assess maintenance of treatment effects [78, 79]. We will assess risk of bias at these same time points for each prespecified outcome [70, 80, 81, 82].

Important outcomes

Important outcomes include broader mental health outcomes not specified under critical outcomes that could potentially be related to traumatic events, such as:

- paranoid or psychotic reactions, measured using the Psychosis Screening Questionnaire (PSQ) [83, 84]; and
- reduction in general psychological distress, measured using theKessler Psychological Distress Scale or General Health Questionnaire.

We will extract outcome data for all prespecified outcomes where available, although not all outcomes are required to be reported in each included study. Where multiple validated measures are reported for the same construct, we will extract data from all relevant instruments.

Search methods for identification of studies

Electronic searches

An experienced Faculty Librarian at Stellenbosch University developed the MEDLINE search strategy in consultation with the review authors (see Supplementary material 1). This will be translated using appropriate controlled vocabulary and syntax for the other databases (Supplementary material 2). All searches will run from database inception, since the eligible conflict settings

include protracted conflicts dating to the 1950s (e.g. first and second Sudanese civil wars), so a date limit would exclude eligible studies. We will search the following databases for primary studies:

- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
- MEDLINE, EBSCO (1946 to present);
- CINAHL (Cumulative Index to Nursing and Allied Health Literature), EBSCO (1937 to present);
- Global Index Medicus, World Health Organization (WHO) (www.globalindexmedicus.net/) (inception to present);
- APA PsycINFO, PsycNET (1806 to present);
- Websites of non-governmental organisations (such as MSF, IFRC, UNRWA, OCHA) and for-profit health service-providing organisations known to support mental health interventions in ongoing conflict zones;
- ISI Web of Science and Google Scholar for papers that have cited studies included in our review.

Searching other resources

We will search the following trial registries:

- WHO International Clinical Trials Registry Platform (ICTRP) (trialsearch.who.int/);
- ClinicalTrials.gov, US National Institutes of Health (www.clinicaltrials.gov).

We will conduct a grey literature search to identify studies not indexed in the databases listed above:

- The Grey Literature Report (www.greylit.org/);
- OpenGrey (www.opengrey.eu/).

We will examine included studies for post-publication amendments including expressions of concern, errata, corrigenda, and retractions.

Data collection and analysis

We will analyse RCTs separately from non-randomised studies (including non-RCTs and CBA studies), as it is not methodologically appropriate to combine different study designs within the same meta-analysis. Where sufficient data are available, we will conduct separate pooled analyses by study design; where pooling is not appropriate, we will synthesise findings narratively.

We will assess statistical heterogeneity using standard measures (e.g. I^2 and Chi^2 statistics) and explore it through prespecified subgroup analyses where feasible. We will conduct Egger's test, a linear regression method used to assess funnel plot asymmetry and potential publication bias, only where there are sufficient studies (typically ≥ 10) within a meta-analysis, and we will not use it as a measure of heterogeneity. We will use Cochrane's RoB 2 tool for RCTs, and ROBINS-I for non-randomised studies of interventions.

Selection of studies

All retrieved records will be imported, de-duplicated, and independently screened by two review authors at title/abstract and full-text stages, with any disagreements resolved by discussion or in consultation with a third review author. We will document the study selection process, including reasons for exclusion, in a PRISMA flow diagram [85] and accompanying tables, and will collate multiple reports of the same study. We will contact study authors to obtain missing or unclear information needed to determine study eligibility.

Data extraction and management

Two review authors per study will independently screen and extract data. We will pilot a data extraction form on a small number of eligible studies. If necessary, a third team member will be consulted to resolve disagreements. We will extract the following data: study design; participants; methods; outcome measurement; results; and other relevant information. We will also document other evidence-based approaches alongside the control or comparison groups utilised, which may encompass standard care or alternative treatments. We will contact study authors for additional data or clarification as needed.

