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Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

Purgato M, Abdulmalik JO, Prina E, Ceccarelli C, Tol WA, van Ginneken N, Uphoff E, Papola D, Amaddeo F, Churchill R, Jordans MJD, Lund C, Barbui C

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[Intervention Protocol]

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries

Marianna Purgato[1,2], Jibril O Abdulmalik[3], Eleonora Prina[1], Caterina Ceccarelli[1], Wietse A Tol[4,5], Nadja van Ginneken[6], Eleonora Uphoff[7], Davide Papola[1,2], Francesco Amaddeo[1], Rachel Churchill[7], Mark JD Jordans[8], Crick Lund[9,10], Corrado Barbui[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]University of Ibadan, Ibadan, Nigeria. [4]Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA. [5]Department of Public Health, University of Copenhagen, Copenhagen, Denmark. [6]Department of Primary Care and Mental Health, University of Liverpool, Liverpool, UK. [7]Cochrane Common Mental Disorders, University of York, York, UK. [8]Centre for Global Mental Health, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK. [9]King's Global Health Institute, Centre for Global Mental Health, Health Service and Population Research Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK. [10]Alan J Flisher Centre for Public Mental Health, Department of Psychiatry and Mental Health, University of Cape Town, Cape Town, South Africa

Contact address: Marianna Purgato, marianna.purgato@univr.it.

A B S T R A C T

Objectives

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

- To assess the effectiveness of delivery by primary workers of interventions for promotion of mental health and for prevention of mental disorders or symptoms of mental illness in LMICs
- To examine the impact of intervention delivery by primary workers on resource use and costs associated with provision of mental health care in LMICs

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BACKGROUND

Description of the condition

Worldwide, the global burden of mental, neurological, and substance abuse disorders is high. The latest global burden of disease studies estimated that mental, behavioural, and neuropsychiatric disorders are among the top 30 causes of all years lived with disability; the highest contributors are anxiety and depressive disorders, drug use disorders, and alcohol use disorders (Kyu 2018). Mental health and behavioural disorders contribute 7.4% of the global burden of disease in the world - more than, for example, tuberculosis (2.0%), HIV/AIDS (3.3%), or malaria (4.6%) (Whiteford 2013). The contribution of major depressive disorders alone to worldwide disability-adjusted life-years (DALYs) increased by 37% between 1990 and 2010 and is predicted to rise further (Murray 2012; Prince 2007). Furthermore, self-inflicted injuries and alcohol-related disorders are likely to increase in the ranking of disease burden due to the decline in communicable diseases and because of a predicted increase in war and violence. The disease burden due to Alzheimer's disease is also increasing; this is linked to the demographic transition towards an ageing population (Vos 2012).

These illnesses also come with substantial economic costs. One recent report on the global economic burden of non-communicable diseases (NCDs) suggests that by the early 2030s, mental health conditions alone will account for the loss of an additional USD 16.1 trillion, with a dramatic impact on productivity and quality of life (Bloom 2011). Data on the macro-economic costs for low-and middle-income country (LMIC) settings remain uncertain (Hu 2006). However, the economic and social costs for individuals and families are substantial. High direct costs are incurred in countries where health spending is met largely through private, as opposed to public, spending, and where health insurance and employer-met health payments are insubstantial (Patel 2007a). High indirect costs are incurred as the result of informal caregiving and lost work opportunities, as well as untreated disorders and their associated disabilities (Chisholm 2000).

All over the world, the gap between individuals in need of mental health interventions and those who actually receive such care is very large (WHO 2018). Previous estimates suggest that more than 56% of persons with depression (De Silva 2014; Kohn 2004; Lora 2012; Patel 2010), along with 78% of persons with alcohol abuse and dependence (Kohn 2004), have not received care. A study of 21 countries via the World Health Organization (WHO) Mental Health Surveys found that 52.6% of persons with depressive disorders in low-income countries had received no treatment in the past 12 months, and only 20.5% of persons with depressive disorders had received minimally adequate treatment (Thronicroft 2016). This is so despite the existence of a range of cost-effective interventions in mental health care available in LMICs (Barbui 2020; Purgato 2018). Major barriers to closing the treatment gap include scarcity of skilled human resources, large inequities and inefficiencies in resource distribution and utilisation, and the significant stigma associated with psychiatric illness (Barber 2019). Recent studies have advocated for scaling-up evidence-based services and task-shifting mental health interventions to non-specialists as key strategies for bridging the treatment gap (Patel 2018).

Description of the intervention

A recent Lancet Commission sought to align global mental health efforts with sustainable development goals and emphasised the importance of efforts to prevent mental health disorders and promote mental health, in addition to scaling-up treatments (Patel 2018). Prevention and promotion in mental health have previously been advocated as critical by the WHO (WHO 2002), and prevention is part of the WHO Mental Health Action Plan (WHO 2013). Prevention and promotion efforts are an important complementary focus, in addition to treatment of mental disorders, given that (1) many mental disorders have risk factors in the social environment (e.g. gender-based violence, poverty) that can be effectively addressed; (2) there are limitations to the extent that treatments alone can reduce the burden associated with mental disorders (e.g. optimal coverage with efficacious treatments in Australia has been estimated to reduce the burden related to depression by 36%) (Andrews 2000); and (3) cost-effective prevention and promotion interventions are available (Knapp 2011).

Primary healthcare workers (PHWs) are first-level providers who have received general health rather than specialist training and can be based in a primary care clinic or in the community. These include professionals (doctors, nurses, midwives, and other general health professionals) and non-professionals (such as trained lay health providers, e.g. traditional birth attendants). PHWs do not include those with specialist mental health training, for example, psychiatrists, psychologists, psychiatric nurses, or mental health social workers. Community workers (CWs) are individuals who work in the community but not within the health sector. These might include teachers, trainers, support workers at schools and colleges, and other volunteers or workers within community-based networks or non-governmental organisations (NGOs). CWs are an additional human resource that can be deployed in delivering promotion and prevention interventions (Patel 2007). In this protocol, both these categories of providers (PHWs and CWs) will be referred to under the umbrella heading of primary-level workers (PWs).

PWs have been deployed for a variety of services, including those delivered in governmental organisations, private clinics, half-way homes, schools, and other community settings. For example, PWs have been involved in supporting and befriending carers and in ensuring intervention adherence (Tol 2020). Nurses, social workers, and CWs may also take on follow-up or educational/promotive roles (Araya 2003; Chatterjee 2003; Patel 2008). In addition, doctors with general mental health training have been involved in identification, diagnosis, treatment, and referral of complex cases (Patel 2008).

In the present review, we will follow the classification of promotion and prevention interventions described by the Institute of Medicine (IOM) report on preventing mental disorders (Institute of Medicine 1994; Institute of Medicine 2009; National Academies of Sciences 2019).

Promotion is an approach that is aimed at strengthening 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 (Table 1) (WHO 2014). The definition of promotion has been recently updated to include a wider set of interventions

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provided at societal, community, and 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 (National Academies of Sciences 2019).

Prevention is an approach aimed at reducing the likelihood of future mental disorders in the general population or among people who are identified as being at risk for developing a full-blown mental disorder (Eaton 2012; Purgato 2020; Tol 2015). Prevention is further subdivided on the basis of the targeted population.

- Universal prevention includes strategies that can be offered to the whole population based on evidence that prevention strategies are likely to provide some benefit to all (i.e. reduce the probability of disorder), which clearly outweighs the costs and risks of negative consequences. Examples of common universal prevention interventions include:

  - community-wide provision of information on the negative effects of alcohol misuse;
  - protection against human rights violations in the whole population (e.g. community mobilisation to reduce gender-based violence); and
  - community-wide efforts to improve livelihood as a key protective factor for mental health (e.g. working on lifting restrictions on movement and employment for everyone in a refugee camp).

- Selective prevention refers to strategies that target subpopulations identified as being at elevated risk for a disorder because they have known risk factors or lack protective factors. Examples include:

  - support for children whose parents have a mental illness;
  - strengthening of community networks for vulnerable families by activating social networks and supportive communication; and
  - stress management training in communities affected by chronic poverty.

