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Non-specialist health worker interventions for mental health care in low- and middle- income countries

Nadja van Ginneken[1], **Prathap Tharyan**[2], **Simon Lewin**[3], **Girish N Rao**[4], **Renee Romeo**[5], and **Vikram Patel**[6]

[1]Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK

[2]South Asian Cochrane Network & Centre, Prof. BV Moses & ICMR Advanced Centre for Research & Training in Evidence Informed Health Care, Christian Medical College, Vellore, India

[3]Preventive and International Health Care Unit, Norwegian Knowledge Centre for the Health Services, Oslo, Norway

[4]Department of Epidemiology, National Institute of Mental Health and Neuro Sciences, Bangalore, India

[5]Health Service and Population Research Department, King's College, London, UK

[6]Nutrition & Public Health Intervention Research Unit, London School of Hygiene & Tropical Medicine, London, UK

Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

Overall objective—In order to assess the impact of delivery by non-specialist health workers (NSHWs) and other professionals with health roles (OPHRs) on the effectiveness of mental healthcare interventions in low- and middle- income countries (LMICs), we will specifically analyse the effectiveness of NSHWs and OPHRS in delivering acute mental health interventions; as well as the effectiveness of NSHWs and OPHRs in delivering long term follow-up and rehabilitation for people with mental disorders; and the effect of the detection of mental disorders by NSHWs and OPHRs on patient and health delivery outcomes. For each of these objectives we

Contact address: Nadja van Ginneken, Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, Keppel St, London, WC1E 7HT, UK. nadja.vanginneken@lshtm.ac.uk. nvanginneken@yahoo.co.uk.

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CONTRIBUTIONS OF AUTHORS

The review was conceived by NvG. All authors contributed to the development of the protocol. NvG, PT and SL wrote the final version. All authors approved the final version.

DECLARATIONS OF INTEREST

NvG: none known.
PT: none known.
GR: none known.
VP: Vikram Patel is a co-author on some of the papers which may be included in this study.
SL: Simon Lewin is an editor for the EPOC Group and the Consumers and Communication Review Group.
RR: none known.

Editorial group: Cochrane Effective Practice and Organisation of Care Group.

*Indicates the major publication for the study

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will examine the current evidence for the impact of delivery by NSHWs and OPHRs on the resource use and costs associated with mental healthcare provision in LMICs.

BACKGROUND

Description of the condition

The global burden of mental illness is high (WHO 2001; Prince 2007). The WHO global burden of disease report has shown that mental and neuropsychiatric disorders account for 31.7% of all years lived with disability, the highest contributors being unipolar depression and substance use disorders (Mathers 2006). This burden is predicted to increase; self-inflicted injuries and alcohol related disorders are predicted 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. Alzheimer's disease will become more common with a predicted demographic transition towards an aging population and increases in life expectancy (Mathers 2006).

These illnesses also come with substantial economic costs. Estimates suggest that mental disorders in the USA account for 2.5% of the gross national product (Rice 1990); in the Netherlands mental disorders account for 23.2% of the health services costs (Meerding 1998); and in the UK these account for 22% of inpatient costs (Patel 1998). Data remain poor on the economic costs for low- and middle- income country (LMIC) settings (Hu 2006). The economic and social costs for individuals and families are also 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. 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 2000; WHO 2003a).

The treatment gap between those who would benefit from mental healthcare interventions and those who receive such care is very large (WHO 2005; WHO 2008); in LMICs 90% of people needing care do not receive it. This is despite the existence of cost-effective interventions in mental health care (Patel 2007a). Major barriers to closing the treatment gap are the huge scarcity of skilled human resources and large inequities and inefficiencies in resource distribution and utilisation (Saxena 2007). The *Lancet* global mental health series has advocated strongly for the task-shifting of mental health interventions to non-specialists as a key strategy for closing the treatment gap (Jacob 2007; Lancet 2007; Patel 2007a; Prince 2007; Saraceno 2007; Saxena 2007).

Description of the intervention

Non-specialist health workers (NSHWs) are first level providers who have received general rather than specialist mental health training. Cadres included are professionals (doctors, nurses and other general paraprofessionals) and non-professionals (such as lay providers). They do not include, for example, psychiatrists, psychologists, psychiatric nurses or mental health social workers. Included in this review are also other professionals with health roles (OPHRs) such as teachers and community-level workers - a further human resource used in delivering mental health care. These OHPRs have an important role, particularly in the promotion of mental health and detection of mental disorders (WHO 2003b; Patel 2007a; Patel 2008b).

NSHWs and OPHRs have been used in various services (including those delivered by governmental, private and non-governmental organisations (NGOs) such as clinics, half-way homes and community outreach services. They have been involved in a variety of activities and roles, including detecting, diagnosing, treating and preventing common and severe

mental disorders, epilepsy and mental retardation. Their roles differ according to their level of training. For example, lay health workers have been involved in supporting caregivers, befriending, ensuring adherence, and in detection of mental health problems (Chatterjee 2003; Dias 2008; Rahman 2008; Tripathy 2010). Nurses, social workers and lay workers may also take on follow-up or educational/promotional roles (Araya 2003; Chatterjee 2003; Patel 2008b). In addition, doctors with general mental health training have been involved in the identification, diagnosis, treatment and referral of complex cases (Murthy 1987; Saxena 2007; Patel 2008b).

