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Psychological and social interventions for the prevention of mental disorders in people living in low- and middle-income countries affected by humanitarian crises (Review)

Papola D, Purgato M, Gastaldon C, Bovo C, van Ommeren M, Barbui C, Tol WA

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[Intervention Review]

Psychological and social interventions for the prevention of mental disorders in people living in low- and middle-income countries affected by humanitarian crises

Davide Papola[1,2], Marianna Purgato[1,2], Chiara Gastaldon[1,2], Chiara Bovo[3], Mark van Ommeren[4], Corrado Barbui[1,2], Wietse A Tol[5,6,7]

[1]Department of Neurosciences, Biomedicine and Movement Sciences, Section of Psychiatry, University of Verona, Verona, Italy. [2]Cochrane Global Mental Health, University of Verona, Verona, Italy. [3]Direzione Sanitaria, Azienda ULSS 20, Verona, Italy. [4]Department of Mental Health and Substance Abuse, World Health Organization, Geneva, Switzerland. [5]Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA. [6]Section of Global Health, Department of Public Health, University of Copenhagen, Copenhagen, Denmark. [7]Peter C. Alderman Program for Global Mental Health, HealthRight International, New York, NY, USA

Contact: Davide Papola, davide.papola@univr.it.

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ABSTRACT

Background

People living in 'humanitarian settings' in low- and middle-income countries (LMICs) are exposed to a constellation of physical and psychological stressors that make them vulnerable to developing mental disorders. A range of psychological and social interventions have been implemented with the aim to prevent the onset of mental disorders and/or lower psychological distress in populations at risk, and it is not known whether interventions are effective.

Objectives

To compare the efficacy and acceptability of psychological and social interventions versus control conditions (wait list, treatment as usual, attention placebo, psychological placebo, or no treatment) aimed at preventing the onset of non-psychotic mental disorders in people living in LMICs affected by humanitarian crises.

Search methods

We searched the Cochrane Common Mental Disorders Controlled Trials Register (CCMD-CTR), the Cochrane Drugs and Alcohol Review Group (CDAG) Specialized Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (OVID), Embase (OVID), PsycINFO (OVID), and ProQuest PILOTS database with results incorporated from searches to February 2020. We also searched the World Health Organization's (WHO) International Clinical Trials Registry Platform and ClinicalTrials.gov to identify unpublished or ongoing studies. We checked the reference lists of relevant studies and reviews.

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Selection criteria

All randomised controlled trials (RCTs) comparing psychological and social interventions versus control conditions to prevent the onset of mental disorders in adults and children living in LMICs affected by humanitarian crises. We excluded studies that enrolled participants based on a positive diagnosis of mental disorder (or based on a proxy of scoring above a cut-off score on a screening measure).

Data collection and analysis

We calculated standardised mean differences for continuous outcomes and risk ratios for dichotomous data, using a random-effects model. We analysed data at endpoint (zero to four weeks after therapy) and at medium term (one to four months after intervention). No data were available at long term (six months or longer). We used GRADE to assess the quality of evidence.

Main results

In the present review we included seven RCTs with a total of 2398 participants, coming from both children/adolescents (five RCTs), and adults (two RCTs). Together, the seven RCTs compared six different psychosocial interventions against a control comparator (waiting list in all studies). All the interventions were delivered by paraprofessionals and, with the exception of one study, delivered at a group level.

None of the included studies provided data on the efficacy of interventions to prevent the onset of mental disorders (incidence). For the primary outcome of acceptability, there may be no evidence of a difference between psychological and social interventions and control at endpoint for children and adolescents (RR 0.93, 95% CI 0.78 to 1.10; 5 studies, 1372 participants; low-quality evidence) or adults (RR 0.96, 95% CI 0.61 to 1.50; 2 studies, 767 participants; very low quality evidence). No information on adverse events related to the interventions was available.

For children's and adolescents' secondary outcomes of prevention interventions, there may be no evidence of a difference between psychological and social intervention groups and control groups for reducing PTSD symptoms (standardised mean difference (SMD) −0.16, 95% CI −0.50 to 0.18; 3 studies, 590 participants; very low quality evidence), depressive symptoms (SMD −0.01, 95% CI −0.29 to 0.31; 4 RCTs, 746 participants; very low quality evidence) and anxiety symptoms (SMD 0.11, 95% CI −0.09 to 0.31; 3 studies, 632 participants; very low quality evidence) at study endpoint.

In adults' secondary outcomes of prevention interventions, psychological counselling may be effective for reducing depressive symptoms (MD −7.50, 95% CI −9.19 to −5.81; 1 study, 258 participants; very low quality evidence) and anxiety symptoms (MD −6.10, 95% CI −7.57 to −4.63; 1 study, 258 participants; very low quality evidence) at endpoint. No data were available for PTSD symptoms in the adult population.

Owing to the small number of RCTs included in the present review, it was not possible to carry out neither sensitivity nor subgroup analyses.

Authors' conclusions

Of the seven prevention studies included in this review, none assessed whether prevention interventions reduced the incidence of mental disorders and there may be no evidence for any differences in acceptability. Additionally, for both child and adolescent populations and adult populations, a very small number of RCTs with low quality evidence on the review's secondary outcomes (changes in symptomatology at endpoint) did not suggest any beneficial effect for the studied prevention interventions.

Confidence in the findings is hampered by the scarcity of prevention studies eligible for inclusion in the review, by risk of bias in the studies, and by substantial levels of heterogeneity. Moreover, it is possible that random error had a role in distorting results, and that a more thorough picture of the efficacy of prevention interventions will be provided by future studies. For this reason, prevention studies are urgently needed to assess the impact of interventions on the incidence of mental disorders in children and adults, with extended periods of follow-up.

PLAIN LANGUAGE SUMMARY

Do psychological and social interventions prevent mental health disorders in low- and middle-income countries affected by humanitarian crises?

Mental health during a humanitarian crisis

A humanitarian crisis is an event, or series of events, that threaten the health, safety, security or well-being of a community or large group of people, usually over a wide area. Examples include: wars, famine, and natural disasters such as earthquakes, hurricanes and floods.

People living through a humanitarian crisis may experience physical and mental distress that make them vulnerable to developing mental health disorders. These include post-traumatic stress disorder, depression and anxiety.

What are psychological and social interventions?

Psychological interventions of a preventive nature usually offer people support and practical help to develop ways of coping, a sense of hope, and focus on building resilience. Social interventions of a preventive nature usually aim to strengthen social support systems and help people to feel more connected.

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Why we did this Cochrane Review

We wanted to know if psychological and social interventions (psychosocial interventions) could help to stop mental health disorders developing in people living through humanitarian crises in low- and middle-income countries. We were interested in:

1)·how many people developed a mental health disorder after taking part in an intervention; and

2) how many people dropped out of a programme or had unwanted effects related to the intervention.

What did we do?

We searched for studies that looked at the preventive effects of psychosocial interventions on people's mental health in low- and middle-income countries affected by humanitarian crises. We looked for randomised controlled studies, in which the interventions people received were decided at random. This type of study usually gives the most reliable evidence about the effects of an intervention.

Search date

We included evidence published up to February 2020.

What we found

We found seven prevention studies with a total of 2398 participants. Five studies were in children and adolescents (aged 7 to 18 years), and two were in adults (aged over 18 years). Two studies were done in Nepal, and one study each in Democratic Republic of Congo, Haiti, Syria, Uganda and Sri Lanka. Six different psychosocial interventions were studied. The studies measured symptoms of depression, anxiety and post-traumatic stress disorder in children and adolescents, and anxiety and depression symptoms in adults, at the beginning of the study, the end of the intervention, and after four weeks and up to four months later. They compared the results with symptoms measured in people on a waiting list to take part in the intervention.

What are the results of our review?

None of the studies measured how many people developed a mental disorder after taking part in a psychosocial intervention, and none measured any unwanted effects of the interventions. There may be little to no difference in how many children and adolescents dropped out of an intervention while taking part, compared with being on a waiting list (5 studies). We were uncertain if there was any difference in the number of adults who dropped out (2 studies). In children and adolescents, only very small differences in symptoms of post-traumatic stress disorder, depression and anxiety were seen at the end of an intervention, compared with being on a waiting list, suggesting no evidence of a difference. However, we are not confident that these results are reliable: the results are likely to change when further evidence is available. In adults, results from one prevention study showed that psychological counselling may lower depression and anxiety symptoms; but this result is from only one study and we are not confident the result is reliable. This result will probably change when more evidence becomes available.

Conclusions

We did not find any randomized evidence whether psychosocial interventions can stop mental health disorders developing in people living through humanitarian crises in low- to middle-income countries. We did not find enough reliable evidence about the benefits of these interventions in reducing mental health symptoms. Larger, well-conducted studies are needed to give more reliable evidence about the short- and long-term effects of psychosocial interventions to prevent mental disorders in people living in low- and middle-income countries affected by humanitarian crises.

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SUMMARY OF FINDINGS

Summary of findings 1. Psychosocial interventions compared with control for the prevention of mental disorders in children and adolescents living in low- and middle- income countries affected by humanitarian crises

Psychosocial interventions compared with control for the prevention of mental disorders in children living low- and middle- income countries affected by humanitarian crises

Patient or population: children and adolescents exposed to traumatic events;
Setting: humanitarian settings in LMICs;
Intervention: psychological and social interventions of selective and indicated prevention;
Comparison: waiting list.

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with waiting list	Risk with psychosocial intervention				
Proportion of individuals with a diagnosis of: PTSD, anxiety, depression, and somatic symptom and related disorders	Study population		-	-	-	not measured.
	-	-				
Dropouts for any reason at endpoint	Study population		RR 0.93 (0.78 to 1.10)	1372 (5 RCTs)	⊕⊕⊖⊖ LOW [1 2]	
	129 per 1000	120 per 1000 (100 to 142)				
Adverse events	Study population		-	-	-	not measured.
	-	-				
Post-traumatic stress disorder symptoms at endpoint (assessed with: CPSS, CRIES)	The mean post-traumatic stress disorder symptoms at endpoint was 0 SD	SMD 0.16 SD lower (0.50 lower to 0.18 higher)	-	590 (3 RCTs)	⊕⊖⊖⊖ VERY LOW [1 2 3]	This is a small effect according to Cohen 1992
Depression symptoms at endpoint (assessed with: DSRS, AYPA, APAI)	The mean depression symptoms at endpoint was 0 SD	SMD 0.01 SD lower (0.29 lower to 0.31 higher)	-	746 (4 RCTs)	⊕⊖⊖⊖ VERY LOW [1 2 3]	This is a small effect according to Cohen 1992
Anxiety symptoms at endpoint (assessed with: SCARED; AYPA)	The mean anxiety symptoms at endpoint was 0 SD	SMD 0.11 SD higher (0.09 lower to 0.31 higher)	-	632 (3 RCTs)	⊕⊖⊖⊖ VERY LOW [1 2 3 5]	This is a small effect according to Cohen 1992

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*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio; **SMD:** Standardized Mean Difference; **SD:** Standard Deviation.

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

APAI: Acholi Psychosocial Assessment Instrument;

AYPA: African Youth Psychosocial Assessment Instrument;

CPSS: Child PTSD Symptom Scale;

CRIES: Children's Revised Impact of Event Scale;

DSRS: Depression Self-Rating Scale;

SCARED: Screen for Child Anxiety Related Emotional Disorder.

[1] Downgraded 1 level owing to study limitations (outcome assessment was not described as masked in all RCTs);
[2] Downgraded 1 level owing to indirectness (We excluded studies that selected participants on the basis of currently meeting criteria of a formal psychiatric diagnosis. However, included studies did not report - at study entry - presence or absence of a mental health condition based on a psychiatric diagnostic interview. Therefore, is it possible that some of the included participants could have met the criteria for a formal psychiatric diagnosis);
[3] Downgraded 1 level owing to inconsistency (I^2 was higher than 50%);
[4] Downgraded 1 level owing to imprecision (outcome based on a small number of participants);
[5] Downgraded 1 level owing to imprecision (outcome based on wide confidence interval).

Summary of findings 2. Psychosocial interventions compared with control for the prevention of mental disorders in adults living in low- and middle-income countries affected by humanitarian crises

Psychosocial interventions compared with control for the prevention of mental disorders in adults living in low- and middle- income countries affected by humanitarian crises

Patient or population: adults exposed to traumatic events;
Setting: humanitarian settings in LMICs;
Intervention: psychological and social interventions of selective and indicated prevention;
Comparison: waiting list.

Outcomes	Anticipated absolute effects* (95% CI)	Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments

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	Risk with waiting list	Risk with psychosocial intervention				
Proportion of individuals with a diagnosis of: PTSD, anxiety, depression, and somatic symptom and related disorders	Study population -	 -	-	-	-	not measured.
Dropouts for any reason at endpoint	Study population 275 per 1000	 264 per 1000 (168 to 412)	RR 0.96 (0.61 to 1.50)	767 (2 RCTs)	⊕⊖⊖⊖ VERY LOW [1 2 3]	
Adverse events	Study population -	 -	-	-	-	not measured.
Post-traumatic stress disorder symptoms at endpoint	-	-	-	-	-	not measured.
Depression symptoms at endpoint (assessed with: BDI)	The mean depression symptoms at endpoint was 0 SD	MD 7.5 SD lower (9.19 lower to 5.81 lower)	-	258 (1 RCT)	⊕⊖⊖⊖ VERY LOW [1 2 4]	The mean difference did reach a clinically important improvement of 17,5% reduction in scores between the comparison groups (Button 2015).
Anxiety symptoms at endpoint (assessed with: BAI)	The mean anxiety symptoms at endpoint was 0 SD	MD 6.1 SD lower (7.57 lower to 4.63 lower)	-	258 (1 RCT)	⊕⊖⊖⊖ VERY LOW [1 2 4]	The BAI scores are classified as minimal anxiety (0 to 7), mild anxiety (8 to 15), moderate anxiety (16 to 25), and severe anxiety (30 to 63). There is no clear guidance about BAI's minimal clinically important difference (MCID).

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio; **SMD:** Standardized Mean Difference; **SD:** Standard Deviation.

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

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BAI: Beck Anxiety Inventory;

BDI: Beck Depression Inventory.

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[1] Downgraded 1 level owing to study limitations (outcome assessment was not described as masked in all RCTs);
[2] Downgraded 1 level owing to indirectness (We excluded studies that selected participants on the basis of currently meeting criteria of a formal psychiatric diagnosis. However, included studies did not report - at study entry - presence or absence of a mental health condition based on a psychiatric diagnostic interview. Therefore, is it possible that some of the included participants could have met the criteria for a formal psychiatric diagnosis);
[3] Downgraded 1 level owing to inconsistency (I^2 was higher than 50%);
[4] Downgraded 1 level owing to imprecision (outcome based on a small number of participants);
[5] Downgraded 1 level owing to imprecision (outcome based on wide confidence interval).

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BACKGROUND

Description of the condition

Humanitarian crises disproportionally affect populations in low- and middle-income countries (LMICs). For example, in 2014 LMICs accounted for 88% of the global reported disaster mortality (Guha-Sapir 2015). A humanitarian crisis is "an event or series of events that represents a critical threat to the health, safety, security or well-being of a community or other large group of people, usually over a wide area" (Humanitarian Coalition 2016). We use the term 'humanitarian setting' here to refer to contexts affected by a broad range of humanitarian crises, including armed conflicts and disasters (e.g. disasters triggered by natural events, such as earthquakes and floods, or technological or industrial events), adopting the definition described by Tol 2011 in a previous systematic review on psychological interventions for children and adults. This definition was also applied previously in a study aimed at setting research priorities for mental health in this field. The goal of the term is to include emergencies broadly rather than focusing specifically on disasters triggered by natural events or armed conflicts separately, given that it is often challenging to clearly delineate categories of emergencies (Tol 2012).

For 2016, the World Bank defined low-income economies as those with a gross national income per capita, calculated using the World Bank Atlas method, of USD 1045 or less in 2013, and middle-income economies are those with a gross national income per capita of more than USD 1045 but less than USD 12,746 (The World Bank 2016).

Mental health consequences of humanitarian crises may range from improved mental health (e.g. post-traumatic growth); no changes in mental health despite exposure to adversity (e.g. resilience – Tol 2013b); transient acute stress reactions and bereavement; to a range of mental disorders (Charlson 2019). In classifying outcomes of interest, we followed the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) classification. Despite its merit, we are aware that the DSM does not provide a fully contextualized view of the experiences of people living in LMICs. The development of culturally sensitive categories and measurement tools may help to better understand mental health, and assist in developing interventions based on the specific needs and cultural contexts of populations, in diverse sociocultural contexts.

Following the DSM classification, mental disorders found to have higher prevalence in humanitarian settings in LMICs encompass disorders that are specifically associated with exposure to stressors, such as post-traumatic stress disorder (PTSD). Diagnostic criteria for PTSD comprise a history of exposure to a traumatic event that meets specific stipulations and symptoms from each of four symptom clusters: intrusion (the inability to keep memories of the traumatic event from returning), persistent avoidance (the attempt to avoid stimuli and triggers that may bring back traumatic memories), negative alterations in cognitions and mood, and alterations in arousal (jumpiness) and reactivity associated with the traumatic event (APA 2013; O'Donnell 2014).

Moreover, humanitarian crises are associated with heightened prevalence of disorders that may also occur in the absence of exposure to stressors, such as:

- anxiety disorders, which are disorders that share features of excessive fear and anxiety and related behavioural disturbances;
- depressive disorders, characterized by the presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that affect the individual's capacity to function (APA 2013);
- somatic symptom and related disorders (van Duijl 2010). Somatic symptoms are characterized by an extreme focus on unpleasant bodily sensations — such as pain or fatigue — that causes major emotional distress.

Charlson and colleagues conducted a systematic review and meta-analysis with conflict-affected populations across 129 studies. Prevalence of mental disorders (depression, anxiety, post-traumatic stress disorder, bipolar disorder, and schizophrenia) was 22.1% (95% CI 18.8 to 25.7) at any point in time in the conflict-affected populations assessed (Charlson 2019).

Studies in conflict-affected populations in Nepal, Uganda, and Guinea Bissau have found associations between traumatic experiences and somatoform and dissociative disorders (e.g. in the form of spirit possession) (Van Ommeren 2001; van Duijl 2010; De Jong 2013). Much less is known about other disorders associated with humanitarian crises.

In this review we are interested in investigating interventions aimed at preventing onset of mental disorders (such as PTSD, anxiety, mood disorders and related disorders) in the general population exposed to humanitarian crises, in subpopulations at elevated risk for a disorder, and in individuals who are identified (or individually screened) as having an increased vulnerability for a disorder based on some individual assessment. Our focus is on populations affected by humanitarian crises in LMICs.

In two parallel reviews, we evaluated the effectiveness of psychological approaches to treat mental disorders (Purgato 2018b); and we will address the issue of promoting well-being or positive aspects of mental health in a dedicated third review. Prevention and promotion are distinct concepts with overlapping boundaries, but they are commonly divided into different types of intervention depending on which outcome and population groups they target. Many interventions can contribute both to strengthening positive aspects of mental health (promotion), and at the same time reduce the chance for developing mental disorders (prevention) (Tol 2015).

Description of the intervention

Mental health and psychosocial support interventions are becoming a standard part of humanitarian programmes. Although this was previously an ideologically divided field, there appears to be growing agreement on best practices, as evidenced by international consensus-based documents (IASC 2007; The Sphere Project 2011). The IASC 2007 guidelines define mental health and psychosocial support as any type of local or outside support that aims to protect or promote psychosocial well-being and/or prevent or treat mental disorder. These documents advocate for multi-layered systems of care, to address the diversity of mental health and psychosocial needs in humanitarian settings. Such recommended multi-layered systems of care are envisioned to consist of interventions that address the broad range of mental health needs in populations affected by humanitarian crises. Furthermore, consensus documents recommend interventions

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across a range of sectors, not just the health sector, including implementing basic services and security in a way that prevents further exposure to human rights violations and harm, and strengthens the capacity of families and communities to support their members (e.g. through self-help, continued cultural, religious, and spiritual practices; strengthening social supports for vulnerable populations) (IASC 2007; Tol 2013a).

In this review we followed the classification of interventions described by the Institute of Medicine (IOM) report on preventing mental disorders in children and adolescents (Institute of Medicine 1994; Institute of Medicine 2009).

Prevention is an approach aimed at reducing the likelihood of future disorder with the general population or with people who are identified as being at risk for a disorder (Eaton 2012; Tol 2015). Prevention is further subdivided, on the basis of the population targeted, into "universal prevention", "selective prevention" and "indicated prevention" (see Types of interventions).

How the intervention might work

Interventions focused on the prevention of mental disorders are commonly aimed at targeting modifiable causal factors or determinants of mental health (Dückers 2013; Hobfoll 2007; Marmot 2014). In general, prevention interventions are aimed at decreasing risk factors for the development of mental disorders or symptoms (e.g. through preventing exposure to further violence and other human rights violations, reducing poverty, preventing social exclusion) (Hobfoll 2007), or at building resilience and increasing a sense of hope and safety to protect against psychological symptom development (e.g. supporting parents to lower the levels of anxiety or depressive symptoms in children) (Tol 2013b). These types of interventions have often been termed 'psychosocial' interventions by agencies in humanitarian settings, and are implemented in diverse humanitarian sectors including child protection, nutrition, and education. Prevention interventions of a psychological nature may offer supportive and practical help to improve coping strategies, and a sense of hope and focus on existing sources of individual resilience. Prevention interventions of a social nature may be aimed at strengthening social support systems and sense of connectedness, which has been shown to reduce the risk of onset on mental disorder (Tol 2015).

A growing body of research has aimed to identify modifiable risk and protective factors for psychological symptoms and mental disorders in humanitarian settings. For example, research has focused on the importance of ongoing and more chronic forms of adversity, such as poverty, intimate partner violence, and social marginalization, as determinants of mental health. In addition, research on protective factors has often focused on the importance of individual coping methods and social support from family and community members. Research on risk and protective factors commonly examines variables at diverse levels of the affected person's social ecology, including individual, family, community, and wider societal levels (Tol 2013b). In public health, these variables are often referred to as "social determinants" of mental health (Allen 2014).

Why it is important to do this review

A considerable number of studies have examined mental health in populations living in humanitarian settings (Attanayake 2009; Charlson 2019; Wang 2013). LMICs may differ from high-income countries with regard to health systems (e.g. the number of mental health professionals available) and humanitarian response capacity. In addition, there may be variation in the distribution of risk and protective factors for the development of mental disorders in low-resource settings, which makes studying interventions in LMICs imperative. For these reason, evidence regarding the effectiveness of prevention interventions implemented in high-income countries may not generalize or be relevant to LMICs. Given the large impact of humanitarian crises in LMICs and unknown generalizability of findings from high-income countries, this review focuses on interventions implemented with populations living in LMICs.