- Indicated prevention includes strategies that are targeted to individuals who are identified (or individually screened) as having increased vulnerability for a disorder based on some individual assessment of symptoms experienced but not meeting criteria for a full-blown mental disorder. These interventions include but are not limited to:

  - mentoring programmes aimed at teachers and caregivers of children with behavioural problems; and
  - prevention of postnatal depression among women with heightened levels of prenatal symptoms (Institute of Medicine 2009).
    * These interventions may be delivered at an individual level or at a group level and include antenatal and postnatal classes, parenthood classes, and continuity of care (home visits, follow-ups) (US Preventive Services Task Force 2019; O'Connor 2019)

A summary of the main definitions is provided in Table 1.

How the intervention might work

Prevention interventions commonly target known modifiable risk and protective factors for mental disorders. Risk factors can include community-level risk factors (e.g. neighbourhood disadvantages, high levels of community violence, community-level gender inequitable norms), family-level risk factors (e.g. intimate partner violence, harsh parenting), or individual-level risk factors (e.g. low self-esteem, maladaptive coping strategies). Similarly, protective factors can operate at multiple levels of the social environment. Promotion interventions may target promotive factors (i.e. factors associated with an increased chance of achieving positive mental health states).

Although a vast array of interventions can be implemented to meet a population's psychosocial needs, there are some common elements, especially when interventions target smaller groups or families. Many interventions include techniques from cognitive-behavioural therapy (CBT) and may comprise, for example, facilitated discussion; strengthening of social networks; space provided for sharing personal experiences and exchange of peer support; opportunities to practice coping skills to manage adversity; problem-solving skills; self-help interventions; and emotional support Interventions that may consist of sessions with psychoeducational contents, strategies for stress management, enhanced insight and relationship/rapport building, networking support, communication skills, and motivational enhancement (Buntrock 2016; Panter-Brick 2018).

In many LMICs, training and retaining sufficient numbers of mental health specialists to meet current needs is not feasible. Therefore, it is important in these settings to consider options for expanding access to mental health promotion and disorder prevention services. Given that they are far more numerous and often more accessible than mental health specialists, deployment of PWs for this purpose is one option that could prove to be of value in LMICs. This review therefore focuses on a task-sharing model as a possible implementation modality in LMICs.

It has been suggested that PWs could deliver general and mental health interventions that are at least as effective and acceptable as those delivered by specialist health workers (Chatterjee 2003). In addition, PW interventions often have lower up-front costs compared with those provided by professional specialist health workers. However, it is possible that these savings may be cancelled out by higher downstream resource use (Chisholm 2000). To address this concern, we aim to include data on the costs and cost-effectiveness of PW interventions.

Why it is important to do this review

This review is limited to LMICs, where the need for PWs is greater than in high-income settings. Far fewer mental health professionals are present in LMICs (the median number of psychiatrists is 172 times lower in low-income countries (LICs) than in high-income countries (HICs)) (Kakuma 2011; WHO 2011a), and mental health services are more poorly organised and resourced. These differences in the organisation of mental health services between LMICs and HICs, with poorer countries having few or no mental health service structures in primary care or in the community, mean that the problem of providing mental health care, especially of preventing mental disorders, is different in such settings. PWs may need to work with little or no support from specialist mental health

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services and fewer options for patient referral. Consequently, PW interventions might be expected to function differently in LMICs as compared to HICs (Cuijpers 2018; Purgato 2019).

The paucity of mental health professionals and the abundance of challenges for mental health systems in LMICs make it imperative to focus attention on prevention and promotion strategies via a public health approach (Tol 2015). To address current shortages of mental health workers, interventions in LMICs have been conceived as short, simple, and delivered through a task-shifting approach that includes different forms of intervention delivery. Delivery strategies range from informal delivery of simple interventions to more complex strategies. Task-shifting is increasingly emphasised in global mental health and holds promise for improving access to mental health interventions (Jensen 2018; Patel 2018). However, reviews on the task-shifting approach to mental health interventions in LMICs have tended to focus more on treatment interventions (Singla 2017). Evidence on the effectiveness of mental health prevention and promotion interventions in LMICs is scarce. Available systematic reviews have focused mainly on populations living in high-income settings, raising applicability concerns related to contextual factors and resource availability, including, for example, the lack of professionals in low-resource contexts (i.e. psychiatrists, psychologists) (Barbui 2020). In addition, LMICs differ from HICs with regard to social determinants of mental health (e.g. exposure to conflicts and wars, poverty, and gender-based violence may be more frequent in LMICs) (Lund 2018).

Populations in LMICs can conceptualise and seek assistance for mental health problems and mental health promotion in a wide variety of ways; these approaches may differ from conceptualisations and help-seeking patterns seen in high-income industrialised countries. Thus, evidence regarding the effectiveness of interventions implemented in HICs may not directly apply or be relevant to LMICs. For the reasons mentioned above, we expect that interventions might be applied differently in LMICs (Abdulmalik 2019).

Finally, this review is in line with the WHO principle of integrating mental health into primary care and with the WHO Action Plan for global mental health, which has a specific prevention objective (WHO 2008).

This review will be conducted in parallel with an update of the Cochrane Review focused on treatment interventions in LMICs (van Ginneken 2013).

OBJECTIVES

- To assess the effectiveness of delivery by primary workers of interventions for promotion of mental health and for prevention of mental disorders or symptoms of mental illness in LMICs
- To examine the impact of intervention delivery by primary workers on resource use and costs associated with provision of mental health care in LMICs

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised trials. We will include trials that employ a cross-over design - whilst we acknowledge that this design is rarely used in intervention studies - and we will use data from the first randomised stage only. We will exclude quasi-randomised trials, such as those that allocate participants by using alternate days of the week. We will consider both individual and cluster-randomised trials as eligible for inclusion.

We will include economic studies conducted as part of included effectiveness studies. We will consider full economic evaluations (cost-effectiveness analyses, cost-utility analyses, or cost-benefit analyses), cost analyses, and comparative resource utilisation studies. We will extract and report only cost and resource usage outcomes from these studies.

Types of participants

Participants

We will include participants of any age, gender, ethnicity, and religion. We intend to conduct two separate meta-analyses on the different outcomes - one for children and adolescents (younger than 18 years) and one for adults (18 years of age and older). 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. For each of these two populations, we will conduct meta-analyses by different outcomes and types of disorders prevented. We will include studies focused on prevention of any mental disorder, including substance misuse and neuropsychiatric conditions. Additionally, we will include carers of study participants (i.e. any relatives or friends of any age who define themselves as key supporters for a study participant), as some interventions may be directed at carers rather than at participants themselves.

Settings

We will consider studies conducted in LMICs. We will use World Bank criteria for categorising a country as low- or middle-income (World Bank 2020); these criteria provide an historical date of when countries were LMICs. If a country was an LMIC at some point during recruitment of study participants, we will include the study. We will exclude studies undertaken in high-income countries (at the time of study recruitment).

We will include mental health promotion and/or prevention interventions delivered in primary care or community settings, refugee camps, schools, communities, survivors' homes, and detention facilities. We will exclude studies evaluating mental health promotion and/or prevention interventions undertaken outside of primary or community settings.

Diagnoses

Given the focus on promotion of mental health and prevention of mental disorders, we will restrict this review to participants without any formal diagnosis at the time the trial was undertaken. However, because many studies screen on the basis of a risk factor or heightened symptoms (without excluding people with diagnosed mental disorders), we cannot exclude trial participants

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who 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. 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 that include participants with physical disorders and studies that focus on prevention of multiple mental disorders.

Types of interventions

Included interventions

We will include trials of primary-level and/or community health worker interventions for promoting mental health and/or preventing mental disorders. Included mental health promotion or prevention interventions will be delivered by primary-level and/ or community workers. Primary-level health workers (PHWs) are first-level providers who have received general health rather than specialist mental health training and can be based in a primary care clinic or in the community. PHWs include professionals (doctors, nurses, midwives, and other general health professionals) and non-professionals (such as trained lay health providers, e.g. traditional birth attendants). PHWs do not include those with specialist mental health training, for example, psychiatrists, psychologists, psychiatric nurses, or mental health social workers. Community workers (CWs) are individuals who work in the community but not within the health sector. These might include teachers, trainers, support workers from schools and colleges, and other volunteers or workers within community-based networks or non-governmental organisations (NGOs). These CWs are not trained health workers but have a mental health role. They represent a further human resource employed in the delivery of promotion and prevention interventions (Patel 2007). In this protocol, both of these categories of providers (PHWs and CWs) will be referred to under the umbrella heading of 'primary-level workers' (PWs).

