Primary-level worker interventions for the care of mental disorders and distress in low- and middle-income countries (Review update)

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[Intervention Review]

An updated protocol to the 2013 review:

Non-specialist health worker interventions for the care of mental,neurologicalandsubstance-abusedisordersinlow- and middle-income countries

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DIFFERENCES BETWEEN 2013 REVIEW AND THIS PROPOSED UPDATE

Three authors (Nadja van Ginneken, Simon Lewin and Paul Garner), were keen to ensure that this review update should be as relevant and valuable for implementers and policy makers as possible.
We therefore performed the following:

- A group face-to-face consultation with 7 LMIC clinicians who are mature students/masters students or PhD students at the Liverpool School of Tropical Medicine (December 2018)
- An online consultation with 7 implementers, academics and policy makers from LMICs , and a further 4 written answer from further stakeholders by email (Feb-April 2019)
- An updated literature review of mental health terminology and description.

The overall messages that emanated from this was to broaden the review to include preventative strategies, in line with the Lancet Commission Mental illness reframing document (REF). This provides an explanation that mental ill health is on a continuum from at-risk, to distress, to sub-syndromal symptoms, to actual classifiable disorders.
However it is clear from the literature that interventions still fall broadly into two categories: those focussed on prevention and mental health promotions, and those that aim to address various forms of psychological distress and diagnostic (and transdiagnostic) categories .

This Cochrane review on treatment interventions for mental disorders is therefore being reframed to include the spectrum of mental ill health as broader than just diagnostic categories (which it was already partly included in the previous version of the review but was not made explicit). The prevention/promotion review features in a separate protocol (see Figure below for a logic model comparison of both reviews)

<u>Minor amendments</u>
Mental conditions:
As mentioned above, the mental conditions included in this review will therefore include any mental ill health symptoms and expressions of distress, not just mental disorders, in line with the transdiagnostic approach.

Also we have removed ‘neurological disorders’ from this review, but kept substance abuse, as the treatment needs for neurological disorders are likely to be different, with more pharmacological treatments. In this update, we plan to focus on the spectrum of mental health conditions seen frequently in primary care.

Terminology:

We received feedback in our consultations that the terms non-specialist health workers (NSHWs) and other professionals with health roles (OPHRs), used in the previous version of this review to describe the types of included mental health care providers, are difficult to understand. We therefore plan to use the following terms in this update: primary care health workers (PHWs) and community workers to replace the previous terms of NSHWs and OPHRs respectively.

Methods:

- *Interventions*

We make clear that the intervention does not include trials which only compare training competencies or methods, which do not have any aim of assessing patient outcomes.
We also want to specify that we have only included studies which have one of our primary outcomes and not only secondary outcomes.

- *Outcomes:*

The outcomes have been adjusted to firstly make health service utilisation a primary outcome (due to the relevance to policy and practice (as recommended by the stakeholders we consulted). In addition we have simplified the secondary outcomes to including direct and indirect costs to patients and health services. We have elaborated on what is included within these costs, by defining opportunity costs better as also including effects on patient’s employment, income, retention etc (see below).

- *Comparison groups:*

We amended the new 2019 protocol (unpublished) to include a third comparison group (not just no care and usual care, but also trained vs untrained health workers). However when it came to subgrouping the studies we realised that these comparison groups were not always so obvious to tease out. We have ended up reverting to a 'usual care' category with a broader definition than 'trained vs untrained' to include enhanced care and some care categories (see definitions. In addition as even the no care categories and usual care categories were on a spectrum (like PTSD comparison) we have pooled all comparisons and done subgroup analyses.

- *Foreign language papers:*

We have been more specific about our management of double data extraction with foreign language papers as we have included several foreign language papers in this review (there was

only one in the last review). The foreign language reviewers extracted and translated the RoB comments/justifications and sent them to the second reviewer in English (witholding their own assessment of risk) so that the second reviewer could then make their own judgement. The foreign language reviewer also sent a translated legend of anything in the outcomes tables that were not clear without translation. Occasionally some papers necessitated more extensive translation (for example if the full paper was around costs) for the health economists were able to extract the data. The foreign language reviewer then reviewed each paper verbally over the phone with the second reviewer to ensure concordance and check accuracy of extraction.

- Time points:
- We grouped outcomes into three sets of time points to indicate the stability of remission:
    - Post intervention (0-1month after intervention) (to detect illness remission= **immediate remission** /or immediate symptom reduction of the intervention)
    - 1 month to six months post intervention (to detect **sustained remission**/ or sustained symptom reduction);
    - 7 to 24 months post intervention (which indicates medium- to **long-term remission I.e.** avoidance of recurrence and chronicity or long-term symptom reduction). (with subgroup for the 1-2 year ones if needed).

This differs from the previous review (0-2months), 4-6 and 8-12months as we felt we wanted to capture better the difference between post intervention and remission and include a measure of long-term outcomes too.