How the intervention might work

In many LMICs, training and sustaining sufficient numbers of specialists is not feasible in the near future. It is therefore important in these settings to consider options for expanding first-level access to mental health services. The use of NSHWs, who are a far more numerous than specialists, is one such option that is of high relevance to LMICs.

Training these NSHWs to deliver mental health interventions may be a way of shifting tasks from specialists to non-specialists and so expanding provision of mental health services as well as making these services more accessible to communities. NSHWs may both substitute for specialists for some health issues and in some settings, and extend mental health services in settings where these are currently not widely available.

It has been suggested that interventions that rely on NSHWs could deliver at least equally effective and acceptable general health and mental health interventions to those delivered by specialist health workers (WHO 2001; Bolton 2003; Chatterjee 2003; McKenzie 2004; Thornicroft 2004; Wiley-Exley 2007; Dias 2008; Lewin 2008; Rahman 2008). NSHW interventions often have a lower up-front cost compared with reliance on professional specialist health workers. However, this evaluation seeks to see whether these savings may be cancelled out by higher downstream resource use, as previously noted by Chisholm 2000.

The differences between LMICs and high income countries with regard to the availability of specialist health workers, the organisation and resourcing of mental health services, and other contextual differences suggest that it will be useful to review separately the effectiveness of mental health interventions in LMICs.

Why it is important to do this review

The ongoing and growing shortages 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 NSHWs and OPHRs in scaling up effective community mental health interventions, including for the detection, treatment and rehabilitation of mental health problems. It is also important to assess the opportunity costs to the health system, and to the process of care for other conditions, of task-shifting or expanding NSHWs' roles within mental health (McPherson 2006; Chopra 2008;).

This systematic review fills a gap in the knowledge of the effectiveness of NSHWs in mental healthcare provision. A better understanding of these issues would support policy development for the implementation and the sustainable scaling up of community mental health services in LMICs (Cohen 2003; Murthy 2008). The intention of this review is to examine not only what interventions are effective in first-level settings, but also which cadres of healthcare providers can effectively deliver different aspects of interventions (for example within prevention, education, detection, treatment, follow-up and rehabilitation).

OBJECTIVES

Overall objective

In order to assess the impact of delivery by non-specialist health workers (NSHWs) and other professionals with health roles (OPHRs) on the effectiveness of mental healthcare interventions in low- and middle- income countries (LMICs), we will specifically analyse the effectiveness of NSHWs and OPHRS in delivering acute mental health interventions; as well as the effectiveness of NSHWs and OPHRs in delivering long term follow-up and rehabilitation for people with mental disorders; and the effect of the detection of mental disorders by NSHWs and OPHRs on patient and health delivery outcomes. For each of these objectives we will examine the current evidence for the impact of delivery by NSHWs and OPHRs on the resource use and costs associated with mental healthcare provision in LMICs.

METHODS

Criteria for considering studies for this review

Types of studies—We will include randomised controlled trials (RCT), non-randomised controlled trials (NRCT), controlled before- after studies (CBA) and interrupted time series studies (ITS). We will only include CBAs with at least two control sites and two intervention sites. We will include controlled and non-controlled ITS that have at least three time points before the intervention and three time points after the intervention (as per the Cochrane Effective Practice and Organization of Care (EPOC) review group criteria) (Ballini 2010). We will include only studies conducted in LMICs. For the detection component of the review, we will include studies involving direct comparisons of NSHWs/ OPHRs (for example, in detecting mental disorders, or problems arising during the course of illness/care such as problems with compliance) and mental health specialists or usual care. The variable that we will consider for this review is not the accuracy of diagnosis but the outcomes for the patient and the health provider. We will not decide on inclusion of studies based on whether a reference or validated standard measure (either a screening instrument or psychiatric assessment) has been used to differentiate the outcomes between those correctly and incorrectly diagnosed by NSHWs but this will feature as part of the assessment of the quality of evidence and will be submitted to sensitivity analysis.

We will also include economic studies conducted as part of included effectiveness studies. These may be 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 adults with mental health problems (mental, neurological and substance abuse disorders) in LMICs seeking first-level care/primary care or those detected in the community. We will define adults as individuals of 18 years of age and older. We will also include children and adolescents with mental health problems in LMICs seeking first-level care or those detected in the community. We will define children and adolescents as individuals who are under 18 years of age. Additionally we will include caregivers of patients with mental health problems (as some of the interventions may be directed more at the caregivers than at the patients themselves, for example interventions related to helping with drug concordance, improving the family's understanding of a condition to improve the acceptance of a person with a mental disorder etc).

(See Table 1 for further definitions of LMIC, primary care and prevention)

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Types of interventions—Clinical, service and social interventions delivered in primary care or the community by NSHWs or by teachers, teaching assistants and OPHRs, and intended to improve mental health. (See Table 1 for definitions of OPHR and NSHW).