This review will include the following comparisons.

- Provision of promotion and/or prevention interventions by primary-level health workers and/or community workers versus usual care (little prevention or promotion strategy).
- Provision of promotion and/or prevention interventions by primary-level health workers and/or community workers versus no prevention or promotion strategy.
- Provision of promotion and/or prevention interventions by primary-level health workers and/or community workers versus interventions delivered by professionals with specialist mental health training.

We will group the interventions as follows.

- Promotion of mental health (e.g. interventions with a mental health or psychological component aimed at creating living conditions and environments that support mental health and encourage healthy lifestyles). We intend to include any types of promotion interventions with a mental health component, delivered at individual, group, family, community, and/or societal levels (National Academies of Sciences 2019).
- Universal prevention (e.g. community-wide provision of information on positive coping methods to help people feel safe and hopeful; to protect against human rights violations; and to support community-wide efforts to reduce poverty as a key risk for mental illness) (IASC 2007).
- Selective prevention (e.g. psychological first aid for people with heightened levels of psychological distress 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 work through 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); a psychological approach (including teaching stress management skills and helping people cope with problems) (WHO 2011); facilitation of community support for vulnerable individuals by activating social networks and communication; and structured cultural and recreational activities supporting the development of resilience (Institute of Medicine 2009), such as traditional dancing, art work, sports, and puppetry (Tol 2011).
- Indicated prevention (e.g. mentoring programmes aimed at children with behavioural problems; psychosocial support for school children with subclinical levels of post-traumatic stress disorder (PTSD), anxiety, depression, or somatic symptoms and related disorders; prevention of postnatal depression in women with heightened levels of prenatal symptoms) (Institute of Medicine 2009).

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 PHWs. Both individual and group interventions will be eligible for inclusion, with no limit placed on the number of sessions.

As this review will be conducted in parallel with the update of the Cochrane Review on treatment interventions (van Ginneken 2013), we will look at the aim of the study and will decide whether the aim was prevention or treatment, and we will look at the inclusion criteria for participants (these criteria must include specific mental distress/prodromal symptoms or a diagnosable disorder). When there is no clear distinction between prevention and treatment groups, we will make a pragmatic decision on whether these trials are primarily about well-being/prevention or about treatment and will then allocate them to the appropriate review, or we will include them in both reviews and will perform sensitivity analyses with or without them.

Excluded interventions

We will exclude interventions aimed at treating people with a diagnosed mental disorder. We will also exclude studies that include participants on the basis of scoring above a cut-off on a symptom checklist, with the explicit authors' stated intention to identify people with mental disorders. We will exclude interventions aimed at treating people with a diagnosed disorder, when they are part of a Cochrane Review on treatment interventions that is currently being updated (van Ginneken 2013).

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Types of outcome measures

Primary outcomes

- Diagnosis (or a proxy thereof, as assessed by scoring above a cut-off for a screening tool) of mental 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-V (APA 2013), International Classification of Diseases (ICD)-10 (WHO 1992a), or any other standardised criteria
- Diagnosis (or a proxy thereof, as assessed by scoring above a cut-off for a screening tool) of mental disorders at 1 to 6 months post intervention
- Diagnosis (or a proxy thereof, as assessed by scoring above a cut-off for a screening tool) of mental disorders at 7 to 24 months post intervention
- Quality of life
- Adverse events experienced during the intervention

Secondary outcomes

- Psychological functioning and impairment;
- Changes in service utilisation and contact coverage, including admission rates to hospital whether related to mental disorder or not; attendance rates with regards to utilisation of primary or community services; or increased demand and/or referral rates from the primary/community setting to a mental health specialist
- Changes in mental health symptoms captured on rating scales
- Social outcomes (e.g. perception of social inclusion)
- Resource use (for health services: personnel time allocated/number of consultations, other opportunity costs of the intervention, or other aspects of the health service; for participants: extra costs of travel, lost productivity, employment status, income, work absenteeism, retention, educational attainment)
- Carer mental health

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

- Post intervention (0 to 1 month after the intervention) (to detect incidence/symptoms, reduction of the intervention).
- 1 to 6 months post intervention (to detect sustained incidence/symptom reduction).
- 7 to 24 months post intervention (indicating medium- to long-term reduction).

We will choose the latest time point within that category if several time points fit within a category. We may however include a time point that correlates best with other studies being compared within each outcome.

We will include studies that report only secondary outcomes of the review.

Search methods for identification of studies

Electronic searches

The EPOC (Effective Practice and Organisation of Care) Information Specialist will develop search strategies in consultation with the review authors. We will search Epistemonikos (https://www.epistemonikos.org)/PDQ-Evidence (https://www.pdq-evidence.org) for related systematic reviews.

We will search the following databases for primary studies, from inception to date of search.

- Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library.
- MEDLINE, Ovid.
- Embase, Ovid.
- Cumulative Index to Nursing and Allied Health Literature (CINAHL), EBSCOhost.
- Global Index Medicus, WHO (www.globalindexmedicus.net/).
- PsycInfo, Ovid.

Search strategies comprised natural language and controlled vocabulary terms. We will not apply any limits on language of publication, and we will search all databases from inception to the date of search, except for MEDLINE and Embase. MEDLINE and Embase will be limited to records from the last few months to find those not yet included in CENTRAL. Searches will be limited by the use of study design filters appropriate to the stated inclusion criteria. See Appendix 1 for the draft MEDLINE search strategy, which we will adapt for other databases.

For this prevention review we will use the search strategies developed for the ongoing update of the complementary Cochrane review on treatment (van Ginneken 2013), with appropriate adaptation when needed.

Searching other resources

Trial registries

- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; www.who.int/ictrp)
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov)

Grey literature

We will conduct a grey literature search to identify studies not indexed in the databases listed above. In particular, we will search such relevant platforms as Mental Health Innovation Network (MHIN) (https://www.mhinnovation.net) and MHPSS.net (https://mhpss.net).

We will also:

- review reference lists of all included studies and relevant systematic reviews for additional potentially eligible primary studies;
- contact authors of included studies/reviews to clarify reported published information and to seek unpublished results/data;
- contact researchers with expertise relevant to the review topic/EPOC interventions;
- conduct cited reference searches for all included studies in Web of Science Core Collection and Clarivate Analytics.

We will provide appendices for all strategies used, including a list of sources screened and relevant reviews/primary studies reviewed.

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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 (NvG, AB, MP, EU) will independently screen titles and abstracts for inclusion. We (NvG, MP, CCEU, EPAB) will retrieve the full-text study report/publication and will independently screen the full text and identify studies for inclusion; we will identify and record reasons for exclusion of ineligible studies. We will resolve disagreements through discussion, or, if required, we will consult a third review author (CB, WT).

We will list in the 'Characteristics of excluded studies' table studies that initially appeared to meet the inclusion criteria but that we later excluded. We will collate multiple reports of the same study, so that each study rather than each report is the unit of interest in the review. We will also provide any information we can obtain about ongoing studies. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009).

Data extraction and management

We will extract descriptive and outcome data for each study using an adapted version of the EPOC standard data collection form (EPOC 2017a). We will pilot the form on at least one study in the review. One review author (MP, DP, CC, EP) will independently extract descriptive data consecutively, and these will be cross-checked by a second review author (EP, EU, JA). We will note in the 'Characteristics of included studies' table if outcome data were reported in an unusable way. We will extract the following study characteristics from the included studies, and we will enter the data into Review Manager 5 (Review Manager 2014).

- Methods: study design; number of study centres and locations; study settings; withdrawals; dates of study; follow-up.
- Participants: number; mean age; age range; gender; clinical conditions; inclusion criteria; exclusion criteria; other relevant characteristics such as ethnicity and socio-economic status.
- Interventions: type and length of intervention; theory of change (hypothesised risk, protective, promotive factors); full description of cadre(s) of primary-level health and/or community workers including details on supervision, training, and length, frequency, and type of experience; intervention components; comparison; fidelity assessment.
- Setting: country; type of health and/or community service (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.

For economic data, we will develop a specific data extraction form based on the format and guidelines used to produce structured abstracts of economic evaluations for inclusion in the National Health Service (NHS) Economic Evaluation Database (NHS EED) (University of York 2002), which we will adapt to the specific requirements of this review.

