ABSTRACT

Introduction: Globally, an estimated 380 million people live with diabetes today—80% in low-income and middle-income countries. The Middle East, Western Pacific, Sub-Saharan Africa and South-East Asia remain the most affected regions where economic development has transformed lifestyles, people live longer and there is an increase in the adult population. Although peer support has been used in different conditions with varied results, yet there is limited evidence to date supporting its effectiveness, particularly for individuals with diabetes. In this review, we will focus on community-based peer-led diabetes self-management programmes (COMP-DSMP) and examine the implementation strategies and diabetes-related health outcomes associated with them in LMIC primary healthcare settings.

Methods and analysis: In accordance with reporting equity-focused systematic reviews PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols 2015 checklist) guidelines, a systematic review with meta-analysis of randomised controlled trials (RCTs), non-randomised controlled trials (CCTs) and quasi-randomised controlled trials (CQCTs) that involve contact with an individual or group of peers (paid or voluntary). Electronic searches will be performed in The Cochrane Library, MEDLINE, PubMed, SCOUPS, CINAHL and PsycINFO Database for the period January up to July 2000 along with manual searches in the reference lists of relevant papers. The analyses will be performed based on baseline data from RCTs, CCTs and preintervention and postintervention means or proportions will be reported for both intervention and control groups, and the absolute change from baseline will be calculated, together with 95% CIs. For dichotomous outcomes, the relative risk of the outcome will be presented compared to the control group. The risk difference will be calculated, which is the absolute difference in the proportions in each treatment group.

Ethics and dissemination: Ethics is not required for this study, given that this is a protocol for a systematic review, which utilises published data. The findings of this study will be widely disseminated through peer-reviewed publications and conference presentations.

Trial registration number: PROSPERO (2014: CRD42014007531).

BACKGROUND

Globally, an estimated 380 million people live with diabetes today—80% in low-income and middle-income countries (LMIC). These countries are also predicted to experience more than a twofold greater increase in the number of people with diabetes over the next 20 years than high-income countries. The Middle East, Western Pacific, sub-Saharan Africa and South-East Asia remain the most affected regions, where economic development has transformed lifestyles, people live longer and there is an increase in the adult population. Furthermore, socioeconomic status (SES) is considered to be a crucial determining factor of health, a significant contributor to health disparities and may play a role in the increasing prevalence of diabetes and related complications. Typically, low SES is associated with poorer access to healthcare.


In most of the LMIC, diabetic care of people with diabetes is provided by the primary care services. A number of organisational models of management for chronic diseases have been suggested and implemented worldwide; the best documented and most effective is the Chronic Care Model (CCM). This model was created by Wagner. Wagner’s Chronic Care Model (CCM) holds that chronic disease is best managed by dynamic interactions between the patient and a healthcare provider team, where chronic care is dealt with in reliable and evidence-based practices for self-management. While community resources have not traditionally been integrated into care, community partnerships should be considered as a means of gaining better care for people with diabetes.

In LMIC, as health resources become more and more strained, healthcare providers and researchers have developed various approaches by which diabetes can be more efficiently and economically managed. Peer support empowers patients to connect with others who have had similar experiences and can have positive benefits for patient satisfaction and motivation. In 2003, Dennis published a comprehensive definition of peer support which was used in a previous Cochrane review. For the purpose of this review, the same definition will be used. According to this definition, peer support within a healthcare context is “the provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor and similar characteristics as the target population.” On the basis of Dennis’s definition, all three types of support are centred on experiential knowledge, rather than arising from formalised sources; however, the notion that informational assistance is based solely on self-experience is under debate. Emotional support involves expressions of caring, empathy, encouragement and reassurance and is generally seen to enhance self-esteem. Appraisal support includes encouraging persistence and optimism for resolving problems, affirmation of a peer’s feelings and behaviours and the reassurance that frustrations can be dealt with. Informational support involves providing advice, suggestions, alternative actions, feedback and factual information relevant to the issue that the peer is dealing with.

In the diabetes context, peers are traditionally defined as people with diabetes or those affected by diabetes, for example, a close family member. In many instances, the former appear to be preferred. However, there is growing interest in the use of community health workers (CHWs) as an approach for improving the health of people and communities that recognise the impact of a person’s and a community’s peer network in health activities. CHWs are considered as peers because they have close relations to the community from which the patients originate and often share the same language and culture; they can provide the ‘context specific’ support and the reciprocal exchange of information for creating lifestyle changes, and they bridge the cultural gap between the person with diabetes and his health.