We will include interventions delivered for both acute mental health problems and for longer term issues. NSHW acute interventions could include various forms of psychotherapy or of pharmacological treatment. NSHW long-term interventions would include roles in follow-up or rehabilitation of people with chronic severe mental disorders, and also their roles in detecting and dealing with relapse/recurrence, compliance issues, side effects of treatment, or arising psycho-social problems.

We will consider the provision of mental health care by NSHWs/OPHRs with some mental health training compared to usual/no care; provision of mental health care by NSHWs/OPHRs trained and supervised in mental health care (i.e. the highest level of training for NSHWs) compared to mental health specialists in primary care and the community; provision of mental health care by NSHWs/OPHRs with some mental health training compared to non-trained NSHWs/OPHRs.

We will investigate the detection of mental health problems and we will include studies that consider the effect of screening, case-finding or detection by NSHWs (with some training in mental health) on subsequent patient and health provider outcomes, compared to NSHWs not actively detecting cases, or where the detection is done by specialists.

The identification methods used by NSHWs could include ‘naturalistic’ detection (i.e. detection in a non-formal way during a clinical consultation), or detection using a validated screening/detection tool. We will not examine diagnostic accuracy between these NSHWs and specialists as this is likely to be confounded by the screening/detection tools used. It would therefore be difficult to tell apart the effect of the screening tool from the skills of the health worker (specialist or non-specialist).

Types of outcome measures

Primary outcomes: Improvement of symptoms (e.g. level of anxiety, depression, psychosis). General psycho-social functioning (e.g. levels of self esteem, perception of coping, quality of life outcomes). Disability improvement (e.g. level of dependency, self-care ability).

Secondary outcomes

1. For studies evaluating the detection of mental disorders and the delivery of acute and chronic mental health interventions

Patient/carer-oriented outcomes and societal outcomes: Patient or carer satisfaction and involvement in decision making processes. Patient health behaviour outcomes: such as rates of patient adherence or treatment/follow-up compliance. Adverse clinical outcomes: such as adverse effects rates, suicide/deliberate self harm rates, relapse or recurrence. Carer and social outcomes: such as return to work, offending rates, patient or carer perception of social inclusion.

Health provider and service delivery related outcomes: Measures of changes in management (such as referral rates, prescribing patterns and appropriateness). Measures of health worker behaviour (such as improvement in knowledge/skills, attitude/acceptability, retention rates, absenteeism). Measures of service delivery change (such as number of supervision sessions, hospital admission/readmission rates, utilisation of primary level services, effect on other health services provided).

2. For studies of costs and resource use: Direct and indirect costs to the patient and health services (including opportunity costs). Resource use (such as the patient's lost productivity, and health service personnel's time allocated/number of consultations).

We have compiled these outcomes by reviewing the Cochrane Consumers and Communication Review Group's outcome taxonomy developed at LaTrobe University (La Trobe 2008), and through consultation with co-reviewers and service users.

The economic outcome measures have been informed by the CCEMG 2010 training material and discussion with co-conveners. We will include only the measures which are related to resource use and costsin this review. We recognise that costs and resource use are intertwined but will divide the outcomes in this way to make it clear which outcomes we intend to measure. Where studies report more than one measure for each relevant outcome, we will abstract the primary or main measure (as defined by the study authors). We will separately document other measures as necessary.

Search methods for identification of studies

Electronic searches—We will search for eligible studies in the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library*. www.thecochranelibrary.com, including the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register
- MEDLINE, Ovid (1950 to present)
- EMBASE, Ovid (1980 to present)
- CINAHL, Ebsco (1982 to present)
- PsycINFO, Ovid (1967 to present)
- LILACS (1982 to present)
- African Indexus Medicus
- EurasiaHealth (Eastern European countries)
- IndMED (Indian Medlars Centre) (1985 to present)
- WHOLIS (1948 to present)
- JOLIS library catalogue
- Science Citation Index and Social Sciences Citation Index will be searched for papers which cite key studies, including studies included in the review

We will incorporate methodological components of the Cochrane Highly Sensitive Search Strategy and the EPOC search strategy, combined with selected index terms and free text terms relating to NSHWs and mental health in our search strategies.

We will search for eligible studies in any language and without any time limits. (See Appendix 1 for our MEDLINE search strategy).

Searching other resources—We will search the following:

- The metaRegister of Controlled Trials (mRCT) (http://www.controlled-trials.com/mrct/);

- The WHO's International Clinical Trials Registry Platforms Search Portal (http://apps.who.int/trialsearch/) for ongoing trials;
- The reference lists of existing reviews (De Vet 2008);
- Grey literature will be sought from experts and will also be searched for in OpenSIGLE: http://opensigle.inist.fr/.

We will retrieve potentially eligible economic analyses when screening records generated from searches of general biomedical databases. We will retrieve economic outcome data from the identified effects studies. Initially we will not search specialised economic databases. However, once we have identified the set of economic studies that meet the inclusion criteria, we will check for a structured abstract in NHS EED (full economic evaluations only) or a structured record in HEED (full economic evaluations and cost analyses). We will use these abstracts to act as a check. We will source full text papers for data extraction. We will also contact the authors of all included effects studies for information on any published or unpublished economic studies related to their trials. We will scan reference lists of eligible trials and economic analyses (where these are reported separately to the eligible trials) for further eligible studies.