A recent literature review summarises that the duration criteria for declaring remission and recovery seem unnecessary. Depressive remission can be defined as the asymptomatic state after a depressive episode, without applying any duration criterion. Stability of remission is then relatively low on the first day but increases gradually with its duration. The term recovery is then used as a concept that would be more than absence of symptoms, and also include better social functioning or subjective well-being, and possibly including the absence of significant treatment as this would better fit the concept of recovery from a patient's perspective (DeZwart 2019).
This review does not attempt to present illness recovery outcome as one outcome, though individual studies will have some of the information pertaining to illness recovery (such as social functioning).

Please find below the amended protocol with changes.

B A C K G R O U N D

Description of the condition

The global burden of mental illnesses including substance-abuse is high. The latest global burden of disease estimates have shown that mental, behavioural and neuropsychiatric disorders all feature in the top 30 causes of all years lived with dis- ability, the highest contributors being major depression (ranked second), anxiety (ranked seventh) and substance-use disorders (ranked twelfth) (Vos et al., 2012). The contribution of major depressive disorders to worldwide disability-adjusted life years (DALYs) has increased by 37% from 1990 to 2010 and is predicted to rise further (Murray et al., 2012; Prince et al., 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 dis- eases and because of a predicted increase in war and violence. The disease burden due to Alzheimer's disease is also increasing, linked to the demographic transition towards an ageing population (Vos et al., 2012). More recently mental health and ill health has been reframed to be seen as a continuum from health, to ill-health, accepting the value of different interventions also for the in between stages from 'at risk', to experiencing 'mental distress', 'subsyndromal symptoms' (some symptoms suggested of a mental disorder but not sufficient to reach diagnostic categories), and finally 'mental disorders' (V. Patel et al., 2018). This reflects the growing approach towards seeing the value in treating mental illhealth as a response to functional issues or common elements (transdiagnostic approach) (Borsboom et al., 2011). This new update is therefore keen to also capture the section of people experiencing distress and beyond [find ref of disease burden under this approach].

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 USD16.1 trillion with dramatic impact on productivity and quality of life (Bloom et al., 2011). Data remain poor on the macro-economic costs for low- and middle-income country (LMIC) settings (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 (V. Patel et al., 2007b). High indirect costs are also incurred due to informal care-giving and lost work opportunities, as well as due to untreated disorders and their associated disability (Chisholm et al., 2000; WHO, 2003).
The gap between those who could benefit from mental health interventions and those who receive such care is very large ((WHO, 2008, 2010)); in LMICs up to 90% of people needing care do not receive it (Vikram Patel et al., 2010). This is despite the existence of a range of cost-effective interventions in mental health care . Major barriers to closing the treatment gap are the huge scarcity of skilled human resources, large inequities and inefficiencies in resource distribution and utilisation, and the significant stigma associated with psychiatric illness (Saxena et al., 2007). Some papers have advocated for scaling up evidence-based services and for the task-shifting of mental health interventions to non-specialists as key strategies for closing the treatment gap (Lancet, 2007; V. Patel et al., 2018).

Description of the intervention

Primary care 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. Cadres included are professionals (doctors, nurses and other general paraprofessionals) and non-professionals (such as lay health providers). PHWs do not include, for example, psychiatrists, psychologists, psychiatric

nurses or mental health social workers. Community workers (CWs) such as teachers and community-level workers, who are not health trained per-se but have a mental health role, are a further human resource used in delivering mental health care and are also included in this review. These community workers have an important role, particularly in the promotion of mental health and the detection of mental disorders ((V. Patel et al., 2007a; WHO, 2003). Further in this document both these categories of providers (PHWs and CWs) will be referred to together as primary-level workers (PWs).

PHWs and community workers have been used in various services, including those delivered by governmental, private and non-governmental organisations (NGOs) in clinics, half-way homes and com- munities. They have been involved in a variety of activities and roles, including detecting, diagnosing, treating and preventing common and severe mental disorders, epilepsy and learning difficulties. Their roles differ according to their level of training. For example, lay health workers (LHW) have been involved in supporting carers, befriending, ensuring adherence and in detection of mental health problems (Chatterjee et al., 2003; Dias et al., 2008; Rahman et al., 2008). Nurses, social workers and lay workers may also take on follow-up or educational/promotional roles (Araya et al., 2003; Chatterjee et al., 2003; V. H. Patel et al., 2008). In addition, doctors with general mental health training have been involved in the identification, diagnosis, treatment and referral of complex cases (Murthy, 1987; V. H. Patel et al., 2008; Saxena et al., 2007). These interventions may also include collaborative care models where a PHW or CW is involved as part of a team or a step-wise process to accessing care. These models may therefore have elements of psychiatric/specialist intervention or support, and patients may even be recruited from secondary care (such as those with SMDs).

How the intervention might work

In many LMICs, training and retaining sufficient numbers of specialists is not feasible in the near future. It is, therefore, important in these settings to consider options for expanding access to mental health services. The use of PHWs, who are far more numerous and affordable than specialists, is one such option that is of high relevance to LMICs. This review therefore focusses on LMICs as the task-sharing model needs to work with much lower specialist resources than in high-income countries (HICs). There are usually more roles given in LMICs to lay health workers and a larger taskforce of PHWs, hence the importance of looking at this non-specialist taskforce in the context of these different resources.