Although prevention interventions have been popular in practice, an earlier systematic review focusing on humanitarian settings did not identify any studies evaluating the benefits of such interventions for mental health. The review authors pointed out that a large gap in knowledge exists about interventions aimed at preventing mental disorders, and promoting psychological well-being (Tol 2011). A Cochrane Review analysed the effectiveness of psychological debriefing for preventing PTSD after trauma and found no significant short-term effects on psychological distress (Rose 2002), but this review did not focus specifically on LMICs or humanitarian settings. Finally, another Cochrane Review that was published recently evaluated psychological interventions for torture survivors and found a moderate effect size for psychological interventions versus control conditions at six-month follow-up, while no differences were identified between interventions and controls at endpoint. However, this review was based on a small number of trials providing sometimes incomplete information and consisted mainly of treatment interventions (Patel 2014), as opposed to our focus on prevention.

In summary, given the broad impacts of humanitarian settings on mental health, this review aims to provide a comprehensive evaluation of the effectiveness of prevention interventions, across a range of disorders in both child and adolescent, and adult populations in LMIC.

OBJECTIVES

To assess the efficacy and acceptability of universal, selective, and indicated prevention psychological and social interventions aimed at preventing mental disorders (post-traumatic stress disorder, major depression, anxiety and somatic symptom and related disorders) in people living in low- and middle-income countries (LMIC) affected by humanitarian crises.

METHODS

Criteria for considering studies for this review

Types of studies

In the present review we included randomized controlled trials (RCTs). Trials that employ a cross-over design were eligible though we would use only data from the first randomized stage. We excluded quasi-RCTs, in which participants are allocated to different arms of the trial using a method of allocation that is not

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truly random (e.g. allocation might be based on date of birth, or the order in which people were recruited). Cluster-RCTs were eligible for inclusion.

Types of participants

Participant characteristics

We considered participants of any age, gender, ethnicity, and religion. We conducted two separate meta-analyses for children and adolescents (less than 18 years), and for adults (18 years) on the different outcomes.

Setting

We considered studies conducted in humanitarian settings, i.e. contexts affected by armed conflicts or by disasters triggered by natural, industrial, or technological hazards in LMICs. We used the World Bank criteria for categorising a country as low- or middle-income (The World Bank 2016). We excluded studies undertaken in high-income countries (The World Bank 2016). Prevention interventions may have been delivered in healthcare settings, refugee camps, schools, communities, survivors' homes, and detention facilities. We included studies with populations during humanitarian crises, as well as in periods after humanitarian crises.

Diagnosis

Given the focus on prevention of mental disorders, we excluded studies that selected participants on the basis of currently meeting criteria of a formal psychiatric diagnosis. We also excluded studies that included participants scoring above a disclosed validated cut-off score at a scale measuring psychological symptoms associated with a particular mental disorder, as this may be considered a proxy of a psychiatric diagnosis. We were not able to guarantee that some participants in trials did not have psychiatric diagnoses at enrolment, however, as this was not necessarily an exclusion criterion for trials. For example, we considered populations who left their homes due to a sudden impact, threat or conflict; exposed to political violence/armed conflicts/natural and industrial disasters; major losses; extreme poverty; belonging to a persecuted group (i.e. discriminated against or marginalized); political oppression; family separation; disruption of social networks; destruction of community structures resources and trust; increased gender-based violence; and undermined community structures or traditional support mechanisms (IASC 2007). Within these populations there will have been people who already had a mental disorder (Charlson 2019).

We only included studies of mixed populations if most participants did not meet a formal psychiatric diagnosis or a proxy thereof (i.e. scoring above the cut-off of a screening measure). We adopted a common-sense strategy, also relying on authors' specific statements of intent, without specifying any arbitrary threshold with regard to cut-offs on symptom checklists, as suggested in the Section 5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Comorbidity

We included studies with participants reporting physical disorders.

Types of interventions

Experimental interventions

We included studies that assessed the effects of any psychological or social interventions aimed at preventing the following mental disorders in humanitarian settings in LMICs: post-traumatic stress disorder (PTSD), anxiety, depression, and somatic symptom and related disorders. We grouped the interventions as follows.

1. Universal prevention. This type of prevention includes strategies that can be offered to the whole population, based on the evidence that it is likely to provide some benefit to all (reduce the probability of disorder), which clearly outweighs the costs and risks of negative consequences. For example, universal prevention interventions may encompass:

- providing access to information on the humanitarian crisis, ongoing humanitarian response, and legal rights of the affected population (IASC 2007);
- community-wide provision of information on positive coping methods (IASC 2007), to help people to feel safe and hopeful;
- protection against human rights violations;
- community-wide efforts to improve livelihoods as a key protective factor for mental health, working on lifting restrictions of movement and employment for everyone in a refugee camp;
- Classroom-based interventions where all children in the classroom get the same social–emotional learning life skills intervention. These interventions frequently but not always involve CBT and creative–expressive (drama, dance, music) techniques;
- structured cultural and recreational activities supporting the development of resilience (Institute of Medicine 2009), such as traditional dancing, art work, sports, and puppetry.

This type of prevention may overlap with the concept of mental health promotion (Tol 2015).

2. Selective prevention. Selective prevention refers to strategies that are targeted at subpopulations identified as being at elevated risk for a disorder, and may include:

- mentoring programmes aimed at children with limited social support networks;
- psychological first aid for people with heightened levels of psychological distress soon after exposure to severe stressors, loss, or bereavement. These interventions involve human, supportive, and practical help covering both a social and a psychological dimension. They emphasize communication (asking about people's needs and concerns; listening to people and helping them to feel calm; practical support (i.e. providing meals or water); and assisting with practical problems where possible (e.g. through referral) (WHO 2011);
- facilitation of community support for marginalized individuals by activating social networks and communication.

3. Indicated prevention. This type of prevention includes strategies that are targeted at individuals who are identified (or individually screened) as having an increased vulnerability for a disorder based on some individual assessment (e.g. based on showing symptoms of a disorder). These interventions comprise, for example:

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- psychosocial support for school children with subclinical levels of PTSD, anxiety, depression, or somatic symptom and related disorders. This can incorporate classroom-based interventions (described above) when the intervention is only offered to children with subclinical levels of mental disorder;
- prevention of postnatal depression in women with heightened levels of prenatal symptoms (Institute of Medicine 2009). These interventions may be delivered at individual or group level. They incorporate antenatal and postnatal classes, parenthood classes, and continuity of care (home visits, follow-ups).

Selective and indicated prevention strategies might involve more intensive interventions and thus involve greater cost to the participants, since their risk and thus potential benefit from participation would be greater (Institute of Medicine 1994; Institute of Medicine 2009; Tol 2015).

Comparator interventions

The control comparators were:

1. no treatment;
2. intervention as usual (TAU) (also called standard/usual care): participants could receive any appropriate general support during the course of the study on a naturalistic basis;
3. waiting list (WL): delaying delivery of the intervention to the control group until after participants in the intervention group have completed treatment. As in TAU, participants in the WL condition could receive any appropriate support during the course of the study on a naturalistic basis;
4. attention placebo: defined as any form of inactive intervention designed by the original authors to be perceived as ineffective by patients;
5. psychological placebo: defined as any form of inactive intervention designed by the original authors to be perceived as effective by patients.

Participants may receive any appropriate medical care during the course of the study on a naturalistic basis, including pharmacotherapy, as deemed necessary by the healthcare staff.

Format of psychological and social interventions

The intervention may be delivered through any means – for example face-to-face meetings, the Internet, radio, telephone, or self-help booklets – and can be delivered by trained professional(s) or para-professional(s). Either individual or group psychological or social interventions were eligible for inclusion, with no limit to the number of sessions.

Excluded interventions

We excluded studies that enrolled participants on the basis of a positive diagnosis of mental disorder (or based on scoring above a cut-off score as proxy for a diagnosis at baseline). We excluded interventions primarily aimed at promoting well-being.

Types of outcome measures

We included studies that met the above inclusion criteria regardless of whether they reported on the following outcomes.

Primary outcomes

Efficacy outcome

- Proportion of individuals with a diagnosis (or a proxy thereof as assessed by scoring above a cut-off of a screening tool) of: PTSD, anxiety, depression, and somatic symptom and related disorders at study endpoint; determined according to the Diagnostic and Statistical Manual of mental disorders (DSM) III (APA 1980), DSM-III-R (APA 1987), DSM-IV-TR (APA 2000), DSM-5 (APA 2013), International Classification of Diseases (ICD) 10 (WHO 1992a), or any other standardized criteria. These different conditions are intended to be a unique outcome.

Acceptability outcomes

- The number of participants who drop out of psychological or social intervention for any reason;
- any adverse event such as suicide, self-harm, or increase in PTSD, depression, anxiety, and 'somatic symptom and related disorders' symptomatology.

Secondary outcomes

- PTSD symptoms, depressive symptoms, anxiety symptoms, or somatic symptoms and related disorders (four separate outcomes): mean change from baseline to the study endpoint at the PTSD Scale (PSS, Foa 1993), Child PTSD Symptom Scale (CPSS, Foa 2001), Beck Depression Inventory (BDI, Beck 1961), Beck Anxiety Inventory (BAI, Beck 1988), or other standardized or commonly used rating scales;
- Functional impairment, mental-health-related disability, and quality of life (three separate outcomes): mean change scores from baseline to the study endpoint at the World Health Organization (WHO) Disability Assessment Schedule 2.0 (WHODAS 2.0, WHO 2010), the Global Assessment of Functioning (GAF, APA 2000), the WHO Quality of Life scale (WHO 1992b), or other commonly used rating scales.

Timing of outcome assessment

Our primary endpoint was immediately after prevention intervention (zero to four weeks after intervention). We also collected information on every other available follow-up assessment. We categorized follow-up data as follows: follow-up immediately after intervention (zero to four weeks); follow-up at one to four months; follow-up at five to eight months; follow-up at nine months to one year; and follow-up at more than one year.

Hierarchy of outcome measures

When more than one outcome measure was available in the domain of interest, as defined in the outcomes, and both described the domain adequately, we chose the measure with most detailed socio-cultural evaluation or that is also used by other trials in the analysis. Secondarily, we chose any measure that the study authors state was tested for suitability in the population of interest.

Search methods for identification of studies

Electronic searches

1. Cochrane Common Mental Disorders Controlled Trials Register (CCMD-CTR)

The Cochrane Common Mental Disorders Review Group maintains an archived specialised register of RCTs, the CCMDCTR. This

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specialist mental health database contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm and other mental disorders within the scope of this Group. The CCMD-CTR is a partially studies-based register with more than 50% of reference records tagged to around 12,500 individually PICO-coded study records. Reports of studies for inclusion in the register were collated from (weekly) generic searches of MEDLINE (1950 to 2016), Embase (1974 to 2016) and PsycINFO (1967 to 2016), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. We also sourced reports of studies from international trials registries, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) can be found on the Group's website, with an example of the core MEDLINE search displayed in Appendix 1.

We cross-searched the CCMD-CTR using terms to represent humanitarian crises in LMICs (only):

#1. (altruis* or humanitarian or human right*):*ti,ab,kw,ky,emt,mh,mc*
#2. (catastrophe* or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or hurricane or cyclone* or landslide* or "land slide*" or "mass casualt*" or tsunami* or tidal wave* or volcano*):t*i,ab,kw,ky,emt,mh,mc*
#3. (genocide or "armed conflict*" or "mass execution*" or "mass violence"):*ti,ab,kw,ky,emt,mh,mc*
#4. ((war or conflict) NEAR2 (affect* or effect* or expos* or related or victim* or survivor*)):*ti,ab,kw,ky,emt,mh,mc*
#5. (displac* NEAR (internal or forced or mass or person* or people* or population*)):*ti,ab,kw,ky,emt,mh,mc*
#6. ("forced migration" or refugee*):*ti,ab,kw,ky,emt,mh,mc*
#7. (politic* NEAR (persecut* or prison* or imprison* or violen*)):*ti,ab,kw,ky,emt,mh,mc*
#8. (#1 or #2 or #3 or #4 or #5 or #6 or #7)
#9. (bereav* or orphan* or widow*):*ti,ab,kw,ky,emt,mh,mc*
#10. (abuse* or conflict or persecut* or rape or torture or violen* or victim* or survivor* or war):*ti,ab,kw,ky,emt,mh,mc*
#11. (aid or relief or rescue or peace*):*ti,ab,kw,ky,emt,mh,mc*
#12. emergenc*:ti or (emergency NEXT (service* or setting)):*ti,ab,kw,ky,emt,mh,mc*
#13. ("critical incident" or "crisis intervention" or CISD):*ti,ab,kw,ky,emt,mh,mc*

We limited lines #9 to #13 to LMICs, using a search filter developed by the Norwegian satellite of the Cochrane Effective Practice and Organisation of Care Group (Appendix 2).

2. The Cochrane Drugs and Alcohol Review Group (CDAG) Specialized Register

We requested a similar search of the specialized register of the Cochrane Drugs and Alcohol Group.

3. Complementary searches

We conducted complementary searches on the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2020, Issue 2) in the Cochrane Library (searched 14 February 2020)
- OVID MEDLINE (1946 to 14 February 2020)
- OVID Embase (1974 to 14 February 2020)
- OVID PsycINFO (all years to 14 February 2020)
- ProQuest PILOTS database (Published International Literature On Traumatic Stress) (1980 to 3 February 2016)

We added a list of demonyms to the LMIC search filter (CENTRAL, MEDLINE, Embase, and PsycINFO) to denote the natives or inhabitants of a particular country. No restrictions were placed on date, language, or publication status to the searches

The search strategies are reported in Appendix 3.

4. International trial registries

We searched international trial registries via the WHO's International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov to identify unpublished or ongoing studies (all years to 14 February 2020).

Searching other resources

Grey literature

We searched sources of grey literature, including dissertations and theses, humanitarian reports, evaluations published on websites, clinical guidelines, and reports from regulatory agencies (where appropriate). In addition, we searched key agencies and initiatives in this field for relevant reports.

Handsearching

We handsearched relevant conference proceedings and academic literature (titles not already indexed in Embase or PsycINFO, or already handsearched within Cochrane).

Reference lists

We checked the reference lists of all included studies and relevant systematic reviews (both Cochrane and non-Cochrane) to identify additional studies missed from the original electronic searches (e.g. unpublished or in-press citations). Also we conducted a cited reference search on the Web of Science.

Correspondence

We contacted trial authors and subject experts for information on unpublished or ongoing studies or to request additional trial data.

Data collection and analysis

Selection of studies

Two review authors (DP and CG) independently screened titles and abstracts of all the potential studies identified by the search strategy for inclusion. We then obtained full-text articles of potentially eligible studies, and the same two review authors independently assessed full-text articles for inclusion. In the case of disagreement, we sought resolution by discussion. When disagreement could not be solved by discussion, arbitration was provided by a third author (MP or CB). Moreover, we identified and recorded reasons for exclusion of the ineligible studies.

We identified and excluded duplicate records and we collated multiple reports that related to the same study so that each study

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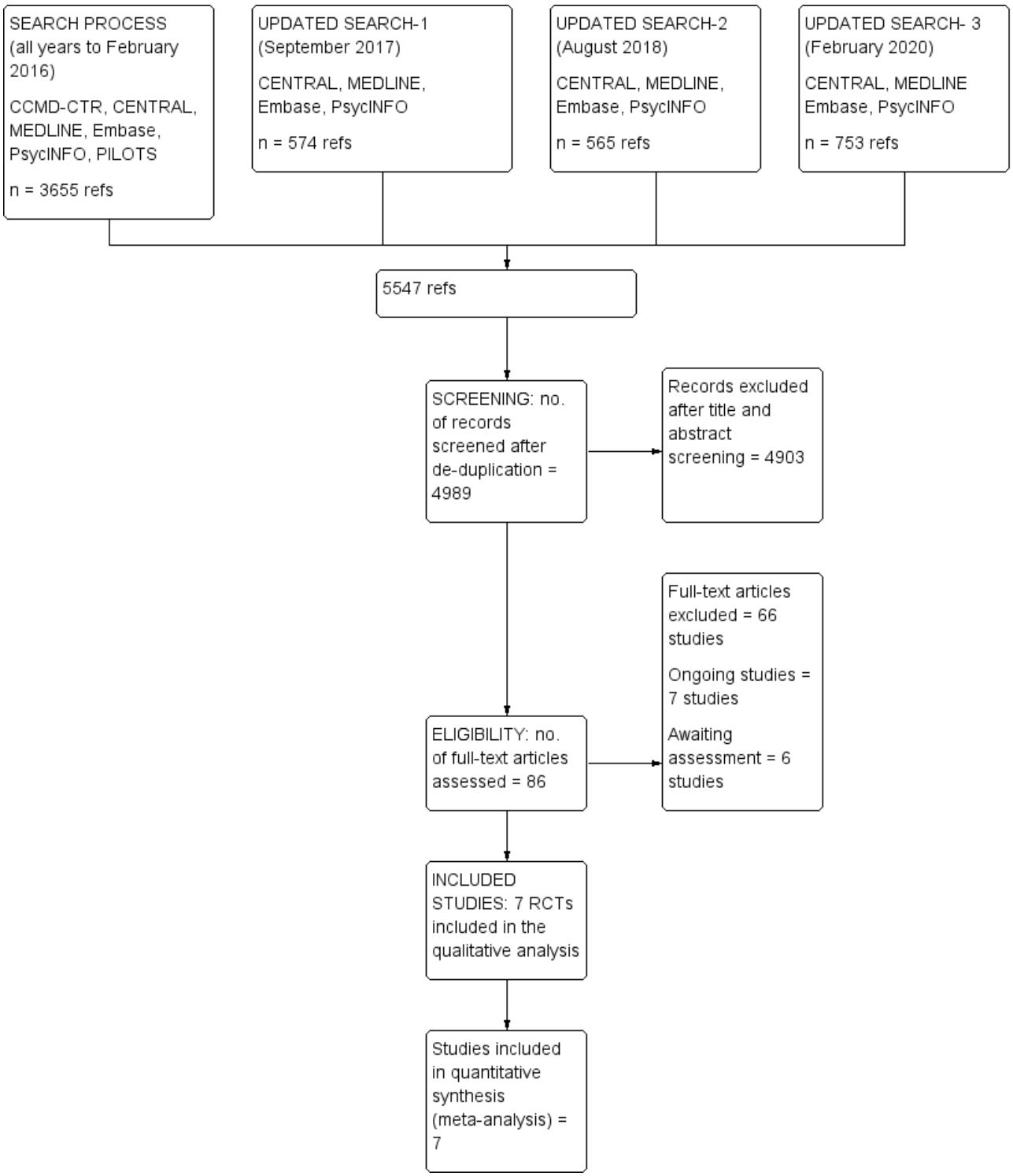
rather than each report was the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram (Figure 1) and a 'Characteristics of excluded studies' table.

Figure 1. Study flow diagram.



Data extraction and management

We used a data collection form, which we piloted on one included study in the review, to extract study characteristics and outcome data. Two review authors (DP and CG) independently extracted study characteristics and outcome data onto this data extraction form. We discussed any disagreement with an additional review author (MP or CB) and, where necessary, we contacted the study authors for further information.

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We extracted the following study characteristics.

1. Methods: phase of humanitarian crisis (ongoing, post-conflict, etc.), type of humanitarian crisis, duration of prevention intervention, number of study centres and location, study setting and date of study, inclusion criteria, and exclusion criteria;
2. Participants: N, mean age, age range, gender, presence or not of disorder, baseline scores at validated rating scales, types of traumatic events, other trauma histories;
3. Prevention interventions and comparisons;
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported;

We noted in the 'Characteristics of included studies' table if the study authors did not report outcome data in a usable way. We resolved disagreements by consensus or by involving a third review author (MP or CB). Two review authors (DP and CG) independently transferred data into the Review Manager 5 (RevMan 5) file (Review Manager 2014). We double-checked whether the review authors entered data correctly by comparing the data presented in the systematic review with the study reports. A third review author (MP) spot-checked study characteristics and outcomes extracted.

Assessment of risk of bias in included studies

Two review authors (DP, CG) independently assessed the risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreements by discussion or by involving another review author (MP or CB). We assessed the risk of bias according to the following domains.

- Random sequence generation
- Allocation concealment
- Blinding of participants and personnel
- Blinding of outcome assessment
- Incomplete outcome data
- Selective outcome reporting
- Other bias

Moreover, to better understand the methodological validity of the included RCTs and to enable an examination of research gaps, we considered in the 'Risk of bias' assessment the following additional items (according to the review carried out by Patel 2014 and to keep consistency with our recent Cochrane Review on psychotherapies in humanitarian settings in LMICs (Purgato 2018a)):

8. Intervention facilitator qualifications: to check whether the paraprofessionals involved in the study were adequately trained and supervised to deliver the interventions.

9. Intervention implementation fidelity: adherence to intervention's manual, which should lead to greater consistency among therapists and clearer distinction from control conditions.

10. Intervention facilitator/investigator allegiance: to state whether the paraprofessionals that delivered the interventions had beliefs and investment in benefit for the active arm of intervention over control arm/s.

Since we expected to include cluster-RCTs, we evaluated these trials according to Section 16.3.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). In particular we considered:

- recruitment bias;
- baseline imbalance;
- loss of clusters;
- incorrect analysis;
- comparability with individually RCTs.

In particular for each cluster-RCT we verified, where possible, whether the included trials:

- randomized all clusters at the same time;
- stratified samples on variables likely to influence outcomes;
- pair-matched clusters;
- had baseline comparability between interventions and control groups.

We judged each potential source of bias as high, low, or unclear risk of bias and provided a supporting quotation from the study report together with a justification for our judgment in the 'Risk of bias' table. We summarized the 'Risk of bias' judgements across different studies for each of the domains listed. Where information on risk of bias relates to unpublished data or correspondence with a trial author, we noted this in the 'Risk of bias' table.

Measures of treatment effect

We performed all comparisons between psychological or social interventions and no intervention, intervention as usual, or waiting list.

Dichotomous data

For dichotomous data, we calculated risk ratios (RRs) with a 95% confidence interval (CI). For statistically significant results, we calculated the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH).

In the case of an eligible study describing its findings using another effect measure, we contacted the study authors to obtain data.

Continuous data

We analysed continuous data as mean difference (MD) values when studies reported outcomes using the same rating scale. We used the standardized mean difference (SMD) values when studies assessed the same outcome measure using different rating scales (Higgins 2011). When only change scores from baseline were reported, we asked the study authors to provide final values. We did not combine final values and change scores together as SMD values.

In the case of an eligible study describing its findings using another effect measure we contacted the study authors to obtain data.

We entered data presented as a scale with a consistent direction of effect. We narratively described skewed data reported as medians and interquartile ranges.