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

Review authors who are authors of included studies will not be involved in the following steps for that study: study selection, data extraction, risk of bias assessment, and GRADE assessment.

Assessment of risk of bias in included studies

Two review authors (EP, CC) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* Section 8.5 (Higgins 2019), along with guidance from the EPOC Group (EPOC 2017b). We will resolve disagreements by discussion or by consultation with a third review author (CB, MP). We will assess 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.
- Baseline outcomes measurement.
- Baseline characteristics.
- Other bias.

We will judge each potential source of bias as having high, low, or unclear risk and will provide a quote from the study report, together with a justification for our judgement, in the 'Risk of bias' table. We will summarise risk of bias judgements across different studies for each of the domains listed. We will assign an overall risk of bias assessment (high, moderate, or low risk) to each of the included studies using the approach suggested in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019). We will consider studies that have low risk of bias for all key domains, or for which it seems unlikely for bias to seriously alter the results, to have low risk of bias. We will consider studies to have unclear risk of bias when risk of bias in at least one domain is unclear, or when studies are judged to have some bias that could plausibly raise doubts about the conclusions. We will consider studies to have high risk of bias when they have high risk of bias in at least one domain, or when we judge that they have serious bias that decreases the certainty of the conclusions.

We will consider blinding separately for different key outcomes when necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported rating scale). When 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 not exclude studies on the grounds of their risk of bias, but we will clearly report the risk of bias when presenting study results.

When considering treatment effects, we will take into account the risk of bias for studies that contribute to that outcome.

We will conduct the review according to this published protocol and will report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will estimate the effect of the intervention by using risk ratio (RR), together with the appropriate associated 95% confidence interval (CI), for dichotomous data; and mean difference (MD)

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or standardised mean difference (SMD), together with the 95% appropriate associated confidence interval, for continuous data (Higgins 2019). 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 2011). We will attempt to establish minimally important differences per outcome (as suggested in Guyatt 2013).

Unit of analysis issues

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 psychological or social intervention between clusters may be influenced by cluster membership, we will include, when possible, data adjusted with an intra-cluster 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 intra-cluster 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 2011; Ukoumunne 1999). We will combine adjusted measures of effects of cluster-randomised trials with results of non-cluster-randomised trials when it is possible to adjust adequately the results of cluster trials.

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 post-baseline 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) or t statistics or P values, we will calculate standard deviations (SDs) according to Altman 1996.

For dichotomous data, we will apply the 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

If we find a sufficient number of studies for which we judge participants, interventions, comparisons, and outcomes to be sufficiently similar, we will conduct a meta-analysis (Borenstein 2009). 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 we will consider the following ranges, according to the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2019).

- 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 will depend on the magnitude and direction of intervention effects and the strength of evidence for heterogeneity (Higgins 2011; Purgato 2012). If we identify substantial heterogeneity, we will explore this through pre-specified 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, intervention, comparison, outcome, and underlying intervention question and the theory of change are similar enough for pooling to make sense) (Borenstein 2009). 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. When multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) must be entered into the same meta-analysis, we will halve the control group to avoid double-counting. We will group studies for comparison by type of provider (e.g. primary-health workers led, community workers led, collaborative), type of intervention (promotion, universal, selective, indicated prevention), and particular risk, protective, or promotive factors targeted (Eaton 2012; Tol 2015).

Given the potential heterogeneity of mental health promotion and prevention 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). We will examine the robustness of this summary measure by checking the results under a fixed-effect model. We will report material differences between models.

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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 2011). 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 (Higgins 2011).

Economic data

We will conduct all elements of the economics component of this review according to current guidance on the use of economics methods in the preparation and maintenance of Cochrane Reviews (Shemilt 2006). We will classify the included economic evaluations based on an established system (Drummond 2005; Trautmann 2016). We will summarise the characteristics and results of included economic evaluations by using additional tables, supplemented by a narrative summary comparing and evaluating the methods used and the principal results of included studies. We will display resource use and cost data in a table, along with unit cost data (when available). A unit cost is defined as the cost of each specific resource input calculated by multiplying the measured number of units (quantities) of an item of resource use (e.g. the number of hours of time provided by a senior teacher) by an applicable unit cost (e.g. the salary cost of one hour of senior teacher time). We will report the currency and price year applicable to measures of costs and unit costs in each original study. Measures of costs are highly likely to vary across and within study settings and over time. This is the product of variations in underlying quantities of resource use and variations in underlying unit costs. This approach is consistent with that used in the parallel review on treatment that is being updated (van Ginneken 2013).

Subgroup analysis and investigation of heterogeneity

Within each comparison, we plan to carry out the following subgroup analyses.

- Category of health worker (e.g. professionals, health workers, non-professional health workers, community workers).
- Setting of care.
  * Community settings, camps, schools.
  * Chronic or acute humanitarian versus non-humanitarian settings.
- Type of prevention intervention (universal, selective, indicated).
- Type of promotion intervention (individual, group).
- Specific risk, protective, or promotive factor targeted.

We will use the following outcomes in subgroup analysis.

- Proportion of individuals developing new mental distress or mental disorders (incidence).
- Quality of life outcomes.
- Harmful outcomes: number of people experiencing harm during the intervention.
- Change from baseline in average rating scale scores (e.g. psychological symptoms) for the study population.

If the number of included studies for each comparison is sufficient, we will perform subgroup analyses to check whether the intervention effect varied with different population characteristics.

When applicable, or when subgroup analysis is not possible, we will describe subgroup differences narratively in the 'Results' section.

For random-effects meta-analyses, we will use the formal chi² test and the I² statistic for subgroup differences in RevMan 5, to detect statistically significant subgroup differences.

Sensitivity analysis

We will perform sensitivity analyses 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 published studies.
- Restricting analysis to studies measuring the incidence of mental disorders (i.e. studies in which all participants at baseline scored below defined symptom thresholds on rating scales).
- Restricting analysis to studies with low risk of bias, as specified in incomplete outcome data and selective reporting.
- Excluding trials with methodological characteristics that might generate highest heterogeneity in a meta-analysis (when a meta-analysis has I² > 75%).

Stakeholder consultation and involvement

Consultation with stakeholders was conducted by authors Nadja van Ginneken, Simon Lewin, and Paul Garner of the parallel review focused on treatment of mental disorders in LMICs (van Ginneken 2013), which is currently being updated. Consultation was organised as follows.

- A group face-to-face consultation with seven LMIC clinicians who are mature students/master's students or PhD students at the Liverpool School of Tropical Medicine (December 2018).
- An online consultation with seven implementers, academics, and policy makers from LMICs, and a further four written answers from further stakeholders received by email (February to April 2019).
- An updated literature review of mental health terminology and descriptions.

The overall message that emanated from this consultation was that we should consider the spectrum of mental illness as broader than encompassing only diagnostic categories (Patel 2018). According to this framework, the current review will complement the parallel review on treatment interventions in LMICs.

Summary of findings and assessment of the certainty of the evidence

Two review authors (EP, CC) will independently assess the certainty of the evidence (high, moderate, low, and very low) using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias) (Guyatt 2008). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2019), and in the EPOC Worksheets (EPOC 2017c), and we will use GRADEpro software (GRADEpro GDT). We will resolve disagreements on certainty ratings by discussion and will provide justification for decisions to downgrade or upgrade ratings by using footnotes in the table and making comments to aid readers' understanding of the review when necessary. We will use plain language statements to report these findings in the review (EPOC 2017c).

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We will summarise review findings in a 'Summary of findings' table(s) for the main intervention comparison(s) and will include the following outcomes.

- Diagnosis (or a proxy thereof, as assessed by scoring above a cut-off of a screening tool) of mental 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-V (APA 2013), International Classification of Diseases (ICD)-10 (WHO 1992a), or any other standardised criteria.
- Quality of life.
- Adverse events experienced during the intervention.
- Change in mental health symptoms seen on rating scales.
- Resource use (for health services: personnel time allocated/number of consultations, other opportunity costs of the intervention, or other aspects of the health service; for participants: extra cost of travel, lost productivity, employment status, income, work absenteeism, retention, educational attainment).
- Psychological functioning and impairment.

