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[Intervention Protocol]

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

Davide Papola[1,2], Eleonora Prina[1,2], Caterina Ceccarelli[1,2], Chiara Gastaldon[1,2], Wietse A Tol[3,4], Mark van Ommeren[5], Corrado Barbui[1,2], Marianna Purgato[1,2]

[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]Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA. [4]Department of Public Health, University of Copenhagen, Copenhagen, Denmark. [5]Department of Mental Health and Substance Abuse, World Health Organization, Geneva, Switzerland

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

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ABSTRACT

Objectives

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

To assess the efficacy of psychosocial interventions aimed at promoting mental health versus control conditions (no intervention, intervention as usual, or waiting list) in people living in LMICs affected by humanitarian crises.

BACKGROUND

Description of the condition

Humanitarian emergencies such as war, natural disasters, or pandemics profoundly disrupt the daily lives of those impacted and often result in psychological distress. This is particularly the case for people living in low- and middle-income countries (LMICs), where the increasing frequency of public health crises over the past decade, including the most recent Coronavirus Disease 2019 (COVID-19) pandemic, has sorely increased the number of people exposed to mental health stressors. Social and environmental factors such as poverty, discrimination, war and violence all play a key role in all aspects of public health, and are risk factors for mental health problems (Lund 2018; Purgato 2018). For example, people living in humanitarian settings (i.e. contexts affected by armed conflicts or by disasters triggered by natural, industrial, or technological hazards) in LMICs may not have adequate access to healthcare, education, or basic resources such as food or shelter. In addition, humanitarian crises often do not provide the conditions that are necessary to promote positive aspects of mental health, such as suitable housing, adequate income, and opportunities for a strong social network.

By the end of 2020, the number of people forcibly displaced due to war, conflict, persecution, human rights violations and humanitarian crises had grown to a startling amount of 82.4 million (UNHCR 2020). Syria, Venezuela, Afghanistan, South Sudan, The Democratic Republic of the Congo, Burkina Faso, and Yemen represent just a few of the many hotspots in 2019 that drove people to seek refuge and safety within their country or flee abroad to seek protection (UNHCR 2020). Most displaced populations remain in their region of origin or flee to neighbouring countries, i.e. an LMIC. In fact, LMICs host 82% of the world's refugee population (UNHCR 2015). Humanitarian crises impact a large part of the world's population, often affecting populations already beset by adversity (e.g. discrimination, gender-based violence, social marginalisation), with 356 million children younger than five years-old living in extreme poverty, which is defined as existing on less than USD 1.90 a day (UNICEF 2021).

Two Cochrane Reviews have evaluated the effectiveness of approaches to treat (Purgato 2018) and prevent (Papola 2020) mental disorders in people living in LMICs affected by humanitarian crises. These reviews followed the classification of interventions described by the Institute of Medicine (IOM) (Institute of Medicine 1994; Institute of Medicine 2009; Tol 2015). The IOM's classification distinguishes treatment from prevention and promotion, in that treatment is aimed at reducing symptoms in people with identified mental disorders; prevention is a complementary approach aimed at reducing the likelihood of future disorder with the general population or people who are identified as being at risk for a disorder. Prevention is further subdivided, on the basis of the population targeted, into universal prevention (interventions with the general population); selective prevention (interventions with subpopulations identified as being at risk for a disorder), and indicated prevention (with individuals having an increased vulnerability for a disorder based on individual assessment, but who are currently asymptomatic) (Institute of Medicine 1994; Institute of Medicine 2009). Although there may be areas of overlap with prevention, mental health promotion does not directly focus on preventing mental disorders, but on improving positive outcomes or well-being (Institute of Medicine 2009).

Given the broad impacts of humanitarian settings on mental health, this review aims to provide a comprehensive evaluation of the effectiveness of promotion interventions to foster positive aspects of mental health in both children, adolescents, and adults living in LMICs affected by humanitarian crises.

Description of the intervention

Mental health and psychosocial support (MHPSS) interventions are becoming a standard part of humanitarian programs. MHPSS interventions cover a wide range of objectives, from addressing the environmental conditions that shape well-being to management of severe (neuro)psychiatric disorders. Accordingly, they are implemented in diverse humanitarian sectors including health, protection, nutrition, shelter, and education (Miller 2021). Although this was previously an ideologically divided field, there appears to be growing agreement on best practices, as suggested by international consensus-based documents (IASC 2007; The Sphere Project 2011). These documents advocate 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 include interventions to address the broad range of mental health needs in populations affected by humanitarian crises.