The WHO reviewed the use of peer support programmes for people with diabetes and suggested that it is a promising strategy for diabetes care with some evidence of some efficacy in limited areas, especially those of high income. However, they proposed that there was a need for more research in the area. Indeed, Caro and Fisher debated that there is still much to learn about how best to organise and deliver effective peer support programmes, which programmes are best for different patients and settings, and how best to integrate peer support interventions into other clinical and outreach services. Moreover, a previous systematic review suggested that further research can answer the remaining questions associated with such issues as cost-effectiveness, sustainability, integration of peers into health and social service delivery systems, and employment, training and support of peers. Continuing to develop and assess innovative models for more successfully mobilising and integrating peers into diabetes care has great potential for successful diabetes outcomes worldwide. Although peer support has been used in different conditions with varied results, yet there is inadequate evidence to date supporting its efficacy, mainly for individuals with diabetes. In this review, we will focus on community-based peer-led diabetes self-management programmes (COMP-DSMP) and examine the implementation strategies and diabetes-related health outcomes associated with them in LMIC primary healthcare settings.

OBJECTIVES
To provide a systematic review of the evidence of the effectiveness of (COMP-DSMP) in improving clinical outcomes and quality of life of adults with diabetes in primary care settings in LMIC.

This systematic review aims to answer the following research questions:
1. What are the effects of (COMP-DSMP) on the clinical and behavioural outcomes of adults in primary care settings, and how consistent are those effects across existing studies?
2. How do (COMP-DSMP) help in improving the quality of diabetes care for adults in primary care settings?

METHODS
The Cochrane Handbook and systematic review study protocol published by the Cochrane Collaboration Methods Groups and mentioned elsewhere provide the guidelines and the methodological framework in designing and conducting this systematic review to enable critical appraisal and replication. This review protocol has been published in the PROSPERO International Prospective Register of systematic reviews, registration number (2014:CRD42014007531).
Criteria for considering studies for this review

Types of studies

Studies that have evaluated the effects of (COMP-DSMP), for example: randomised controlled trials (RCTs), non-randomised controlled trials, quasi-randomised controlled trials (CCTs) and observational studies—both those with a comparison group (controlled observational studies) and uncontrolled observational (‘pre-post’ or ‘before and after’) study designs—will be included.

Types of participants

Participants from all ethnicities, socioeconomic and educational backgrounds and with diabetes using the standard diagnostic criteria will be eligible for inclusion. Both newly diagnosed and participants with established diabetes will be included.

Types of interventions

Interventions that involve contact with an individual or a group of peers (paid or voluntary) offering (COMP-DSMP), for example, (community health worker, peer leader, lay health advisor, lay health educators, lay workers, peer coaching, etc) will be considered. Telephone-based peer support, as well as web-based and email-based support, will be excluded. Interventions led or facilitated by a professional (or non-peer) will be included, providing that the focus of the intervention is to provide peer-to-peer interaction. Studies in which peer support is part of a multicomponent/complex intervention, where the effects of the peer support element cannot be isolated, will be excluded.

Types of outcome measures

Studies reporting at least one of the following outcomes will be included:

Primary outcomes

1. Behavioural outcomes: physical activity/fitness, glucose monitoring, adherence to medication, improved nutrition, self-care.
2. Psychological health outcomes: (self)efficacy, knowledge, attitudes, quality of life, confidence, self-esteem, well-being, vitality, social functioning, coping, as assessed by validated measures, eg, Short Form with 36 Items (SF-36).

Secondary outcomes

Clinical outcomes, including fasting and random blood sugar levels, glycated haemoglobin, cholesterol, blood pressure, symptoms of hypoglycaemia and hyperglycaemia.

Search methods for identification of studies

Database

The following search strategy will be used to search the following databases: Cochrane Library, MEDLINE, PubMed, SCOPUS, CINAHL and PsycINFO Database for the period January 2000 up to July 2014, using combinations of keywords for intervention and method of the following keywords: “Diabetes” “peer based interventions,” “peer-led interventions,” “peer education,” “peers,” “peer support,” “peer counselling,” “group support,” “group education,” “peer leader,” “lay health educators,” “lay workers,” “lay health advisor,” “community health worker” “Adult” “intervention,” “control trial,” “randomized control trial,” and “experiment.” “LMIC.” Other database resources such as the WHO International Clinical trials Registry Platform, Clinicaltrials.gov, Pan African Clinical Trials Registry (PACTR) and HINARI (Health InterNetwork Access to Research Initiative) for LMIC will be searched (see online supplementary table S1).

Reference lists

Manual-search lists of references of included studies, tables of contents of relevant journals and conference abstracts for relevant material will be conducted. A grey literature search strategy will be developed to conduct web-based searches to obtain key unpublished sources. No restrictions for language of publication will be made on searching.