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. Only the post-intervention time point will be presented for each outcome in the 'Summary of findings' tables.

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REFERENCES

Additional references

Abdulmalik 2019

Abdulmalik J. Optimal Mental Health: An Everyday Guide. Ibadan, Nigeria: Inspiration House Publishing, 2019.

Altman 1996

Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**(7066):1200.

Andrews 2000

Andrews G, Sanderson K, Corry J, Lapsley HM. Using epidemiological data to model efficiency in reducing the burden of depression. *Journal of Mental Health Policy and Economics* 2000;**3**(4):175-86.

APA 1980

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-III). 3rd edition. Washington, DC: American Psychiatric Association, 1980.

APA 1987

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R). 3rd revised edition. Washington, DC: American Psychiatric Association, 1987.

APA 2000

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). 4th revised edition. Washington, DC: American Psychiatric Association, 2000.

APA 2013

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-V). 5th edition. Washington, DC: American Psychiatric Association, 2013.

Araya 2003

Araya R, Rojas G, Fritsch R, Gaete J, Rojas M, Simon G, et al. Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial. *Lancet* 2003;**361**:995-1000.

Barber 2019

Barber S, Gronholm PC, Ahuja S, Rüsch N, Thornicroft G. Microaggressions towards people affected by mental health problems: a scoping review. *Epidemiology and Psychiatric Sciences* 2019;**29**:e82.

Barbui 2020

Barbui C, Purgato M, Abdulmalik J, Acarturk C, Eaton J, Gastaldon C, et al. Efficacy of psychosocial interventions for mental health outcomes in low-income and middle-income countries: an umbrella review. *Lancet Psychiatry* 2020;**7**(2):162-72.

Bloom 2011

Bloom D, Cafiero E, Jané-Llopis E, Abrahams-Gessel S, Bloom L, Fathima S, et al. The Global Economic Burden of Noncommuicable Diseases. Geneva: World Economic Forum, 2011.

Borenstein 2009

Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. When does it make sense to perform a meta-analysis? In: Introduction to Meta-Analysis. Chichester, UK: John Wiley & Sons, Ltd, 2009.

Buntrock 2016

Buntrock C, Ebert DD, Lehr D, Smit F, Riper H, Berking M, Cuijpers P. Effect of a web-based guided self-help intervention for prevention of major depression in adults with subthreshold depression: a randomized clinical trial. *JAMA* 2016;**315**(17):1854-63.

Chatterjee 2003

Chatterjee S, Patel V, Chatterjee A, Weiss HA. Evaluation of a community-based rehabilitation model for chronic schizophrenia in rural India. *British Journal of Psychiatry* 2003;**182**:57-62.

Chisholm 2000

Chisholm D, Sekar K, Kishore Kumar KV, Saeed K, James S, Mubbashar MH, et al. Integration of mental health care into primary care. *British Journal of Psychiatry* 2000;**176**:581-8.

Cohen 1988

Cohen J. Statistical Power Analysis in the Behavioral Sciences. 2nd edition. Hillsdale (NJ): Lawrence Erlbaum Associates, Inc, 1988.

Cuijpers 2018

Cuijpers P, Karyotaki E, Reijnders M, Purgato M, Barbui C. Psychotherapies for depression in low- and middle-income countries: a meta-analysis. *World Psychiatry* 2018;**17**(1):90-101.

De Silva 2014

De Silva MJ, Lee L, Fuhr DC, Rathod S, Chisholm D, Schellenberg J, et al. Estimating the coverage of mental health programmes: a systematic review. *International Journal of Epidemiology* 2014;**43**(2):341-53.

Drummond 2005

Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. Methods for the Economic Evaluation of Health Care Programmes. Oxford, UK: Oxford University Press, 2005.

Eaton 2012

Eaton W. Public Mental Health. New York (NY): Oxford University Press, 2012.

EPOC 2017a

Cochrane Effective Practice and Organisation of Care (EPOC). Data collection form. EPOC resources for review authors, 2017. Available from epoc.cochrane.org/epoc-specific-resources-review-authors.

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

11

Copyright © 2021 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

EPOC 2017b

Cochrane Effective Practice and Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC resources for review authors, 2017. Available from epoc.cochrane.org/epoc-specific-resources-review-authors.

EPOC 2017c

Cochrane Effective Practice and Organisation of Care (EPOC). EPOC worksheets for preparing a 'Summary of findings' table using GRADE. EPOC resources for review authors, 2017. Available from epoc.cochrane.org/epoc-specific-resources-review-authors.

Furukawa 2002

Furukawa TA, Guyatt GH, Griffith LE. Can we individualize the 'number needed to treat'? An empirical study of summary effect measures in meta-analyses. *International Journal of Epidemiology* 2002;**31**(1):72-6.

GRADEpro GDT [Computer program]

McMaster University (developed by Evidence Prime) GRADEpro GDT. Version accessed 2 July 2020. Hamilton (ON): McMaster University (developed by Evidence Prime), 2015. Available at gradepro.org.

Guyatt 2008

Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al, GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;**336**(7650):924-6.

Guyatt 2013

Guyatt GH, Thorlund K, Oxman AD, Walter SD, Patrick D, Furukawa TA, et al. GRADE guidelines: 13. Preparing summary of findings tables and evidence profiles for continuous outcomes. *Journal of Clinical Epidemiology* 2013;**66**:e173-83.

Higgins 2011

Higgins JP, Green S. Cochrane Handbook for Systematic Reviews of Interventions. Chichester: John Wiley & Sons, Ltd, 2011.

Higgins 2019

Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated July 2019). Cochrane, 2019. Available from www.training.cochrane.org/handbook.

Hu 2006

Hu TW. Perspectives: an international review of the national cost estimates of mental illness, 1990-2003. *Journal of Mental Health Policy and Economics* 2006;**9**:3-13.

IASC 2007

Inter-Agency Standing Committee Task Force on Mental Health and Psychosocial Support in Emergency Settings. IASC Guidelines on Mental Health and Psychosocial Support in Emergency Settings. http://www.who.int/hac/network/interagency/news/iasc_guidelines_mental_health_psychososial.pdf?ua=1 (accessed 19/10/2016).

Institute of Medicine 1994

Institute of Medicine. Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research. Washington, DC: The National Academies Press, 1994.

Institute of Medicine 2009

Institute of Medicine. Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities. Washington, DC: The National Academies Press, 2009.

Jensen 2018

Jensen JK, Ciolino JD, Diebold A, Segovia M, Degillio A, Solano-Martinez J, et al. Comparing the effectiveness of clinicians and paraprofessionals to reduce disparities in perinatal depression via the mothers and babies course: protocol for a cluster-randomized controlled trial. *JMIR Research Protocols* 2018;**7**(11):e11624.

Kakuma 2011

Kakuma R, Minas H, van Ginneken N, Dal Poz MR, Desiraju K, Morris JE, et al. Human resources for mental healthcare: current situation and strategies for action. *The Lancet* 2011;**378**:1654-63.

Knapp 2011

Knapp H, Fletcher M, Taylor A, Chan K, Goetz MB. No clinic left behind: providing cost-effective in-services via distance learning. *Journal of Healthcare Quality* 2011;**33**(5):17-24.

Kohn 2004

Kohn R, Saxena S, Levav I, Saraceno B. The treatment gap in mental health care. *Bulletin of the World Health Organization* 2004;**82**(11):858-66.

Kyu 2018

Kyu HH, Abate D, Abate KH. Global, regional, and national disability-adjusted life-years (DALYs) for 359 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet* 2018;**392**:1859-922.

Lewin 2010

Lewin S, Munabi-Babigumira S, Glenton C, et al. Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Database of Systematic Reviews* 2010;**3**:1-178.

Liberati 2009

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine* 2009;**6**(7):e1000100.

Lora 2012

Lora A, Kohn R, Levav I, McBain R, Morris J, Saxena S. Service availability and utilization and treatment gap for schizophrenic disorders: a survey in 50 low- and middle-income countries. *Bulletin of the World Health Organization* 2012;**90**(1):47-54.

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Lund 2018

Lund C, Brooke-Sumner C, Baingana F, Baron EC, Breuer E, Chandra P, et al. Social determinants of mental disorders and the sustainable development goals: a systematic review of reviews. *Lancet Psychiatry* 2018;**5**(4):357-69.