Data collection and analysis

Selection of studies—At least two authors will screen the records obtained from the searches. We will retrieve full text copies of all articles identified as potentially relevant by at least one review author. Two authors will independently evaluate each full paper for inclusion. Two review authors will resolve disagreements on inclusionby discussion. If no agreement can be reached, we will ask a third author to make an independent assessment. Where appropriate, we will contact the study authors for further information.

Data extraction and management—Two authors will independently extract descriptive and outcome data for each paper using an adapted version of the EPOC data collection checklist. Review authors will obtain any missing data by contacting trial authors. Two authors (NvG and PT) will double-enter the checked data into RevMan for meta-analysis.

We will extract the following information for all included studies that evaluate interventions.

Details of the intervention: the type and length of each of the clinical, social and service interventions; a full description of cadre(s) of NSHW consulting with the patient including details of their training and supervision/support; and the length, frequency and type of intervention delivered by each NSHW; description of the specialist providing care (type, experience, training in using reference standard).

Participants: a full description of the patients (sex, age, socio-economic status, ethnicity) including details of the mental health condition being treated.

Setting: country; type of health service (e.g. publicly 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).

In addition, for non-randomised trials we will record whether the study restricted participant selection, and/or demonstrated balance or matching between intervention and control groups on prognostic factors. An imbalance of these may act as confounders (such as age, sex, socio-economic status). We will also record whether the study adjusted for confounders in

statistical analyses to quantify the effect size Reeves 2009. We will enter these assessments into additional tables.

For studies assessing detection of mental illness, we will also extract the following information.

Details of the screening instrument or procedure(s) used by non-specialists: (where relevant) whether validated and citation details; if translated, language of translation and methods used; if modified from the original, details of modifications such as number of items or content change; cut off thresholds used; self rated or observer rated.

Details of the reference standard used by specialists: structured questionnaire/interview and publication details; diagnostic criteria used and citations; whether modified and details of any modifications.

Pre-study procedures: (where relevant) methods used to address inter-observer variation and in selecting threshold values.

Study procedures: sampling technique; time period between non-specialist and specialist assessments; independence of classifying those with and without disorder by specialists and non-specialists.

Assessment of risk of bias in included studies

Two authors will independently assess each study for risk of bias. This assessment will be informed by the following.

- The Cochrane Handbook for Systematic Reviews of Interventions 'risk of bias' tool (sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting, other sources of bias). Our judgements on the risk of bias - that is to decide whether the study is at high, unclear or low risk of bias - will be based on assessing the conduct of the study rather than the reporting of it (Higgins 2009).
- Additional criteria developed by the Cochrane EPOC group (Ballini 2010) to assess risk of bias for each of the study designs (RCT, CBA, NRCT, ITS). Such criteria include follow-up of professionals, follow-up of patients or episodes of care, baseline measurement, and protection against contamination.
- For economic studies, we will use the CHEC criteria list (see Appendix 2).

We will incorporate risk of bias assessments by generating 'risk of bias' summary graphs and figures using RevMan 2008 and by incorporating these judgements in evaluating study limitations while preparing GRADE 'Summary of findings' tables.

Measures of treatment effect

Measures of intervention effect regarding clinical, service and social interventions—For dichotomous outcomes we will use risk ratios, for continuous outcomes we will use the mean difference. We will express all effect estimates with their 95% confidence intervals (CI).

We will transform ordinal outcomes (such as symptom severity, general psychosocial functioning, levels of dependency in disability, and any other outcomes measured on a scale) into binary data (for example symptom improvement will become improvement or no improvement).

For specific outcomes, if eligible studies report mainly continuous data, we will use continuous data for the main analysis, and vice versa if the outcomes are predominantly expressed as dichotomous data. Where studies report predominantly dichotomous data for specific outcomes, we will manage any continuous data for these outcomes as follows.

1. If the studies that report continuous data use the same scales or instruments as those used for the studies reporting dichotomous data, we will transform the continuous data to dichotomous data using the cut-offs used in the studies reporting dichotomous data.
2. If the studies that report continuous data do not use the same scales or instruments as those used for the studies reporting dichotomous data, we will convert any continuous data for those outcomes to dichotomous data using the methods described in Deeks 2009.

We will then express the pooled results for the dichotomous and transformed continuous data as odds ratios and absolute measures by using the formula SMD=($\sqrt{3}/\pi$) ln OR (Chinn 2000). This will allow us to pool dichotomous and continuous data in one meta-analysis.

If one or more studies included in a meta-analysis report data either on a continuous scale or a dichotomous scale and in either scenario have been transformed, the transformed data will be excluded in sensitivity analyses.

Measures of effect of detection of mental disorders interventions—We will report the effects of detection of mental disorders by NSHWs or OPHRs in several ways: we will measure the patient outcome by looking at the proportion of patients who recover or improve over a specific length of time determined by the eligible studies. We will measure health worker outcomes by the change in prescribing rates, referral rates and treatment initiation rates.