If multiple effect estimates were available, we chose: the Child Post Traumatic Symptoms Scale, clinician administered (Foa

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2001), the Clinician-Administered Post Traumatic Stress Disorder Scale for adults (CAPS) (Blake 1995) (for PTSD); the Screen for Anxiety Related Emotional Disorder (SCARED-5) for children and adolescents (Birmaher 1997), the Hospital Anxiety and Depression Scale - Anxiety Subscale (HAD-A) for adults (Zigmond 1983) (for anxiety); the Children Depression Rating Scale (Poznanski 1979), the Depression Self-Rating Scale (DSRS) (Birleson 1987) for children and adolescents (for depression); the Somatic Symptom Scale-8 (Gierk 2014), the Patient Health Questionnaire-15 (Kroenke 2002), the Rating Scale of Somatic Symptoms (Kellner 1988) (for somatic symptom and related disorders); the WHO Disability Assessment Schedule 2.0 (WHODAS) (WHO 2010) (for functional impairment); and the WHO Quality of Life scale (WHO 1992b) (for quality of life).

In this review we performed direct comparisons only. We did not undertake any kind of indirect comparison.

Unit of analysis issues

Cluster-randomized trials

We included cluster-RCTs where healthcare facilities, schools, or classes within schools are the unit of allocation rather than single individuals. Since variation in response to psychological or social intervention between clusters may be influenced by cluster membership, we considered or calculated, whenever possible, data adjusted with an intra-cluster correlation coefficient (ICC). If the ICC value is not reported or not available from trial authors directly, we assumed it to be 0.1 (Ukoumunne 1999; Higgins 2011).

Cross-over trials

We considered trials employing a cross-over design using data from the first randomized stage only, whilst we acknowledge that this design is rarely used in psychological or social intervention studies.

Studies with multiple intervention groups

We considered studies that included two or more formats of the same intervention in a meta-analysis by combining group arms into a single group, as recommended in Section 16.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Conversely, we considered studies that included two or more different interventions without combining group arms of the study into a single group, but we considered each intervention and each control group in separate meta-analyses. If the control group was 'shared' for both interventions (i.e. multiple interventions but one single control group), we split the 'shared control group' into two or more groups with smaller sample size, and included two or more (reasonably independent) comparisons. We followed Section 16.5.4 of the *Cochrane Handbook for Systematic Reviews of Interventions,* in order to avoid including the same group of participants twice in the same meta-analysis (Higgins 2011).

Dealing with missing data

We contacted investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible. We documented all correspondence with trial authors and reported which trial authors responded. For cluster-RCTs, we contacted study authors for an ICC value where data were not adjusted and could not be identified from the trial report. Where ICCs were neither available from the trial reports nor directly available from the trial authors, we assumed it to be 0.1 (Ukoumunne 1999).

For continuous data we applied a looser form of intention-to-treat (ITT) analyses, whereby all participants with at least one post-baseline measurement are represented by their Last Observations Carried Forward (LOCF). If the authors of the RCTs stated that they used a LOCF approach, we checked details on LOCF strategy and used data as reported by study authors. When the study authors only reported the standard error (SE) or t statistics or P values, we calculated the standard deviations (SDs) according to Altman 1996.

For dichotomous data we applied the ITT analysis, whereby we considered all the dropouts not included in the analyses as negative outcomes (i.e. it was assumed they would have experienced the undesired outcome by the end of the trial).

Assessment of heterogeneity

We quantified heterogeneity using the I^2 statistic, which calculates the percentage of variability due to heterogeneity rather than chance.

According to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), we used the following thresholds for the interpretation of the I^2 statistic.

- 0% to 40%: might not be important
- 30% to 60%: may represent moderate heterogeneity
- 50% to 90%: may represent substantial heterogeneity
- 75% to 100%: considerable heterogeneity

The importance of the observed I^2 statistic depended on the magnitude and direction of intervention effects and the strength of evidence for heterogeneity (Higgins 2011; Purgato 2012).

If any meta-analysis was associated with substantial levels of heterogeneity (i.e. the I^2 statistic ≥ 75%), MP and DP independently checked data to ensure they were entered correctly. Assuming data were entered correctly, we investigated the source of this heterogeneity by visually inspecting the forest plots and we removed each trial that had a very different result to the general pattern of the others until homogeneity was restored as indicated by an I^2 statistic value of less than 75%. We reported the results of this sensitivity analysis in the text of the review alongside hypotheses regarding the likely causes of the heterogeneity.

Assessment of reporting biases

As far as possible, we minimized the impact of reporting biases by undertaking comprehensive searches of multiple sources, increasing efforts to identify unpublished material without language restrictions.

We visually inspected funnel plots to identify asymmetry in any of the comparisons between psychological or social interventions and comparators. We are aware that funnel plots are of limited power to detect small-study effects. We did not use funnel plots for outcomes where there are fewer than 10 studies, or where all studies are of similar sizes (Sterne 2011). In other cases where funnel plots are possible, we asked for statistical advice in their interpretation.

Data synthesis

Given the potential heterogeneity of psychological and social interventions, we used a random-effects model in all analyses. The random-effects model has the highest generalizability in

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empirical examination of summary effect measures for meta-analyses (Furukawa 2002).

Specifically, for dichotomous data, we used the Mantel-Haenszel method as this is preferable in Cochrane Reviews given its better statistical properties when there are few events (Higgins 2011). We adopted the inverse variance method for continuous data: this method minimizes the imprecision of the pooled effect estimate as the weight given to each study is chosen to be the inverse of the variance of the effect estimate (Higgins 2011).

Subgroup analysis and investigation of heterogeneity

We planned the following subgroup analyses.

- Type of intervention context (e.g. school, camp, healthcare setting). The context in which the intervention is implemented is expected to have an impact on outcomes. Where possible, we categorized the intervention contexts as school, camp, or healthcare setting.
- Type of traumatic events. We considered the following categories: bereavement; displacement; sexual and other forms of gender-based violence; torture; witnessing violence/atrocities; other traumatic events (IASC 2007). Different types of traumatic events might influence the effectiveness of interventions as they have different consequences/impact on psychological functioning and individual response to health interventions (US Department of Health and Human Services 2014).
- Type of humanitarian crisis. We considered the following categories: protracted emergencies, such as armed conflicts and long-term food shortages, acts of terrorism, fires, and industrial accidents, major disasters with airplanes and trains, and disasters triggered by natural hazards such as geophysical (earthquakes, tsunamis, volcanic eruptions), hydrological (floods, avalanches), climatological (droughts), or meteorological hazards (storms, cyclones), or biological epidemics (e.g. plagues) (OCHA 2016). The type of humanitarian crisis is expected to have an impact on outcomes as people's needs, vulnerabilities, and capacities (including their capacity to respond to psychological and social interventions) may vary according to the different humanitarian contexts in which they live (The Sphere Project 2011).

Sensitivity analysis

We planned the following sensitivity analyses.

- Exclusion of trials with high risk of bias in the following domains: incomplete outcome data and selective reporting
- Exclusion of trials of mixed populations
- Exclusion of trials with high levels of heterogeneity (I^2 statistic value ≥ 75%)

'Summary of findings' tables

We used the GRADE approach to interpret findings (Langendam 2013). Using GRADEpro software (GRADEpro GDT), we imported data from RevMan 5 to create 'Summary of findings' tables (Review Manager). These tables provide outcome-specific information concerning the overall quality of evidence from studies included in the comparison, the magnitude of effect of the psychological and social interventions examined, and the sum of available data on the outcomes we considered. We adhered to the standard methods for the preparation and presentation results outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review authors (DP, CG) independently performed GRADE assessments.

We included the following outcomes in the 'Summary of findings' tables.

- Diagnosis of PTSD, anxiety, depression, and somatic symptom and related disorders
- Dropouts due to any cause
- Adverse events
- Change in PTSD symptoms
- Change in depression symptoms
- Change in anxiety symptoms

For continuous outcomes, we adopted the Cohen's approach for interpretation of effect size (0.2 represents a small effect; 0.5 represents a moderate effect; 0.8 represents a large effect) (Cohen 1992).

Summary of findings and assessment of the certainty of the evidence

RESULTS

Description of studies

Results of the search

From 5547 records (identified from searches to February 2020), we identified 86 studies for full-text screening (see Figure 1 for the search flow diagram). We included seven RCTs with a total of 2398 participants (see Characteristics of included studies) and excluded 66 studies (see Characteristics of excluded studies). Seven studies are ongoing (Ongoing studies); and six studies are awaiting classification (Studies awaiting classification). We identified two cluster-randomised trials (Jordans 2010; Tol 2012). We identified no cross-over trials.

Included studies

See Characteristics of included studies.

Design

Sample sizes

Included studies involved 2398 participants, and the number of participants in each trial ranged from 145 in Richards 2014 to 603 in Panter-Brick 2018.

Setting

Two studies were carried out in Nepal (Markkula 2019; Jordans 2010), one in the Democratic Republic of the Congo (O'Callaghan 2014), one in Syria (Panter-Brick 2018), one in Sri Lanka (Tol 2012), one in Haiti (James 2020), and one in Uganda (Richards 2014). In all studies bar James 2020 the humanitarian crisis was the aftermath of war or armed conflicts. The context of treatment varied across studies: four studies delivered the intervention in community settings (O'Callaghan 2014; Richards 2014; James 2020; Markkula 2019); two in schools (Jordans 2010; Tol 2012); and one in youth centres designated as 'Adolescent Friendly Spaces' (Panter-Brick 2018). Aside from Panter-Brick 2018 and James 2020, all of the

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included studies delivered psychological and social interventions after the acute crisis period had ended.

Participants

Five studies considered children or adolescents between 7 and 18 years of age: two studies enrolled adolescents between 11 and 14 years of age (Jordans 2010; Richards 2014); one study enrolled children between 9 and 12 years of age (Tol 2012); one study enrolled children and adolescents between 7 and 18 years of age (O'Callaghan 2014); and one considered for inclusion adolescents between 12 and 18 years of age (Panter-Brick 2018). In all of the studies, most (more than 50%) participants were male. Main types of traumatic events were bereavement (O'Callaghan 2014); bereavement and abduction (Richards 2014); displacement (Panter-Brick 2018); and a series of compounded stressors without an identifiable recurrent event (Jordans 2010). No studies enrolled children or adolescents formally diagnosed with mental disorders.

Two studies focused on adults (> 18 years of age). In one study almost all the participants were female (Markkula 2019); in James 2020 both sexes were equally represented. The main types of traumatic events were compounded stressors and bereavement (James 2020 and Markkula 2019 respectively). No studies enrolled adults formally diagnosed with mental disorders.

Interventions and comparators

The Included trials compared a psychological or social intervention versus an inactive control intervention (waiting list in all studies). Jordans 2010 and Tol 2012 delivered a school-based psychosocial intervention named the Classroom-Based Intervention (CBI). CBI is a five-week, 15-session (approximately 60-minute sessions) protocolised group intervention. CBI is an eclectic intervention based on concepts from creative-expressive and experiential therapy, co-operative play and cognitive behavioural therapy. CBI combines specific techniques such as psycho-education, socio-drama, movement/dance, group cohesion activities, stress inoculation techniques and trauma-processing through (voluntary) narrative exposure through drawings. O'Callaghan 2014 delivered a psychosocial intervention based on three components: (1) ChuoChaMaisha, a youth life skills leadership programme developed and piloted in Tanzania; (2) Mobile Cinema clips: narrative, fictional films, produced and created in the local language to address stigma and discrimination and model how young people, parents and the village community could welcome formerly abducted children back into their communities; and (3) Relaxation Technique scripts used in Trauma-Focused CBT. Panter-Brick 2018 delivered a programme called Advancing Adolescents, an eight-week programme of structured activities informed by a profound stress attunement (PSA) framework. The profound stress attunement approach is a community-based, non-clinical programme of psychosocial care to meet the psychosocial needs of at-risk children and improve social interactions with participatory approaches. It focuses on the practice of attunement, for developing safe emotional spaces, managing stressors and establishing healthy relationships. Richards 2014 delivered an intervention named "sport-for-development", which aimed to use sport as a vehicle to promote physical fitness and mental health as well as achieve peace-building objectives in the community. James 2020 delivered an experiential intervention named "Mental health integrated disaster preparedness", that included facilitated discussion, space for sharing personal experiences and exchange of peer-support, practising coping skills targeting disaster-related distress. Finally, Markkula 2019 deployed an intervention focusing on problem-solving, emotional support and coping strategies.

We judged the interventions delivered by Jordans 2010, O'Callaghan 2014, Panter-Brick 2018, Richards 2014, and Tol 2012 as indicated prevention because they mainly offered focused psychosocial support for school children with subclinical symptoms. We judged the interventions delivered by James 2020 and Markkula 2019 as selective prevention, because they provided psychological first aid for people with heightened levels of psychological distress soon after exposure to severe stressors. These interventions involved human, supportive, and practical help covering both a social and a psychological dimension.

All the interventions in the included trials were delivered by paraprofessionals (i.e. trained lay counsellors; community health workers). Six out of seven of the trials delivered psychological and social interventions at a group level and one (Markkula 2019) at an individual level. Four trials delivered the intervention during the acute phase of the humanitarian crisis (Jordans 2010; Markkula 2019; Richards 2014; Tol 2012), whilst three studies were performed while the acute crisis was still ongoing (James 2020; O'Callaghan 2014; Panter-Brick 2018).

Outcomes

At the end of the reviewing process, seven RCTs provided data for meta-analyses. For primary outcomes, no study provided data on the efficacy of interventions to prevent the onset of a mental disorder (incidence), that is no study provided data on the proportion of individuals with a newly developed diagnosis of PTSD, anxiety, depression, or somatic symptom and related disorders at study endpoint in both intervention and control conditions. No information on adverse events related to the interventions was available. For the primary outcome of acceptability, seven RCTs provided data on total dropouts for any cause. While no participants were included in the analysis for the efficacy primary outcome, a total of 2612 participants were included in the primary outcome of acceptability (both children and adolescents, and adults).
For secondary outcomes, 882 participants were included in the efficacy analysis for the continuous outcome PTSD symptoms at endpoint (441 participants randomised to interventions and 441 randomised to control – only children and adolescents); 1285 participants were included in the efficacy analysis for the continuous outcome depression at endpoint (639 participants randomised to interventions and 646 randomised to control); 1127 participants were included in the efficacy analysis for the continuous outcome anxiety at endpoint (561 participants randomised to interventions and 566 randomised to control); 724 participants were included in the efficacy analysis for the continuous outcome functional impairment at endpoint (363 participants randomised to interventions and 361 randomised to control – only children and adolescents); no study provided data for the outcomes "somatic symptom and related disorders", "mental health-related disability", and "quality of life".

The following outcome measurement tools were considered in the meta-analyses.

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PTSD symptoms

- Child PTSD Symptom Scale (CPSS): a 17-item scale which measures symptoms of PTSD according to the DSM-IV with a four-point response scale (Foa 2001).
- Children's Revised Impact of Event Scale (CRIES): a brief child-friendly measure designed to screen children at risk for PTSD. The CRIES is designed for use with children aged eight years and above who are able to read independently. It consists of four items measuring intrusion and four items measuring avoidance (Perrin 2005).

Depression symptoms

- Acholi Psychosocial Assessment Instrument (APAI): designed to assess depression-like (two tam, par and kumu), anxiety-like (ma lwor) and conduct problems (kwo maraco) among war-affected adolescents in northern Uganda (Betancourt 2009).
- African Youth Psychosocial Assessment Instrument (AYPA): is derived from APAI after items were optimized and reconfigured into this new 41 item scale. The AYPA is a refined dimensional assessment of emotional and behavioural problems in African youth (Betancourt 2014b).
- Beck Depression Inventory (BDI): a 21-item, self-report rating inventory that measures characteristic attitudes and symptoms of depression (Beck 1961).
- Depression Self-Rating Scale (DSRS): a depression 18-item self-rating scale for children (Birleson 1987).

Anxiety symptoms

- Beck Anxiety Inventory (BAI): is a 21-item self-report measure of anxiety (Beck 1988).
- Screen for Child Anxiety Related Emotional Disorder (SCARED): a 41-item inventory rated on a 3-point Likert-type scale. The purpose of the instrument is to screen for signs of anxiety disorders in children (Birmaher 1997).

Functioning

- Children's Function Impairment (CFI): a questionnaire developed in Nepal for cross-cultural and sex-specific function assessment (Bolton 2002).

Excluded studies

See Characteristics of excluded studies.

Of the 86 studies initially selected as potentially relevant, we excluded 15 because of inapplicable setting (no humanitarian crisis in LMICs); 12 due to being a different design (no RCT or incorrect randomisation procedure); and three because of an inapplicable comparison (no psychosocial intervention compared with control). Moreover, we excluded 29 RCTs because of different participant population, one study as it was a secondary publication and six deployed a wrong intervention. Furthermore, we excluded studies that employed rating scales with cut-off scores at baseline as inclusion criterion. As cut-offs could be considered as a proxy of a diagnosis, we excluded these studies because we reasoned they were not really meant to be focused on prevention (but more on treatment).

Ongoing studies

We classified seven studies as ongoing: four are completed but results are not yet available (NCT01729325; NCT03075475; NCT03359486; NCT03387007); two are recruiting (NCT03567083; NCT03960892); and one has just completed the recruitment phase (NCT03058302). See Characteristics of ongoing studies.

Risk of bias in included studies

See Characteristics of included studies. For graphical representations of overall risk of bias in included studies, see Figure 2 and Figure 3.

Allocation

Researchers described generation of a random sequence that we considered to lead to low risk of bias in six studies (Jordans 2010; Panter-Brick 2018; Tol 2012; James 2020; Markkula 2019; O'Callaghan 2014); the remaining study we considered at high risk of being biased (Richards 2014). Regarding allocation concealment, we considered two of the included trials to be at low risk (Richards 2014; O'Callaghan 2014); and the five remaining RCTs did not describe allocation concealment – we therefore rated them as having unclear risk.

Blinding

Participants (both personnel and study participants) would have been aware of whether they had been assigned to an intervention group or a control group in six trials (O'Callaghan 2014; Jordans 2010; Richards 2014; Tol 2012; James 2020; Markkula 2019); therefore, we rated these studies as having high risk of performance bias. We rated the remaining trial as having unclear risk of performance bias (Panter-Brick 2018). We rated trials as having low risk of bias when researchers described blinded assessment of outcomes (O'Callaghan 2014; Panter-Brick 2018; Richards 2014; Tol 2012). We rated three trials as having high risk of bias, as the assessors were described as likely to be aware of participant allocation (Jordans 2010; James 2020; Markkula 2019).

Incomplete outcome data

With the exception of one RCT (James 2020), the risk of attrition bias was low in the studies included in this review, as researchers clearly reported low dropout rates.

Selective reporting

Five out of seven of the included studies showed consistency between Results and Methods sections (Jordans 2010; Panter-Brick 2018; Richards 2014; James 2020; Markkula 2019). One study did not report data for the control group at follow-up (O'Callaghan 2014), and another reported only data at 3-month follow-up and did not report data for the assessment done one week after the completion of the intervention (Tol 2012). For this reason we rated them at high risk of bias. None of the included trials reported information on study protocols.

Other potential sources of bias

We rated risk of other bias as low in two trials because in the manuscript it is clearly stated that the funders had no role in the realization of the studies (Richards 2014; Tol 2012); and as unclear in the remaining trials. We did not inspect funnel plots to identify asymmetry in any of the comparisons between psychosocial

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treatments and comparators because fewer than 10 studies were identified for this review.

We considered in our risk of bias evaluation the following additional items.

1. Intervention facilitator qualification: we considered no trials as having low risk of bias with regard to the qualifications of intervention facilitators, as psychosocial intervention was delivered by lay counsellors after a brief training, or by trained volunteer adults from local communities.

2. Intervention fidelity: two trials described the system used to monitor intervention implementation fidelity, and we rated their risk of bias as low (O'Callaghan 2014; Panter-Brick 2018). We evaluated risk as unclear for the remaining trials because researchers provided no details about fidelity checks.

3. Intervention facilitator/investigator allegiance: we rated the risk of intervention facilitator or investigator allegiance as unclear for all the trials.

Effects of interventions

See: **Summary of findings 1** Psychosocial interventions compared with control for the prevention of mental disorders in children and adolescents living in low- and middle- income countries affected by humanitarian crises; **Summary of findings 2** Psychosocial interventions compared with control for the prevention of mental disorders in adults living in low- and middle- income countries affected by humanitarian crises

All results of this systematic review must be interpreted with consideration of the characteristics and risk of bias profile of each included study (see Characteristics of included studies).

Comparison 1: Psychological and social interventions versus control

Primary outcomes

1.1 Efficacy outcome: proportion of individuals with a diagnosis of PTSD, anxiety, depression, and somatic symptom and related disorders at study endpoint

Adults: no study provided data for these outcomes.

Children and adolescents: no study provided data for these outcomes.

1.2 Acceptability outcome: number of participants who dropped out of psychological and social intervention for any reason

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (RR 0.93, 95% CI 0.78 to 1.10; I^2 = 0%; 5 RCTs, 1372 participants; Analysis 1.1).

Adults: We noted no significant differences between psychological and social interventions and control comparators for this outcome (RR 0.96, 95% CI 0.61 to 1.50; I^2 = 44%; 2 RCTs, 767 participants; Analysis 1.2).

1.3 Acceptability outcome: adverse events

Children and adolescents: no study provided data for this outcome.

Adults: no study provided data for this outcome.

Secondary outcomes

1.4 PTSD symptoms at endpoint

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (SMD −0.16, 95% CI −0.50 to 0.18; I^2 = 65%; 3 RCTs, 590 participants; Analysis 1.3).

Adults: no study provided data for this outcome.

1.5 PTSD symptoms at three months' follow-up

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (MD −1.18, 95% CI −0.41 to 2.77; 1 RCT, 399 participants; Analysis 1.4).

Adults: No study provided data for this outcome.

1.6 Depressive symptoms at endpoint

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (SMD 0.01, 95% CI −0.29 to 0.31; I^2 = 71%; 4 RCTs, 746 participants; Analysis 1.5).

Adults: we identified a significant difference in favour of psychological counselling versus control for this outcome (MD −7.50, 95% CI −9.19 to −5.81; 1 RCT, 258 participants; Analysis 1.6).

1.7 Depressive symptoms at three months' follow-up

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (MD 0.22, 95% CI −0.64 to 1.08; 1 RCT, 399 participants; Analysis 1.7).

Adults: we identified a significant difference in favour of psychological counselling versus control for this outcome (MD −7.40, 95% CI −9.09 to −5.71; 1 RCT, 258 participants; Analysis 1.8).

1.8 Anxiety symptoms at endpoint

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (SMD 0.11, 95% CI −0.09 to 0.31; I^2 = 29%; 3 RCTs, 632 participants; Analysis 1.9).

Adults: we identified a significant difference in favour of psychological counselling versus control for this outcome (MD −6.10, 95% CI −7.57 to −4.63; 1 RCT, 258 participants; Analysis 1.10.