Murray 2012

Murray CJ, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet* 2012;**380**:2197-223.

National Academies of Sciences 2019

National Academies of Sciences, Engineering, and Medicine. Fostering Healthy Mental, Emotional, and Behavioral Development in Children and Youth: A National Agenda. Washington, DC: The National Academies Press, 2019..https://doi.org/10.17226/25201.

O'Connor 2019

O'Connor E, Senger CA, Henninger ML, Coppola E, Gaynes BN. Interventions to Prevent Perinatal Depression: Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA* 2019;**321**(6):588-601.

Panter-Brick 2018

Panter-Brick C, Dajani R, Eggerman M, Hermosilla S, Sancilio A, Ager A. Insecurity, distress and mental health: experimental and randomized controlled trials of a psychosocial intervention for youth affected by the Syrian crisis. *Journal of Child Psychology and Psychiatry* 2018;**59**(5):523-41.

Patel 2007

Patel V, Araya R, Chatterjee S, Chisholm D, Cohen A, De Silva M, et al. Treatment and prevention of mental disorders in low-income and middle-income countries. *The Lancet* 2007;**370**:991-1005.

Patel 2007a

Patel V, Chisholm D, Kirkwood BR, Mabey D. Prioritizing health problems in women in developing countries: comparing the financial burden of reproductive tract infections, anaemia and depressive disorders in a community survey in India. *Tropical Medicine & International Health* 2007;**12**:130-9.

Patel 2008

Patel VH, Kirkwood BR, Pednekar S, Araya R, King M, Chisholm D, et al. Improving the outcomes of primary care attenders with common mental disorders in developing countries: a cluster randomized controlled trial of a collaborative stepped care intervention in Goa, India. *Trials* 2008;**9**(4):1-11.

Patel 2010

Patel V, Maj M, Flisher AJ, et al. Reducing the treatment gap for mental disorders: a WPA survey. *World Psychiatry* 2010;**9**(3):169–76.

Patel 2018

Patel V, Saxena S, Lund C, Thornicroft G, Baingana F, Bolton P, et al. The Lancet Commission on global mental health and sustainable development. *The Lancet* 2018;**392**:1553-98.

Prince 2007

Prince M, Patel V, Saxena S, Maj M, Maselko J, Phillips MR, et al. No health without mental health. *The Lancet* 2007;**370**:859-77.

Purgato 2012

Purgato M, Adams CE. Heterogeneity: the issue of apples, oranges and fruit pie. *Epidemiology and Psychiatric Sciences* 2012;**21**(1):27-9.

Purgato 2018

Purgato M, Gastaldon C, Papola D, van Ommeren M, Barbui C, Tol WA. Psychological therapies for the treatment of mental disorders in low- and middle-income countries affected by humanitarian crises. *Cochrane Database of Systematic Reviews* 2018;**7**(7):1-195.

Purgato 2019

Purgato M, Jayaram G, Surkan PJ, Bass J, Bolton P. Encompassing a global mental health perspective into psychotherapy research: a critique of approaches to measuring the efficacy of psychotherapy for depression. *Epidemiology and Psychiatric Sciences* 2019;**28**(3):275-7.

Purgato 2020

Purgato M, Uphoff E, Singh R, Thapa Pachya A, Abdulmalik J, van Ginneken N. Promotion, prevention and treatment interventions for mental health in low-and middle-income countries through a task-shifting approach. *Epidemiology and Psychiatric Sciences* 2020;**29**:1-8.

Review Manager 2014 [Computer program]

Nordic Cochrane Centre, The Cochrane Collaboration Review Manager 5 (RevMan 5). Version 5.3. Copenhagen: Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Shemilt 2006

Shemilt I, Mugford M, Drummond M, Eisenstein E, Mallender J, McDaid D, et al, Campbell & Cochrane Economics Methods Group (CCEMG). Economics methods in Cochrane systematic reviews of health promotion and public health related interventions. *BMC Medical Research Methodology* 2006;**6**(55):1-11.

Singla 2017

Singla DR, Kohrt BA, Murray LK, Anand A, Chorpita BF, Patel V. Psychological treatments for the world: lessons from low- and middle-income countries. *Annual Review of Clinical Psychology* 2017;**13**:149-81.

Sterne 2011

Sterne JA, Sutton AJ, Ioannidis JP, Terrin N, Jones DR, Lau J, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ* 2011;**343**:d4002. [DOI: 10.1136/bmj.d4002]

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Thronicroft 2016

Thornicroft G, Chatterji S, Evans-Lacko S, et al. Undertreatment of people with major depressive disorder in 21 countries. *British Journal of Psychiatry* 2017;**210**(2):119-24.

Tol 2011

Tol WA, Barbui C, Galappatti A, Silove D, Betancourt TS, Souza R, et al. Mental health and psychosocial support in humanitarian settings: linking practice and research. *The Lancet* 2011;**378**(9802):1581-91.

Tol 2015

Tol WA, Purgato M, Bass JK, Galappatti A, Eaton W. Mental health and psychosocial support in humanitarian settings: a public mental health perspective. *Epidemiology and Psychiatric Sciences* 2015;**24**(6):484-94.

Tol 2020

Tol WA, Leku MR, Lakin DP, Carswell K, Augustinavicius J, Adaku A, et al. Guided self-help to reduce psychological distress in South Sudanese female refugees in Uganda: a cluster randomised trial. *Lancet Global Health* 2020;**8**(2):e254-63.

Trautmann 2016

Trautmann S, Rehm J, Wittchen HU. The economic costs of mental disorders. *Science & Society* 2016;**17**(9):1245-9.

Ukoumunne 1999

Ukoumunne OC, Gulliford MC, Chinn S, Sterne JA, Burney PG. Methods for evaluating area-wide and organisation-based interventions in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5):iii-92.

University of York 2002

NHS Centre for Reviews and Dissemination. The NHS Economic Evaluation Database (NHS EED) Effectiveness Matters. York: University of York, 2002;**6**(1).

US Preventive Services Task Force 2019

US Preventive Services Task Force, Curry SJ, Krist AH, Owens DK, Barry MJ, Caughey AB, Davidson KW, et al. Interventions to prevent perinatal depression: US Preventive Services Task Force Recommendation Statement. *JAMA* 2019;**321**(6):580-7.

van Ginneken 2013

van Ginneken N, Tharyan P, Lewin S, Rao GN, Romeo R, Patel V. Non-specialist health worker interventions for the care of mental, neurological and substance-abuse disorders in low- and middle-income countries. *Cochrane Database of Systematic Reviews* 2013;**11**:1-293.

Vos 2012

Vos T, Flaxman A, Naghavi M. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a

systematic analysis for the Global Burden of Disease Study 2010. *The Lancet* 2012;**380**:2163-96.

Whiteford 2013

Whiteford HA, Degenhardt L, Rehm J, Baxter AJ, Ferrari AJ, Erskine HE, et al. Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. *The Lancet* 2013;**382**:1575-86.

WHO 1992a

World Health Organization. The Tenth Revision of the International Classification of Diseases and Related Health Problems (ICD-10). Geneva: World Health Organization, 1992.

WHO 2002

World Health Organization. Prevention and Promotion in Mental Health, 2002. https://www.who.int/mental_health/media/en/545.pdf.

WHO 2008

World Health Organization and World Organization of Family Doctors (WONCA). Integrating mental health into primary care: a global perspective, 2008. https://www.who.int/mental_health/resources/mentalhealth_PHC_2008.pdf.

WHO 2011

World Health Organization, War Trauma Foundation and World Vision International. Psychological first aid: guide for field workers. http://www.who.int/mental_health/publications/guide_field_workers/en/ (accessed 19/10/2016).

WHO 2011a

World Health Organization. Mental Health Atlas. Geneva: World Health Organization, 2011. https://www.who.int/mental_health/publications/mental_health_atlas_2011/en/.

WHO 2013

World Health Organization. Mental Health Action Plan 2013-2020, 2013. https://www.who.int/mental_health/publications/action_plan/en/.

WHO 2014

World Health Organization. Mental Health: Strengthening Our Response, 2014. http://www.who.int/mediacentre/factsheets/fs220/en/.

WHO 2018

World Health Organization. mhGAP Operations Manual: Mental Health Gap Action Programme (mhGAP). Geneva: World Health Organization, 2018. https://apps.who.int/iris/bitstream/handle/10665/275386/9789241514811-eng.pdf?ua=1.