Data collection and analysis

Selection of studies

Full copies of articles identified by the search, and considered to meet the inclusion criteria, based on the title and abstract will be obtained for data synthesis. Initially, studies will be screened using predefined inclusion and exclusion criteria. Two reviewers will apply the criteria independently to the results of the searches, based first on titles and abstracts only. Studies will then be (A) excluded, (B) included or (C) marked as ‘Pending’ if the reviewer is unsure about their inclusion. The two independent reviews will be compared and contradictory judgements or ‘pending’ will be temporarily ‘included’, and then moved to the next phase of review of full texts. Once full texts have been retrieved, two reviewers will independently apply inclusion and exclusion criteria, based on quick assessments of the full texts. Disagreements in reviewer selections will be resolved at a meeting between reviewers prior to the selected articles being retrieved. All studies which initially appear to meet inclusion criteria but on closer inspection do not meet the inclusion criteria will be detailed in the table ‘Characteristics of excluded studies.’ A flow chart will be produced to facilitate transparency of the process.

Data extraction and management

Data will be extracted independently by three reviewers (MW, PR and NP). The data abstraction forms are based on the Cochrane Consumers and Communication Review Group’s Data Extraction Template for Cochrane Reviews, and will be modified to fit this review. We will extract data on: author, year of publication, geographic region, study design, description of the intervention (including process, cost programme, cost of effectiveness if available and presence of other contentions), context of intervention (ie, primary health facility),
details about group leader (demographics, training, professional status, etc), details about participants (including number in each group, baseline health information, demographic characteristics), length of intervention and follow-up, definition of peer used, health outcomes. Consensus will be reached by discussion and consultation with other reviewers (ME, NSL) where necessary.

Risk of bias (quality) assessment
Two review authors (MW, PR) will independently assess the risk of bias in the included studies by considering the following characteristics, in accordance with the guidelines of the Cochrane Consumers and Communication Review Group and the Cochrane Handbook which recommended the explicit reporting of the following individual quality elements:
1. Randomisation sequence generation
   - Was the allocation sequence (used to assign participants to the treatment and control groups) adequately generated? (This criterion only applies to randomised controlled trials.)
2. Treatment allocation concealment
   - Was the allocated treatment adequately concealed from study participants and clinicians and other healthcare or research staff at the enrolment stage?
3. Blinding
   - Were the personnel assessing outcomes and analysing data sufficiently blinded to the intervention allocation throughout the trial?
4. Completeness of outcome data
   - Were participant exclusions, attrition and incomplete outcome data adequately addressed in the published report?
5. Selective outcome reporting
   - Is there evidence of selective outcome reporting and might this have affected the study results?
6. Other sources of bias
   - Was the trial apparently free of any other problems that could produce a high risk of bias?
   
The results of the assessment will be included in the review through systematic narrative description and analysis about each of these domains, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review’s results.

Data synthesis
The data synthesis will be conducted according to the following steps:
A. The measures of effect for continuous outcomes of the included studies will be expressed as mean difference, standardised mean difference and proportions whereas Dichotomous outcomes will be presented as Risk ratios it is also called as relative risk (RR) and OR. We will calculate 95% CI for each type of effect size to define the uncertainty inherent in the point estimates.9
B. Synthesis tables of included studies will be grouped according to the type of study design.
   
   Data analysis will be conducted using the Cochrane Collaboration Review Manager V.5.1 statistical software (http://ims.cochrane.org/RevMan).
   
   We will pool the individual study estimates from studies with similar design and outcome using random-effects model meta-analysis.
C. Heterogeneity between studies will then be assessed using the Q and I² statistics. The I² statistic estimates the percentage of total variation across studies due to a true difference rather than chance. In general, I² values greater than 60–70% indicate the presence of substantial heterogeneity. We will explore sources of heterogeneity by comparing the pooled study estimates between subgroups defined by study-level characteristics. We will assess the presence of publication bias by using a funnel plot and the Egger test of bias.
D. Subgroup and sensitivity analyses will be conducted to look at the effects of certain factors on the effectiveness of peer support, for example: geographic region, age and gender and diabetes type of participating patients.

Reporting of this review
This systematic review will be reported according to PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols 2015 checklist; see online supplementary table S2).26

Ethics and dissemination
Ethics approval is not required for this study, given that this is a protocol for a systematic review, which utilises published data. The findings of this study will be disseminated through peer-reviewed publications and conference presentations.

Author affiliations
1Department of Medicine, Faculty of Health Science, University of Cape Town, Chronic Disease Initiative for Africa, Cape town, Western Cape, South Africa
2Department of Medicine, Faculty of Health Science, University of Cape Town, Cape Town, Western Cape, South Africa
3Department of Medicine, University of Cape Town, Cape Town, Western Cape, South Africa
4Department of Geriatric Medicine, Faculty of Health Science, University of Cape Town, Cape Town, South Africa
5Department of Internal Medicine, Faculty of Health Science, University of Cape Town, Cape Town, South Africa
6South African Medical Research Council, Cape Town, South Africa
7Chronic Disease Initiative for Africa, Cape Town, Western Cape, South Africa
8Chronic Diseases of Lifestyle Research Unit, Durban, Durban, South Africa
9Department of Geriatric Medicine, Faculty of Health Science, University of Cape Town, Cape Town, South Africa
10South African Medical Research Council, Cape Town, South Africa

Acknowledgements The authors acknowledge Ms Tamzyn Suliaman, UCT Libraries, Health Sciences and Information Services Librarian, who provided technical support and assisted in the planning of the search strategy and reference management. They gratefully acknowledge support of the Evidence-Based Medicine Research Support Unit, Faculty of Health Sciences at University of Cape Town.