A Lancet Commission set up in 2018 to align global mental health efforts with sustainable development goals has emphasised the importance of action to promote mental health (Patel 2018). Promotion is an approach that aims to strengthen positive aspects of mental health and psychosocial well-being; it includes, for example, intervention components that foster pro-social behaviour, self-esteem, positive coping with stress, and decision-making capacity (WHO 2018a). Mental health promotion usually targets the entire population (universal), but may target high-risk populations such as refugees, asylum seekers, and internally displaced persons (selective health promotion). It considers outcomes related to positive aspects of psychological functioning and well-being rather than ill health (Purgato 2021a; Tol 2015). Psychosocial interventions aimed to promote mental health delivered in LMICs affected by humanitarian crises may include individual-level, group-based, or community-based interventions. For example, activities to encourage good mental health and development for children may take place in classrooms or in refugee camps widely. A recent definition of promotion includes a wider set of interventions provided at societal, community, individual and family levels. These updates reflect important trends in research in the field of public mental health, and reveal the enduring importance of a spectrum of key tools for fostering mental health and reducing the treatment gap between high-income and low- and middle-income countries (National Academies of Sciences 2019).

In the last decade, 'task shifting' strategies have been increasingly advocated as a pivotal tool to deliver psychosocial interventions to treat, prevent or promote mental health in low-resource settings (Patel 2010; van Ginneken 2021), and in humanitarian settings (Barbui 2020; Papola 2020; Purgato 2018). The World Health Organization (WHO) defines task shifting as “the rational redistribution of tasks among health workforce teams” (WHO 2018b). In other words, specific functions are shifted, where appropriate, from highly-qualified health workers to health workers with shorter training and fewer qualifications, to make more efficient use of the available human resources for health. The

specialist role shifts from direct service provider toward supervisor and consultant to train 'primary-level health workers'. Systematic reviews and conventional meta-analyses of randomised controlled trials (RCTs) show that psychosocial interventions delivered by locally available primary-level health workers in community and primary care settings are promising to treat common mental disorders in LMICs. (Purgato 2018). Mental health promotion interventions are very often implemented outside of health care settings in community settings.

How the intervention might work

Mental health promotion activities are contingent on the definition of mental health as being more than the absence of disease, i.e. as "a state of well-being in which every individual realises his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community" (WHO 2018c). The aim of psychosocial promotion interventions is to achieve better mental health by improving the social, physical and economic environments that influence mental health.

Psychosocial interventions work through resilience improvement, for example introducing creative expressive elements (co-operative activities, structured movement, relaxation), reinforcing self-esteem, social support (even group cohesion within the intervention group), empowerment, and emotion regulation. Reinforcing people's resilience in terms of (re)building feelings of safety, coping resources and hope, in turn, reduces psychological suffering (Wessells 2015; Wessels 2018). Psychosocial interventions to promote mental health are delivered in an empowering, collaborative and participatory manner to foster positive aspects of mental health in individuals, such as coping capacity and resilience. They increase connections between individuals and communities, create opportunities for income generation and employment, and strengthen positive family and peer relations and other social support mechanisms (Hobfoll 2007; WHO 2004). Mental health promotion is commonly attempted through multi-level interventions across a wide number of sectors, policies, programs, settings and environments. Mental health promotion requires action to influence the full range of potentially modifiable determinants of mental health (Hobfoll 2007; Marmot 2014). These include not only those related to the actions of individuals, such as behaviours and ways of life, but also factors such as income and social status, education, employment and working conditions, access to appropriate health services, and the physical environment (Walker 2005).

A popular conceptual framework for psychosocial interventions in humanitarian settings is that of 'ecological resilience' (Tol 2013), which has been defined as "those assets and processes on all socioecological levels that have been shown to be associated with good developmental outcomes after exposure to situations of conflict" (Tol 2008). Ecological resilience refers to a process whereby people attain desirable outcomes despite significant risks to their adaptation and development. These processes are thought to involve dynamic relationships between risk, protective factors and promotive factors at different levels of the persons' social ecology (e.g. individual, family, neighbourhood levels) (Betancourt 2008; Betancourt 2013).

Mental health promotion aims to raise the position of mental health in the scale of values of individuals, families and societies, so that decisions taken by government and business can ensure social conditions and factors that create positive environments for the good mental health and well-being of populations, communities and individuals (Frankish 2018).