Training these PHWs to deliver mental interventions may be a way of expanding provision of mental health services as well as making these services more accessible to communities. With regards to intervening at the mental distress or subsyndromal level, this could prevent full blown mental disorders becoming established, which for many of these become chronic or relapsing conditions (V. Patel et al., 2018). It has been suggested that interventions that rely on PHWs could deliver general health and mental health interventions that are at least as effective and acceptable as those delivered by specialist health workers (Chatterjee et al., 2003; Lewin et al., 2008; Thornicroft & Tansella, 2004; Wiley-Exley, 2007). In addition, PHW interventions often have lower up-front costs compared with reliance on professional specialist health workers. However, it is possible that these savings may be cancelled out by higher down- stream resource use (Chisholm et al., 2000), and this review will, therefore, include data on the costs and cost-effectiveness of PHW interventions.

The review is limited to LMICs where the need for PHWs is greater than in high-income settings. The prevalence of psychiatrists and psychiatric nurses is much lower in LMICs (the median number of psychiatrists is 172 times lower in low-income countries (LICs) than high-income countries (HICs) (Kakuma et al., 2011; WHO, 2011)) and the organisation and resourcing of mental health services is poorer. These differences in the organisation of mental health services between LMICs and HICs, with poorer countries having little or no mental health service structures in primary care or the community, means that the problem of providing mental health care is different in such settings. PWs may need to work with little or no support from specialist mental health services and fewer options for referral. Consequently, PWs interventions might be expected to function differently in many LMICs compared

with HICs.

Why it is important to do this review

The continuing shortage of specialist human resources for health in LMICs has made the need to involve non-specialists in Mental healthcare provision more urgent. Reliable evidence is needed on the effectiveness of PHWs and community workers in scaling up mental health interventions, including for the detection, treatment and rehabilitation of Mental disorders. This systematic review will provide the evidence needed to inform policy development for the sustainable scaling up of mental health services in LMICs.
The intention of this review is to examine which non-specialised cadres of healthcare and community providers can effectively deliver different aspects of treatment interventions for mental disorders and distress.

O B J E C T I V E S

To assess the effectiveness of the delivery of mental care treatment interventions by primary-level health workers (PHWs) and community workers in LMICs.

This includes the effects on patient and health delivery outcomes of primary-level workers:

- Delivering early clinical interventions and monitoring for those with mental distress/subsyndromal symptoms;
- delivering acute mental interventions for those with mental disorders in the acute phase;
- delivering long-term follow-up and rehabilitation for people with chronic mental disorders.

The comparisons could be either

- the *same intervention* either delivered by a PW or a specialist (to understand the role of taskshifting)
- different interventions involving PWs:
    - Trained/supervised PWs vs untrained/unsupervised PWs
    - Intervention involving PWs vs usual/no care (no PWs).

For each of these areas, we have also examined the impacts of delivery by primary-level workers on the resource use and costs associated with mental healthcare provision in LMICs.

On the request of a panel of stakeholders (clinicians delivering care in LMICs, project implementers, academics and policy makers), we are planning a new review on PWs' roles in delivering interventions focused on prevention of mental ill-health and increasing wellbeing.

M E T H O D S

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCT) only. In the previous version of this review we included a range of non-randomised studies (NRS). However, these other study designs (non-randomised trials (NRT), controlled before-and-after (CBA) studies and interrupted time series (ITS) studies) contributed little to the final results due to serious risk of bias (see appendix with contribution of these studies). In addition these NRS were often used as precursor studies to randomised trials.

We will include studies conducted in LMICs, as defined by the World Bank, but not studies conducted in high income countries (HICs). As explained above this review focusses on LMICs as the task-sharing model is a response to the lack of availability of specialist human resources and other health infrastructure compared to HICs.

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 or comparative resource utilisation studies. We will extract and report only cost and resource usage outcomes from these studies.

Types of participants

We will include children (aged below 18 years) or adults with any mental condition (distress/prodromal stage or disorder) seeking first-level care/primary care or who are detected in the community in LMICs. The only exception would be those who have a diagnosis established in secondary care and where the intervention is to utilize primary- or community- settings to help follow up, improve/maintain mental health after discharge or as a process of collaborative care. Additionally we will include carers of people with mental conditions (i.e. any relative or friend of any age who defined themselves as a key supporter to a person with an mental condition) as some interventions may be directed at the carers rather than at patients themselves - for example interventions to alleviate carer burden.
(See Table 1 for further definitions of mental conditions, participants, 'LMIC' and 'primary care'.)

Types of interventions

Clinical (medical and psychological) and service interventions delivered in primary care or the community by primary-level workers, and intended to improve mental disorders and distress (mental conditions) will be included (see Table 1 for definitions of primary healthcare workers and community workers and types of interventions). We will not include social interventions (such as income generation or general social support) if the trial did not also include a specific mental intervention.