1.9 Anxiety symptoms at three months' follow-up

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (MD 0.28, 95% CI −0.75 to 0.19; 1 RCT, 399 participants; Analysis 1.11).

Adults: we identified a significant difference in favour of psychological counselling versus control for this outcome (MD −5.80, 95% CI −7.35 to −4.25; 1 RCT, 258 participants; Analysis 1.12).

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1.10 Functional impairment at endpoint

Children and adolescents: we identified a significant difference in favour of a classroom based intervention versus control for this outcome (SMD −0.31, 95% CI −0.49 to −0.12; I^2 = 0%; 2 RCTs, 458 participants; Analysis 1.13).

Adults: no study provided data for this outcome.

1.11 Functional impairment at three months' follow-up

Children and adolescents: we noted no significant differences between psychological and social interventions and control comparators for this outcome (MD −0.88, 95% CI −1.73 to −0.03; 1 RCT, 399 participants; Analysis 1.14).

Adults: no study provided data for this outcome.

1.12 Somatic symptoms

Children: no study provided data for this outcome.

Adults: no study provided data for this outcome.

1.13 Mental health-related disability

Children and adolescents: no study provided data for this outcome.

Adults: no study provided data for this outcome.

1.14 Mental health-related disability at three months' follow-up

Children and adolescents: no study provided data for this outcome.

Adults: no study provided data for this outcome.

1.15 Quality of life

Children and adolescents: no study provided data for this outcome.

Adults: no study provided data for this outcome.

1.16 Quality of life at three months' follow-up

Children and adolescents: no study provided data for this outcome.

Adults: no study provided data for this outcome.

Subgroup analyses

The small number of RCTs included in this review did not allow us to undertake subgroup analyses.

Sensitivity analyses

Owing to the small number of RCTs included in this review it was not possible to carry out sensitivity analyses. There were no RCTs focusing on adults.

Due to lack of data, we were unable to calculate the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH).

DISCUSSION

Summary of main results

Of the seven included studies in this review, none provided data on the primary outcome of interest: the proportion of individuals with a diagnosis (or a proxy thereof as measured by scoring above a cut-off of a screening measure) of PTSD, anxiety, depression, or somatic symptom and related disorders at study endpoint. This hampered the possibility to understand whether psychological and social interventions are beneficial in decreasing the incidence of mental disorders in people living in LMIC affected by humanitarian crises.

In terms of acceptability, the likelihood of leaving the study prematurely for any reason may be similar for participants enrolled in the psychological and social intervention groups and for those enrolled in control groups, for both children and adolescents (low-quality evidence - Analysis 1.1), and adults (very low quality evidence - Analysis 1.2), suggesting that interventions were not experienced as more acceptable than the waiting list condition. These results were based on small numbers of studies and participants, however. No information on adverse events related to the interventions was available.

For secondary outcomes we identified some data for both children and adolescents, and adults. Very low quality evidence suggested that for children and adolescents there may be no difference between psychological and social interventions and control conditions in reducing PTSD symptoms (Analysis 1.3), depressive symptoms (Analysis 1.5) and anxiety symptoms (Analysis 1.9) at study endpoint or at 3-month follow-up, all with wide confidence intervals. No data were available for the outcomes 'mental-health-related disability' and 'quality of life'. Functional impairment was positively influenced in one study by the "classroom-based intervention" (Characteristics of included studies) as compared with control condition (Analysis 1.13) at study endpoint and 3-month follow-up (Tol 2012). In the adult population, very low quality evidence coming from just one trial suggests that psychosocial counselling may be helpful in decreasing symptoms of depression and anxiety, both at study endpoint and at 3-month follow-up (Analysis 1.6; Analysis 1.8; Analysis 1.10; Analysis 1.12). No long-term follow-up (four months to twelve months) data were identified for PTSD, depressive symptoms, anxiety symptoms, somatic symptoms, functioning, mental health-related disability or quality of life for either juvenile or adult populations.

Overall, these limited preliminary findings suggest a lack of trustworthy evidence of a preventive benefit in decreasing symptoms of PTSD, depression and anxiety in the short term (up to three months' follow-up); no information is provided over the longer term.

These results suggest that evidence is largely absent on what might be achieved through psychological and social prevention interventions in practice.

Overall completeness and applicability of evidence

We chose to focus exclusively on research carried out in LMICs because results from studies conducted in high-income countries may not apply to lower-income settings and would, therefore, raise generalizability issues (Barbui 2020). This could be explained by contextual factors: adapting the interventions to

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humanitarian emergencies occurring in LMICs poses numerous challenges, such as heightened urgency to prioritize and allocate scarce resources, limited time to train healthcare providers and limited access to specialists (for training, supervision, mentoring, referrals or consultations) (van Ginneken 2013); and, moreover, the population's need for basic services may likely overwhelm local health care systems capacity. For these reasons, the linkage between LMICs settings and the deployment of the interventions may vary depending on the extent and availability of local, national and international humanitarian assistance.

As for the phase of the humanitarian crisis, we did not restrict the review to an isolated stage of pre- or post-conflict. Indeed, we considered RCTs that evaluated interventions during the acute phase of humanitarian crises, and afterwards; different stages of conflict and displacement did not affect selection of studies for inclusion. We argue this is a general strength of the review.

The type of psychosocial interventions considered in this review comprised a range of interventions. Each of the seven RCTs included in this review applied a different intervention. Five studies comprised an eclectic combination of different components, such as creative-expressive and experiential elements, co-operative play, relaxation techniques and profound stress attunement processes with a cognitive-behavioural therapy (CBT) orientation (Jordans 2010; O'Callaghan 2014; Panter-Brick 2018; Tol 2012; James 2020); another study tested psychological counselling (Markkula 2019); and the last study deployed an intervention primarily aimed at improving mental health performance through using fitness and physical activity as a social vehicle (Richards 2014).

In the present review the two studies focusing on adults provided interventions of selective prevention (i.e. strategies that are targeted to subpopulations identified as being at elevated risk for a disorder) (James 2020; Markkula 2019); whilst the five studies focusing on children and adolescents deployed indicated prevention interventions (i.e. interventions that include strategies aimed at individuals who have subthreshold symptoms of a mental disorder but do not meet diagnostic criteria) (Jordans 2010; O'Callaghan 2014; Panter-Brick 2018; Richards 2014; Tol 2012). No RCTs on universal prevention were identified. Investigations on universal prevention are difficult to carry out, given that universal prevention targets not only the psychological domain (e.g. building resilience and increasing a sense of hope and safety), but many of the risk factors for mental health conditions that have social and/or environmental roots (such as gender-based violence, poverty, unemployment, social marginalization, and lack of education). Furthermore, the boundaries between the concept of "universal prevention" and mental health "promotion" are blurred, representing on one hand two distinct concepts from a theoretical point of view, but on the other hand entities often overlapping when it comes to practically implementing the interventions.

Therefore, the most important outcome for this review – that is proportion of individuals diagnosed with a mental disorder (or proxy thereof as assessed by scoring above the cut-off of a screening measure) at endpoint – was never reported. Interventions aimed at reducing the incidence of disorder must enrol participants not currently meeting criteria or proxy criteria for mental disorders, and assess whether participation in an intervention is associated with lower rates of new disorders than a control condition.

Studies considered for this review did not specifically exclude participants for meeting criteria for mental disorder, and thus it is likely that a proportion of participants in the included studies could have met criteria for a mental disorder.

Considering the absence of data on incidence, this review may inform on the efficacy of prevention interventions in terms of symptom severity (secondary outcomes) only - which can serve as a suboptimal indicator for potential preventive benefits.

Based on these considerations, it is acknowledged that the included studies were not designed to measure "change in the incidence of a disorder" (namely, the outcome of a classical prevention programme); on the other hand, the included studies cannot be considered treatment either, as being diagnosed with a mental health condition (or scoring above the threshold of a relevant screening measure) was an exclusion criterion. On the other hand, we acknowledge that prevention and promotion are distinct concepts with overlapping boundaries, because many psychological and social interventions can contribute both to strengthening positive aspects of mental health (promotion), and at the same time reduce the chance for developing mental disorders (prevention). This could be especially the case of 'universal prevention' interventions. Since we identified no studies on universal prevention we are confident that the findings of this review do not overlap with mental health promotion.

A recent Lancet Commission, which aimed to align global mental health efforts with sustainable development goals, emphasized the importance of efforts to prevent mental disorders and promote mental health in addition to scaling up treatments (Patel 2018). If rigorous prevention trials measuring incidence of disorders are to be implemented, a substantial increase in economic and human resources is needed. Furthermore, there are challenges to the integration of mental health care into primary care settings, scarcity of trained mental health personnel, and shortage of public health expertise among mental health leaders that represent further important barriers to the conceiving, planning and execution of RCTs on prevention interventions for mental health conditions in LMICs affected by humanitarian crises.

Because of this review, we now know that to date there are no studies specifically designed to assess the efficacy of prevention interventions in reducing the incidence of mental disorders in people living in LMIC affected by humanitarian crises. This review highlights the importance of prioritizing prevention intervention trials, an important area of research that is still in its nascent stage and needs further development.

Quality of the evidence

Risk of bias assessment of the RCTs is summarized in Figure 2 and in Figure 3. We added into the risk of bias evaluation items related to psychological and social intervention and interventionist characteristics, according to Patel 2014.

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Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

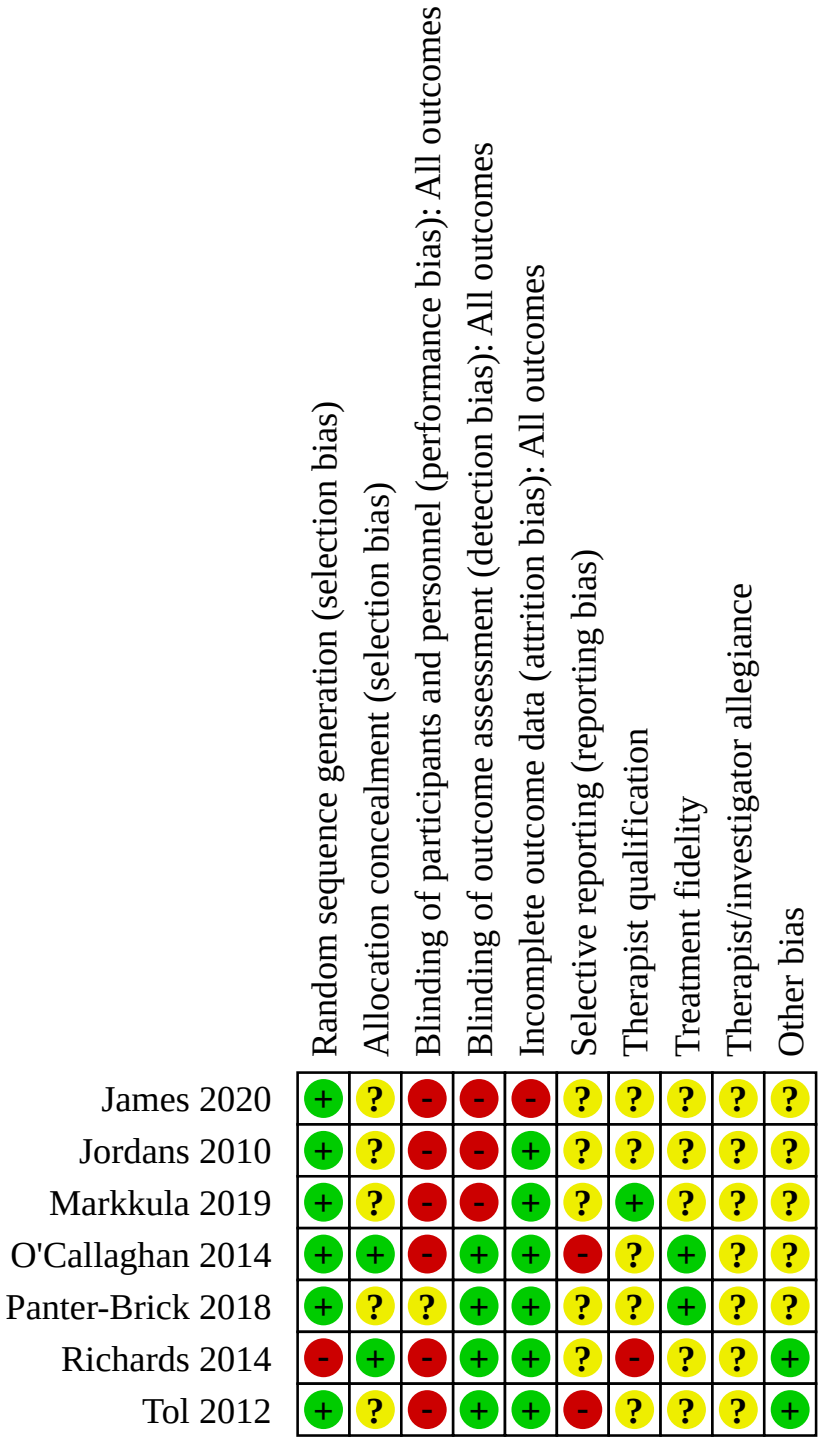

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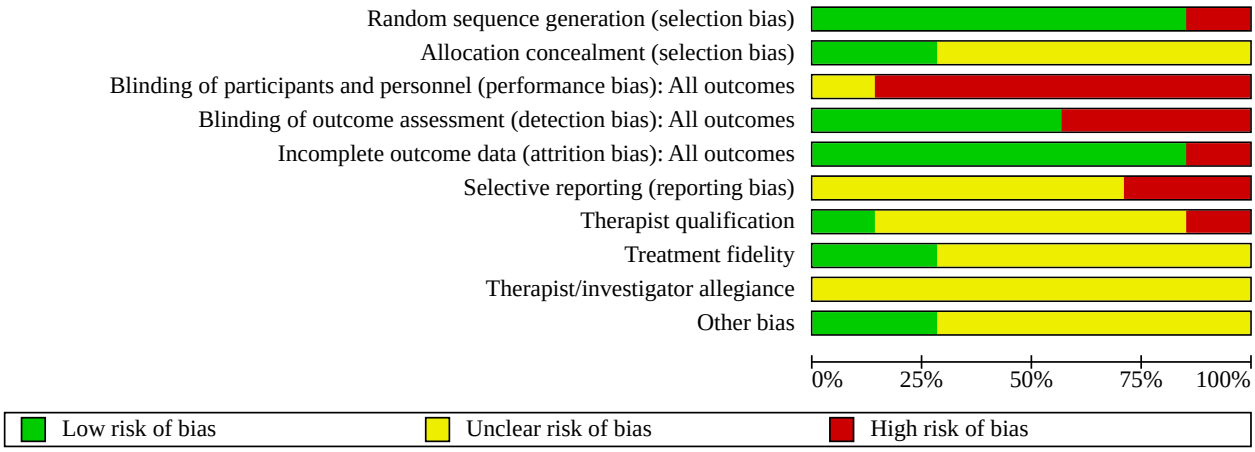
Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



The risk of bias assessment holds a strong influence on the interpretation of trial results and therefore deserves particular attention. The seven studies were RCTs, but their quality was not easy to assess, given the complexity of psychological and social interventions. Overall, we considered risk of selection bias as low in six out of seven trials because the random sequence generation process was properly described, but in Richards 2014 we considered the risk was high as randomization failed to create balanced comparison groups. We rated the risk of allocation bias as low or unclear because some study authors provided insufficient details to permit a judgment. We considered most of the included RCTs to have a high risk of performance bias, as participants were probably aware of whether they were receiving the psychological and social intervention or not. It is important to bear in mind that in studies focused on psychological and social interventions, it is very challenging or even impossible to maintain participants' and facilitators' blinding to study condition allocation. On the contrary, we evaluated all trials bar one (James 2020) as having low rate of drop-outs (low risk of attrition bias) and although outcomes were properly reported in five out of seven studies, none of the included studies reported information on study protocols (two studies rated as high risk of bias and five as unclear risk of bias). Regarding the specific items on psychological and social interventions, four studies stated that interventions were delivered by trained lay counsellors; whilst the last one failed to be clear about intervention facilitator qualifications (Richards 2014). Two of the RCTs properly described methods to check fidelity of intervention implementation, while for the remaining five the risk of bias was unclear due to lack of information. As none of the trials reported information on intervention facilitator/ investigator allegiance we judged them as having unclear risk of bias.

We judged the quality of evidence as low for acceptability in the children and adolescents' population group, indicating that additional data from further studies may have an impact on our confidence in the estimate of effect. For all of the other evaluated outcomes we judged evidence at endpoint as very low quality, meaning that there is very little confidence in the effect estimate, and that the true effect is likely to be substantially different from the estimate of effect (Balshem 2011).

Potential biases in the review process

Studies of populations in humanitarian settings in LMICs may consider a wide range of outcomes. These measures may not undergo the conceptual scrutiny that should precede translation and testing (Johnson 2006), and measures may not be translated into the first or fluent language of research participants and tested before use (Vara 2012).

The studies included in this review did not report presence or absence of a mental health condition based on a psychiatric diagnostic interview at study entry. For this reason, we could not check whether there is a larger proportion of people who remained without a diagnosis at study endpoint in the intervention in comparison to control condition. Instead, all studies were designed to establish whether interventions could decrease symptoms.

There was low risk of publication bias, as we conducted a comprehensive search of published and unpublished studies without any language restrictions. Nevertheless, there is a chance some trials were missed during the search including unpublished studies, particularly those with negative results; as well as some studies in non-English languages. We did not construct a funnel plot to assess publication bias due to the small number of studies (Sterne 2011).

Panter-Brick 2018 and James 2020 reported data unsuitable for meta-analysis on symptomatologies, but contributed to the meta-analysis on the acceptability outcome. We tried to contact the studies' principal investigators, without success.

Agreements and disagreements with other studies or reviews

To our knowledge, this is the first review focusing on the specific issue of prevention interventions to lower the incidence of mental disorders in people living in LMIC affected by humanitarian crises.

As in other reviews on prevention, our primary outcome focused on variation of rates of mental disorder incidence (either by having as a reference changes in diagnosis rate or a proxy of it based on cut-off scores). Our secondary outcomes focused on prevention

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through a proxy of symptom reduction associated with prevention interventions. Given the lack of studies to inform the primary outcome of this review, findings of this review cannot confirm those of Cochrane Reviews that found good evidence for the effectiveness of prevention interventions for reducing incidence of PTSD either for children and adolescents (Gillies 2016) and adults (Roberts 2019) exposed to trauma, and in the prevention of adverse consequences of child sexual abuse (MacDonald 2012). Another meta-analysis claimed that psychological interventions within one month following trauma should deliver psychoeducation, coping skills and exposure (Kramer 2011). However, trials included in these systematic reviews were conducted both in high-income countries (HIC) and LMIC and no subgroup analyses were conducted to test for difference in the impact of interventions in these two different settings.

While the present review provides little convincing evidence of the effects on depressive outcomes among children, adolescents and adults, the broader literature provides evidence of the efficacy of prevention interventions for depressive disorder in adults, measured as impact on depression diagnosis or on a proxy based on cut-off scores at medium-term follow-up (Cuijpers 2008; van Zoonen 2014). However, as for the aforementioned example of PTSD, the prevention trials included in the meta-analytic reviews were not conducted in LMIC humanitarian settings. This fact cast doubts on how such indirect results could be compared with the findings of the present review. Furthermore, the scarcity of studies included in this review makes plausible that random error has played an important role in distorting results, and that a more thorough picture of the evidence profile will become clearer with future studies. Apparent lack of effect shown for prevention interventions on symptoms may be due to lack of data. Aside from the key issue of the paucity of information for LMIC contexts, a recent review of trials conducted in HIC found that school-based prevention programmes can have some beneficial effect not only on depressive but also on anxiety symptoms when compared to a control condition (Werner-Seidler 2017).

AUTHORS' CONCLUSIONS

Implications for practice

To date there is not enough evidence to assess the potential efficacy of psychological and social prevention interventions in LMICs affected by humanitarian crises.

There is lack of definitive evidence in favour of psychological and social prevention interventions in decreasing sub-threshold depressive and anxiety symptoms in adults up to three months post intervention. Only one RCT provided data on these outcomes and the quality of evidence was very low. The evidence on the slight improvement in functional impairment observed in children and adolescents must be considered with caution: only two RCTs provided data for the analysis and the quality of evidence we judged to be very low. No data were available for somatic symptom and related disorders. We found no information on mental-health-related disability and quality of life.

In conclusion, there is no direct evidence on prevention interventions (i.e. interventions deployed within RCTs primarily aimed at measuring changes in incidence of disorders), and evidence for changes in symptomatology for both the juvenile and the adult population is too scant to allow any clear practice and policy implications.

Implications for research

To date there is lack of studies on prevention interventions providing data on the proportion of individuals with a diagnosis of PTSD, anxiety, depression, or somatic symptom and related disorders at study endpoint, and current evidence shows that acceptability may be similar for participants enrolled in the psychological and social intervention groups and for those enrolled in control group. More evidence is therefore needed to evaluate the effectiveness of prevention psychological and social interventions both in the short and in the longer term on the incidence of mental disorders. Future research should aim to understand the efficacy of psychosocial preventative interventions in decreasing the occurrence of new disorders in populations assessed as currently not meeting diagnostic criteria for mental disorders. Moreover, the prevention field would benefit from studies that specifically measure the mechanisms through which prevention is theorized to occur (i.e. mechanisms of change). Although it is likely that the benefit-risk ratio among desirable and undesirable effects of psychological and social interventions would be in favour of the benefits, we acknowledge that evidence on adverse events is lacking. Our observation is in line with Cusack 2016, who pointed out that few studies explicitly report on side effects and adverse effects of PTSD psychotherapy, and with the American Psychological Association 2017 guidelines that call for more research to be conducted on the side effects of psychotherapy.

The finding, based on low-quality evidence from one trial that psychological counselling may improve depressive and anxiety symptoms in adults (Markkula 2019), and low quality evidence that a "classroom-based intervention" may improve functional impairment in children and adolescents (Jordans 2010; Tol 2012), should encourage the design of prevention trials in the future. In addition, an individual participant data meta-analysis of 11 RCTs evaluating focused psychosocial interventions for treatment of children and adolescents in LMIC humanitarian settings, many of which describe overlapping prevention aims, showed encouraging results both for decreasing PTSD symptoms, reducing functional impairment and increasing strengths (coping, hope, social support) (Purgato 2018a). The latter especially is encouraging with regard to the aim of strengthening resilience and reducing incidence of disorders. All meta-analyses could benefit from trialists making individual participant data available for individual participant data meta-analysis.

This review identified a large gap between what it is known and what still needs to be addressed. A number of important research questions remain. Below we list some recommendations for researchers that could be of help in the designing and conducting of future trials.