We will extract detailed information on intervention characteristics, including the type of psychological or psychosocial intervention, treatment modality, duration of the intervention, number and frequency of sessions, session length (intensity), mode of delivery (e.g. individual, group, or digital), provider characteristics (e.g. specialist, trained lay worker), and setting (e.g. community-based, clinical, or remote delivery in conflict-affected contexts), as well as the follow-up period.

We will record mental health outcomes assessed, including symptom reduction, functional improvement, and quality of life measures, with attention to the standardised instruments employed for these evaluations. To assess potential biases, we will note any missing data and other risk factors, as well as the sources of funding and any conflicts of interest declared by study authors. When necessary, we will reach out to the original authors for clarification or additional information. One review author will input the extracted data into RevMan software [86], and a second review author will independently verify the accuracy of the data entry. All collected data will be synthesised into a narrative review, with studies organised according to their design.

Risk of bias assessment in included studies

We will assess risk of bias for each prespecified outcome at each relevant time point. For RCTs, two review authors will independently assess risk of bias using the Cochrane RoB 2 tool, including the cluster-specific domain where applicable. The effect of interest will be the effect of assignment to the intervention (intention-to-treat (ITT) effect), consistent with Cochrane guidance. This approach is particularly appropriate in ongoing conflict settings, where deviations from assigned interventions and non-compliance may occur because of displacement, insecurity, or exposure to violence [87].

However, we will assess the effect of adhering to the intervention for adverse effects. RoB 2 assessments will address:

- bias arising from the randomisation process;
- bias due to deviations from the intended interventions;
- bias due to missing outcome data;
- bias in measurement of the outcome;
- bias in selection of the reported result.

Signalling questions will be answered using standard RoB 2 response options, and overall judgements will be classified as low risk of bias, some concerns, or high risk of bias [88].

Two review authors will independently assess non-randomised studies using ROBINS-I, with any disagreements resolved through discussion or in consultation with a third review author [89]. ROBINS-I assessments will consider:

- confounding;
- selection of participants;
- classification of interventions;
- deviations from intended interventions;
- missing data;
- measurement of outcomes;
- selection of the reported result.

For CBA and ITS studies, we will additionally apply the EPOC checklist to assess methodological features including independence of intervention effects, completeness of outcome data, and appropriate analysis of time trends.

In traditional non-randomised studies, social determinants would certainly need to be considered as confounders. We will consider demographic and contextual variables, where reported, such as age, gender, education, and socioeconomic status, as these may influence access to interventions and treatment outcomes. For non-randomised studies, we anticipate several important confounders that may influence both uptake of the intervention and differential outcomes in ongoing conflict settings. These include baseline severity of trauma-related symptoms, cumulative trauma exposure, forced displacement, fluctuating security conditions, re-escalation of conflict, breakdowns in healthcare and community infrastructure, loss of socioeconomic resources, differential access to humanitarian assistance, and outbreaks of infectious disease.

Measures of treatment effect

For dichotomous outcomes, we will calculate or extract risk ratios (RRs), re-analysing data where necessary (e.g. CBA studies) and converting odds ratios to RRs when required. For continuous outcomes, we will use mean differences (MDs) when measures are consistent and standardised mean differences (SMDs) when different scales are used, combining endpoint and change scores where appropriate; CBA studies will be analysed using difference-in-differences methods [81]. Where multiple measures of the same outcome are reported, we will prioritise the study's stated primary outcome, the outcome used in the sample size calculation, or, if neither is specified, select the median-ranked effect estimate [90, 91, 92].

Unit of analysis issues

For studies with multiple intervention arms, we will account for the potential impact of these designs during the analysis. For example, where a study includes more than two eligible intervention groups, we will include each relevant pair-wise comparison separately. To avoid double-counting of participants, we will split the shared control group equally across comparisons, in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* [89].

For cluster RCTs that do not adequately account for clustering in their analysis, we will adjust the analysis for clustering if we can extract the following information.