We will include interventions delivered for any mental disorder or distress. Acute interventions delivered by primary health- and community- workers could include various forms of psychotherapy or pharmacological treatment. In addition we include broader interventions delivered by PHWs which may be delivered to those with mental distress/ prodromal symptoms such as training in self help interventions, informal support, transdiagnostic psychosocial support (individualized plan addressing social and emotional functioning and problems) , and high-risk individual identification. From our previous review we noticed that 12/38 included studies had interventions which combined both treatment and prevention. Where trials include subgroup analyses that split out these different populations, the treatment outcomes will be

retained in this review and the prevention outcomes will be included in our parallel prevention review. Where there is not a clear distinction, we will either make a pragmatic decision on whether these trials are primarily about wellbeing / prevention or about treatment and then allocate them to the appropriate review, or we will include these in both reviews and do sensitivity analyses with or without them.

Long-term interventions delivered by primary and community workers could include roles in follow-up or rehabilitation of people with chronic severe mental disorders, and roles in detecting and dealing with relapse/recurrence, compliance issues, treatment resistance, side effects of treatment or psychosocial problems. The modifications to the interventions included are in accordance with the new recommendations of the Lancet Commission staging approach to mental disorder classification (see below) (Patel 2018).

We will consider the following comparisons:

- provision of mental healthcare by primary-level workers with mental healthcare training +/- supervision compared with no care (I.e. where usual care is equivalent to no care);
- provision of mental healthcare by primary-level workers trained and supervised in mental healthcare (i.e. the highest level of training for primary-level workers) compared with mental health specialists in primary care and the community;
- provision of mental healthcare by primary-level workers with mental healthcare training +/- supervision compared with non-trained primary-level workers (ie usual care = some care by primary-level workers)

We will include studies where a specialist teaches primary-level workers about psychiatric illness and its management. The only interventions of this type that we will exclude are those where there are no patient outcomes (i.e. where they only assessed knowledge or attitude changes, such as pre-post training interventions).

We will include studies that considered the effect of detection, screening or case-finding of mental distress and disorders by primary-level workers on subsequent patient and health provider outcomes, compared with primary-level workers not actively detecting cases, or where specialists did the detection.

The identification methods used by primary-level workers could include 'naturalistic' detection (i.e. detection in the course of a routine clinical consultation), or detection using a validated screening/detection tool (e.g. in the context of a trial). We did not examine diagnostic accuracy between these primary-level workers and specialists, as this was likely to be confounded by the screening/detection tools used. Therefore, it would be difficult to differentiate between the effect of the screening tool and the skills of the health worker (specialist or non-specialist).

Types of outcome measures

We organised these outcomes into categories drawing on the Cochrane Consumers and Communication Review Group's outcome taxonomy (La Trobe 2008), and consultation with co-reviewers and service users from the Movement for Global Mental Health discussion board and through recent consultations with current implementers and policymakers in LMICs (see below). In the previous study, where studies reported more than one measure for each relevant outcome, we abstracted the primary or main measure (as defined by the study authors). We separately documented the other measures used, as necessary.

We grouped outcomes into three sets of time points:

- Post intervention (0-1month after intervention) ((to detect illness recovery/symptom reduction of

the intervention)

- 1 month to six months post intervention (to detect sustained illness recovery/symptom reduction);
- 7 to 24 months post intervention (which indicates medium- to long-term avoidance of recurrence and chronicity). (with subgroup for the 1-2 year ones if needed)

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

For depression and other common mental disorders, in the last review we did not group results up to three months post intervention i.e. we did not report this time point. This time point would normally elicit whether the length of a depressive episode would be shortened compared with spontaneous recovery (which occurs for 50% of people with depression at three months after treatment initiation and for 65% of people with depression at six months) ((Spijker et al., 2002). However, most of these studies had very variable lengths of interventions (zero to 18 months) and it was difficult to ascertain how long the depression had been present when treatment started (we could assume that people who have not recovered naturally within three months seek help). Pooled results up to three months post intervention would, therefore, not reflect whether the intervention shortened recovery from depression to less than or equal to a spontaneous recovery. For the coming review we will attempt to group results at 3 months if the studies are clearer and more homogeneous in their 3 month post-intervention measurement.

Primary outcomes

1.1 Clinical illness recovery: Number of people who recover from mental distress or mental disorder (defined by the authors as number of people reaching minimal or no symptom category on a recognised symptom score system (such as HAD, Beck's, PHQ-9, GHQ)

1.2. Clinical symptom change: Change in average clinical scores for study population from baseline (ie an average improvement or change in symptom scale across the study population)

1.3. Quality of life: meaningful functioning and human development (such as WHOQOL)

1.4. Functional impairment and disability as measured by levels of dependency

1.5. Changes in service utilisation (demand) and coverage (supply)

1.5.1. admission/ readmission rates to hospital

1.5.2. attendance rates: utilization of primary/community services/increased demand,

1.5.3. referral rates from primary/community care setting

1.6. Adverse events: Number of people who have sustained harm during the intervention measured by rates of adverse effects of interventions, which could be clinical indicators (e.g. suicide/deliberate self harm rates, relapse, recurrence), social indicators (social exclusion), service delivery indicators (hospital admission/ readmission rates).

Quality of life outcomes were deemed different from outcomes related to psychosocial functioning as the former encompass a summary of many other aspects of life in addition to psychosocial functioning. We have added 'sense of wellbeing' as this subjective measure is not included necessarily in quality of life measures.