Trialists could consider:

- designing future RCTs focusing on prevention outcome, namely changes in the incidence of disorders;
- including more rigorous local validation of outcome instruments to evaluate outcomes, and agreeing on pre-planned sets of standard instruments for specific outcomes and disorders to facilitate pooling and comparisons;

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- Including considerations on contextual factors and their impact on mental health such as, for example, time since trauma exposure, the types and amount of potentially traumatic events experienced, and the type of humanitarian crisis (Purgato 2018a; Purgato 2020). This set of information will help an in-depth understanding of how, when, and for whom psychological or social interventions could be effective in the aftermath of catastrophic natural or man-made events;
- including assessments of potential adverse effects or unintended consequences of the psychological and social interventions;
- considering the importance of stronger partnerships between programme implementers (LMICs governments, international non-governmental organizations (INGOs) and multilateral agencies), and researchers, to enhance scientific rigor;
- including economic analysis to inform policy makers and health planning.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

James 2020

Study characteristics	
Methods	**Study design:** randomized controlled trial **Study grouping:** parallel group.
Participants	**Inclusion criteria:** interviewers approached every fifth dwelling in the order encountered when walking through the community, starting from the side of the community most affected by flooding in past seasons. At each household, researchers used a recruitment script to assess interest and eligibility (age 18 to 65; household decision-maker; availability to attend 3-day intervention training). There were no specific screen out or in criteria, assuming the community member was able to give consent. **Weeks of follow-up:** 12 **Intervention sample:** 240 **Control sample:** 240 **Type of humanitarian crisis:** natural disaster

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James 2020 *(Continued)*

	Phase of humanitarian crisis: during the acute crisis (mortality is still higher than it was before the crisis). The study was conducted between July 2014 and April 2015 **Main type of traumatic event:** compounded stressors **Presence of psychological comorbidities:** no **Age range:** 18 to 65 years **Gender:** 239/480 (49.8%) female; 241/480 (50.2%) male
Interventions	**Type of psychosocial intervention:** the mental health integrated disaster preparedness intervention utilizes an experiential approach, including facilitated discussion, space for sharing personal experiences and exchange of peer-support, establishing safety and practising coping skills targeting disaster-related distress, and hands-on training in disaster preparedness and response techniques for use by participants in their own lives and to support other community members. **Level:** group level **Delivered by:** para-professionals: two trained Haitian lay mental health workers **Format of therapy:** face to face **Number of sessions (total):** 3 **Type of control:** waiting list
Outcomes	PTSD symptoms • **Outcome type**: continuous outcome • **Scale**: MPSS Symptom Scale Depression symptoms • **Outcome type**: continuous outcome • **Scale**: ZLDSI Symptom Scale Anxiety symptoms • **Outcome type**: continuous outcome • **Scale**: BAI symptom scale Dropout • **Outcome type**: dichotomous outcome Functional impairment • **Outcome type**: continuous outcome
Identification	**Sponsorship source:** not reported **Country:** Haiti **Setting:** rural communities in Port-au-Prince **First author name:** Leah Emily James **Institution:** University of Colorado **Email:** leah.james@colorado.edu **Address:** Institute of Behavioral Science, Natural Hazards Center, University of Colorado-Boulder, 483 UCB, Boulder, CO 80309-0483, USA.

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James 2020 *(Continued)*

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Quote: "Randomization occurred using a random number generator applied to participant lists"
Allocation concealment (selection bias)	Unclear risk	Judgement comment: allocation concealment procedures were not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding procedures were not reported; however it is likely that participants were aware of their treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: Quote: "Due to staffing constraints, interviewers were not blind to condition, as team members served as both interviewers and intervention facilitators (though participants were not typically interviewed by the same staff person who facilitated their group's intervention)."
Incomplete outcome data (attrition bias) All outcomes	High risk	Judgement comment: high attrition rates: 78/240 (32.5%) dropouts in the intervention group and 94/240 (39%) dropouts in the wait-list group.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: all measures described in the Methods section of the article were also reported in the results. No trial protocol available.
Therapist qualification	Unclear risk	No information provided on therapist qualification and background.
Treatment fidelity	Unclear risk	No information on how fidelity to treatment was recorded/checked.
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Unclear risk	Judgement comment: no information provided about other possible source of bias.

Jordans 2010

Study characteristics

Methods	**Study design:** cluster randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** school-going children, aged 11 to 14 years, living in 4 districts in southwestern Nepal (Banke, Dang, Bardia, Kailali) **Exclusion criteria:** (a) schools in Village Development Committees (VDC; the smallest administrative unit in Nepal) where CBI had already been implemented and schools in adjoining VDCs to avoid contamination; (b) schools in parts of the district with large geographic or ethnic differences compared to the majority of the district to increase group homogeneity within districts **Weeks of follow-up:** 4

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Jordans 2010 *(Continued)*

	Intervention sample: 164 **Control sample:** 161 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** after the acute crisis (mortality is similar or less to what it was before the crisis). The study was conducted between December 2006 and January 2007 **Main type of traumatic event:** compounded stressors **Presence of psychological comorbidities:** no **Age range:** 11 to 14 years **Gender:** 158/325 (48%) female; 167/325 (52%) male
Interventions	**Type of psychosocial intervention:** the Classroom-Based Intervention (CBI) is a 5-week,15-session (approximately 60-minute sessions) group intervention. CBI is an eclectic intervention based on concepts from creative-expressive and experiential therapy, cooperative play and cognitive behavioral therapy. CBI combines specific techniques such as psycho-education, sociodrama,movement/dance, group cohesion activities, stress inoculation techniques and trauma-processing through (voluntary) narrative exposure through drawings **Level:** group level **Delivered by:** para-professionals: a gender-balanced group of interventionists was selected, based on previous experience and affinity to work with children, from targeted communities and trained during a 15-day skills-oriented course. An experienced counsellor provided regular supervision **Format of therapy:** face to face **Number of sessions (total):** 15 **Type of control:** waiting list
Outcomes	PTSD symptoms • **Outcome type**: continuous outcome • **Scale**: Child PTSD Symptom Scale Depression symptoms • **Outcome type**: continuous outcome • **Scale**: Depression Self-Rating Scale Anxiety symptoms • **Outcome type**: continuous outcome • **Scale**: SCARED = Screen for Child Anxiety Related Emotional Disorder Dropout • **Outcome type**: dichotomous outcome Functional impairment • **Outcome type**: continuous outcome • **Scale:** Children's Function Impairment
Identification	**Sponsorship source:** not reported **Country:** 4 districts in southwestern Nepal (Banke, Dang, Bardia, Kailali)

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Jordans 2010 *(Continued)*

Setting: school-based psychosocial intervention in conflict-affected, rural Nepal

First author name: Mark Jordans

Institution: Vrije Universiteit; Department of Research & Development

Email: mjordans@healthnettpo.org

Address: Tolstraat 127, 1074 VJ, Amsterdam, the Netherlands

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Quote: "first, districts were randomly allocated to either CBI or control condition. Second, two schools per district were randomly selected from a list of all eligible schools (...). Third, children were randomly selected from a list of children aged 11-14 years in the school. The randomization was done, without imposing a randomization constraint, by use of computer generated random numbers (in SPSS) by the research team in Amsterdam".
Allocation concealment (selection bias)	Unclear risk	Judgement comment: allocation concealment procedures were not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding procedures were not reported; however it is likely that participants were aware of their treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: Quote: "it was not possible to blind assessors to treatment status as they needed to visit schools to conduct the interviews".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: dropouts were reported together with reasons (2/164 dropouts in the intervention group and 0/161 dropouts in the wait-list group).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: all measures described in the methods section of the article were also reported in the results. Accounting for clustering. quote: "We calculated Intra-Cluster Correlations to estimate the amount of nested variance of the data. To correct for multiple comparisons we considered p-values of <0.01 as statistically significant. We used linear mixed (effects) methods, including fixed and random effects to analyze impact of the intervention when adjusted for nested variances. We compared intervention and control (waitlist) groups with different linear models to adjust for standard errors for clustering at school and district levels". No trial protocol available.
Therapist qualification	Unclear risk	No information provided on therapist qualification and background.
Treatment fidelity	Unclear risk	No information on how fidelity to treatment was recorded/checked.
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Unclear risk	Judgement comment: no information provided about other possible source of bias.

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Jordans 2010 *(Continued)*

	Cluster-RCT ROB extension 1. Recruitment bias; the recruited population belonged to the same catchment area. Low risk of bias 2. Baseline imbalance; cluster balance was maintained after randomization. Low risk of bias 3. Loss of clusters; none of the clusters were lost. Low risk of bias 4. Incorrect analysis; the analyses were correctly conducted and reported. Low risk of bias

Markkula 2019

Study characteristics	
Methods	**Study design:** randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** (1) age 16 years or older, (2) scoring 6 or above on the General Health Questionnaire, (3) being able to fluently communicate in Nepali, (4) residence in Dang for the subsequent 10 months **Exclusion criteria:** persons with severe illnesses or conditions requiring urgent attention, such as psychotic symptoms or suicidality **Weeks of follow-up:** 4 **Intervention sample:** 141 **Control sample:** 146 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** after the acute crisis (mortality is similar or less to what it was before the crisis). The study was conducted between May 2016 and October 2017 **Main type of traumatic event:** bereavement **Presence of psychological comorbidities:** unclear **Age range:** 16 years and older **Gender:** 9% male 91% female
Interventions	**Type of psychosocial intervention:** psychological counselling. The intervention focuses on problem-solving, emotional support and coping strategies, and skills **Level:** individual level **Delivered by:** para-professional **Format of therapy:** face to face **Number of sessions (total):** 5 **Type of control:** waiting list
Outcomes	Depression symptoms • **Outcome type**: continuous outcome • **Scale**: Beck Depression Inventory

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Markkula 2019 *(Continued)*

	Anxiety symptoms • **Outcome type**: continuous outcome • **Scale**: Beck Anxiety inventory Dropout • **Outcome type**: dichotomous outcome
Identification	**Sponsorship source:** this study was carried out with funding provided by the Ministry for Foreign Affairs of Finland **Country:** Nepal **Setting:** Dang district, Western Nepal **Authors name:** N Markkula **Institution:** Helsinki University **Email:** bhushan@cvict.org.np **Address:** Helsinki Hospital, Helsinki, Finland
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Quote: "Participants were randomized to either EUC or the psychosocial counselling intervention (PSY) using simple randomization and an online randomization chart on 1:1 basis".
Allocation concealment (selection bias)	Unclear risk	Judgement comment: allocation concealment procedures were not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: Quote: "Blinding of participants and research counsellors was not possible due to the nature of the intervention".
Blinding of outcome assessment (detection bias) All outcomes	High risk	Judgement comment: Quote: "Blinding of participants and research counsellors was not possible due to the nature of the intervention".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: low attrition rate according to figure 1. Dropouts were reported together with reasons (16/141 dropouts in the intervention group and 12/146 dropouts in the wait-list group).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: all the data are correctly reported. No trial protocol available.
Therapist qualification	Low risk	Judgement comment: Quote: "The counsellors delivering the intervention were lay persons with a minimum of 12 years of education completed who had received a 6-month training in psychosocial counselling provided by Centre for Victims of Torture."
Treatment fidelity	Unclear risk	No information on how fidelity to treatment was recorded/checked.

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Markkula 2019 *(Continued)*

Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Unclear risk	Judgement comment: no information provided about other possible source of bias.

O'Callaghan 2014

Study characteristics	
Methods	**Study design:** randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** children ages 7 to 18 and their caregivers living in a war-affected community facing current risks of attack/abduction by armed groups **Weeks of follow-up:** 12 **Intervention sample:** 79 **Control sample:** 80 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** during the acute crisis (mortality is still higher than it was before the crisis) **Main type of traumatic event:** bereavement **Presence of psychological comorbidities:** unclear **Age range:** 7 to 18 years **Gender:** 55% male 45% female
Interventions	**Type of psychosocial intervention:** a psychosocial intervention based on 3 components: (1) "ChuoChaMaisha", a youth life skills leadership programme developed and piloted in Tanzania; (2) Mobile Cinema clips: narrative, fictional films, produced and created in the local language to address stigma and discrimination and model how young people, parents and the village community could welcome formerly abducted children back into their communities and (3) Relaxation Technique scripts used in Trauma-Focused CBT **Level:** group level **Delivered by:** para-professional **Format of therapy:** face to face **Number of sessions (total):** 8 **Type of control:** waiting list
Outcomes	PTSD **Outcome type**: continuous outcome • **Scale**: CRIES • **Data value**: Endpoint Depression/anxiety symptoms

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O'Callaghan 2014 *(Continued)*

- **Outcome type**: continuous outcome
- **Scale**: AYPA depression/anxiety
- **Data value**: endpoint

Dropout

- **Outcome type**: dichotomous outcome

Identification	**Sponsorship source:** this project was funded by a donor who wishes to remain anonymous **Country:** Democratic Republic of Congo **Setting:** rural communities in the Haut-Uele Province of northern Democratic Republic of Congo **Authors name:** Paul O'Callaghan **Institution:** School of Psychology, Queen's University **Email:** pocallaghan02@qub.ac.uk **Address:** Belfast, Northern Ireland, UK
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Quote: "each member (...) was randomly assigned to either the treatment or the control group using a computer generated random sequence (www.random.org). This sequence was supplied by one of the authors off site. The lead author then allocated participants using the randomized sequence".
Allocation concealment (selection bias)	Low risk	Judgement comment: Quote: "Selection bias was reduced by ensuring treatment allocation was concealed from those responsible for participant enrolment and by ensuring the person responsible for assigning participants met none of the participants prior to the group allocation".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding procedures were not reported. Anyway it is likely that participants were not blinded to treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: Quote: "data were collected by the same blinded outcome assessors (...). Blinding involved with holding the randomization sequence form the assessors, having no overlap between the assessors and the intervention facilitation team, having no contact between assessors and participants during the intervention and requesting that the assessors do not ask participants which group they were in during the post-intervention and follow-up assessment".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: low attrition rate according to figure 1. Dropouts were reported together with reasons (3/79 dropouts in the intervention group and 3/80 dropouts in the wait-list group).
Selective reporting (reporting bias)	High risk	Judgement comment: data for control group are missing for follow-up. No trial protocol available.
Therapist qualification	Unclear risk	Judgement comment: Quote: "Three male and three female local lay facilitators living in Dungu and working for SAIPED, a Dungu-based humanitarian

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O'Callaghan 2014 *(Continued)*

		NGO, delivered the intervention in the church in Kiliwa in the morning and in the church in Li-May in the afternoon every second day."
Treatment fidelity	Low risk	Judgement comment: Quote: "To enhance treatment fidelity, facilitators were given a copy of the manualised intervention in French and met for three hours with the lead researcher the day before delivering each module in order to review the previous module taught, prepare for the subsequent module and discuss any suggested cultural changes to the module (e.g., using culturally familiar songs and games as warm-up activities etc.)".
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Unclear risk	Judgement comment: no information provided about other possible source of bias.

Panter-Brick 2018

Study characteristics	
Methods	**Study design:** randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** refugee and host-community youth. Eligibility is based on vulnerability and need, determined by the staff during screening interviews to assess age, self-reported mental health difficulties and poor access to local services **Exclusion criteria:** not being a refugee; not having self-reported mental health difficulties and poor access to local services **Weeks of follow-up:** 10 weeks **Intervention sample:** 292 **Control sample:** 311 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** during the acute crisis (mortality is still higher than it was before the crisis) **Main type of traumatic event:** displacement **Presence of psychological comorbidities:** unclear **Age range:** 12 to 18 years **Gender:** 55% male 45% female
Interventions	**Type of psychosocial intervention:** the Advancing Adolescents (Arabic: Nubader) programme is a structured, 8-week psychosocial intervention for adolescents in humanitarian crises, based on profound stress attunement processes. It features three elements that are widely viewed as important to support youth adjustment in contexts of complex emergencies: (a) safety: establishment of a 'safe space' within the community as a base for activities and site of protection; (b) support: facilitation of social support and self-expression; and (c) structured, group-based activities **Level:** group level **Delivered by:** para-professional

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Panter-Brick 2018 *(Continued)*

	Format of therapy: face to face **Number of sessions (total):** 16 over 8 weeks **Type of control:** waiting list
Outcomes	PTSD • **Outcome type**: continuous outcome • **Scale**: Child Revised Impact of Events Scale (CRIES) • **Data value**: endpoint Dropout • **Outcome type**: dichotomous outcome
Identification	**Sponsorship source:** this research was funded by Elrha's Research for Health in Humanitarian Crises (R2HC) Programme (elrha.org/r2hc), which aims to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises **Country:** Syria and Jordan **Setting:** Youth centres, designed as 'Adolescent Friendly Spaces' in partnership with local community-based organizations engaged in building civic society or development training, open 9 am to 9 pm. In northern Jordan, the programme was implemented in the urban centres of Irbid, Jarash, Mafraq, Ajloun and Zarqa governorates **Authors name:** Catherine Panter-Brick **Institution:** Yale University **Email:** catherine.panter-brick@yale.edu **Address:** 10 Sachem Street, New Haven, CT 06511, USA
Notes	Aside from dropouts, the study authors did not report outcome data in a usable way. We wrote twice to the first study author to have correct data, without success

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: unclear strategy of sequence generation. Quote: "Families consented to a coin-toss allocation (ratio 1:1) of lollipop colours to study arms, with each youth selecting one of two coloured lollipops from an opaque cloth bag. Once baseline assessments were complete, one author (RD) completed the coin toss, informing families of an immediate or delayed programme start-date".
Allocation concealment (selection bias)	Unclear risk	Judgement comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Judgement comment: this is an open-label trial.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: assessors were blinded to treatment allocation.

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Panter-Brick 2018 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: nearly 50% of both intervention arm and control group patients were lost to follow-up at study end-point. Anyway outcome data are missing in both intervention groups, and reasons for these are both reported and balanced across groups, then important bias would not be expected.
Selective reporting (reporting bias)	Unclear risk	Judgement comment: all measures described in the methods section of the article were also reported in the results. No trial protocol available.
Therapist qualification	Unclear risk	Judgement comment: interventions were delivered by trained lay counsellors.
Treatment fidelity	Low risk	Judgement comment: Quote: "Training, implementation, and assessments (e.g. session plans, delivery of technical skills, goal-setting for youth in development plans, attendance) are undertaken by the Mercy Corps monitoring and evaluation team. Training guidelines reinforce an understanding of key objectives, quality assurance and quality improvement. A lay coordinator monitors and supports the project plans during their development and implementation. Weekly meetings are scheduled to review progress, share experiences and address issues arising. Refresher training courses are offered to lay coaches before each new cycle of implementation."
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Unclear risk	Judgement comment: no other sources of bias can be detected.

Richards 2014

Study characteristics	
Methods	**Study design:** randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** adolescents aged 11 to 14 years in Gulu municipality. All pupils enrolled in sixth grade at schools could take part **Intervention sample:** 74 **Control sample:** 71 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** after the acute crisis (mortality is similar or less to what it was before the crisis) **Main type of traumatic event:** displacement and abduction **Age range:** 11 to 14 years **Gender:** boys 47% intervention group and 100% control
Interventions	**Type of psychosocial intervention:** a sport-for-development programme **Level:** group level **Delivered by:** paraprofessional. The intervention was delivered by six paid staff who selected and trained 32 volunteer adults from the local community to become football and peace-building coaches **Format of therapy:** face to face

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Richards 2014 *(Continued)*

	Number of sessions (total): varies (each coach was provided with equipment to conduct at least one 1.5 hour training session per week. Each weekend the GMKL participants took part in a 40-minute game of football) **Type of control:** waiting list
Outcomes	**Primary outcome in evaluation:** physical fitness Depression symptoms • **Outcome type**: continuous outcome • **Scale**: Acholi Psychosocial Assessment Instrument (APAI) Anxiety symptoms • **Outcome type**: continuous outcome • **Scale**: Acholi Psychosocial Assessment Instrument (APAI) Dropout • **Outcome type**: dichotomous outcome
Identification	**Sponsorship source:** this study was funded by the DPhil scholarship at the University of Oxford of the chief investigator and the sponsors of the sport-for-development organisations that implemented the intervention (OA Projects, The Kids League). The funders had no role in study design, data collection, data analysis, data interpretation and/or writing of the manuscript. All researchers had access to all of the data **Country:** Gulu, Uganda **Setting:** schools **First authors name:** Justin Richards **Institution:** University of Oxford, Nuffield Department of Population Health, British Heart Foundation Health Promotion Research Group **Email:** justin.a.richards@gmail.com **Address:** Rosemary Rue Building, Old Road Campus, Roosevelt Drive, Headington, Oxford OX3 7LF, UK
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Judgement comment: for girls the intervention and control group were unbalanced, whereas for boys it was balanced.
Allocation concealment (selection bias)	Low risk	Quote: "To avoid selection bias the identity and performance of those who had been measured at baseline was concealed until after group allocation was complete."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: not possible.

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Richards 2014 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: Quote: "all measurements at baseline and follow up were conducted by an independent local research team (...) blinded to group allocation".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: dropouts were reported according to each outcome (for mental health outcomes: 1/74 dropouts in the intervention group and 1/71 dropouts in the wait-list group).
Selective reporting (reporting bias)	Unclear risk	Judgement comment: all measures described in the methods section of the article were also reported in the results. No trial protocol available.
Therapist qualification	High risk	Judgement comment: Quote: "The intervention was delivered by six paid staff who selected and trained 32 volunteer adults from the local community to become football and peace-building coaches".
Treatment fidelity	Unclear risk	No information on how fidelity to treatment was recorded/checked.
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Low risk	Quote: "(OA Projects, The Kids League). The funders had no role in study design, data collection, data analysis, data interpretation and/or writing of the manuscript. All researchers had access to all of the data."

Tol 2012

Study characteristics	
Methods	**Study design:** cluster randomized controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria:** children aged 9 to 12 with the existence of risk factors (i.e. reporting exposure to war-related events, distress during such exposure, current psychological symptoms, and affected school functioning) and with the absence of protective factors (i.e. reporting a lack of social support and coping capacity) **Weeks of follow-up:** 12 **Intervention sample:** 199 **Control sample:** 200 **Type of humanitarian crisis:** war/armed conflict **Phase of humanitarian crisis:** after the acute crisis (mortality is similar or less to what it was before the crisis) **Main type of traumatic event:** bereavement **Age range:** 9 to 12 **Gender:** 61% male 39% female
Interventions	**Type of psychosocial intervention:** school-based group intervention **Level:** group level **Delivered by:** paraprofessionals

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Tol 2012 *(Continued)*

	Format of therapy: face to face **Number of sessions (total):** 15 **Type of control:** waiting list
Outcomes	PTSD symptoms **Outcome type**: continuous outcome; • **Scale**: Child PTSD Symptom Scale (CPSS) • **Data value**: 3 months Depressive symptoms • **Outcome type**: continuous outcome • **Scale**: Depression Self-Rating Scale (DSRS) • **Data value**: 3 months Anxiety symptoms • **Outcome type**: continuous outcome; • **Scale**: Screen Anxiety Related Emotional Disorders (SCARED-5) • **Data value**: 3 months Functional impairment • **Outcome type**: continuous outcome • **Scale**: - • **Data value**: 3 months Dropout • **Outcome type**: dichotomous outcome
Identification	**Sponsorship source:** PLAN Netherlands **Country:** Sri Lanka **Setting:** schools **First authors name:** Wietse A Tol **Institution:** HealthNet TPO, Department of Research & Development **Email:** wtol@healthnettpo.org **Address:** Tolstraat 127, 1074 VJ, Amsterdam, the Netherlands
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement comment: Quote: "We used a two-step randomization procedure. First, within district divisions, we randomly allocated each division to either the intervention or waitlist control condition. Second, we randomly selected schools for inclusion in the study. All schools on the government-provided list were eligible".