Why it is important to do this review

The present review is necessary, and considered particularly timely, for at least three reasons.

1. The largest populations affected by humanitarian crises live in LMICs. For example, four out of the five countries most often hit by disasters associated with natural hazards in the last decade are LMICs (China, the Philippines, India, and Indonesia) (Centre for research on epidemiology of disasters - CRED). Similarly, 30 of the 32 armed conflicts and wars recorded by the Uppsala Conflict Data Program in 2012 took place in LMICs (93.8%) (Themnér 2013). A considerable number of studies have examined mental health in populations affected by humanitarian crises (Attanayake 2009; Augustinavicius 2018; Greene 2017; Jordans 2016: Morina 2017; Papola 2020; Purgato 2018; Siriwardhana 2014; Steel 2009; Tol 2015).
2. In general, LMICs differ from high-income countries (HIC) with regard to numerous characteristics; thus, LMICs and HICs are to be reviewed separately. Among the most striking differences between LMICs and HICs are: health system indicators (e.g. the number of mental health professionals available); humanitarian response capacity; and distribution of the determinants of mental health before the onset of humanitarian crises. In addition, there is a large variety of ways in which populations conceptualise and seek assistance for mental health problems in LMICs that may differ from conceptualisations and help-seeking patterns in high-income industrialised countries (Kohrt 2013). Evidence regarding the effectiveness of interventions implemented in high-income countries may therefore not generalise or be relevant to LMICs. Given the large impact of humanitarian crises in LMICs and unknown generalisability of findings from high-income countries, this review focuses on psychosocial interventions aimed at promoting mental health implemented with populations living in LMICs.
3. There is currently no systematic review of psychosocial interventions specifically aimed at promoting mental health of people living in LMICs affected by humanitarian crises (Uphoff 2020). Although psychosocial promotion interventions have been popular in practice, an earlier systematic review did not identify a great number of rigorous studies evaluating the benefits of such interventions for mental health (Tol 2011). Similar results were found in a Cochrane overview of reviews (Uphoff 2020). A review focused on the efficacy of process-based forgiveness interventions among samples of adolescents and adults who had experienced a range of hurt or violence provided evidence suggesting that forgiving a variety of real-life interpersonal offences can be effective in promoting different dimensions of mental well-being (Akhtar 2018). Regardless of such conflicting results, it should be noted that none of these reviews focused specifically on LMICs.

OBJECTIVES

To assess the efficacy of psychosocial interventions aimed at promoting mental health versus control conditions (no

intervention, intervention as usual, or waiting list) in people living in LMICs affected by humanitarian crises.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs). Trials that employ a cross-over design will be eligible, though we would use only data from the first randomised stage. We will exclude quasi-RCTs, in which participants are allocated to different arms of the trial using a method of allocation that is not truly random (e.g. allocation might be based on date of birth, or the order in which people were recruited). We will consider both individual and cluster-randomised trials as eligible for inclusion.

Types of participants

Participant characteristics

We will consider participants of any age, gender, ethnicity and religion. Consistent with the two parallel Cochrane Reviews mentioned in the Description of the condition, (Papola 2020; Purgato 2018; Purgato 2021b), we intend to conduct two separate meta-analyses on the different outcomes, one for children and adolescents (<18 years), and one for adults (≥18 years). Studies with mixed population groups (children and adolescents; adults) will be allocated according to the proportion of participants belonging to the child and adolescent age range, or to the adult age range.

Setting

We will consider studies conducted in humanitarian settings in LMICs, i.e. contexts affected by armed conflicts or by disasters triggered by natural, industrial, or technological hazards. We will apply the World Bank criteria for categorising a country as low- or middle-income (World Bank 2021). We will exclude studies undertaken in high-income countries. According to the World Bank (World Bank 2021), for the current 2021 fiscal year, low-income economies are defined as those with a gross national income (GNI) per capita of USD 1035 or less in 2019; middle-income economies are those with a GNI per capita between USD 1036 and USD 4045; upper middle-income economies are those with a GNI per capita between USD 4046 and USD 12,535; high-income economies are those with a GNI per capita of USD 12,536 or more. Psychosocial interventions aimed at promoting mental health may have been delivered in healthcare settings, refugee camps, schools, communities, survivors' homes, and detention facilities. We will include studies with populations during humanitarian crises, as well as in periods after humanitarian crises.