For the detection component of the review, we aimed to consider the outcomes for the patient, the carer, the health provider, or a combination of these people, not the accuracy of diagnosis *or the competency* among PHWs, compared with specialists. Diagnostic accuracy is likely to be confounded by the screening/detection tools used, therefore it would be difficult to differentiate between the effect of the screening tool and the skills of the health worker (specialist or non-specialist). The competency of health workers was not included if part of that competency was not assessing patient outcomes. We did not base inclusion decisions on whether a reference or validated standard measure (either a screening instrument or psychiatric assessment) had been used in studies to differentiate between those correctly and incorrectly diagnosed by PHWs, but this featured as part of the assessment of the quality of evidence (within study limitations).

We have included the service delivery and utilization outcomes as primary rather than secondary outcomes as this was of great interest to stakeholders (decision makers and providers).

Secondary outcomes (economic studies)

2.1. Direct and indirect costs of the interventions identified in the review.

- direct and indirect costs to the patient and health services (including opportunity costs, employment status, income, work absenteeism, retention, educational attainment.);
- resource use such as:
    - the patient's lost productivity,
    - and health service personnel's time allocated/number of consultations.

The economic outcome measures considered will be informed by the training material of, and discussion with, the Campbell & Cochrane Economics Methods Group (CCEMG 2010). We will include only measures related to resource use and costs in this review. We recognise that costs and resource use are intertwined but divided the outcomes in this way to make it clear which outcomes we intended to assess.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases for primary studies 2012-2019:

- the Cochrane Central Register of Controlled Trials (CENTRAL) 2019, Issue 6 (including the Cochrane EPOC Group Specialised Register;
- MEDLINE In-Process & Other Non-Indexed Citations 14 June 2019, OvidSP;
- EMBASE, 1980 to 2012 week 23, OvidSP;
- CINAHL (Cumulative Index to Nursing and Allied Health Literature), 1980 to 19 June 2019, EBSCOhost;
- PsycINFO, 2019, OvidSP
- Latin American and Caribbean Health Sciences database (LILACS), Virtual Health Library (VHL); (We will ask collaborators in Santiago, Chile to translate the strategy in Spanish)
- WHO Global Health Library (World Health Organization Library Information System (WHOLIS), AIM (AFRRO), IMEMR (EMRO), IMSEAR (SEARO, WPRIM, WPRO);
- Science Citation Index and Social Sciences Citation Index,

- ISI Web of Knowledge.

The EPOC Trials Search Co-ordinator (TSC) (Marit Johansen), in consultation with the authors, developed the search strategies for the first review. The search strategies are being updated and reviewed with the new review team including Paul Miller (EPOC Information Specialist) to incorporate new search terms to include additions (such as mental distress, subsyndromal depression) and to remove some exclusions (such as epilepsy) . Search strategies were comprised of keywords and controlled vocabulary terms (selected index terms and free-text terms relating to PWs and mental health).
We will apply no language limits. We will search all databases from database start date to date of search.
We will use a combination of two methodology search filters to limit retrieval to appropriate study designs: a modified version of the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximising version - 2008 revision) to identify RCTs (cf. *Cochrane Handbook for Systematic Reviews of Interventions* Section 6.4d) and one for LMICs. .

Searching other resources

Trial Registries

- International Clinical Trials Registry Platform (ICTRP), WHO (apps.who.int/trialsearch/)

We also will search:

- the reference lists of existing reviews (De Vet 2008);
- other grey literature (unpublished material), through contacting experts;
- conducted cited reference searches for all included studies
- in ISI Web of Knowledge.

We will not search for economic analyses. We will retrieve potentially eligible economic analyses when screening records generated from the various searches reported above, but only select those performed alongside identified effects studies. We will contact the authors of all included effects studies for information on any published or unpublished economic studies related to their trials. We will also scan the reference lists of eligible trials and economic analyses (where these were reported separately to the eligible trials), and other related reviews and papers, for further eligible studies. See Appendix 1 for search strategies.

Data collection and analysis

Selection of studies

Review authors will include study double-screened all records obtained from the searches. If any studies are retrieved in languages that the authors are not competent in, we will find further reviewers for these papers. We will retrieve full-text copies of all articles identified as potentially relevant by at least one review author. Two review authors will check each full paper for inclusion criteria. We will resolve disagreements on inclusion by discussion. If no agreement is reached, we will ask a third review author to make an independent assessment (SL). Where appropriate, we will contact the study authors for further information.

Data extraction and management

Review authors will extract descriptive and outcome data for each paper using an adapted version of the

EPOC data collection checklist. Two review authors will extract data consecutively (by one and cross-checked by another). Only outcomes and RoB assessment will be extracted separately (double extraction). For non-English papers, the foreign language reviewer extracted and translated the RoB comments/justifications and sent them to the second reviewer in English (witholding their own assessment of risk) so that the second reviewer could then make their own judgement. The foreign language reviewer also sent a translated legend of anything in the outcomes tables that were not clear without translation. Occasionally some papers necessitated more extensive translation (for example if the full paper was around costs) for the health economists were able to extract the data. The foreign language reviewer then reviewed each paper verbally over the phone with the second reviewer to ensure concordance and check accuracy of extraction.