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Tol 2012 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Judgement comment: method of concealment was not described. All clusters were randomized at once. Baseline imbalance: tests to compare study conditions at baseline on demographic characteristics and scores on the outcomes measures were conducted and no statistically significant differences between study conditions were found.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Judgement comment: blinding procedures were not reported. Anyway it is likely that participants were not blinded to treatment allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Judgement comment: "All instruments were interviewadministered by a group of assessors not involved in service delivery, in a private environment at schools (...). Assessors were not informed about which schools received intervention".
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: missing data on outcome measures were reported.
Selective reporting (reporting bias)	High risk	Judgement comment: no data available for the assessment carried out 1 week after the intervention. Only data at 3 months follow-up were reported. Accounting for clustering. Quote: "To account for intracluster correlation, we multiplied 35 by 1+ (m-1)ρ, with m = 30 (average cluster size), ρ = 0.1 (intracluster correlation), and a power of 95%, resulting in an appropriate sample size of 137. To compensate attrition, we aimed at oversampling to reach approximately 180 children per study condition. We estimated that at least one group of 15 children per school woul meet inclusion criteria after screening, and therefore decided to sample 12 schools per study condition". No trial protocol available.
Therapist qualification	Unclear risk	Judgement comment: Quote: "Locally identified non-specialized personnel trained and supervised in implementing the intervention for one year prior to the study. Interventionists had at least a high school diploma and were selected for their affinity and capacity to work with children as demonstrated in role-play sand interviews."
Treatment fidelity	Unclear risk	No information on how fidelity to treatment was recorded/checked.
Therapist/investigator allegiance	Unclear risk	No information provided.
Other bias	Low risk	Judgement comment: none detected. Quote: "The funder had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript."

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Akiyama 2018	Wrong design.
Ali 2019	Wrong design.

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Study	Reason for exclusion
Alsmadi 2018	Wrong comparator.
Annan 2017	Wrong setting.
Anonymous 2013	Wrong patient population.
Bangirana 2013	Wrong patient population.
Başoğlu 2005	Wrong patient population.
Berger 2018	Wrong intervention.
Betancourt 2014a	Wrong patient population.
Betancourt 2020	Wrong setting.
Bolton 2007	Wrong patient population.
Bonilla-Escobar 2018	Wrong patient population.
Bruno 2019	Wrong design.
Bryant 2017	Wrong patient population.
Chibanda 2016	Wrong patient population.
Crombach 2018	Wrong patient population.
Dawson 2018	Wrong patient population.
Dhital 2019	Wrong intervention.
DRKS00016154	Wrong setting.
Ducasse 2018	Wrong setting.
El Khani 2018	Wrong comparator.
Foka 2020	Wrong design.
Gordon 2008	Wrong patient population.
Gormez 2017	Wrong comparator.
Green 2018	Wrong patient population.
Gureje 2019	Wrong setting.
Hall 1997	Wrong study design.
Hirani 2018	Wrong intervention.
Ho 2017	Wrong study design.
Khan 2017	Wrong patient population.

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Study	Reason for exclusion
Kim 2017	Wrong setting.
Knefel 2020	Wrong setting.
Kubitary 2018	Wrong design.
Latif 2017	Wrong patient population.
Li 2005	Wrong patient population.
Mahmooth 2018	Wrong patient population.
Mohammadzadeh 2019	Wrong setting.
NCT01822366	Wrong patient population.
NCT01856673	Wrong study design.
NCT02145429	Wrong setting.
NCT03127982	Wrong patient population.
NCT03470779	Wrong patient population.
NCT03515564	Wrong setting.
NCT03951909	Wrong setting.
NCT04081441	Wrong intervention.
Ordonez 2019	Wrong setting.
Peltonen 2019	Wrong setting.
Pillay 2019	Wrong design.
Punamäki 2014	Secondary publication of Qouta 2012.
Qouta 2012	Wrong patient population.
Rahman 2016a	Wrong patient population.
Rahman 2016b	Wrong patient population.
Ramaswamy 2018	Wrong study design.
Rockers 2018	Wrong intervention.
Sang 2018	Wrong setting.
Sangraula 2018	Wrong study design.
Shaw 2018	Wrong setting.
Sijbrandij 2018	Wrong study design.

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Study	Reason for exclusion
SLCTR/2018/008	Wrong intervention.
Tol 2008	Wrong patient population.
Tol 2014	Wrong patient population.
Tol 2018	Wrong patient population.
Tol 2020	Wrong patient population.
Unterhitzenberger 2014	Wrong patient population.
Wang 2017	Wrong patient population.
Yurtsever 2018	Wrong patient population.

Characteristics of studies awaiting classification *[ordered by study ID]*

ACTRN12618001917224

Methods	Randomized controlled trial
Participants	Adolescent Syrian refugees in Jordan
Interventions	Group psychological help
Outcomes	Unclear
Notes	who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12618001917224

ACTRN12619000168156

Methods	Randomized controlled trial
Participants	Syrian refugees in Jordan
Interventions	Group psychological help
Outcomes	Unclear
Notes	who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000168156

ACTRN12619000340134

Methods	Randomized controlled trial
Participants	Syrian refugees in Jordan
Interventions	Group psychological help

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ACTRN12619000340134 *(Continued)*

Outcomes	Unclear
Notes	who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000340134

ACTRN12619000341123

Methods	Randomized controlled trial
Participants	Adolescent Syrian refugees in Jordan
Interventions	Group psychological help
Outcomes	Unclear
Notes	who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000341123

LBCTR2019040213

Methods	Randomized controlled trial
Participants	8- to 17-year-old Syrian refugee children
Interventions	Phone-delivered psychological intervention (t-CETA)
Outcomes	Unclear
Notes	who.int/trialsearch/Trial2.aspx?TrialID=LBCTR2019040213

NCT03912077

Methods	Randomized controlled trial
Participants	Syrian refugee women exposed to psychological trauma
Interventions	Psychosocial interventions
Outcomes	Unclear
Notes	clinicaltrials.gov/show/nct03912077

Characteristics of ongoing studies *[ordered by study ID]*

NCT01729325

Study name	Prevention of post-traumatic stress disorder in soldiers
Methods	Randomized controlled trial

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NCT01729325 *(Continued)*

Participants	118 Burundian male soldiers exposed to traumatic experiences
Interventions	Preventive Narrative Exposure Therapy
Outcomes	Primary outcome measures 1) Severity of traumatic symptoms measured via the Post-traumatic Stress Disorder Scale-Interview (PSS-I) - Time frame: 15 months; 2) Extent of appetitive aggression via the Appetitive Aggressions Scale (AAS) - Time frame: 15 months; Secondary outcome measures 1) Severity of depressive symptoms measured via the Patient Health Questionnaire-9 (PHQ-9) - Time frame: 15 months; 2) Strength of suicidal ideation measured via the MINI - Time frame: 15 months; 3) Physical health complains - Time frame: 15 months.
Starting date	20 November 2012
Contact information	Anselm Crombach, University of Konstanz
Notes	Recruitment status: completed, but no results posted

NCT03058302

Study name	Study of effectiveness and implementation of a mental health intervention with conflict-affected communities in Ukraine
Methods	Randomized controlled trial
Participants	Ukrainian adults (age 18 or older) who are either Internally Displaced Persons (IDPs) or military veterans of the conflict in East Ukraine, and their adult family members.
Interventions	CETA (Common Elements Treatment Approach).
Outcomes	Primary outcome measures 1) Change in mental health symptom levels from baseline (monthly for all groups) - Time frame: Monthly for 6 months; 2) Change in Impaired functioning levels (monthly for all groups) - Time frame: 6 months post-baseline; Secondary outcome measures 1) Change in mental health symptom levels from baseline (Monthly for all groups) - Time frame: Monthly for 6 months.
Starting date	First posted: 20 February 2017.
Contact information	Johns Hopkins Bloomberg School of Public Health.
Notes	Recruitment status: active, not recruiting.

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NCT03075475

Study name	Effectiveness study of a treatment to improve the mental health of children and adolescents
Methods	Randomized controlled trial.
Participants	Children 8 to 17 years of age.
Interventions	CETA (Common Elements Treatment Approach).
Outcomes	Primary outcome measures 1) Change in child mental health scores from composite measure - Time frame: the time between pre- and post-test intervention assessment will be 8 to 12 weeks for treatment group (according to the number of CETA sessions) and 10 weeks for wait list participants. Secondary outcome measures 1) Change in child behaviour problem scores - Time frame: the time between pre- and post-test intervention assessment will be 8 to 12 weeks for treatment group (according to the number of CETA sessions) and 10 weeks for wait list participants; 2) Change in child functional impairment - Time frame: the time between pre- and post-test intervention assessment will be 8 to 12 weeks for treatment group (according to the number of CETA sessions) and 10 weeks for wait list participants.
Starting date	9 March 2017
Contact information	Johns Hopkins Bloomberg School of Public Health.
Notes	Recruitment status: completed, but no results posted.

NCT03359486

Study name	Pilot feasibility study of psychosocial support to improve well-being of adults in humanitarian crises in Nepal (PM+).
Methods	Randomized controlled trial
Participants	Nepalese people 18 years and older, affected by the 2015 earthquakes.
Interventions	Group problem management plus (PM+).
Outcomes	Primary outcome measures 1) Depression - Patient Health Questionnaire - Time frame: 1 week post-intervention; Secondary outcome measures 1) Daily functioning - World Health Organization Disability Assessment Scale - Time frame: 1 week post-intervention; 2) General psychological distress - General Health Questionnaire - Time frame: 1 week post-intervention; 3) Posttraumatic Stress Disorder - Posttraumatic Stress Disorder Checklist - Time frame: 1 week post-intervention; 4) Personalized Measure of Distress - Psychological Outcome Profiles - Time frame: 1 week post-intervention;

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NCT03359486 *(Continued)*

	5) Culture-specific general psychological distress - Nepali Psychosocial and Mental Health Problems - Time frame: 1 week post-intervention; 6) Reducing Tension Checklist for Problem Management Plus Skills - Time frame: 1 week post-intervention.
Starting date	2 December 2017.
Contact information	Mark van Ommeren, World Health Organization.
Notes	Recruitment status: completed, but no results posted.

NCT03387007

Study name	Psychosocial support on mental health and hope of adolescents affected by earthquake in Nepal
Methods	Randomized controlled trial
Participants	adolescents 10 years to 17 years
Interventions	Psychosocial support training for school teachers
Outcomes	Primary outcome measures 1) Change from baseline post traumatic stress symptoms at 6 months - Time frame: baseline and 6-month follow-up; 2) Change from baseline depression symptoms at 6 months - Time frame: baseline and 6-month follow-up; 3) Change from baseline hope at 6 months - Time frame: baseline and 6-month follow-up.
Starting date	29 December 2017
Contact information	Rolina Dhital, Tokyo University
Notes	Recruitment status: completed, but no results posted.

NCT03567083

Study name	Implementation of Problem Management Plus (PM+) in adult Syrian refugees in Turkey: Pilot (STRENGTHS)
Methods	Randomized controlled trial
Participants	Adult Syrian refugees in Turkey
Interventions	Problem Management Plus (PM+)
Outcomes	Primary outcome measures 1) Hopkins Symptom Checklist-25 (HSCL-25) - Time frame: change from baseline assessment, at 1-week post-intervention assessment (6 weeks after baseline), and change from post-assessment at 3-month post-intervention assessment (4 to 4.5 months after baseline);

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NCT03567083 *(Continued)*

	Secondary outcome measures 1) PTSD Checklist for DSM-5 (PCL-5) - Time frame: Change from baseline assessment, at 1-week post-intervention assessment (6 weeks after baseline), and change from post intervention assessment at 3-month post-intervention assessment (4 to 4.5 months after baseline); 2) Psychological Outcome Measures (PSYCHLOPS) - Time frame: Change from baseline assessment, at 1-week post-intervention assessment (6 weeks after baseline), and change from post intervention assessment at 3-month post-intervention assessment (4 to 4.5 months after baseline); 3) Client Service Receipt Inventory (CSRI) - Time frame: Change from baseline assessment, at 1-week post-intervention assessment (6 weeks after baseline), and change from post-assessment at 3-month post-intervention assessment (4 to 4.5 months after baseline); 4) Access to health care: own questionnaire - Time frame: Change from baseline assessment, at 1-week post-intervention assessment (6 weeks after baseline), and change from the post-intervention assessment at 3-month post-intervention assessment (4 to 4.5 months after baseline).
Starting date	25 June 2018
Contact information	Zeynep Ceren Acartürk, Istanbul Sehir University
Notes	Recruitment status: recruiting

NCT03960892

Study name	Implementation of Group Problem Management Plus (PM+) in adult Syrian refugees in Turkey: RCT (STRENGTHS) ((STRENGTHS))
Methods	Randomized controlled trial
Participants	Adult Syrian refugees in Turkey
Interventions	Problem Management Plus (PM+)
Outcomes	Primary outcome measures Hopkins Symptom Checklist-25 (HSCL-25) - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), change from post-assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline), and change from at 12 month post intervention assessment Secondary outcome measures 1) PTSD Checklist for DSM-5 (PCL-5) - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), and change from post intervention assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline) and change from at 12 month post intervention assessment; 2) Psychological Outcome Measures (PSYCHLOPS) - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), and change from post intervention assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline) and change from at 12 month post intervention assessment; 3) Client Service Receipt Inventory (CSRI) - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), and change from post-assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline) and change from at 12 month post intervention assessment;

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NCT03960892 *(Continued)*	4) Access to health care: own questionnaire - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), and change from the post-intervention assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline) and change from at 12 month post intervention assessment; 5) Socio-demographic information and disability: WHODAS - Time Frame: Change from baseline assessment, at 1 week post-intervention assessment (6 weeks after baseline), change from post-assessment at 3 month post-intervention assessment (4 to 4.5 months after baseline), and change from at 12 month post intervention assessment.
Starting date	29 December 2018
Contact information	Zeynep Ceren Acartürk, Istanbul Sehir University.
Notes	Recruitment status: enrolling by invitation.

DATA AND ANALYSES

Comparison 1. Psychosocial interventions versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Drop-out: children	5	1372	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.78, 1.10]
1.1.1 Classroom-based intervention versus control	2	465	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.13, 71.07]
1.1.2 Advancing adolescents vs control	1	603	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.79, 1.12]
1.1.3 Psychosocial intervention versus control	1	159	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.27, 1.42]
1.1.4 Sport for development versus control	1	145	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.06, 15.05]
1.2 Dropout: adults	2	767	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.61, 1.50]
1.2.1 Psychosocial counselling versus control	1	287	Risk Ratio (M-H, Random, 95% CI)	1.38 [0.68, 2.81]
1.2.2 Mental health integrated disaster preparedness versus control	1	480	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.65, 1.06]
1.3 PTSD symptoms at endpoint: children	3	590	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.50, 0.18]
1.3.1 Classroom-based intervention versus control	2	432	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.16, 0.22]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.3.2 Psychosocial intervention versus control	1	158	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.72, -0.09]
1.4 PTSD symptoms at 3 months follow-up: children	1	399	Mean Difference (IV, Random, 95% CI)	1.18 [-0.41, 2.77]
1.4.1 Classroom-based intervention versus control	1	399	Mean Difference (IV, Random, 95% CI)	1.18 [-0.41, 2.77]
1.5 Depression at endpoint: children	4	746	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.29, 0.31]
1.5.1 Classroom-based intervention versus control	2	443	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.31, 0.06]
1.5.2 Psychosocial intervention versus control	1	158	Std. Mean Difference (IV, Random, 95% CI)	-0.09 [-0.40, 0.22]
1.5.3 Sport for development versus control	1	145	Std. Mean Difference (IV, Random, 95% CI)	0.46 [0.13, 0.79]
1.6 Depression at endpoint: adults	1	258	Mean Difference (IV, Random, 95% CI)	-7.50 [-9.19, -5.81]
1.6.1 Psychosocial counselling versus control	1	258	Mean Difference (IV, Random, 95% CI)	-7.50 [-9.19, -5.81]
1.7 Depression at 3 months follow-up: children	1	399	Mean Difference (IV, Fixed, 95% CI)	0.22 [-0.64, 1.08]
1.7.1 Classroom-based intervention versus control	1	399	Mean Difference (IV, Fixed, 95% CI)	0.22 [-0.64, 1.08]
1.8 Depression at 3 months follow-up: adults	1	258	Mean Difference (IV, Fixed, 95% CI)	-7.40 [-9.09, -5.71]
1.8.1 Psychosocial counselling versus control	1	258	Mean Difference (IV, Fixed, 95% CI)	-7.40 [-9.09, -5.71]
1.9 Anxiety at endpoint: children	3	632	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.09, 0.31]
1.9.1 Classroom-based intervention versus control	2	487	Std. Mean Difference (IV, Random, 95% CI)	0.02 [-0.16, 0.19]
1.9.2 Sport for development vs control	1	145	Std. Mean Difference (IV, Random, 95% CI)	0.32 [-0.00, 0.65]
1.10 Anxiety at endpoint: adults	1	258	Mean Difference (IV, Random, 95% CI)	-6.10 [-7.57, -4.63]
1.10.1 Psychosocial counselling versus control	1	258	Mean Difference (IV, Random, 95% CI)	-6.10 [-7.57, -4.63]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.11 Anxiety at 3 months follow-up: children	1	399	Mean Difference (IV, Fixed, 95% CI)	-0.28 [-0.75, 0.19]
1.11.1 Classroom-based intervention versus control	1	399	Mean Difference (IV, Fixed, 95% CI)	-0.28 [-0.75, 0.19]
1.12 Anxiety at 3 months follow-up: adults	1	258	Mean Difference (IV, Fixed, 95% CI)	-5.80 [-7.35, -4.25]
1.12.1 Psychosocial counselling versus control	1	258	Mean Difference (IV, Fixed, 95% CI)	-5.80 [-7.35, -4.25]
1.13 Functional impairment at endpoint: children	2	458	Std. Mean Difference (IV, Random, 95% CI)	-0.31 [-0.49, -0.12]
1.13.1 Classroom-based intervention versus control	2	458	Std. Mean Difference (IV, Random, 95% CI)	-0.31 [-0.49, -0.12]
1.14 Functional impairment at 3 months follow-up: children	1	399	Mean Difference (IV, Fixed, 95% CI)	-0.88 [-1.73, -0.03]
1.14.1 Classroom-based intervention versus control	1	399	Mean Difference (IV, Fixed, 95% CI)	-0.88 [-1.73, -0.03]

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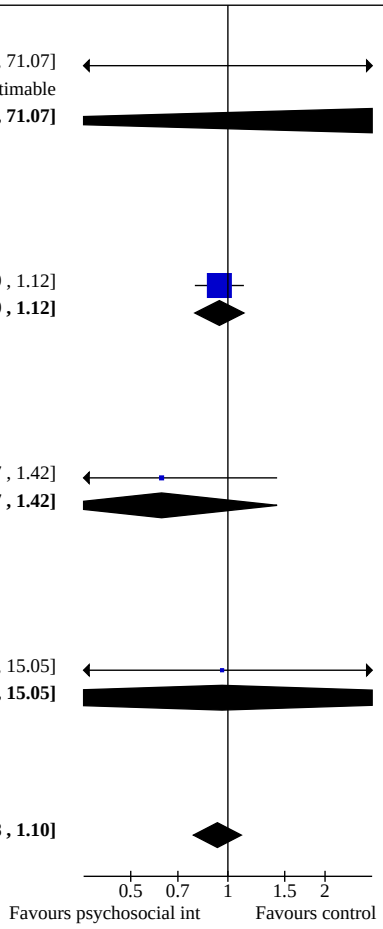
Analysis 1.1. Comparison 1: Psychosocial interventions versus control, Outcome 1: Drop-out: children

Study or Subgroup	Psychosocial Intervention Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.1.1 Classroom-based intervention versus control						
Jordans 2010	1	33	0	33	0.3%	3.00 [0.13 , 71.07]
Tol 2012	0	199	0	200		Not estimable
Subtotal (95% CI)		**232**		**233**	**0.3%**	**3.00 [0.13 , 71.07]**
Total events:	1		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.68 (P = 0.50)						
1.1.2 Advancing adolescents vs control						
Panter-Brick 2018	129	292	146	311	95.0%	0.94 [0.79 , 1.12]
Subtotal (95% CI)		**292**		**311**	**95.0%**	**0.94 [0.79 , 1.12]**
Total events:	129		146			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.68 (P = 0.50)						
1.1.3 Psychosocial intervention versus control						
O'Callaghan 2014	8	79	13	80	4.3%	0.62 [0.27 , 1.42]
Subtotal (95% CI)		**79**		**80**	**4.3%**	**0.62 [0.27 , 1.42]**
Total events:	8		13			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.12 (P = 0.26)						
1.1.4 Sport for development versus control						
Richards 2014	1	74	1	71	0.4%	0.96 [0.06 , 15.05]
Subtotal (95% CI)		**74**		**71**	**0.4%**	**0.96 [0.06 , 15.05]**
Total events:	1		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.03 (P = 0.98)						
Total (95% CI)		**677**		**695**	**100.0%**	**0.93 [0.78 , 1.10]**
Total events:	139		160			
Heterogeneity: Tau² = 0.00; Chi² = 1.46, df = 3 (P = 0.69); I² = 0%						
Test for overall effect: Z = 0.86 (P = 0.39)						
Test for subgroup differences: Chi² = 1.45, df = 3 (P = 0.69), I² = 0%						