Diagnosis

Given the focus on mental health promotion, we will exclude studies that selected participants currently meeting criteria for a formal psychiatric diagnosis at enrolment in the study. We will also exclude studies that included participants scoring above a disclosed validated cut-off score at a scale measuring psychological symptoms associated with a particular mental disorder at baseline, as this may be considered a proxy of a psychiatric diagnosis. However, because many studies screen on the basis of a risk factor or heightened symptoms, we cannot exclude the possibility that trial participants might have fulfilled criteria for an actual psychiatric diagnosis that remained unobserved because it was not investigated when the trial was undertaken. For example, we will include populations who left their homes due to a sudden impact, threat, or conflict; populations exposed to political violence/armed conflicts/natural and industrial disasters; those with major losses or in poverty; and those belonging to a group (i.e. people who are discriminated against or marginalised) experiencing political oppression, family separation, disruption of social networks, destruction of community structures and resources and trust, increased gender-based violence, and undermined community structures or traditional support mechanisms (IASC 2007).

Comorbidities

We will include studies with participants reporting physical disorders.

Types of interventions

Included interventions

We will include studies assessing any types of intervention with a psychosocial component aimed at promoting mental health (e.g. interventions with a psychological or social component aimed at creating living conditions and environments that support mental health and encourage positive healthy lifestyles, as well as teaching people social and emotional skills).

Included mental health promotion interventions could be delivered by a range of facilitators, including by primary-level health workers, or community workers. Primary-level health workers include professionals (doctors, nurses, midwives, and other general health professionals) and nonprofessionals (such as trained lay health providers, e.g. traditional birth attendants) working in non-specialised health care settings (e.g. primary care, HIV/AIDS care, maternal care). Community workers are non-healthcare professionals who work in the community, and represent an important human resource employed in the delivery of promotion and prevention interventions (Patel 2007). Community workers might include teachers, trainers, support workers from school and colleges, social workers and other volunteers or workers within community-based networks or non-governmental organisations (NGOs). In this protocol, both primary-level health workers and community workers will be referred to under the umbrella heading of 'non-specialist workers' (NSWs) (see also Description of the intervention).

Psychosocial interventions could be delivered at individual, group, family, community, or societal levels (National Academies of Sciences 2019). Interventions may be delivered through any means, including, for example, face-to-face meetings, digital tools, radio, telephone, or self-help booklets, between participants and primary-level health workers. Both individual and group interventions will be eligible for inclusion, with no limit placed on the number of sessions.

Excluded interventions

We will exclude interventions that aim to treat people with a diagnosed mental disorder, or explicitly aim to prevent mental disorders (i.e. specifically aiming to reduce the incidence of mental disorders). We will use the following criteria to define a study that aims to prevent mental disorders:

- the primary outcome of the study aims to measure the incidence of mental disorders by means of a formal diagnostic assessment;
- the primary outcome of the study utilises a rating scale which was dichotomised to set a cut-off, above which the participant is considered to have a diagnosis of mental disorder;
- the study measures the frequency of the diagnosis at follow-up.

We will also exclude studies that include participants on the basis of scoring above a cut-off on a symptom checklist.

Comparators

The control comparators will be:

1. no intervention;
2. intervention as usual (IAU) (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: delaying delivery of the intervention to the control group until all participants in the intervention group have completed intervention. As in IAU, participants in the waiting-list control could receive any appropriate support during the course of the study on a naturalistic basis.

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.

Types of outcome measures

We will include studies that meet the above inclusion criteria regardless of whether they report on the following outcomes.