Review authors will obtain any missing data by contacting trial authors. Review authors will enter the final agreed descriptive extracted data into the relevant tables of characteristics in Review Manager 5 (RevMan 2012). The main author (NvG) will enter the checked outcome data into Review Manager 5 for meta-analysis and a further author will check it (RevMan 2012).

We will extract the following information for all included studies, in the form that this is reported in the original text:

- details of the intervention: the type and length of each of the clinical, psychosocial and service interventions; a full description of cadre(s) of primary-level workers consulting with the patient, including details of their training and supervision/support; and the length, frequency and type of intervention delivered by each PW; description of the specialist providing care (type, experience, training in using reference standard);
- participants: a full description of the participants (sex, age, socioeconomic status, ethnicity), including details of the mental condition being treated;
- setting: country; type of health service (e.g. government funded, NGO, etc.), organisation of the primary care and specialist services; specialist outreach or generalist;
- results: organised into patient, provider and process outcomes (see above).

Assessment of risk of bias in included studies

Several review authors will work in pairs to independently assessed each study for risk of bias. Two lead authors will independently checked assessments for all studies. We will follow the Cochrane EPOC group format (EPOC, 2017a, b) (which follows the Cochrane Collaboration approach (Higgins 2009)) to assess risk of bias for RCTs. For two of the EPOC risk of bias criteria, we did the following in the last review, and will maintain this in this update:

- divided detection bias into two categories, assessing whether subjective (requiring a judgement, such as clinical improvement) and objective outcomes (such as number of hospitalised days, etc.) were assessed blindly;
- assessed attrition bias for two types of outcome: efficacy outcomes and safety outcomes (e.g. adverse events and unintended consequences).

For economic studies, we adapted the Consensus on Health Economic Criteria (CHEC) criteria list (see Appendix 2) to include an extra question on the sources of data used, and we excluded some questions that were already covered as part of the main risk of bias assessment described above. We will use this adapted CHEC criteria for this update too.

We will incorporate risk of bias assessments by generating 'Risk of bias' summary graphs and figures using Review Manager 5 (RevMan 2012).

Measures of treatment effect

Measures of intervention effect regarding clinical (medical and psychological) and service interventions

For dichotomous outcomes, we will use risk ratios (RR). For continuous outcomes, we will use the mean difference (MD), standardised mean difference (SMD) or mean change difference (MCD). We will express all effect estimates with their 95% confidence intervals (CI). For SMDs, we will use the *Cochrane Handbook for Systematic Reviews of Interventions* to interpret their clinical relevance: 0.2 represented a small effect, 0.5 a moderate effect, and 0.8 a large effect (Cohen 1988). We attempted to establish minimally important differences per outcome (as suggested in Guyatt 2013) but this was not possible due to the wide variety of instruments used.

Measures of effect of detection of Mental disorders interventions

We will report the effects of detection of mental distress and disorders by primary-level workers by assessing patient outcomes, looking at the proportion of patients who recovered or improved over a specific length of time as described in the included studies. We wil measure health worker outcomes by examining changes in prescribing rates, referral rates and treatment initiation rates.

Unit of analysis issues

Where possible, we will reanalyse studies that randomised or allocated clusters (patients, health professionals, healthcare settings or geographical areas) but did not account for clustering in their analysis (Ukoumunne 1999). We will adjust the results for clustering by multiplying the standard errors of the estimates by the square root of the design effect where 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. All of the included studies reported the ICCs that we needed.

We will combine the adjusted measures of effects of cluster-randomised trials with the results of non-cluster trials, if it was possible to adjust adequately the results of the cluster trials. There were too few studies per meta-analysis to perform sensitivity analyses comparing the effects estimates with and without the inclusion of the cluster trials. However if there are sufficient numbers in this review we will perform sensitivity analyses.

We will contact authors when we needed additional information for the analysis.

Multiple observations (repeated data points)
There should be a note there about what should be done when more than one data point is available, e.g. data on 2 months, 3 months and 6 months available for the 2-6 months time frame of reported. Which one was chosen?

Dealing with missing data

For missing or unclear information, we will contact the study investigators for clarification or additional information. Several attempts will be made to contact study authors. If information is still not provided this will be highlighted in the Characteristics of included studies tables. To reduce the risk of overly positive answers, we will use open-ended questions (as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*, Higgins 2009).
Where possible, we will extract data to allow an intention-to-treat (ITT) analysis in which all randomised participants are analysed in the groups to which they were originally assigned. If ITT data is not present, where possible, we will do a full ITT analysis where we consider four scenarios in which the people

reassigned to the control and intervention groups either had the condition or not. For studies that report continuous data but do not report standard deviations, we will either calculate these from other available data such as standard errors, or imputed these using the methods suggested in Higgins 2009. We will not make any assumptions about loss to follow-up for continuous data and we will analyse results for those who completed the trial.