- An estimate of the intracluster (or intraclass) correlation coefficient (ICC). For cluster RCTs that do not report an ICC, we will first attempt to extrapolate the ICC from other included cluster RCTs. If this is not possible, we will estimate the ICC from external sources for similar studies and clusters. We will only exclude these studies from meta-analysis if no reasonable external estimate can be identified.
- The number of clusters (or groups) randomised to each intervention group or the average (mean) size of each cluster.
- The outcome data ignoring the cluster design, for the total number of individuals included in the study (e.g. number or proportion of individuals with events, or means and standard deviations).
- We will use inflated variances to adjust appropriately for clustering [81]. For cluster RCTs where study authors do not take clustering into account in the original analysis and where re-analysis is not possible, we will only report the estimate of effect.

Dealing with missing data

We will attempt to contact study authors to obtain or clarify any missing data. If these efforts are unsuccessful, we will document the data as missing [88] and report the data as missing in the risk of bias tables, and will not attempt to impute values. For all outcomes, we will carry out analysis, to the greatest degree possible, on an ITT basis based on available cases. We will attempt to include all participants randomised to each group in the analyses, and analyse data according to initial group allocation irrespective of whether participants received, or complied with, the planned intervention. Adhering to the ITT principle may be misleading when assessing adverse events, therefore we will relate the results to the treatment received. This means that for adverse effects we will base the analyses on the participants who actually received the intervention and the number of adverse events that are reported in the studies.

Reporting bias assessment

We will attempt to be as comprehensive as possible in our search strategy to find and include all relevant studies and to reduce any possible publication bias. This will include a search of published studies, grey literature, and registers of prospective trials, and discussions with colleagues [81]. We will use funnel plots to make a visual assessment of whether there is asymmetry, which may signal the presence of reporting bias, even if it is not a definitive indicator of such bias. If we find more than 10 studies that report similar outcomes, we will consider statistical testing for funnel plot asymmetry. For continuous outcomes with intervention effects measured as MDs, we will use the test proposed by Egger 1997 [93] to test for funnel plot asymmetry. For dichotomous outcomes with intervention effects measured as RRs, and continuous outcomes with intervention effects measured as SMDs, we will not consider funnel plot calculations because funnel plots using risk differences are seldom of interest. We will interpret the results of tests for funnel plot asymmetry in light of visual inspection of the funnel plot, as the statistical results may not be representative if there are small-study effects [89].

Synthesis methods

Where studies are sufficiently similar in design, participants, interventions, and outcome measurement, we will conduct meta-analysis in RevMan [86]. We will analyse randomised and non-randomised studies separately, and will not pool different non-randomised designs [89, [89].

We will use random-effects meta-analysis with an inverse-variance approach, as we anticipate heterogeneity in interventions, populations, and implementation strategies [94, [89]. We will estimate between-study variance using the restricted maximum likelihood (REML) method. When at least three studies are included and heterogeneity is greater than zero, confidence intervals for pooled effects will be calculated using the Hartung-Knapp-Sidik-Jonkman method; otherwise, Wald-type confidence intervals will be used.

We will synthesise cluster-randomised trials and studies reporting only adjusted or relative effect estimates using the generic inverse-variance method [94, 88, [89]. For non-randomised studies, we will use adjusted estimates where available to account for potential confounding. For RCTs, we will use unadjusted estimates for the primary analysis, as randomisation is intended to distribute confounders evenly across groups. Where both adjusted and unadjusted estimates are reported, we will undertake sensitivity analyses using unadjusted estimates to assess their impact on the pooled effect estimate.