Unit of analysis issues

If possible we will re-analyse studies that randomise or allocate clusters (patients, health professionals, healthcare settings or geographical areas) but do not account for clustering in their analysis (Ukoumunne 1999). We will attempt to 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 average cluster size and ICC is the intra-cluster correlation coefficient.

We will combine the adjusted measures of effects of cluster-randomised trials with the results of non-cluster trials, if it is possible to adjust adequately the results of the cluster trials. We will also perform sensitivity analyses on meta-analyses including cluster randomised trials in which we compare the effects estimates with and without the inclusion of the cluster trials.

We will contact authors if more information is needed for the analysis. Where no information on the intra-cluster correlation coefficient (ICC) is reported, we will extrapolate the ICC from other cluster RCTs, if available (Campbell 2000). If this is not possible, we will not combine the findings of these studies in a meta-analysis, but will present the results in an additional table.

Dealing with missing data

If information is missing or unclear, the authors will contact the study investigators for clarification or additional information. To reduce the risk of overly positive answers, we will use open-ended questions (as recommended in the *Cochrane Handbook,* 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. We will calculate the percentage loss to follow-up in each group and report this information if there are discrepancies between the numbers randomised and the numbers analysed in each treatment group. We will assign the worse outcome to those lost to follow-up for dichotomous outcomes and assess the impact of this in sensitivity analyses, where the available cases are used as the basis for analysis. 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 impute 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 complete the trial.

Assessment of heterogeneity

Statistical heterogeneity assesses observed intervention effects are more different from each other than one would expect due to random error (chance) alone. We will obtain an initial visual overview of heterogeneity through scrutinising the forest plots, looking at the overlap between confidence intervals 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, but only if the number of studies is significant enough to detect heterogeneity. In the latter case, we will define an I^2 of > 50% as revealing substantial heterogeneity. We will also interpret the significance of the I^2 test in light of (i) the magnitude and direction of effects and (ii) the strength of evidence for heterogeneity (for example a confidence interval for the I^2, or the P value as compared to 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 will include searching the grey literature and prospective trial registration databases to overcome time-lag bias.

We will use funnel plots to ‘eyeball’ whether there is asymmetry, though this does not indicate publication bias. If we find more than 10 studies in this review, we will consider statistical testing for funnel plot asymmetry. For continuous outcomes with intervention effects measured as mean differences, we will use the test proposed by Egger 1997 to test for funnel plot asymmetry. For dichotomous outcomes with intervention effects measured as odds ratios, we will use the test by Rücker 2008 as, due to the nature of this review, heterogeneity variance is expected to be high. For dichotomous outcomes with intervention effects measured as risk ratios, and continuous outcomes with intervention effects measured as standardised mean differences, we will not consider funnel plot calculations because funnel plots using risk differences are seldom of interest.

We will interpret the results of tests for funnel plot asymmetry in the light of visual inspection of the funnel plot, as the statistical results may not be representative if there are small-study effects.

Data synthesis

For each comparison, we will report tables of summary statistics for each of the included studies (RCTs, NRCTs, CBAs and controlled/non-controlled ITSs). These tables will include study design, baseline and follow-up summary statistics, effect estimates and their statistical significance, and, if available, information on effect modifiers. We will use forest plots to display the data graphically.

We will first assess observable heterogeneity amongst the study questions and methods to determine whether meta-analysis is appropriate. We will also look at the study participants, settings, interventions, and reported outcomes. We will pay particular attention to the homogeneity of methodology (such as variances in blinding and concealment of allocation) within and across included studies. Where the outcomes assessed and the settings and interventions are very diverse, it may not be 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). If selected studies are sufficiently homogeneous, then we will apply a fixed-effect model. The most likely outcome, however, is that the studies will be heterogeneous. We will use a random-effects model in this case, unless the data are sufficiently heterogeneous (i.e. little or no homogeneity in their PICOS) that any kind of meta-analysis is not appropriate.In this case we will summarise the findings within the text of the review.

We shall report the results separately for RCTs and for non-randomised studies. ITS and cITS studies are often incorrectly analysed as they use statistical methods that do not account for the autocorrelation of data points (Ramsay 2003). If possible, we will use time series regression to re-analyse each comparison (Ramsay 2003).

We will use effect estimates adjusted for confounding (baseline differences in control and intervention groups) where possible, and use 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 summarise the characteristics and results of included economic evaluations using additional tables, supplemented by a narrative summary that will compare and evaluate methods used and principal results between studies.

We will display resource use and cost data in a table, along with unit cost data (if this is 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 (for example the number of hours of time provided by a senior teacher) by an applicable unit cost (for example 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. For studies reporting details of currency and price year, unit costs and measures of resource use in disaggregated form, we will convert unit costs to 2010 International Dollars using a web-based tool (Shemilt 2010). We will re-estimate costs by multiplying the measured quantity of each resource by the adjusted unit cost. If details of the original price year cannot be collected, we will contact the study author for such information; failing this we will use rational assumptions to infer the price year. If unit costs and measures of resource use are not reported separately we will instead convert estimates of costs to 2010 International Dollars using the same methods. We will undertake

adjustments for currency and price year in order to facilitate a meaningful comparison between estimates of costs and unit costs collected from studies conducted in different settings and at different times.