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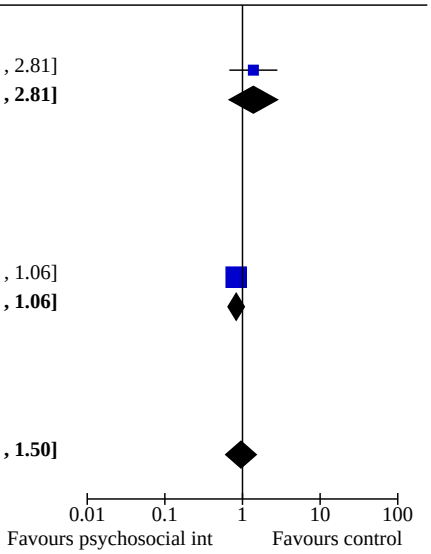
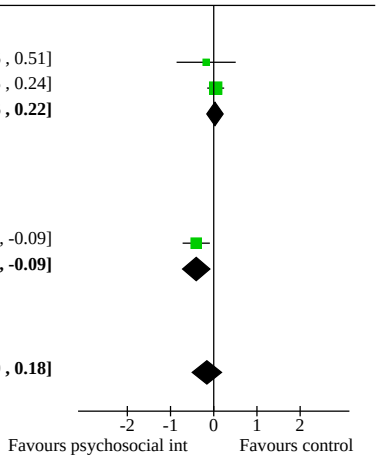
Analysis 1.2. Comparison 1: Psychosocial interventions versus control, Outcome 2: Dropout: adults

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
1.2.1 Psychosocial counselling versus control						
Markkula 2019	16	141	12	146	27.8%	1.38 [0.68 , 2.81]
Subtotal (95% CI)		**141**		**146**	**27.8%**	**1.38 [0.68 , 2.81]**
Total events:	16		12			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.89 (P = 0.37)						
1.2.2 Mental health integrated disaster preparedness versus control						
James 2020	78	240	94	240	72.2%	0.83 [0.65 , 1.06]
Subtotal (95% CI)		**240**		**240**	**72.2%**	**0.83 [0.65 , 1.06]**
Total events:	78		94			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						
Total (95% CI)		**381**		**386**	**100.0%**	**0.96 [0.61 , 1.50]**
Total events:	94		106			
Heterogeneity: Tau² = 0.06; Chi² = 1.79, df = 1 (P = 0.18); I² = 44%						
Test for overall effect: Z = 0.20 (P = 0.84)						
Test for subgroup differences: Chi² = 1.76, df = 1 (P = 0.18), I² = 43.3%						



Analysis 1.3. Comparison 1: Psychosocial interventions versus control, Outcome 3: PTSD symptoms at endpoint: children

Study or Subgroup	Psychosocial intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.3.1 Classroom-based intervention versus control								
Jordans 2010	17.71	4.83	16	18.62	5.26	17	16.9%	-0.18 [-0.86 , 0.51]
Tol 2012	11.77	8.76	199	11.39	7.97	200	46.1%	0.05 [-0.15 , 0.24]
Subtotal (95% CI)			**215**			**217**	**63.0%**	**0.03 [-0.16 , 0.22]**
Heterogeneity: Tau² = 0.00; Chi² = 0.37, df = 1 (P = 0.54); I² = 0%								
Test for overall effect: Z = 0.30 (P = 0.77)								
1.3.2 Psychosocial intervention versus control								
O'Callaghan 2014	10.03	4.76	78	12.17	5.7	80	37.0%	-0.41 [-0.72 , -0.09]
Subtotal (95% CI)			**78**			**80**	**37.0%**	**-0.41 [-0.72 , -0.09]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.52 (P = 0.01)								
Total (95% CI)			**293**			**297**	**100.0%**	**-0.16 [-0.50 , 0.18]**
Heterogeneity: Tau² = 0.05; Chi² = 5.72, df = 2 (P = 0.06); I² = 65%								
Test for overall effect: Z = 0.92 (P = 0.36)								
Test for subgroup differences: Chi² = 5.35, df = 1 (P = 0.02), I² = 81.3%								



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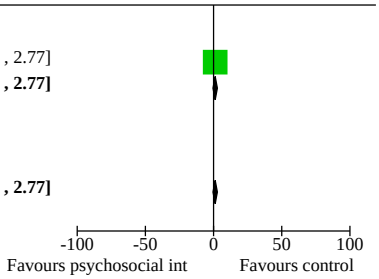
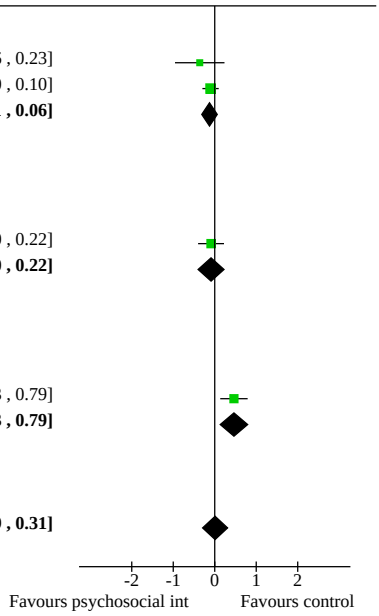
Analysis 1.4. Comparison 1: Psychosocial interventions versus control, Outcome 4: PTSD symptoms at 3 months follow-up: children

Study or Subgroup	Psychosocial intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.4.1 Classroom-based intervention versus control								
Tol 2012	-5.24	8.14	198	-6.42	8.11	201	100.0%	1.18 [-0.41 , 2.77]
Subtotal (95% CI)			**198**			**201**	**100.0%**	**1.18 [-0.41 , 2.77]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.45 (P = 0.15)								
Total (95% CI)			**198**			**201**	**100.0%**	**1.18 [-0.41 , 2.77]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.45 (P = 0.15)								
Test for subgroup differences: Not applicable								



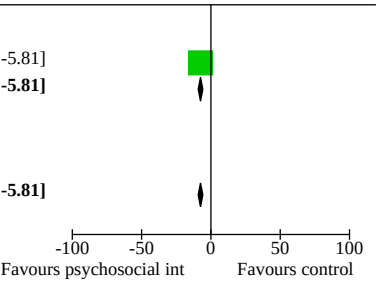
Analysis 1.5. Comparison 1: Psychosocial interventions versus control, Outcome 5: Depression at endpoint: children

Study or Subgroup	Psychosocial intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.5.1 Classroom-based intervention versus control								
Jordans 2010	11.41	3.53	22	12.6	2.91	22	15.2%	-0.36 [-0.96 , 0.23]
Tol 2012	7.36	4.72	199	7.84	4.81	200	32.3%	-0.10 [-0.30 , 0.10]
Subtotal (95% CI)			**221**			**222**	**47.5%**	**-0.13 [-0.31 , 0.06]**
Heterogeneity: Tau² = 0.00; Chi² = 0.66, df = 1 (P = 0.42); I² = 0%								
Test for overall effect: Z = 1.32 (P = 0.19)								
1.5.2 Psychosocial intervention versus control								
O'Callaghan 2014	11.57	5.36	78	12.09	6.26	80	26.7%	-0.09 [-0.40 , 0.22]
Subtotal (95% CI)			**78**			**80**	**26.7%**	**-0.09 [-0.40 , 0.22]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.56 (P = 0.58)								
1.5.3 Sport for development versus control								
Richards 2014	24.35	13.92	74	18.63	10.32	71	25.8%	0.46 [0.13 , 0.79]
Subtotal (95% CI)			**74**			**71**	**25.8%**	**0.46 [0.13 , 0.79]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.75 (P = 0.006)								
Total (95% CI)			**373**			**373**	**100.0%**	**0.01 [-0.29 , 0.31]**
Heterogeneity: Tau² = 0.06; Chi² = 10.28, df = 3 (P = 0.02); I² = 71%								
Test for overall effect: Z = 0.06 (P = 0.96)								
Test for subgroup differences: Chi² = 9.62, df = 2 (P = 0.008), I² = 79.2%								



Analysis 1.6. Comparison 1: Psychosocial interventions versus control, Outcome 6: Depression at endpoint: adults

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.6.1 Psychosocial counselling versus control								
Markkula 2019	10.6	6.1882	124	18.1	7.6081	134	100.0%	-7.50 [-9.19 , -5.81]
Subtotal (95% CI)			**124**			**134**	**100.0%**	**-7.50 [-9.19 , -5.81]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.71 (P < 0.00001)								
Total (95% CI)			**124**			**134**	**100.0%**	**-7.50 [-9.19 , -5.81]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.71 (P < 0.00001)								
Test for subgroup differences: Not applicable								



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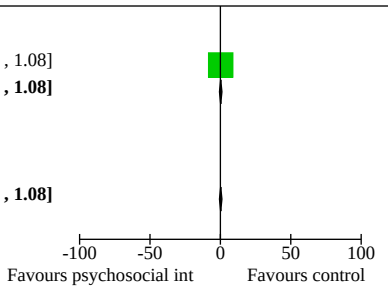
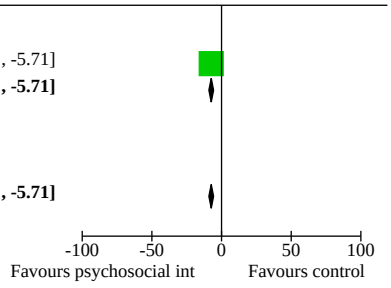
Analysis 1.7. Comparison 1: Psychosocial interventions versus control, Outcome 7: Depression at 3 months follow-up: children

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.7.1 Classroom-based intervention versus control								
Tol 2012	-1.56	4.45	198	-1.78	4.3	201	100.0%	0.22 [-0.64 , 1.08]
Subtotal (95% CI)			**198**			**201**	**100.0%**	**0.22 [-0.64 , 1.08]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.50 (P = 0.62)								
Total (95% CI)			**198**			**201**	**100.0%**	**0.22 [-0.64 , 1.08]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.50 (P = 0.62)								
Test for subgroup differences: Not applicable								



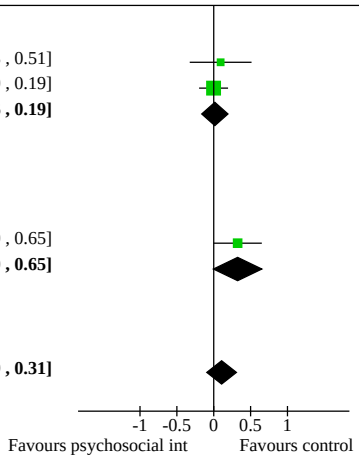
Analysis 1.8. Comparison 1: Psychosocial interventions versus control, Outcome 8: Depression at 3 months follow-up: adults

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.8.1 Psychosocial counselling versus control								
Markkula 2019	6.6	6.1882	124	14	7.6081	134	100.0%	-7.40 [-9.09 , -5.71]
Subtotal (95% CI)			**124**			**134**	**100.0%**	**-7.40 [-9.09 , -5.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.60 (P < 0.00001)								
Total (95% CI)			**124**			**134**	**100.0%**	**-7.40 [-9.09 , -5.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.60 (P < 0.00001)								
Test for subgroup differences: Not applicable								



Analysis 1.9. Comparison 1: Psychosocial interventions versus control, Outcome 9: Anxiety at endpoint: children

Study or Subgroup	Psychosocial intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.9.1 Classroom-based intervention versus control								
Jordans 2010	3.84	1.53	41	3.71	1.23	47	18.9%	0.09 [-0.33 , 0.51]
Tol 2012	2.2	186	199	2.47	1.98	200	53.2%	-0.00 [-0.20 , 0.19]
Subtotal (95% CI)			**240**			**247**	**72.2%**	**0.02 [-0.16 , 0.19]**
Heterogeneity: Tau² = 0.00; Chi² = 0.16, df = 1 (P = 0.69); I² = 0%								
Test for overall effect: Z = 0.17 (P = 0.87)								
1.9.2 Sport for development vs control								
Richards 2014	8.73	4.9	74	7.31	3.71	71	27.8%	0.32 [-0.00 , 0.65]
Subtotal (95% CI)			**74**			**71**	**27.8%**	**0.32 [-0.00 , 0.65]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.94 (P = 0.05)								
Total (95% CI)			**314**			**318**	**100.0%**	**0.11 [-0.09 , 0.31]**
Heterogeneity: Tau² = 0.01; Chi² = 2.80, df = 2 (P = 0.25); I² = 29%								
Test for overall effect: Z = 1.04 (P = 0.30)								
Test for subgroup differences: Chi² = 2.64, df = 1 (P = 0.10), I² = 62.1%								



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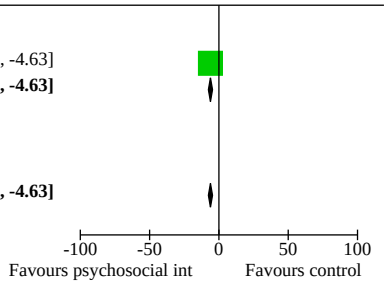
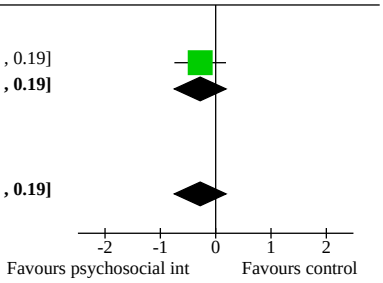
Analysis 1.10. Comparison 1: Psychosocial interventions versus control, Outcome 10: Anxiety at endpoint: adults

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.10.1 Psychosocial counselling versus control								
Markkula 2019	9.3	5.6256	124	15.4	6.4376	134	100.0%	-6.10 [-7.57 , -4.63]
Subtotal (95% CI)			**124**			**134**	**100.0%**	**-6.10 [-7.57 , -4.63]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.12 (P < 0.00001)								
Total (95% CI)			**124**			**134**	**100.0%**	**-6.10 [-7.57 , -4.63]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 8.12 (P < 0.00001)								
Test for subgroup differences: Not applicable								



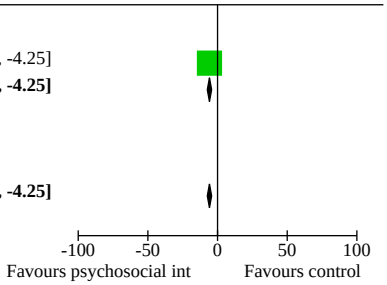
Analysis 1.11. Comparison 1: Psychosocial interventions versus control, Outcome 11: Anxiety at 3 months follow-up: children

Study or Subgroup	Psychosocial intervention Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.11.1 Classroom-based intervention versus control								
Tol 2012	-1.54	2.45	198	-1.26	2.3	201	100.0%	-0.28 [-0.75 , 0.19]
Subtotal (95% CI)			**198**			**201**	**100.0%**	**-0.28 [-0.75 , 0.19]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.18 (P = 0.24)								
Total (95% CI)			**198**			**201**	**100.0%**	**-0.28 [-0.75 , 0.19]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.18 (P = 0.24)								
Test for subgroup differences: Not applicable								



Analysis 1.12. Comparison 1: Psychosocial interventions versus control, Outcome 12: Anxiety at 3 months follow-up: adults

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.12.1 Psychosocial counselling versus control								
Markkula 2019	5	5.6256	124	10.8	7.0229	134	100.0%	-5.80 [-7.35 , -4.25]
Subtotal (95% CI)			**124**			**134**	**100.0%**	**-5.80 [-7.35 , -4.25]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 7.35 (P < 0.00001)								
Total (95% CI)			**124**			**134**	**100.0%**	**-5.80 [-7.35 , -4.25]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 7.35 (P < 0.00001)								
Test for subgroup differences: Not applicable								



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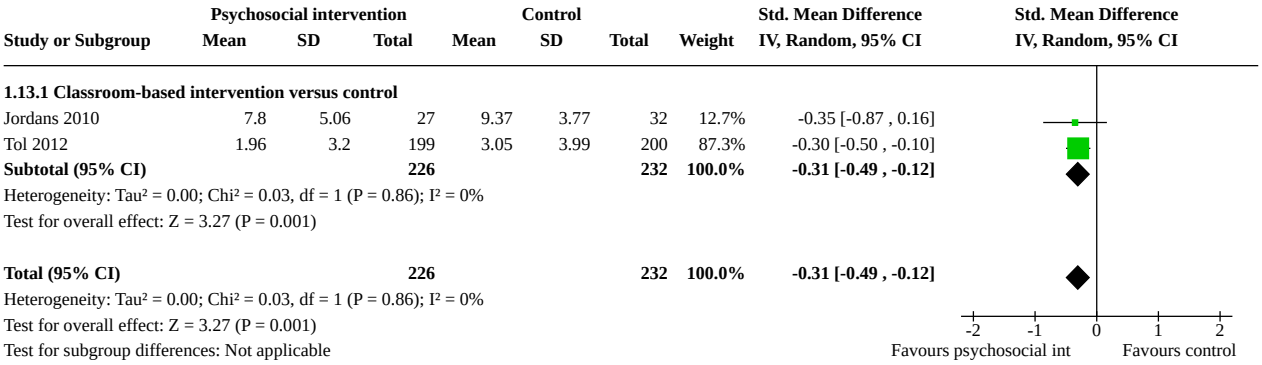
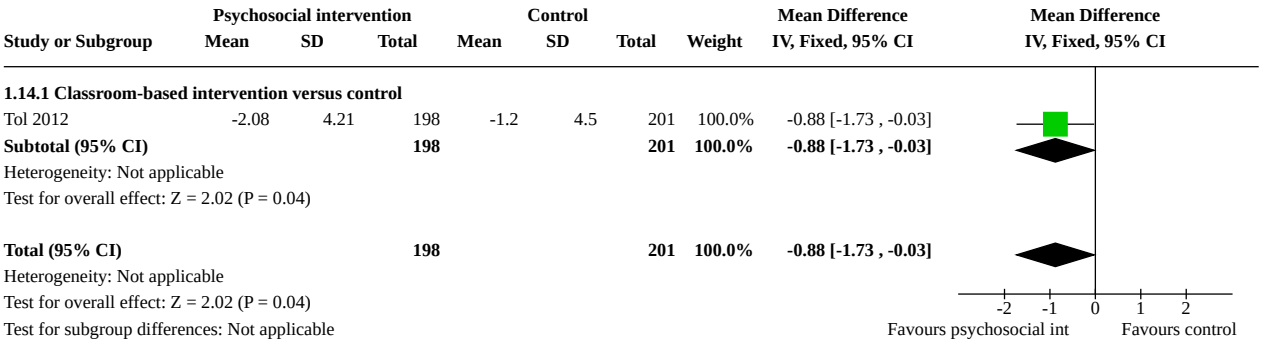
Analysis 1.13. Comparison 1: Psychosocial interventions versus control, Outcome 13: Functional impairment at endpoint: children



Analysis 1.14. Comparison 1: Psychosocial interventions versus control, Outcome 14: Functional impairment at 3 months follow-up: children



APPENDICES

Appendix 1. CCMDCTR - core MEDLINE search

Core search strategy used to inform the Cochrane Common Mental Disorders Group's specialised register: OVID MEDLINE A weekly search alert based on condition + RCT filter only

1. *[MeSH Headings]:* eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/

2. *[Title/ Author Keywords]:* (eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or

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munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.

3. *[RCT filter]:* (controlled clinical trial.pt. or randomized controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab. or placebo*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control* adj3 (trial* or study or studies)).ab,ti. or ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy*)).mp. or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or randomized controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random*)).ti,ab. or ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.)

4. (1 and 2 and 3)

Records were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record. Similar weekly search alerts were also conducted on OVID Embase and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

Appendix 2. LMIC search filter

The Norwegian Satellite of the Cochrane Effective Practice and Organisation of Care Group created the LMIC filter in 2012. It is based on the World Bank list of countries (2009), which are classified as either low-income, lower-middle-income, or upper-middle-income economies (The World Bank 2014) (We updated the search syntax for the Cochrance Register of Studies (CRS)).

#1 (Africa or Asia or Caribbean or "West Indies" or "South America" or "Latin America" or "Central America"):ti,ab,kw,ky,emt,mh,mc

#2 (Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or "Burkina Faso" or "Burkina Fasso" or "Upper Volta" or Burundi or Urundi or Cambodia or "Khmer Republic" or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or "Cape Verde" or "Central African Republic" or Chad or Chile or China or Colombia or Comoros or "Comoro Islands" or Comores or Mayotte or Congo or Zaire or "Costa Rica" or "Cote d'Ivoire" or "Ivory Coast" or Croatia or Cuba or Cyprus or Czechoslovakia or "Czech Republic" or Slovakia or "Slovak Republic"):ti,ab,kw,ky,emt,mh,mc

#3 (Djibouti or "French Somaliland" or Dominica or "Dominican Republic" or "East Timor" or "East Timur" or "Timor Leste" or Ecuador or Egypt or "United Arab Republic" or "El Salvador" or Eritrea or Estonia or Ethiopia or Fiji or Gabon or "Gabonese Republic" or Gambia or Gaza or Georgia or Georgian or Ghana or "Gold Coast" or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or "Isle of Man" or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or "Kyrgyz Republic" or Kirghiz or Kirgizstan or "Lao PDR" or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania):ti,ab,kw,ky,emt,mh,mc

#4 (Macedonia or Madagascar or "Malagasy Republic" or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or "Marshall Islands" or Mauritania or Mauritius or "Agalega Islands" or Mexico or Micronesia or "Middle East" or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or "Netherlands Antilles" or "New Caledonia" or Nicaragua or Niger or Nigeria or "Northern Mariana Islands" or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or "Puerto Rico"):ti,ab,kw,ky,emt,mh,mc

#5 (Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or "Saint Kitts" or "St Kitts" or Nevis or "Saint Lucia" or "St Lucia" or "Saint Vincent" or "St Vincent" or Grenadines or Samoa or "Samoan Islands" or "Navigator Island" or "Navigator Islands" or "Sao Tome" or "Saudi Arabia" or Senegal or Serbia or Montenegro or Seychelles or "Sierra Leone" or Slovenia or "Sri Lanka" or Ceylon or "Solomon Islands" or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or "Togolese Republic" or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or "Soviet Union" or "Union of Soviet Socialist Republics" or Uzbekistan or Uzbek or Vanuatu or "New Hebrides" or Venezuela or Vietnam or "Viet Nam" or "West Bank" or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia):ti,ab,kw,ky,emt,mh,mc

#6 ((developing or "less* developed" or "under developed" or underdeveloped or "middle income" or "low* income" or underserved or "under served" or deprived or poor*) NEAR (countr* or nation* or population* or world)):ti,ab,kw,ky,emt,mh,mc

#7 ((developing or "less* developed" or "under developed" or underdeveloped or "middle income" or "low* income") NEXT (economy or economies)):ti,ab,kw,ky,emt,mh,mc

#8 (low* NEXT (GDP or GNP or "gross domestic" or "gross national")):ti,ab,kw,ky,emt,mh,mc

#9 (low NEAR3 middle NEAR3 countr*):ti,ab,kw,ky,emt,mh,mc

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#10 (LMIC or LMICs or "third world" or "LAMI country" or "LAMI countries"):ti,ab,kw,ky,emt,mh,mc

#11 ("transitional country" or "transitional countries"):ti,ab,kw,ky,emt,mh,mc

#12 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)

Appendix 3. Other database search strategies

Searches were first conducted in February 2016, with updates run in September 2017, August 2018 and February 2020.