World Bank 2020

The World Bank. World Bank Country and Lending Groups. https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

ADDITIONAL TABLES

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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Table 1. Definitions

Adults	Patients who were ≥ 18 years old. If some studies had an age range from, for example, 16 years upwards, and a majority of participants were over 18 years of age, we will include these study participants as adults
Children and adolescents	Children (from birth to 18 years) were considered as a separate group of participants, as they have: • different patterns of psychopathology/mental disorders; and • different help-seeking behaviours that would, therefore, require different interventions, in different settings (e.g. schools) and a different approach to care (e.g. worker interventions such as teacher-led interventions)
Promotion	Promotion is an approach aimed at strengthening positive aspects of mental health and psychosocial well-being; it includes, for example, components to foster pro-social behavior, self-esteem, positive coping with stress, and decision-making capacity (National Academies of Sciences 2019; WHO 2014). Prevention is an approach aimed at reducing the likelihood of future disorder within the general population or among people who are identified as being at risk for developing a full-blown disorder (Eaton 2012; Tol 2015)
Universal prevention	Universal prevention includes strategies that can be offered to the whole population, based on evidence that prevention strategies are likely to provide some benefit to all (i.e. reduce the probability of a disorder), which clearly outweighs the costs and risks of negative consequences. Examples of common universal prevention interventions include: • community-wide provision of information on the negative effects of alcohol misuse; • protection against human rights violations in the whole population (e.g. community mobilisation to reduce gender-based violence); and • community-wide efforts to improve livelihood as a key protective factor for mental health (e.g. working on lifting restrictions of movement and employment for everyone in a refugee camp)
Selective prevention	Selective prevention refers to strategies that are targeted to subpopulations identified as being at elevated risk for a disorder; it includes: • support for children whose parents have a mental illness; • strengthening of community networks for vulnerable individuals by activating social networks and supportive communication; and • stress management training in communities affected by chronic poverty.
Indicated prevention	Indicated prevention includes strategies that are targeted to individuals who are identified (or individually screened) as having increased vulnerability for a disorder based on some individual assessment. These interventions include: • mentoring programmes aimed at teachers and caregivers of children with behavioural problems; and • prevention of postnatal depression in women with heightened levels of prenatal symptoms (Institute of Medicine 2009). These interventions may be delivered at an individual or group level. They include antenatal and postnatal classes, parenthood classes, and continuity of care (home visits, follow-ups)
First-level care, primary care, and community care	First-level contact with formal health services consists of community-based interventions or primary care interventions (or both), on their own or attached to hospital settings, provided they had no specialist input apart from supervision (modified from Wiley-Exley 2007). This would include promotion or prevention programmes in outpatient clinics or primary care practices. This would not include programmes in hospitals unless these programmes were providing prevention interventions to outpatients. Community programmes involve detection of mental disorders in all age groups, often done outside the health facility, for example, through school, training, and other community settings

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Table 1. Definitions *(Continued)*

Low- and middle-income country (LMIC)	Any country that has ever been an LMIC, as defined by the World Bank lists of LMICs
Primary care health workers (PHWs)	Health workers who are not specialising in mental disorders or have not received in-depth professional specialist training in this clinical area. They work in primary care centres or in the community. These individuals include doctors, nurses, auxiliary nurses, lay health workers, and allied health personnel such as social workers and occupational therapists. This category does not include professional specialist health workers such as psychiatrists, psychiatric nurses, or mental health social workers. For inclusion, PHWs received some training in mental conditions (in the control group or in the intervention group), but this would not constitute a professional category. Study authors made a judgement of what constitutes 'some training'. Examples of 'some training' may include an undergraduate module or a short course in mental health
Community workers (CWs)	People involved as community-level workers but who are not within the health sector, as many people, particularly adolescents and young adults, have limited contact with health workers. This category includes teachers/trainers/support workers from schools and colleges, along with other volunteers or workers within community-based networks or non-governmental organisations. These CWs have an important role, particularly in promotion of mental health and detection of mental disorders (Patel 2007a; Patel 2008). We excluded from this review studies that looked at informal care provided by family members or that extended care only to members of their own family (i.e. who were unavailable to other members of the community). As was previously highlighted in Lewin's Cochrane Review, "these interventions are qualitatively different from other LHW [lay health worker] interventions included in this review given that parents or spouses have an established close relationship with those receiving care, which could affect the process and effects of the intervention" (Lewin 2010)
Primary-level workers (PWs)	Broad term to encompass both CWs and PHWs

A P P E N D I C E S

Appendix 1. MEDLINE search strategy

MEDLINE and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions 1946 to May 12, 2020, Ovid

#	Searches	Results
1	exp mental disorders/	1227780
2	mental health/	37488
3	depression/	117171
4	child development/	45740
5	mentally disabled persons/	3568
6	exp self-injurious behavior/	70030
7	(mental health* or mental* ill* or mental* disorder* or mental* well*).ti,ab,kf.	210467

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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(Continued)

8	((substance or alcohol or opioid or morphine or marijuana or heroin or cocaine) adj2 (disorder? or illness* or dependence or abuse or misuse or "use")).ti,ab,kf.	141233
9	(depressi* adj2 (sign* or symptom* or disorder?)).ti,ab,kf.	111383
10	(depress* adj3 (acute or clinical* or diagnos* or disorder* or major or unipolar or illness or scale* or score* or adult* or child* or adolesc* or teen* or youth? or elder* or late* life* or patient* or participant* or people or inpatient* or in-patient* or outpatient* or out-patient*)).ti,ab,kf.	169468
11	((depress* or distress*) adj3 (postnatal* or post natal* or maternal*)).ti,ab,kf.	8279
12	(depression or anxiety or alzheimer? or schizoaffective or mania or manic or borderline personality or (stress adj2 disorder*) or adjustment disorder? or (psychological adj1 trauma*) or schizophrenia or psychoses or psychosis or stress syndrome? or distress syndrome? or combat disorder? or war disorder? or ptsd or dementia).ti,ab,kf.	826356
13	((post-trauma* or posttrauma*) adj3 (stress* or disorder?)).ti,ab,kf.	33963
14	(psychological trauma or psychotrauma*).ti,ab,kf.	1763
15	(alcoholism or alcoholic? or drug addict* or drug abus* or drug misuse or drug user?).ti,ab,kf.	133282
16	((learning or mental* or intellectual) adj (disabled or disabilit* or disorder? or difficult*)).ti,ab,kf.	77091
17	((dissociative adj3 (disorder* or reaction*)) or dissociation).ti,ab,kf.	110238
18	((bipolar or behavio?ral or obsessive or panic or mood or delusional) adj2 (disorder? or illness* or disease?)).ti,ab,kf.	75900
19	(trichotillomani* or OCD or obsess*-compulsi* or GAD or stress reaction? or acute stress or neuros#s or neurotic).ti,ab,kf.	54369
20	(affective* adj (disorder? or disease? or illness* or symptom?)).ti,ab,kf.	19341
21	((mental or psychological or emotional or psycho-social or psychosocial) adj (stress* or distress*)).ti,ab,kf.	48749
22	((sub-syndrom* or sub-threshold or sub-clinical or subsyndrom* or subthreshold or subclinical or minor or brief) adj (symptom* or disorder* or condition* or depress* or anxiety)).ti,ab,kf.	6716
23	(mental relapse or fatigue or somatic symptom? or worry or worries or panic or low mood? or mood problem?).ti,ab,kf.	126570
24	(anxiety disorder? or agoraphobi* or general* anxi* or separation anxiety or neurocirculatory asthenia or neurotic disorder? or social phobi* or self-harm* or self-injur* or suicid*).ti,ab,kf.	118603
25	(slow* adj (thought? or think*)).ti,ab,kf.	68
26	(mental* adj develop*).ti,ab,kf.	3208

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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(Continued)