Contributors: MW codrafted the protocol manuscript. PR, NP and SK provided critical guidance on the analysis and overall direction of the study. ME, APK and NSL revised it for methodological and clinical content. All authors conceived the study and were responsible for designing the protocol.
All authors critically revised successive drafts of the manuscripts and approved the final version.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

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Correction

Werfalli M, Raubenheimer P, Engel M, et al. Effectiveness of community-based peer-led diabetes self-management programmes (COMP-DSMP) for improving clinical outcomes and quality of life of adults with diabetes in primary care settings in low and middle-income countries (LMIC): a systematic review and meta-analysis. *BMJ Open* 2015;5:e007635. The title of this paper should be: Effectiveness of community-based peer and non-professional health worker-led diabetes self-management programmes (COMP-DSMP) for improving clinical outcomes and quality of life of adults with diabetes in primary care settings in low and middle income countries (LMICs): a systematic review protocol.

*BMJ Open* 2015;5:e007635. doi:10.1136/bmjopen-2015-007635corr1
### Supplementary Table 1. Describing search strategy for PubMed

| Description | Keywords |
|-------------|----------|
| Diabetes Mellitus | Diabetes Mellitus[Mesh] OR "diabetes mellitus"[MeSH Terms] OR "diabetes"[All Fields] AND "mellitus"[All Fields] OR "diabetes mellitus"[All Fields] AND (((((((((peer[All Fields] AND based[All Fields] AND interventions[All Fields]) OR (peer-led[All Fields] AND interventions[All Fields])) OR (peer[All Fields] AND ("education"[Subheading] OR "education"[All Fields] OR "educational status"[MeSH Terms] OR ("educational"[All Fields] AND "status"[All Fields]) OR "educational status"[All Fields] OR "education"[All Fields] OR "education"[MeSH Terms]))) OR "Social Support"[Mesh]) OR peers[All Fields]) OR (peer[All Fields] AND support[All Fields])) OR (peer[All Fields] AND ("counselling"[All Fields] OR "counseling"[MeSH Terms] OR "counseling"[All Fields]))) OR "Self-Help Groups"[Mesh] OR ("population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[All Fields] OR "group"[All Fields]) AND support[All Fields]) OR (("population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[All Fields] OR "group"[All Fields]) AND support[All Fields]) OR (peer[All Fields] AND ("counselling"[All Fields] OR "counseling"[MeSH Terms] OR "counseling"[All Fields]))) OR "Self-Help Groups"[Mesh] OR ("population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[All Fields] OR "group"[All Fields]) AND support[All Fields]) OR (("population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[All Fields] OR "group"[All Fields]) AND support[All Fields]) OR (peer[All Fields] AND lead[All Fields]) OR (lay[All Fields] AND ("health educators"[MeSH Terms] OR ("health"[All Fields] AND "educators"[All Fields]) OR "health educators"[All Fields])) OR (lay[All Fields] AND ("manpower"[Subheading] OR "manpower"[All Fields] OR "workers"[All Fields]))) OR (lay[All Fields] AND ("health"[MeSH Terms] OR "health"[All Fields] AND advisor[All Fields]) OR "Community Health Workers"[Mesh]) OR ("community health workers"[MeSH Terms] OR ("community"[All Fields] AND "health"[All Fields] AND "workers"[All Fields]) OR "community health workers"[All Fields]) OR ("community"[All Fields] AND "health"[All Fields] AND "worker"[All Fields]) OR "community health worker"[All Fields]))) AND ((("poverty"[MeSH Terms] OR "poverty"[All Fields] OR ("low"[All Fields] AND "income"[All Fields]) OR "low income"[All Fields]) AND countries[All Fields]) OR (middle[All Fields] AND ("income"[MeSH Terms] OR "income"[All Fields]) AND countries[All Fields]) OR (low-middle[All Fields] AND ("income"[MeSH Terms] OR "income"[All Fields]) AND countries[All Fields]))) AND (((interventions[All Fields] OR "Randomized Controlled Trial"[Publication Type]) OR RCT[All Fields]) OR "Controlled Clinical Trial"[Publication Type]) OR CCT[All Fields]) OR experiment[All Fields]) AND ("2000/01/01"[PDAT] : "2014/07/31"[PDAT]) AND "adult"[MeSH Terms])