We will calculate total costs per patient by summing the adjusted costs of all measured items of resource use resulting from the intervention. We may also make an interim calculation (i.e. at a level between the cost of a specific item of resource use and total costs of an intervention)in which the costs of several items of resource use are summed to estimate the costs incurred per specific NSHW provider.

Subject to the availability of requisite data, we will pool measures of resource use and costs using standard meta-analysis techniques (see 'Data synthesis' above). We will undertake the pooling of these data primarily as a vehicle to measure heterogeneity and facilitate investigation of factors contributing to variations in resource use and costs between studies (for example differences in the organisation of services between settings such as different staff grades, or different frequency of patient contacts; variations in market; economies of scale etc). We will make decisions about whether to present pooled estimates of resource use and costs based on the results of the above assessments of observable heterogeneity of studies and populations.

We will focus the economics component of the review exclusively on evidence collected from economic evaluations conducted alongside eligible RCTs (and other eligible study designs, if included). We will therefore exclude any economic evaluations conducted using evidence assembled from several different sources (for example economic modelling studies). In principal, this has the potential to impact on the results of the economics component of the review.

Subgroup analysis and investigation of heterogeneity

We will perform subgroup analyses to check if the intervention effect varies with different population, intervention or setting characteristics. Each subgroup analysis will depend on having sufficient trials to perform a statistically significant comparison between groups. We will perform meta-regression to investigate both the effect of the intervention on the estimates of effects and to investigate the effect of multiple characteristics (regarding setting and the intervention) simultaneously (Deeks 2009) only if there are ten times or more observations (studies) available than the number of independent variables (characteristics). This would mean that if we want to perform meta-regression simultaneously on two independent variables we would need 20 or more studies, and so on.

If there are fewer than 10 studies per variable, for fixed-effect meta-analyses we will assess subgroup differences by interaction tests (Altman 2003). For random-effects meta-analyses we will use non-overlapping CIs to indicate a statistically significant difference in treatment effect between the subgroups.

If the decision has been taken not to perform a meta-analysis, we will summarise the results of the subgroups within the text of the review.

We will analyse the following subgroups.

- by setting (low- versus middle-income countries);
- by intervention characteristics: by group of disorders (common mental disorders, severe mental disorders and substance abuse disorders) These categories fit with current models of service delivery in LMICs; by category of health worker

(professionals (i.e. doctors, nurses, other professionals) and OPHRs compared with non-professionals (i.e. lay health or non-health workers));

- by types of community intervention (pharmacological, non-pharmacological, and mixed approach).

Sensitivity analysis

The carrying out of a sensitivity analysis will depend on whether the studies identified are at high or low risk of bias, or a combination of these.

We will look at an initial visual impression of the impact of bias by graphing results according to risk of bias (separating out those at high-, unclear- and low-risk of bias on the forest plots). If possible, we will formally compare intervention effects according to risk of bias using meta-regression (risk ratio (RR) in studies with high and unclear risk of bias versus RR in low risk of bias studies).

If there are sufficient studies identified as low risk of bias, we will restrict a primary analysis to these. We will then include the 'unclear' and 'high-risk' of bias studies in a sensitivity analysis to show how the conclusions may be affected by this inclusion.

We will consider additional sensitivity analyses as follows:

- based on specific decisions made during the review process, such as how ICCs are imputed for cluster trials;
- based on whether the included cluster randomised trials find different estimates of effect to non-cluster trials for specific outcomes, bu excluding cluster randomised trials;
- based on whether the study reports a validated tool that confirms the NSHWs diagnostic accuracy;
- if one or more studies report outcomes using either a continuous scale or a dichotomous scale and in either scenario have been transformed (to dichotomous or continuous variable respectively);
- based on the effect of including or not those lost to follow-up, where the available cases are used as the basis for analysis.

For the economic analyses, we will conduct sensitivity analysis to explore the impact of different assumptions made with respect to price year for those studies that do not report price year (Shemilt 2010).

Summarising and interpreting results—We shall use the GRADE approach to assess the quality of evidence related to each of the key outcomes (Schünemann 2009). We will use the GRADE profiler (GRADE 2004) to import data from Review Manager (RevMan 2008) and create 'Summary of findings' tables. For assessments of the overall quality of evidence for each outcome that includes pooled data from RCTs only, we will downgrade the evidence by one level from 'high quality' for serious (or by two for very serious) study limitations (risk of bias) that include: indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias. Data from observational studies will start at low quality, but we may upgrade this to moderate or high quality if the pooled estimates reveal a large magnitude of effect, negligible concerns about confounders, or a strong dose-response gradient.

We will use these assessments, along with the evidence (or lack) 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 NSHWs in mental healthcare provision in low and middle income countries.