27	or/1-26	2175113
28	primary health care/	76639
29	physicians, family/	16326
30	physicians, primary care/	3382
31	general practitioners/	7753
32	general practice/	13189
33	family practice/	65111
34	exp social support/	70312
35	community health workers/	5193
36	allied health personnel/	11685
37	exp community health services/	301277
38	schools/	37596
39	school health services/	17097
40	rural health/	23320
41	rural population/	58592
42	nurses, community health/	843
43	nurses, public health/	405
44	family nursing/	1449
45	primary care nursing/	477
46	rural nursing/	107
47	community health nursing/	19564
48	school nursing/	5279
49	(primary adj5 (care or health*)).ti,ab,kf.	163025
50	(family practi* or family doctor* or family physician* or gp* or general practi*).ti,ab,kf.	268535
51	(school* or teacher* or rural* or community).ti,ab,kf.	861747
52	(non-specialist* or nonspecialist* or social worker* or trainer?).ti,ab,kf.	21784
53	(psycho-social or psychosocial).ti,ab,kf.	98645
54	(caregiver* or care giver? or layperson*).ti,ab,kf.	67025

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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(Continued)

55	(lay adj2 (heal* or person* or counsellor? or counselor? or worker? or therapist?)).ti,ab,kf.	2135
56	(paraprofessional? or para-professional? or (allied health* adj (professional? or person* or staff or worker?)) or non-physician? or non-clinician?).ti,ab,kf.	5008
57	(midwife or midwive* or pharmacist* or pharmacy or pharmacies or practice nurs* or district nurs* or health visitor?).ti,ab,kf.	97030
58	or/28-57	1743633
59	27 and 58	329089
60	(afghanistan or albania or algeria or american samoa or angola or "antigua and barbuda" or antigua or barbuda or argentina or armenia or armenian or aruba or azerbaijan or bahrain or bangladesh or barbados or republic of belarus or belarus or byelarus or belorussia or byelorussian or belize or british honduras or benin or dahomey or bhutan or bolivia or "bosnia and herzegovina" or bosnia or herzegovina or botswana or bechuanaland or brazil or brasil or bulgaria or burkina faso or burkina fasso or upper volta or burundi or urundi or cabo verde or cape verde or cambodia or kampuchea or khmer republic or cameroon or cameron or cameroun or central african republic or ubangi shari or chad or chile or china or colombia or comoros or comoro islands or iles comores or mayotte or democratic republic of the congo or democratic republic congo or congo or zaire or costa rica or "cote d'ivoire" or "cote d'ivoire" or cote divoire or cote d ivoire or ivory coast or croatia or cuba or cyprus or czech republic or czechoslovakia or djibouti or french somaliland or dominica or dominican republic or ecuador or egypt or united arab republic or el salvador or equatorial guinea or spanish guinea or eritrea or estonia or eswatini or swaziland or ethiopia or fiji or gabon or gabonese republic or gambia or "georgia (republic)" or georgian or ghana or gold coast or gibraltar or greece or grenada or guam or guatemala or guinea or guinea bissau or guyana or british guiana or haiti or hispaniola or honduras or hungary or india or indonesia or timor or iran or iraq or isle of man or jamaica or jordan or kazakhstan or kazakh or kenya or "democratic people's republic of korea" or republic of korea or north korea or south korea or korea or kosovo or kyrgyzstan or kirghizia or kirgizstan or kyrgyz republic or kirghiz or laos or lao pdr or "lao people's democratic republic" or latvia or lebanon or lebanese republic or lesotho or basutoland or liberia or libya or libyan arab jamahiriya or lithuania or macau or macao or "macedonia (republic)" or macedonia or madagascar or malagasy republic or malawi or nyasaland or malaysia or malay federation or malaya federation or maldives or indian ocean islands or indian ocean or mali or malta or micronesia or federated states of micronesia or kiribati or marshall islands or nauru or northern mariana islands or palau or tuvalu or mauritania or mauritius or mexico or moldova or moldovian or mongolia or montenegro or morocco or ifni or mozambique or portuguese east africa or myanmar or burma or namibia or nepal or netherlands antilles or nicaragua or niger or nigeria or oman or muscat or pakistan or panama or papua new guinea or new guinea or paraguay or peru or philippines or philipines or phillipines or phillippines or poland or "polish people's republic" or portugal or portuguese republic or puerto rico or romania or russia or russian federation or ussr or soviet union or union of soviet socialist republics or rwanda or ruanda or samoa or pacific islands or polynesia or samoan islands or navigator island or navigator islands or "sao tome and principe" or saudi arabia or senegal or serbia or seychelles or sierra leone or slovakia or slovak republic or slovenia or melanesia or solomon island or solomon islands or norfolk island or norfolk islands or somalia or south africa or south sudan or sri lanka or ceylon or "saint kitts and nevis" or "st. kitts and nevis" or saint lucia or "st. lucia" or "saint vincent and the grenadines" or saint vincent or "st. vincent" or grenadines or sudan or suriname or surinam or dutch guiana or netherlands guiana or syria or syrian arab	1891771

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republic or tajikistan or tadjikistan or tadzhikistan or tadzhik or tanzania or tanganyika or thailand or siam or timor leste or east timor or togo or togolese republic or tonga or "trinidad and tobago" or trinidad or tobago or tunisia or turkey or "turkey (republic)" or turkmenistan or turkmen or uganda or ukraine or uruguay or uzbekistan or uzbek or vanuatu or new hebrides or venezuela or vietnam or viet nam or middle east or west bank or gaza or palestine or yemen or yugoslavia or zambia or zimbabwe or northern rhodesia or global south or africa south of the sahara or sub-saharan africa or subsaharan africa or africa, central or central africa or africa, northern or north africa or northern africa or magreb or maghrib or sahara or africa, southern or southern africa or africa, eastern or east africa or eastern africa or africa, western or west africa or western africa or west indies or indian ocean islands or caribbean or central america or latin america or "south and central america" or south america or asia, central or central asia or asia, northern or north asia or northern asia or asia, southeastern or southeastern asia or south eastern asia or southeast asia or south east asia or asia, western or western asia or europe, eastern or east europe or eastern europe or developing country or developing countries or developing nation? or developing population? or developing world or less developed countr* or less developed nation? or less developed population? or less developed world or lesser developed countr* or lesser developed nation? or lesser developed population? or lesser developed world or under developed countr* or under developed nation? or under developed population? or under developed world or underdeveloped countr* or underdeveloped nation? or underdeveloped population? or underdeveloped world or middle income countr* or middle income nation? or middle income population? or low income countr* or low income nation? or low income population? or lower income countr* or lower income nation? or lower income population? or underserved countr* or underserved nation? or underserved population? or underserved world or under served countr* or under served nation? or under served population? or under served world or deprived countr* or deprived nation? or deprived population? or deprived world or poor countr* or poor nation? or poor population? or poor world or poorer countr* or poorer nation? or poorer population? or poorer world or developing economy* or less developed economy* or lesser developed economy* or under developed economy* or underdeveloped economy* or middle income economy* or low income economy* or lower income economy* or low gdp or low gnp or low gross domestic or low gross national or lower gdp or lower gnp or lower gross domestic or lower gross national or lmic or lmics or third world or lami countr* or transitional countr* or emerging economies or emerging nation?).ti,ab,sh,kf.

61	exp randomized controlled trial/	506284
62	controlled clinical trial.pt.	93664
63	randomi#ed.ti,ab.	617779
64	placebo.ab.	207660
65	randomly.ti,ab.	333749
66	Clinical Trials as topic.sh.	191121
67	trial.ti.	218088
68	or/61-67	1331658
69	exp animals/ not humans/	4698080
70	68 not 69	1227558

Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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(Continued)

71	59 and 60 and 70	3898

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CONTRIBUTIONS OF AUTHORS

Conceiving the protocol: MP, CB, NvG.

Designing the protocol: MP, CB.

Co-ordinating the protocol: MP, CB.

Designing search strategies: MJ, MP, NvG.

Writing the protocol: MP, CB, WT, CL, MJ, NvG, JA, RC, DP, EU, CC, EP, FA.

Providing general advice on the protocol: CB, CL, FA, MJ, WT.

Securing funding for the protocol: CB.

Performing previous work that was the foundation of the current study: MP, CB, WT, CL, MJ, DP, NvG, JA, RC.

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Review authors involved in the conduct, analysis, and publication of a study that could be included in the review will not be involved in study eligibility decisions, data extraction, or risk of bias or GRADE assessments for that study.

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Primary-level and community worker interventions for the prevention of mental disorders and the promotion of well-being in low- and middle-income countries (Protocol)

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