Primary outcomes

- Mental well-being. Having good mental health, or being mentally healthy, is more than just the absence of illness, rather it's a state of overall well-being (WHO 2018c). The concept of mental health well-being generally relates to enjoyment of life, having the ability to cope with and 'bounce back' from stress and sadness, being able to set and fulfil goals, and having the capability to build and maintain relationships with others. Mental well-being is generally measured with the WHO Five Well-Being Index (WHO-5) (Bech 2004), or with other validated rating scales (Clarke 2011).
- Functioning: i.e. an objective performance in a given life domain, is generally measured with the WHO Disability Assessment Scheme (WHO 2010), Global Assessment of Functioning (APA 2000), or with other validated rating scales.
- Quality of life: defined by the WHO as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHO 2018b). It can be measured with the Quality of Life Scale (CASP-19) (Hyde 2003), the WHO Quality of Life scale (WHO 2012), or with other validated rating scales (Burckhardt 2003).
- Resilience: the capacity to recover from difficult life events. Resilience is generally measured with the Resilience Scale for Adults (RSA) (Hjemdal 2011), or with other validated rating scales (Wagnild 1993).
- Coping: intended as the capacity to use a series of actions, or a thought process used in meeting a stressful or unpleasant situation or in modifying one's reaction to such a situation. Coping is usually measured with the Kidcope (Spirto 1988), or with other validated rating scales (Carver 1989).
- Hope: the expectation that one will have positive experiences, or that a potentially threatening or negative situation will not materialise or will ultimately result in a favourable state of affairs. Hope is generally measured with the Children's Hope Scale (CHS) (Snyder 1997), or with other validated rating scales (Snyder 1991).
- Prosocial behaviour. Prosocial behaviour is a behaviour that could bring benefit to other people or society as a whole. Prosocial behaviour activities are those such as helping, sharing, donating, co-operating, and volunteering. Prosocial behaviour is generally measured with the prosocial subscale derived from the Strengths and Difficulties Questionnaire (SDQ) (Goodman 1997), or with other validated rating scales (Carlo 2002).

Secondary outcomes

- The number of participants who drop out of the trial for any reason.

Timing of outcome assessment

We will group primary and secondary outcomes into three sets of time points:

- postintervention (up to one month after the intervention);
- one to six months postintervention;
- 7 to 24 months postintervention.

Hierarchy of outcome measures

If more than one relevant outcome measure is available in the domain of interest and both describe the domain adequately, we will choose the measure with the most detailed sociocultural evaluation or the one that is also used by other trials in the analysis. Secondarily, we will choose any measure that the study authors state was tested for suitability in the population of interest.

Search methods for identification of studies

Electronic searches

We will search the following databases using relevant keywords, subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

- Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library;
- MEDLINE (Ovid) (1946 onwards) (Appendix 1);
- Embase (Ovid) (1974 onwards);
- PsycINFO (Ovid) (1806 onwards);
- PTSDpubs (ProQuest) (all available years);
- ERIC (EBSCO) (Education Resources Information Center; all available years);
- EconLit (Ovid) (1886 onwards);
- JSTOR (all available years);
- Campbell Collaboration (all available years);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov/; all available years);
- WHO International Clinical Trials Registry Platform (apps.who.int/trialsearch/; all available years).

We will place no restrictions on date, language, or publication status to the searches.

Searching other resources

Grey literature

We will search sources of grey literature, including dissertations and theses, humanitarian reports and evaluations published on websites, clinical guidelines and reports from regulatory agencies (where appropriate).

Reference lists

We will check 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. We will also perform forward-citation searches (of the included study reports) using the Web of Science and Google Scholar.

Correspondence

We will contact trialists and subject experts for information on unpublished or ongoing studies, or to request additional trial data.

Data collection and analysis

Selection of studies

We will download all titles and abstracts retrieved by electronic searching to a reference management database, and will remove duplicates. Review authors (DP, EP, CC, CG) will independently screen titles and abstracts for inclusion. We will resolve any disagreement through discussion or, if required, we will consult a third review author (CB, MP). Then, the same authors will retrieve the full-text study report/publication of eligible titles and abstracts and will independently screen the full text to finally identify studies for inclusion. We will resolve any disagreement through discussion or, if required, we will consult a third review author (CB, MP). When screening the articles, we will inspect them to identify trials that meet the following inclusion criteria:

1. randomised controlled trials;
2. any psychosocial intervention that aims to promote mental health compared with no intervention, waiting-list control or intervention as usual;
3. children, adolescents and adults living in humanitarian settings in LMICs without a formal diagnosis of post-traumatic stress disorder (PTSD), anxiety, depression according to DSM III (APA 1980), DSM-III-R (APA 1987), DSM-IV-TR (APA 2000), DSM-V (APA 2103) or ICD-10 (WHO 1992), or any other standardised criteria.

We will identify and exclude duplicate records, and will collate multiple reports that relate to the same study so that each study rather than each report will be the unit of interest in the review. We will identify and record reasons for exclusion of the ineligible full-text articles. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and characteristics of excluded studies table.