Assessment of heterogeneity

We first will make a qualitative assessment of the extent to which the studies assessing a particular comparison are similar to one another. This will include an assessment of the settings, the interventions, the participants and outcomes to determine whether meta-analysis is appropriate. We will obtain an initial visual overview of statistical heterogeneity through scrutinising the forest plots, looking at the overlap between CIs around the estimate for each included study. To quantify the inconsistency across studies, and thus the impact of heterogeneity on the meta-analysis, we will use the I^2 statistic, and will define an I^2 greater than 50% as indicative of substantial heterogeneity. We will consider these assessments when interpreting the results of a pooled analysis: the importance of an observed I^2 will be interpreted in light of 1. the magnitude and direction of effects and, 2. the strength of evidence for heterogeneity (e.g. a CI for the I^2, or the P value from the Chi^2 test).

Assessment of reporting biases

To reduce possible publication bias, we will employ strategies to search for and include relevant unpublished studies. These strategies include searching the grey literature and prospective trial registration databases to overcome time-lag bias.
We will use funnel plots for the outcomes with more than four studies to visualise whether there was asymmetry. We will perform statistical testing for funnel plot asymmetry if the latter is present..

Data synthesis

We will group the studies for comparison by type of disorders (common mental disorders, severe mental disorders, and substance-abuse disorders); by mix of healthcare providers (Primary Healthcare Worker-led, community worker led, collaborative, etc); and by types of community intervention (pharmacological, non-pharmacological and mixed approach). We will do this as these categories fit with current models of service delivery in LMICs.
Each comparison will be outlined in the results section. For each comparison (groups of disorders), we will create tables of summary statistics including baseline and follow-up summary statistics, effect estimates and their statistical significance. We will use forest plots to display the data graphically.
Where the outcomes assessed and the settings and interventions are very diverse (as agreed by at least two review authors), we will not consider it appropriate to combine the results quantitatively. For these results, we will present a descriptive summary of data. For all data syntheses, we will use the generic inverse-variance model of analysis as this allows the analysis of continuous and dichotomous data and allows clustered and non-clustered data to be combined. We will base the choice of whether to use a fixed-effect or random-effects model on the extent to which studies are similar, or homogeneous, based on their PICOS characteristics (population, intervention, comparators, outcomes and settings).

We used effect estimates adjusted for confounding (baseline differences in control and intervention groups) where possible, and used the methods described in Reeves 2009 to guide data synthesis.

Economic data

We will conduct all the 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 2009).

We will classify the included economic evaluations based on an established system (Drummond 2005). We will summarize the characteristics and results of included economic evaluations using additional tables, supplemented by a narrative summary that compared and evaluated methods used and principal results between studies.

We will display resource use and cost data in a table, along with unit cost data (where 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 the underlying quantities of resource use and variations in the underlying unit costs.

If the data on resource use and costs are sufficiently homogeneous, meta-analysis may be appropriate, if not we will present the findings narratively. We discussed the limitations of this approach below.

Subgroup analysis and investigation of heterogeneity

Within each comparison, the following subgroups will be considered: by category of health worker (professionals: e.g. doctors, nurses), community workers and non-professionals (LHWs); by types of community intervention (e.g. collaborative versus psychological interventions); and by setting (government versus non-government). If the number of included studies for each comparison is sufficient we will perform subgroup analyses to check if the intervention effect varied with different population characteristics. Where applicable or if subgroup analysis is not possible, we will describe subgroup differences narratively under Main results.

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

Sensitivity analysis

If there is sufficient data, we will compare intervention effects according to risk of bias using meta-regression. We will conducted sensitivity analyses based on attempting to reduce clinical heterogeneity.

One example of sensitivity analysis may be for example for studies in which the intervention combines treatment and prevention. We will perform sensitivity analyses to see if there is any difference between including those that include prevention and those that do not.

Summarising and interpreting results

We will use the GRADE approach to assess the quality of evidence related to each of the key outcomes (Schünemann et al., 2011). We will use the GRADE profiler (GRADE 2007), to import data from Review Manager 5 (RevMan 2012) and create 'Summary of findings' tables.
For assessments of the overall quality of evidence for each outcome that included pooled data from RCTs only, we will downgrade the evidence from 'high quality' by one level for serious (or by two for very serious) study limitations (risk of bias), indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. We will use these assessments, along with the evidence for absolute benefit or harm of the interventions and the sum of available data on all critical and important outcomes from each study included for each comparison, to draw conclusions about the effectiveness of Primary-level workers in mental healthcare provision in LMICs. 'Summary of findings' tables will present

critically important clinical and functional outcomes identified in the selected trials.

When judging the importance of SMDs, we acknowledge that 0.2 represents a slight effect, 0.5 a moderate effect, and 0.8 a significant effect; we chose a threshold of 0.5 to indicate a minimum clinically important difference for the last review, and will maintain this threshold for this update (Guyatt 2008; Higgins 2011).