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APPENDICES

Appendix 1
MEDLINE search strategy

#	Searches
1	Allied Health Personnel/
2	Community Health Aides/
3	Nurses' Aides/
4	Psychiatric Aides/
5	Caregivers/
6	Voluntary Workers/
7	Community Networks/
8	exp Self-Help Groups/
9	Social Support/
10	Health Manpower/
11	"Personnel Staffing and Scheduling"/
12	(lay adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff)).tw
13	((voluntary or volunteer?) adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff)).tw

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#	Searches
14	(untrained adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff or nurse? or doctor? or physician? or therapist?)).tw
15	(trained adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staffor nurse? or doctor? or physician? or therapist?)).tw
16	(unlicensed adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staffor nurse? or doctor? or physician? or therapist?)).tw
17	((nonprofessional? or non professional?) adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff)).tw
18	((non medical or non health or non healthcare or non health care) adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff)).tw
19	(community adj3 (worker? or visitor? or attendant? or aide or aides or support* or person* or helper? or carer? or caregiver? or care giver? or consultant? or advisor? or counselor? or counsellor? or assistant? or staff)).tw
20	(paraprofessional? or paramedic or paramedics or paramedical worker? or paramedical personnel or allied health personnel or allied health worker? or support worker? or non specialist? or specially trained or barefoot doctor? or nurse* aide? or psychiatric aide? or psychiatric attendant? or social worker? or teacher? or school staff or trainer?).tw
21	(health* adj3 (auxiliary or auxiliaries)).tw.
22	(nurs* adj1 (auxiliary or auxiliaries)).tw.
23	(informal adj (caregiver? or care giver? or carer?)).tw.
24	(self help group? or support group?).tw.
25	((social or psychosocial) adj (care or support)).tw.
26	(village adj3 worker?).tw.
27	community based.tw.
28	(community adj3 intervention?).tw.
29	community network?.tw.
30	((health or health care or healthcare) adj manpower).tw.
31	human resources.tw.
32	(task? adj3 shift*).tw.
33	(staff* adj3 chang*).tw.
34	or/1-33 [NSHWorOPHR]
35	Mentally Ill Persons/
36	Mentally Disabled Persons/
37	exp Mental Disorders/
38	Drug Users/
39	Nervous System Diseases/
40	Epilepsy/
41	Mental Health Services/
42	Community Mental Health Services/
43	Emergency Services, Psychiatric/
44	Social Work, Psychiatric/
45	((mentally or psycholog*) adj (ill or disabled or handicapped or retarded or disturb* or traumati* or deficient)).tw

#	Searches
46	(intellectually adj (disabled or handicapped or retarded or deficient)).tw
47	(mental adj (retardation or deficienc*)).tw.
48	((mental or behavioural or behavioral or anxiety or obsessive or compulsive or panic or phobic or schizotypal or delusional or stress or cognitive or cognition or dissociative or personality or impulse control or mood or affective or bipolar or depressive or neurotic or paranoid or psychotic or somatoform or neurologic* or nervous or nervous system or eating) adj (disorder? or illness* or disease?)).tw
49	((substance related or alcohol or opioid or morphine or marijuana or heroin or cocaine) adj (disorder? or illness* or dependence or abuse or misuse)).tw
50	(depression or anxiety or schizophrenia or psychoses or stress syndrome? or distress syndrome? or combat disorder? or war disorder? or pain disorder? or dementia or alzheimer or epilepsy or down syndrome or alcoholism or substance abuse or drug addict* or drug abus* or drug misuse or drug user?).tw
51	(psychiatric adj (patient? or service? or care or assistance or help or work)).tw
52	(mental health service? or mental health care or mental healthcare or mental care).tw
53	((psychiatric or psychosocial) adj (service? or care or assistance or help or work)).tw
54	or/35-53 [Mental disorders]
55	Developing Countries.sh,kf.
56	(Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America).hw,kf,ti,ab,cp
57	(Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia Republic or Georgian Republic or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or Sudan or Suriname or Surinam or Swaziland or Syria or Tajikistan or Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).hw,kf,ti,ab,cp
58	((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor*) adj (countr* or nation? or population? or world)).ti,ab
59	((developing or less* developed or under developed or underdeveloped or middle income or low* income) adj (economy or economies)).ti,ab
60	low* adj (gdp or gnp or gross domestic or gross national)).ti,ab
61	(low adj3 middle adj3 countr*).ti,ab.
62	(lmic or lmics or third world or lami countr*).ti,ab.
63	transitional countr*.ti,ab.
64	or/55-63 [LMIC]

#	Searches
65	randomized controlled trial.pt.
66	controlled clinical trial.pt.
67	multicenter study.pt.
68	(randomised or randomized or randomly).ti,ab.
69	placebo.ti,ab.
70	trial.ti,ab.
71	groups.ti,ab.
72	intervention*.ti,ab.
73	evaluat*.ti,ab.
74	control*.ti,ab.
75	effect?.ti,ab.
76	impact.ti,ab.
77	(time series or time points).ti,ab.
78	((pretest or pre test) and (posttest or post test)).ti,ab.
79	(quasi experiment* or quasiexperiment*).ti,ab.
80	((multicenter or multicentre or multi center or multi centre) adj study).ti,ab
81	or/65-80
82	Animals/
83	Humans/
84	82 not (82 and 83)
85	81 not 84 [Methods filter - terms from CHSSS + EPOC terms]
86	34 and 54 and 64 and 85[NSHW or OPHR+mental disorders+LMIC+methods filter]
87	(diagnos* or detect* or case finding?).tw.
88	54 and 87
89	34 and 64 and 85 and 88 [NSHW or OPHR+Mental disorders+LMIC+detection filter+ methods filter]
90	86 or 89
91	"comment on".cm.
92	(systematic review or literature review).ti.
93	(editorial or comment or meta-analysis or news or review).pt
94	"cochrane database of systematic reviews".jn.
95	or/91-94
96	90 not 95