Data extraction and management

We will extract descriptive and outcome data for each study using an adapted version of the Cochrane Effective Practice and Organisation of Care (EPOC) standard data collection form (EPOC 2017). We will pilot the form on at least one study in the review. One review author (DP, CG, EP, CC) will independently extract descriptive data consecutively, and a second review author (MP, WT, CB) will cross-check the data against the publication. We will extract the following study characteristics from the included studies and enter the data into Review Manager 5 (Review Manager 2020).

- Methods: study design; number of study centres and locations; study settings; dates of study; follow-up
- Participants: number; mean age; age range; gender; health conditions; inclusion criteria; exclusion criteria; duration of exposure to the crisis; other relevant characteristics such as ethnicity and socioeconomic status
- Interventions: type and length of intervention; full description of cadre(s) of primary-level health or community workers, including details on supervision, training, and length, frequency, and type of experience; intervention components; comparison; timing of the intervention (during or after the crisis); presence of a fidelity assessment
- Setting: country; type of implementation setting (e.g. workplace, school, community); type of humanitarian crisis; type of traumatic event
- Type of delivery agent (e.g. NGO, government funded)
- Outcomes: main and other outcomes specified and collected; time points reported
- Notes: funding for the trial; notable conflicts of interest of trial authors; ethical approval

We plan to seek key unpublished information by contacting study authors of included studies via email.

Assessment of risk of bias in included studies

Two review authors (DP, CG) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We will resolve any disagreements by discussion or by involving another author (CB or MP). We will assess the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment
5. Incomplete outcome data
6. Selective outcome reporting
7. Other bias

Since we expect to include cluster-randomised trials, we will evaluate these trials according to section 16.3.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). In particular we will consider: (i) recruitment bias, (ii) baseline imbalance, (iii) loss of clusters, (iv) incorrect analysis, and (v) comparability with individually randomised trials. For each cluster-RCT we will verify, where possible: (i) if all clusters were randomised at the same time, (ii) if samples were stratified on variables likely to influence outcomes, (iii) if clusters were pair-matched, and (iv) if there was baseline comparability between psychosocial interventions and control groups.

We will judge each potential source of bias as high, low or unclear and provide a supporting quotation from the study report together

with a justification for our judgment in the risk of bias table. We will summarise 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 trialist, we will note this in the risk of bias table.

We will evaluate the risk of bias in the included studies through the first version of the Cochrane Risk of Bias tool (RoB 1) (Higgins 2017), for consistency with methods in the two previous reviews on psychosocial interventions that aimed to treat (Purgato 2018) and prevent (Papola 2020) mental health disorders in people living in LMICs affected by humanitarian crises.

Measures of treatment effect

We will estimate the effect of the psychosocial intervention by using the risk ratio (RR) with its 95% confidence interval (CI) for dichotomous data, and the mean difference (MD) or standardised mean difference (SMD) with 95% CIs for continuous data (Higgins 2021). We will ensure that an increase in scores for continuous outcomes can be interpreted in the same way for each outcome, will explain the direction to the reader, and will report when the directions were reversed, if this was necessary. For SMDs, we will use the *Cochrane Handbook for Systematic Reviews of Interventions* to interpret their clinical relevance: 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect (Cohen 1988; Higgins 2021). We will attempt to establish minimally important differences per outcome, as suggested by Guyatt 2013.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-RCTs when primary healthcare facilities, schools, or classes within schools rather than single individuals are the unit of allocation. Because variation in response to psychosocial interventions between clusters may be influenced by cluster membership, we will include, when possible, data adjusted with an intracluster correlation coefficient (ICC). We will adjust the results for clustering by multiplying standard errors of the estimates by the square root of the design effect when the design effect is calculated as DEff = 1 + (M - 1) ICC, where M is the mean cluster size and ICC is the intracluster correlation coefficient. When included studies do not report ICCs for respective outcome measures, we will derive ICCs from a different outcome from the same study, or from a different study included in the same meta-analysis. If the ICC value is not reported or is not available from trial authors directly, we will assume it to be 0.05 (Higgins 2021; Ukoumunne 1999). We will combine adjusted measures of effects of cluster-randomised trials with results of individually-randomised trials when it is possible to adjust the results of cluster trials adequately.

Cross-over trials

We will consider trials employing a cross-over design using data from the first randomised stage only, whilst we acknowledge that this design is rarely used in psychosocial intervention studies.