For CBA studies, we will report relative effects adjusted for baseline differences. For ITS and repeated measures studies, we will extract changes in level and changes in slope from studies that have used regression methods that account for time trends (adjusted for autocorrelation and any periodic changes), or an autoregressive integrated moving average analysis (ARIMA) [73, 89]. If the included ITS studies do not report an adequate analysis that appropriately accounts for time trends, we will re-analyse the data using a linear model, provided the necessary data points are available. Where feasible, we will present both immediate effects (change in level) and longer-term effects (change in slope). We will use the generic inverse-variance method to combine study data (separately for ITS and CBA study designs), where meta-analysis is appropriate [73, 94].

If quantitative synthesis is not appropriate, we will present the results using structured narrative synthesis and summarise the range and direction of effects in the review text [89, 71, [89]. Where relevant, this synthesis may also describe intervention mechanisms across studies in relation to the review logic model (Figure 1).

Investigation of heterogeneity and subgroup analysis

We will assess statistical heterogeneity within each meta-analysis by visual inspection of forest plots, the Chi^2 test, and the I^2 statistic. Prespecified subgroup factors may include:

- intervention type (e.g. TF-CBT, narrative exposure therapy, EMDR, or other psychosocial interventions);
- delivery format (individual, group, or remote);
- provider type (specialist mental health worker versus non-specialist or lay provider);
- setting or level of care (community, primary care, or hospital);
- participant characteristics where reported (e.g. sex/gender, exposure severity, or baseline mental health status).

If sufficient studies are available, we may conduct meta-regression to explore the influence of study-level characteristics; however, such analyses will be considered exploratory and interpreted cautiously. If meta-analysis is not appropriate, we will summarise subgroup findings narratively in the review text.

We will conduct subgroup analyses where at least 10 studies are available. We will use the approach described by Deeks 2011 and apply the test for subgroup differences available in RevMan [94]. Studies including both adults and children will be handled by extracting and analysing adult data only; children will not be included as a subgroup. We expand on exposure severity as a critical feature of PTSD epidemiology. We are guided by the World Mental Health Survey (WMHS) PTSD analyses, where attention is given to the severity of traumatic events quantified by the number of events, and how respondents would rate their subjective and worst experience of trauma, as well as the impact of a random trauma [95].

Equity-related assessment

This review aims to synthesise evidence of a reduction of mental health symptoms in groups at risk of trauma. In line with Cochrane guidelines, we will specifically consider PROGRESS-Plus characteristics [96] relevant to civilians in ongoing conflict, including place of residence (active conflict zones), occupation (civilian status), gender (as a factor in exposure severity), and socioeconomic status (focusing on LMIC). These factors are selected because social and structural inequities significantly impact mental health outcomes and access to care in highly destabilised environments.

Sensitivity analysis

Where feasible, we will perform sensitivity analyses to examine the robustness of the findings by excluding studies at high risk of bias, excluding preprint studies, and comparing adjusted with unadjusted estimates where both are available. If we combine individually randomised and cluster-randomised trials, we will also assess the impact of varying the ICC used to adjust cluster trials and, where appropriate, excluding cluster-randomised trials from pooled analyses. If meta-analysis is not appropriate, the influence of these decisions will be described narratively in the review text.

Certainty of the evidence assessment

We will prepare summary of findings tables in GRADEpro GDT for the primary comparisons and critical outcomes [71]. These will include baseline risk or mean, absolute and relative effects where appropriate, and the numbers of participants and studies contributing data [71].

Two review authors will independently assess the certainty of the evidence for each critical outcome using the GRADE approach, considering the five GRADE domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias, with any disagreements resolved through discussion or in consultation with a third review author [97].

The primary comparisons of interest are as follows:

- psychosocial or psychotherapeutic interventions, or both, versus standard care or no intervention (including waitlist controls);
- psychosocial or psychotherapeutic interventions, or both, versus alternative active interventions.

Where sufficient data are available, and where intervention types are analysed separately, more specific comparisons (e.g. TF-CBT versus standard care) will be explored; however, these will be reported in supplementary materials if not prioritised as primary comparisons for the summary of findings tables.