Table 1. Definitions

Adult	Patients who were ≥ 18 years old. However, if some studies had an age range from, for example, 16 years upwards and the majority of participants are over 18 years, we included 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 1. different patterns of psychopathology/mental disorders; 2. different help-seeking behaviours that would, therefore, require different interventions, in different settings (e.g. schools) and a different approach to care- worker interventions (such as teacher-led interventions
Mental disorders	This review included mental disorders as defined by any criteria within included papers. For the purpose of subgroup analysis, we subcategorised these disorders using the International Classification of Diseases (ICD)-10 criteria for mental and behavioural disorders and epilepsy in adults (the related ICD-10 code is listed in brackets). These categories are most likely to be used in LMIC mental health service delivery, and are based on Patels classification (Patel 2003c), and the World Health Organization (WHO) Mental disorder categorisation (WHO 2008) 1. Common mental disorders Mild to moderate mood (affective) disorders (F32-38) Neurotic, stress-related and somatoform disorders (F40-49) Behavioural syndromes associated with physiological disturbances and physical factors (F50-59) 2. Severe mental disorders Schizophrenia, schizotypal and delusional disorders (F20-F29) Bipolar affective disorder (F31) Severe depressive episode with/without psychosis (F32.2, F32.3) 3. Neuropsychiatric disorders Organic, including symptomatic, mental disorders (includes dementia) (F1-9) Mental retardation (F70-79) 4. Disorders caused by substance abuse Mental and behavioural disorders due to psychoactive substance use (F10-19) 5. Mental disorders specifically related to childhood/development Conduct disorders (F91) Eating disorders (F50) Pervasive developmental disorders (F80-89) The diagnosis could be made in clinical practice or in the context of the trial
Mental condition	Term used to encompass mental disorders, mental distress, subsyndromal mental illnesses and chronic and relapsing conditions
Mental distress/ prodromal stage	Term used to describe the spectrum of symptoms and states that may or may not lead to a mental disorder, but which are responsive to mental health interventions which are appropriate for different stages. For example early signs of mental distress may respond to

	increased self care, and informal network support, whereas subthreshold symptoms may require transdiagnostic psychosocial support from PHC and increased monitoring (Patel 2018).
First level care, primary care and community	First level of contact with formal health services were 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 individuals with mental illness living in the community and programmes in outpatient clinics or primary care practices. This would not include programmes in hospitals unless the programmes in the hospitals were providing care to outpatients (i.e. generalists in outpatient departments) Community: as mentioned above detection of mental disorders in all age groups were often done outside the health facility, for example through school, training and other community settings. Therefore, we considered interventions outside the health sector
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 were not specialised in mental disorders or have not received in-depth professional specialist training in this clinical area. These included doctors, nurses, auxiliary nurses, lay health workers, as well as allied health personnel such as social workers, occupational therapists. This was further subdivided into health professionals (defined as people with professional training in health or social care e.g. physician, nurse, social worker, physician assistant) and Lay Health workers. As per Lewin 2010's review, lay health workers (LHWs) perform diverse functions related to healthcare delivery. While LHWs are usually provided with job-related training, they have no formal professional or paraprofessional tertiary education and can be involved in either paid or voluntary care. The term LHW is thus necessarily broad in scope and includes, for example, community health workers, village health workers, treatment supporters, and birth attendants. This category did not include professional specialist health workers such as psychiatrists, neurologists, psychiatric nurses or mental health social workers. For inclusion, PHWs received some training in mental disorders (in either the control or the intervention group), but this would not constitute a professional category. The authors made a judgement of what constitutes 'some training'. Examples of 'some training' may be an undergraduate module or a short course in mental health.
Community workers (CWs)	People who were involved as community-level workers but were not

	within the health sector, as many people, particularly adolescents and young adults, have low contact with health workers. This category included teachers/trainers/support workers from schools and colleges, and other volunteers or workers within community-based networks or non-governmental organisations. We excluded certain health workers that we classified as a specialist including those who were not traditionally thought of as specialists by the psychiatry/medical system: for example school counsellors who were trained to exclusively do that and who had a qualification, with or without extra experience and where their sole focus was on child psychology/counselling. These CWs have an important role particularly in the promotion of mental health and detection of mental disorders (Patel 2007c; Patel 2008a; WHO 2003a) We excluded studies that looked at informal care provided by family members or extended members only to members of his or her own family (i.e. who were unavailable to other members of the community) from this review. As 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). We also excluded all healthcare providers within non-biomedical systems (e.g. a yoga master) as we had not searched for these specifically and it was difficult to judge, from our perspective, what constituted for them a mental health intervention
Primary-level workers (PWs)	Broad term to encompass both CWs and PHWs.
Clinical interventions	1. Detection (recognition and diagnosis) of illness, including screening 2. Acute interventions: drug treatment, non-drug treatment/care (such as specific psychological therapies, or interventions with psychosocial components like counselling, psychoeducation, coping skills, etc.), referral 3. Follow-up, rehabilitation, role in detecting and dealing with relapse/recurrence, compliance issues, treatment resistance, side effects of treatment or psychosocial problems. 4. Prodromal interventions: those with prodromal symptoms/ distress may receive interventions such as training in self-help, informal support, transdiagnostic psychosocial support (individualized plan addressing social and emotional functioning and problems), and high-risk individual identification.
Service interventions	These include change in staffing, or change in mechanism of mental health service delivery (e.g. extension of mental health services through camps and such other outreach services, mobile vans, etc.
Social interventions	**a.**social integration **b.** return to employment, or school

	c. helping reduce stigma and other barriers to mental health care **d.** other social or wellbeing support

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Appendix:
Logic Model of both Prevention/promotion and treatment reviews