Studies with multiple intervention groups

For studies that include two or more formats of the same psychosocial intervention, we will include them in meta-analyses by combining group arms into a single group, as recommended in section 23.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021). Conversely, we will consider studies that included two or more different interventions without combining group arms of the study into a single group, but we will consider each psychosocial 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 will split the shared control group into two or more groups with smaller sample size, and will include two or more (reasonably independent) comparisons. We will follow the Section 23.3.4 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 2021).

Dealing with missing data

We will contact investigators to verify key study characteristics and to obtain missing outcome data when possible (e.g. when a study is identified as abstract only). We will try to compute missing summary data from other reported statistics. We will document all correspondence with trial authors and will report in the full review which trial authors responded. For cluster-RCTs, we will contact study authors for an ICC value when data are not adjusted and cannot be identified from the trial report. As mentioned above, when the ICC is neither available from the trial reports nor directly available from the trial authors, we will be assume it to be 0.05 (Ukoumunne 1999). For continuous data, we will apply a looser form of intention-to-treat (ITT) analysis, whereby all participants with at least one postbaseline measurement are represented by their last observation carried forward (LOCF). If the authors of included RCTs stated that they used an LOCF approach, we will check details on LOCF strategy and will use data as reported by study authors. When study authors report only the standard error (SE), t statistics or P values, we will calculate standard deviations according to Altman 1996. For dichotomous data, we will apply ITT analysis, whereby we will consider all dropouts not included in the analyses as negative outcomes (i.e. it was assumed they would have experienced the negative outcome by the end of the trial).

When it is not possible to obtain data, we will report the level of missingness and will consider how that might impact the certainty of evidence.

Assessment of heterogeneity

We will obtain an initial visual overview of statistical heterogeneity by scrutinising the forest plots, while looking at the overlap between CIs around the estimate for each included study. To quantify the impact of heterogeneity on each meta-analysis we will use the I^2 statistic and consider the following ranges, according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021):

- 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 will depend on the magnitude and direction of intervention effects and the strength of evidence for heterogeneity (Higgins 2021; Purgato 2012). If we identify substantial heterogeneity in the primary outcome analysis, we will explore this through prespecified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 trials in a meta-analysis, we will create and examine a funnel plot to explore possible publication biases and will interpret the results with caution (Sterne 2011).

Data synthesis

We will undertake meta-analyses only when this is meaningful (i.e. when the population, psychosocial intervention, comparison, outcome, underlying intervention question and the theory of change are similar enough for pooling to make sense) (Borenstein 2019). A common way that trialists indicate when they have skewed data is by reporting medians and interquartile ranges. When we encounter this, we will note that the data are skewed and will consider the implications of this. We will group studies for comparison by type of provider (e.g. primary-health worker led, community worker led, collaborative), and particular risk, protective, or promotive factors targeted (Tol 2015).

Given the potential heterogeneity of mental health promotion psychosocial interventions, we will use a random-effects model in all analyses. The random-effects model has the highest generalisability in empirical examinations of summary effect measures for meta-analyses (Furukawa 2002). Specifically, for dichotomous data, we will use the Mantel-Haenszel method, as this is preferable in Cochrane Reviews given its better statistical properties when there are few events (Higgins 2021). We will adopt the inverse variance method for continuous data: this method minimises 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 (Hjemdal 2011).

Subgroup analysis and investigation of heterogeneity

We will carry out the following subgroup analyses for primary outcomes.

- 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 will categorise the intervention contexts as school, camp, or healthcare setting.
- Type of traumatic events. We will consider 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 (HHS 2014).
- Type of humanitarian crisis. We will consider 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 2021). 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 psychosocial interventions) may vary according to the different humanitarian contexts in which they live (The Sphere Project 2011).
- Type of promotion intervention (individual, group).
- Having a physical condition (yes, no). To understand if having a physical condition had an effect on the review outcomes, we will perform a subgroup analysis separating those studies that enrolled participants with or without a physical condition.

For random-effects meta-analyses, we will use the formal Chi^2 test and the I^2 statistic for subgroup differences in RevMan 5, to detect statistically significant subgroup differences.

Sensitivity analysis

We will perform sensitivity analysis defined a priori to assess the robustness of our conclusions and to explore its impact on effect sizes. This will involve the following.

• Restricting analysis to studies with low risk of bias.