We will assess the certainty of evidence across prespecified, clinically meaningful time points. These include: (1) short-term follow-up at ≥ 1 month post-intervention, reflecting the minimum clinically relevant period for assessing change in trauma-related symptoms; and (2) long-term follow-up at approximately 12 months post-intervention, to evaluate the maintenance of treatment effects. Baseline measures will be extracted but will not be subject to GRADE assessment, as they do not reflect intervention effects.

For randomised trials, certainty will begin at high and may be downgraded across the five GRADE domains [97]. Randomised evidence will not be upgraded. For non-randomised studies of interventions, certainty will also begin at high, in line with current Cochrane and GRADE guidance using the target-trial framework [89, 98]. For non-randomised studies assessed using EPOC criteria rather than ROBINS-I, certainty will begin at low [97]. In particular, judgements will be informed by ROBINS-I domain-level concerns, especially bias due to confounding and selection of participants [98]. Where appropriate, we may upgrade the certainty of non-randomised evidence for a large magnitude of effect, evidence of a dose-response gradient, or where all plausible residual confounding would reduce an observed effect or suggest a spurious effect when no effect is observed [97].

Where evidence from randomised and non-randomised studies is available for the same outcome, certainty will be assessed separately by study design and presented transparently in the summary of findings tables.

In the case of sufficient data, the primary summary of findings tables will prioritise evidence from RCTs, with certainty of evidence assessed using the GRADE approach and presented for each prespecified outcome, comparison, and time point. Where non-randomised studies of interventions contribute relevant evidence, these will be assessed separately, and their findings will be incorporated transparently alongside RCT evidence. This will include the use of footnotes within the summary of findings tables to clearly indicate when evidence is derived from non-randomised studies of interventions, as well as any differences in certainty ratings or reasons for downgrading or upgrading the evidence. Where meta-analysis is not possible, narratively synthesised findings from both RCTs and non-randomised studies of interventions will be incorporated into the summary of findings tables where appropriate, with clear indication of study design.

We will justify all decisions to downgrade or upgrade the certainty of evidence and express it as high, moderate, low, or very low [97]. If meta-analysis is not possible, we will still incorporate narratively synthesised findings into the summary of findings tables where appropriate [71].

Consumer involvement

The review was informed by the field experience of team members working in conflict-affected settings, with outcomes shaped by consultation with local health workers and decision-makers. Professional networks in these contexts will support interpretation and dissemination of findings, while recognising that sustained patient or community involvement may be constrained by ongoing instability and prioritisation of safety.

SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: 10.1002/14651858.CD016367.

Supplementary material 1 Search strategies

Supplementary material 2 Narrative regarding search strategy

ADDITIONAL INFORMATION

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Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Adib Essali, Community Mental Health, Counties Manukau Health, Manukau, New Zealand;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Sam Hinsley, Cochrane Central Editorial Service;
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Contributions of authors

SMK, KD, SM, SH, and AK contributed to the conceptualisation and writing of the original draft. AK, KD, and SM were responsible for supervision. All authors (SMK, KD, SM, SH, AH, YB, GV, YR, YA, and AK) contributed to development of the methodology and writing and editing of the protocol.

Declarations of interest

SMK: mental health professional and no commercial or non-commercial conflicts of interest relevant to this review.

SM: no commercial or non-commercial conflicts of interest relevant to this review.

KD: no commercial or non-commercial conflicts of interest relevant to this review.

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YA: Psychiatrist and the Director of the Gaza Community Mental Health Programme, an NGO that provides mental health services in the Gaza Strip, and no commercial or non-commercial conflicts of interest relevant to this review.

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Registration and protocol

Cochrane approved the review proposal (MS# COCHRANEEMD-2024-01314) January 2025.

Data, code and other materials

Data sharing not applicable to this article as it is a protocol, so no datasets were generated or analysed.

Notes

Published notes in RevMan are for editor use only. Authors should leave this section blank.

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