APPENDICES

Item	Yes	No	Extract
1. Is the study population clearly described?			
2. Are competing alternatives clearly described?			

Item	Yes	No	Extract
3. Is a well-defined research question posed in answerable form?			
4. Is the economic study design appropriate to the stated objective?			
5. Is the chosen time horizon appropriate to include relevant costs and consequences?			
6. Is the actual perspective chosen appropriate?			
7. Are all important and relevant costs for each alternative identified?			
8. Are all costs measured appropriately in physical units?			
9. Are costs valued appropriately?			
10. Are all important and relevant outcomes for each alternative identified?			
11. Are all outcomes measured appropriately?			
12. Are outcomes valued appropriately?			
13. Is an incremental analysis of costs and outcomes of alternatives performed?			
14. Are all future costs and outcomes discounted appropriately?			
15. Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis?			
16. Do the conclusions follow from the data reported?			
17. Does the study discuss the generalizability of the results to other settings and patient/client groups?			
18. Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)?			
19. Are ethical and distributional issues discussed appropriately?			

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Table 1

Definitions

Adult	The cut off point will be patients who are 18 years old or above. However if some studies have an age range from, for example, 16 years upwards and the majority of participants are over 18, we would also include these study participants as adults
Children and adolescents	Children (from birth to 18 years) are considered as a separate group of participants as they have (i) different patterns of psychopathology/mental disorders; (ii) different help seeking behaviours which would therefore require; (iii) 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 will include mental disorders as defined by any criteria within included papers. For the purpose of subgroup analysis, we will subgroup these disorders using the ICD-10 criteria for mental and behavioural disorders and epilepsy in adults (the related ICD-10 code is listed in brackets). We will sub-categorise these disorders according to most likely mental health service delivery in LMIC, based on Patel's classification (Where there is no psychiatrist) (Patel 2003) and the recent WHO MNS (mental, neurological and substance abuse disorders) categorisation (WHO 2008). i. 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) ii. Severe mental disorders Schizophrenia, schizotypal and delusional disorders (F20-F29) Bipolar affective disorder (F31) Severe depressive episode with/without psychosis (F32.2, F32.3) iii. Neuropsychiatric disorders Organic, including symptomatic, mental disorders (includes dementia) (F1-9) Mental retardation (F70-79) Epilepsy (G40) iv. Disorders caused by substance abuse Mental and behavioural disorders due to psychoactive substance use (F10-19) v. Mental disorders specifically related to childhood/development Conduct disorders Developmental disorders Eating disorders Pervasive developmental disorders
First level care, primary care and community	First level of contact with formal health services are community based interventions and/or primary care interventions, on their own or attached to hospital settings, provided they have 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 outpatients) Community: as mentioned above detection of mental disorders in all age groups are often done outside the health facility, for example through school, training and other community settings. Therefore we will consider interventions outside the health sector
LMIC	Any country that has ever been a low- or middle-income country, as defined by the World Bank lists of low- and middle- income countries. If a multi-centre trial is found which includes LMICs and a few HICs, we will also include this
Non-specialist health workers (NSHWs)	Those who are not specialised in mental health or have not received in-depth professional specialist training in this clinical area. These include doctors, nurses, auxiliary nurses, lay health workers, as well as allied health personnel such as social workers, occupational therapists. This category does not include professional specialist health workers such as psychiatrists, psychiatric nurses or mental health social workers. NSHWs may have received some training in mental health, but this would not constitute a professional category. The authors will make a judgement of what constitutes 'some training'. Examples of'some training' may be an undergraduate module or short course in mental health
Other professionals with health roles (OPHRs)	These will include people who are involved as community-level workers but are not within the health sector, as many people, particularly adolescents and young adults, have low contact with health workers. This category includes teachers/trainers/support workers from schools and colleges, and other volunteers or workers within community-based networks or NGOs. These OPHRs have an important role particularly in the promotion of mental health and detection of mental disorders (WHO 2003a; Patel 2007b; Patel 2008a). We will exclude studies which look at informal care provided by family members or extended members only to members of his or her own family (i.e. who are unavailable to other members of the community) from this review. As previously highlighted in Lewin's recent Cochrane review, "these interventions are qualitatively different from other LHW 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).
Clinical interventions	**a.** Detection (recognition and diagnosis) of illness, including screening **b.** Acute interventions: drug treatment, non-drug treatment/care, referral **c.** Follow-up, rehabilitation **d.** Prevention and education

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 psycho-social support

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