Summary of findings and assessment of the certainty of the evidence

We will use the GRADE approach to interpret findings (Langendam 2013). Using GRADEpro software we will import data from Review Manager 5 (Review Manager) to create summary of findings tables. These tables will provide outcome-specific information concerning the overall quality of evidence from studies included in the comparison, the magnitude of effect of the psychosocial interventions examined, and the sum of available data on the outcomes we considered. We will adhere to the standards methods for the preparation and presentation results outlined in the *Cochrane Handbook* (Higgins 2021). Two review authors (DP, CG) will independently perform the GRADE assessments.

We will include the following outcomes in the summary of findings tables.

1. Mental well-being
2. Functioning
3. Quality of life

If during the review process we become aware of an important outcome that we failed to list in our planned summary of findings tables, we will include the relevant outcome and explain the reasons for this in the section 'Differences between protocol and review'. We will consider whether there is any additional outcome information that could not be incorporated into meta-analyses and will note this in the comments; we will state if this supports or contradicts information derived from meta-analyses. If it is not possible to meta-analyse the data, we will summarise the results in the text. We will only present the postintervention time point for each outcome in the summary of findings tables.

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APPENDICES

Appendix 1. MEDLINE search

Ovid MEDLINE(R) ALL <1946 to 6 December 2021>

[Humanitarian Crises]
1 Crisis Intervention/ 5932
2 exp Disasters/ 93064
3 Refugees/ 11707
4 Adaptation, Psychological/ or Resilience, Psychological/ 105625
5 exp Terrorism/ 13258
6 exp War/ 11368
7 Torture/ 2220
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. 3219
9 (genocide or armed conflict* or mass execution* or mass violence).mp. 3193
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. 141124
11 (refugee* or forced migration or (displac* adj2 (internal or forced or mass or person* or people* or population*))).mp. 18212
12 (torture* or (politic* adj2 (persecut* or prison* or imprison* or violen*))).mp. 3789
13 (warfare or (war adj (affected or afflicted or trauma*)) or (war and (abuse* or crime* or rape* or survivor* or victim*))).mp. 40820
14 (bereav* or orphan* or widow*).mp. 39344
15 or/1-14 397099

[LMIC war affected persons]
16 ((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 Armenian 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 Georgian 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*s 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*)).mp. 8906

[LMIC setting]
17 Developing Countries/ 78273

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. 188686
19 ((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj1 (economy or economies)).mp. 757
20 (low* adj1 (GDP or GNP or gross domestic or gross national)).mp. 306
21 (low adj3 middle adj3 countr*).mp. 23918
22 (LMIC or LMICs or third world or LAMI country or LAMI countries).mp. 10525
23 (transitional country or transitional countries).mp. 177
24 (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. 2206040
25 or/17-24 2285021

[Mental health promotion/mental disorders]
26 Mental Health/ 49265
27 Health Promotion/ 78322
28 exp Mental Disorders/ 1337182
29 (mental or psychiatri* or psycho* or affective disorder* or affective symptom* or mood or depressi* or depressed or MDD).mp. 2633154
30 (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. 430230
31 (substance use* or substance abuse* or SUD or addict*).mp. 160435
32 (somatiz* or somatis* or hysteri* or briquet or multisomat* or multi somat* or MUPs or medically unexplained).mp. 15079
33 ((dissociative adj3 (disorder* or reaction*)) or dissociation).mp. 118558
34 or/26-33 3433942

[RCT Filter]
35 randomized controlled trial.pt. 552312
36 (randomi#ed or randomi#ation).ab,ti. 715988
37 (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. 547999
38 ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab. 7324
39 intervention as usual.ab. 1594
40 or/35-39 1051687
41 (15 and 25 and 34 and 40) 915
42 (16 and 34 and 40) 230
43 (41 or 42) 998

CONTRIBUTIONS OF AUTHORS

DP, MP, and WAT wrote the protocol.

CB has contributed and supervised all phases of the protocol development.
WAT, MP, DP and CG contributed to design the methods.
WAT and CB given suggestions for refinement of the protocol, and revised the protocol.
All reviewers have contributed actively to the protocol proposal, participated in discussions and helped clarify questions and provided suggestions for overall preparation.

DECLARATIONS OF INTEREST

DP: none known.
EP: none known.
CC: none known.
CG: none known.
WAT: none known.
MvO: none known.
CB: none known.
MP: none known.

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- Department of Mental Health and Substance Abuse, World Health Organization, Geneva, Switzerland

  Author support: MvO

External sources

- No sources of support provided