1. Cochrane Central Register of Controlled Trials (CENTRAL)

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (all years to issue 2 of 12, 2020) using terms for: (humanitarian crises and LMIC and mental health)

#1. MeSH descriptor: [Crisis Intervention] explode all trees
#2. MeSH descriptor: [Disasters] explode all trees
#3. MeSH descriptor: [Refugees] this term only
#4. MeSH descriptor: [Adaptation, Psychological] explode all trees
#5. MeSH descriptor: [Resilience, Psychological] this term only
#6. MeSH descriptor: [Terrorism] explode all trees
#7. MeSH descriptor: [War] explode all trees
#8. MeSH descriptor: [Torture] this term only
#9. (humanitarian and (aid or affair* or agenc* or assistance or catastrophe* or crisis or crises or disaster* or effort* or emergenc* or evacuation* or integration or reintegration or mission or organization* or organisation* or program* or relief or setting* or support* or task force or work*))
#10. (genocide or "armed conflict*" or "mass execution*" or "mass violence")
#11. (cataclysmic or catastroph* or devastation or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or hurricane or cyclone* or landslide* or "land slide*" or landslide or "mass casualt*" or tsunami* or "tidal wave*" or volcano*)
#12. (refugee* or forced migration or (displac* near/2 (internal or forced or mass or person* or people* or population*)))
#13. (torture* or (politic* near/2 (persecut* or prison* or imprison* or violen*)))
#14. (war and (abuse* or crime* or rape* or survivor* or victim*))
#15. (bereav* or orphan* or widow*)
#16. (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15)
#17. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America or Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia)
#18. MeSH descriptor: [Developing Countries] this term only
#19. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) near (countr* or nation* or population* or world))
#20. ((developing or less* developed or under developed or underdeveloped or middle income or low* income) next (economy or economies))
#21. (low* next (GDP or GNP or "gross domestic" or "gross national"))

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#22. (low near middle near countr*)
#23. (LMIC or LMICs or third world or LAMI country or LAMI countries)
#24. (transitional country or transitional countries)
#25. (#17 or #18 or #19 or #20 or #21 or #22 or #23 or #24)
#26. MeSH descriptor: [Mental Health] this term only
#27. MeSH descriptor: [Health Promotion] this term only
#28. MeSH descriptor: [Mental Disorders] explode all trees
#29. (anxi* or phobi* or agrophobi* or PTSD or post-trauma* or posttrauma or post trauma* or (combat near/2 disorder*) or panic* or OCD or obsess* or compulsi* or GAD or stress disorder* or stress reaction* or acute stress or neurosis or neuroses or neurotic or psychoneuro*)
#30. ("substance use*" or "substance abuse*" or SUD or addict*)
#31. (somatiz* or somatis* or hysteri* or briquet or multisomat* or multi somat* or MUPs or "medically unexplained")
#32. ((dissociative near/3 (disorder* or reaction*)) or dissociation)
#33. (mental or psychiatri* or psycho* or "affective disorder*" or "affective symptom*" or mood or depressi* or depressed or MDD)
#34. (#26 or #27 or #28 or #29 or #30 or #31 or #32 or #33)
#35. (#16 and #25 and #34)

After the initial search conducted in February 2016 we appended the following terms to all update searches (to 14 February 2020):

(i) Demonyms:
((Africa? or Asia? or Arab or Caribbean or West Indi* or South America? or Latin America? or Central America? or Afghan* or Albania? or Algeria? or Angola? or Antigu* or Barbuda? or Argentin* or Armenia? or Aruba? or Azerbaijan? or Bahrain* or Bangladesh? or Barbados or Barbadian? or Bajan* or Benin* or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Beliz* or Bhutan* or Bolivia? or Bosnia? or Herzegovina? or Hercegovin* or Botswana? or Brasil* or Brazil* or Bulgaria? or Burkina Faso or Burkina Fasso or Upper Volta or Burundi* or Urundi* or Cambodia? or Khmer Republic* or Kampuchea? or Cameroon* or Cameroons or Cameron* or Camerons or Cape Verde* or Central Africa* or Chad* or Chile* or China or Chinese or Colombia? or Comoros or Comoro Island* or Comores or Comoran or Mayotte* or Congo* or Zaire* or Costa Rica? or Cote d'Ivoire or Ivory Coast or Croatia? or Cuba? or Cyprus or Cyprian or Czechoslovakia? or Czech Republic* or Slovakia? or Slovak Republic or Djibouti* or French Somaliland or Dominica? or Dominican Republic or East Timor* or East Timur* or Timor Leste* or Timorese or Ecuador* or Egypt* or United Arab Republic or El Salvador* or Eritrea? or Estonia? or Ethiopia? or Fiji* or Gabon or Gabonese or Gambia? or Gaza? or Georgia? or Ghana or Ghanaian or Gold Coast or Greece or Greek or Grenada or Grenadian or Guatemala? or Guinea? or Guam* or Guiana or Guyana? or Haiti* or Hondura? or Hungary or Hungarian or India? or Maldives or Maldivian? or Indonesia? or Iran* or Iraq? or Isle of Man or Jamaica? or Jordan* or Kazakhstan or Kazakh or Kenya? or Kiribati* or Korea? or Kosov* or Kyrgyzstan or Kirghizia or Kyrgyz or Kirghiz or Kirgizstan or Lao PDR or Lao? or Latvia? or Lebanon or Lebanese or Lesotho* or Basutoland or Liberia? or Libya? or Lithuania? or Macedonia? or Madagasca? or Malagasy Republic or Malaysia or Malay? or Sabah* or Sarawak* or Malawi* or Nyasaland or Mali or Malta or Maltese or Marshall Island* or Mauritania? or Mauritius or Mauritian or Agalega Islands* or Mexico or Mexican or Micronesia or Middle East* or Moldova or Moldovia or Moldovian or Mongolia? or Montenegro or Morocc* or Ifni or Mozambique or Myanmar or Myanma or Burma or Burmese or Namibia? or Nepal* or Netherlands Antilles or New Caledonia? or Nicaragua? or Niger or Nigeria? or Northern Mariana Island* or Oman* or Muscat or Pakistan? or Palau or Palestin* or Panama or Paraguay or Peru or Peruvian or Philippin* or Philipin* or Phillipin* or Phillippin* or Poland or Polish or Portugal or Portuguese or Puerto Ric* or Romania? or Rumania? or Roumania? or Russia or Russian or Rwanda? or Ruanda? or Saint Kitts or St Kitts or Nevis or Saint Lucia? or St Lucia? or Saint Vincent or St Vincent or Grenadines or Samoa? or Samoan Island* or Navigator Island* or Sao Tom* or Saudi Arabia? or Senegal* or Serbia? or Montenegr* or Seychell* or Sierra Leon* or Slovenia? or Slovak* or Sri Lanka? or Ceylon or Solomon Island* or Somali* or Sudan* or Surinam* or Swaziland* or Syria? or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania? or Thailand or Thai or Togo or Togolese or Tonga? or Trinidad* or Tobag* or Tunisia? or Turkey or Turkish or Turkmenistan? or Turkmen or Uganda? or Ukrain* or Uruguay* or USSR? or Soviet Union? or Union of Soviet Socialist Republics or Uzbekistan? or Uzbek? or Vanuat* or New Hebride* or Venezuel* or Vietnam* or Viet Nam* or West Bank or Yemen? or Yugoslavia? or Zambia? or Zimbabwe* or Rhodesia?) adj3 (combatant? or ex-combatant? or soldier? or ((conflict or terroris* or war) adj2 (affected or afflicted or trauma*)) or refugee? or survivor? or victim? or orphan* or widow*)) [Title, Abstract, Keywords (PsycINFO, CENTRAL, MEDLINE, Embase)]*

(ii) Additional terms for warfare:
(conflict-affected or warfare or (war adj (affected or afflicted or trauma)) or (war and (abuse* or crime* or rape* or survivor* or victim*))) [Title, Abstract, Keywords (PsycINFO, CENTRAL, MEDLINE, Embase)]*

(iii) Additional terms for mental health in low or poor resource settings:
(((low or poor) adj resource setting?) and (anxi or phobi* or agrophobi* or PTSD or post-trauma* or posttrauma* or post trauma* or (combat adj3 disorder*) or panic* or OCD or obsess* or compulsi* or GAD or stress disorder* or stress reaction* or acute stress or neurosis or neuroses or neurotic or psychoneuro* or mental or psychiatr* or psycho* or affective disorder* or affective symptom* or mood or depressi* or depressed or MDD or substance use* or substance abuse* or SUD or addict* or somatiz* or somatis* or hysteri* or briquet or multisomat* or multi somat* or MUPs or medically unexplained or (dissociative adj3 (disorder* or reaction*)) or dissociation)).ti,ab,id,hw. [PsycINFO only]*

2. Ovid MEDLINE

[Humanitarian Crises]
1. CRISIS INTERVENTION/
2. exp DISASTERS/

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3. REFUGEES/
4. ADAPTATION, PSYCHOLOGICAL/ or RESILIENCE, PSYCHOLOGICAL/
5. exp TERRORISM/
6. exp WAR/
7. TORTURE/
8. (humanitarian adj3 (aid or affair* or agenc* or assistance or catastrophe* or crisis or crises or disaster* or effort* or emergenc* or evacuation* or integration or reintegration or mission or organization* or organisation* or program* or relief or setting* or support* or task force or work*)).mp.
9. (genocide or armed conflict* or mass execution* or mass violence).mp.
10. (cataclysmic or catastroph* or devastation or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or hurricane or cyclone* or landslide* or land slide* or mass casualt* or tsunami* or tidal wave* or volcano*).mp.
11. (refugee* or forced migration or (displac* adj2 (internal or forced or mass or person* or people* or population*))).mp.
12. (torture* or (politic* adj2 (persecut* or prison* or imprison* or violen*))).mp.
13. (war and (abuse* or crime* or rape* or survivor* or victim*)).mp.
14. (bereav* or orphan* or widow*).mp.
15. or/1-14

[Location]

16. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America or Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).mp.
17. DEVELOPING COUNTRIES/
18. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj3 (countr* or nation* or population* or world)).mp.
19. ((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj1 (economy or economies)).mp.
20. (low* adj1 (GDP or GNP or gross domestic or gross national)).mp.
21. (low adj3 middle adj3 countr*).mp.
22. (LMIC or LMICs or third world or LAMI country or LAMI countries).mp.
23. (transitional country or transitional countries).mp.
24. or/16-23

[Mental disorders]

25. HEALTH PROMOTION/
26. MENTAL HEALTH/
27. exp MENTAL DISORDERS/
28. (anxi* or phobi* or agrophobi* or PTSD or post-trauma* or posttrauma or post trauma* or (combat adj3 disorder*) or panic* or OCD or obsess* or compulsi* or GAD or stress disorder* or stress reaction* or acute stress or neurosis or neuroses or neurotic or psychoneuro*).mp.
29. (substance use* or substance abuse* or SUD or addict*).mp.
30. (somatiz* or somatis* or hysteri* or briquet or multisomat* or multi somat* or MUPs or medically unexplained).mp.
31. ((dissociative adj3 (disorder* or reaction*)) or dissociation).mp.
32. (mental or psychiatr* or psycho* or affective disorder* or affective symptom* or mood or depressi* or depressed or MDD).mp.
33. or/25-32

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[RCT filter - precision maximizing]
34. randomized controlled trial.pt.
35. (randomi#ed or randomi#ation).ab,ti.
36. (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab.
37. ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.
38. intervention as usual.ab.
39. or/33-37
40. (15 and 24 and 33 and 39)

3. Ovid Embase

[Humanitarian Crises]
1. (crisis or crises).mp.
2. ADAPTATIVE BEHAVIOR/
3. ALTRUISM/
4. exp COPING BEHAVIOR/
5. exp DISASTER/
6. exp EMOTIONAL DEPRIVATION/
7. exp MILITARY PHENOMENA/
8. exp REFUGEE/
9. exp VIOLENCE/
10. (humanitarian and (aid or affair* or agenc* or assistance or catastrophe* or crisis or crises or disaster* or effort* or emergenc* or evacuation* or integration or reintegration or mission or organization* or organisation* or program* or relief or setting* or support* or task force or work*)).ti,ab,kw.
11. (genocide or armed conflict* or mass execution* or mass violence).ti,ab,kw.
12. (refugee* or forced migration or (displac* adj2 (internal or forced or mass or person* or people* or population*))).ti,ab,kw.
13. (torture* or (politic* adj2 (persecut* or prison* or imprison* or violen*))).ti,ab,kw.
14. (war and (abuse* or crime* or rape* or survivor* or victim*)).ti,ab,kw.
15. (bereav* or orphan* or widow*).ti,ab,kw.
16. (cataclysmic or catastroph* or devastation or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or hurricane or cyclone* or landslide* or "land slide*" or landslide or "mass casualt*" or tsunami* or "tidal wave*" or volcano*).mp.
17. or/1-16
[Location]
18. DEVELOPING COUNTRY/
19. LOWEST INCOME GROUP/
20. MIDDLE INCOME GROUP/
21. RED CROSS/
22. UNITED NATIONS/
23. WORLD HEALTH ORGANIZATION/
24. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj3 (countr* or nation* or population* or world)).ti,ab,kw.
25. ((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj1 (economy or economies)).ti,ab,kw.
26. (low* adj1 (GDP or GNP or "gross domestic" or "gross national")).ti,ab,kw.
27. (low adj3 middle adj3 countr*).ti,ab,kw.
28. (LMIC or LMICs or third world or LAMI country or LAMI countries).ti,ab,kw.
29. (transitional country or transitional countries).ti,ab,kw.
30. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America or Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia

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or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).mp.
31. exp AFRICAN/ or exp ASIAN/ or exp "CARIBBEAN (person)"/ or exp CENTRAL AMERICAN/ or exp EASTERN EUROPEAN/ or exp MELANESIAN/ or exp MICRONESIAN/ or exp POLYNESIAN/ or exp SOUTH AMERICAN/
32. or/18-31
[Mental disorders]
33. exp MENTAL DISEASE/
34. exp "PSYCHOLOGICAL and PSYCHIATRIC PROCEDURES"/
35. PSYCHOSOCIAL CARE/
36. (anxi* or phobi* or agrophobi* or PTSD or post-trauma* or posttrauma or post trauma* or (combat adj2 disorder*) or panic* or OCD or obsess* or compulsi* or GAD or stress disorder* or stress reaction* or acute stress or neurosis or neuroses or neurotic or psychoneuro*).ti,ab,kw.
37. (substance use* or substance abuse* or SUD or addict*).ti,ab,kw.
38. (somatiz* or somatis* or hysteri* or briquet or multisomat* or multi somat* or MUPs or medically unexplained).ti,ab,kw.
39. ((dissociative adj3 (disorder* or reaction*)) or dissociation).ti,ab,kw.
40. (mental or psychiatri* or psycho* or affective disorder* or affective symptom* or mood or depressi* or depressed or MDD).ti,ab,kw.
41. or/33-40
[RCT filter - precision maximizing]
42. randomiz*.de.
43. (randomi#ed or randomi#ation).ab,ti,kw.
44. (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab.
45. ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.
46. intervention as usual.ab.
47. or/42-46
48. (17 and 32 and 41 and 47)

4. Ovid PsycINFO

[Humanitarian Crises]
1. CONFLICT/
2. CRISES/
3. CRISIS INTERVENTION/
4. exp DISASTERS/
5. REFUGEES/
6. "RESILIENCE (Psychological)"
7. exp TERRORISM/
8. WAR/
9. TORTURE/
10. VICTIMIZATION/
11. (humanitarian adj3 (aid or affair* or agenc* or assistance or catastrophe* or crisis or crises or disaster* or effort* or emergenc* or evacuation* or integration or reintegration or mission or organization* or organisation* or program* or relief or setting* or support* or task force or work*)).ti,ab,id.
12. (genocide or armed conflict* or mass execution* or mass violence).ti,ab,id.
13. (cataclysmic or catastroph* or devastation or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or hurricane or cyclone* or landslide* or land slide* or mass casualt* or tsunami* or tidal wave* or volcano*).ti,ab,id.
14. (refugee* or forced migration or (displac* adj2 (internal or forced or mass or person* or people* or population*))).ti,ab,id.
15. (torture* or (politic* adj2 (persecut* or prison* or imprison* or violen*))).ti,ab,id.
16. (war and (abuse* or crime* or rape* or survivor* or victim*)).ti,ab,id.
17. (bereav* or orphan* or widow*).ti,ab,id.
18. or/1-17
[Location - country where study was conducted]
19. (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America or Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin

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or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).ti,ab.id,lo.
20. ((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj3 (countr* or nation* or population* or world)).ti,ab,id.
21. ((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj1 (economy or economies)).ti,ab,id.
22. (low* adj1 (GDP or GNP or gross domestic or gross national)).ti,ab,id.
23. (low adj3 middle adj3 countr*).ti,ab,id.
24. (LMIC or LMICs or third world or LAMI country or LAMI countries).ti,ab,id.
25. (transitional country or transitional countries).ti,ab,id.
26. or/19-25
[RCT filter]
27. treatment effectiveness evaluation.sh.
28. clinical trials.sh.
29. mental health program evaluation.sh.
30. randomly.ab.
31. randomi#ed.ti,ab,id.
32. (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab.
33. trial.ti,ab.
34. (control* adj3 (trial or study or group*)).ti,ab.
35. "2000".md.
36. (quasi adj (experimental or random*)).mp.
37. ((waitlist* or wait* list* or treatment as usual or usual treatment or TAU or no treatment or care as usual or usual care or standard care) and (control or group)).ab.
38. or/20-30
39. (18 and 26 and 38)

5. ProQuest Published International Literature on Traumatic Stress (PILOTS)

This database covers post-traumatic stress disorder (PTSD) and other mental-health sequelae of traumatic events. We searched it (all years to 3 February 2016) using terms for: (humanitarian crises or LMIC) and RCTs. We did not repeat the PILOTS search after this date as it did not retrieve any unique studies.

[Humanitarian Crises]
S1 SU.EXACT("Humanitarian Intervention")
S2 (SU.EXACT.EXPLODE("Accidents" OR "Agent Orange" OR "Air Traffic Accidents" OR "Avalanches" OR "Blizzards" OR "Building Collapse" OR "Disasters" OR "Drought" OR "Earthquakes" OR "Epidemics" OR "Epizootics" OR "Explosions" OR "Famine" OR "Fires" OR "Floods" OR "Home Accidents" OR "Hurricanes" OR "Industrial Accidents" OR "Landmines" OR "Landslides" OR "Lightning" OR "Motor Traffic Accidents" OR "Natural Disasters" OR "Nuclear Accidents" OR "Nuclear Testing" OR "Oil Spills" OR "Pedestrian Accidents" OR "Railroad Accidents" OR "Ship Accidents" OR "Technological Disasters" OR "Tornadoes" OR "Toxic Contamination" OR "Tsunamis" OR "Volcanoes"))
S3 (altruis* or humanitarian or “human right*”)

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S4 (cataclysmic or catastroph* or devastation or disaster* or drought* or earthquake* or evacuation* or famine* or flood or floods or genocide or hurricane or cyclone* or landslide* or land slide* or "mass casualt*" or tsunami* or “tidal wave*” or volcano*)
S5 ((war or conflict) near/2 (affect* or effect* or expos* or related or victim* or survivor*))
S6 (refugee* or “forced migration”) or (displac* NEAR/2 (internal or forced or mass or person* or people* or population*))
S7 (politic* near/2 (persecut* or prison* or imprison* or violen*))
S8 SU.EXACT("Developing Countries")
[Location]
S9 (Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America or Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia or Georgian or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia)
[RCT filter - precision maximizing]
S10 (randomiz* OR randomis*)
S11 (waitlist* OR "wait list*" OR "waiting list*" OR "treatment as usual" OR TAU) NEAR/3 (control* OR group)
S12 “no intervention”
S13 (random* NEAR/3 (administer* OR allocat* OR assign* OR class* OR control* OR determine* OR divide* OR division OR distribute* OR expose* OR fashion OR number* OR place* OR recruit* OR substitute* OR treat*))
[((Humanitarian Crises OR Location) AND RCT filter)]
S14 (S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9) and (S10 or S11 or S12 or S13)

WHAT'S NEW

Date	Event	Description
2 September 2020	Amended	Author affiliations updated

HISTORY

Protocol first published: Issue 11, 2016
Review first published: Issue 9, 2020

CONTRIBUTIONS OF AUTHORS

DP, CG, MP, CBo, WT, MvO, and CB designed the review structure. DP, CG, and MP collected data; DP, CG, MP and CB ran the analyses; DP, MP, and CB drafted and critically revised the manuscript. MvO and WT critically revised the manuscript.
All review authors contributed actively to development of the review, participated in discussions, helped clarify questions, and provided suggestions for overall preparation.

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The review authors alone are responsible for the views expressed in this article, which do not necessarily represent the views, decisions, or policies of the institutions with which they are affiliated.

DECLARATIONS OF INTEREST

Davide Papola has no known conflicts of interest; Chiara Gastaldon has no known conflicts of interest; Chiara Bovo has no known conflicts of interest; Marianna Purgato has no known conflicts of interest; Mark van Ommeren has no known conflicts of interest; Corrado Barbui has no known conflicts of interest; Wietse Tol was an author of two of the included studies (Jordans 2010; Tol 2012). Wietse Tol did not perform the data analysis, the risk of bias assessments, or GRADE ratings in this review.

SOURCES OF SUPPORT

Internal sources

- WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation, Department of Public Health and Community Medicine, University of Verona, Italy
- Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The differences between this review and its registered protocol (Purgato 2016) are:

1) Studies were presented as a single comparison, instead of grouping results into universal prevention versus control (no studies), selective prevention versus control (James 2020; Markkula 2019), indicated prevention versus control Jordans 2010; O'Callaghan 2014; Panter-Brick 2018; Richards 2014; Tol 2012). This was primarily due to the low number of trials included. Moreover, none of the included trials provided data for all the outcomes considered for this review. The combination of these two factors would have led to scattered and not useful meta-analytic findings in case of grouping studies as stated in the protocol.

2) We reported the outcome 'Adverse effects' in the 'Summary of findings' tables, although we did not mention it at the protocol level. We thought this ensures a more balanced evidence overview.

INDEX TERMS

Medical Subject Headings (MeSH)

Age Factors; Anxiety [diagnosis] [epidemiology]; Bias; Depression [diagnosis] [epidemiology]; *Developing Countries [statistics & numerical data]; Mental Disorders [etiology] [*prevention & control]; Patient Dropouts [statistics & numerical data]; *Psychotherapy; Randomized Controlled Trials as Topic; Social Problems [*psychology]; Stress Disorders, Post-Traumatic [diagnosis] [epidemiology]; *Stress, Physiological; Stress, Psychological [*complications]; Waiting Lists

MeSH check words

Adolescent; Adult; Child; Humans

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