BMJ Open

Long-term effectiveness of group-based diabetes self-management for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046692
Article Type:	Protocol
Date Submitted by the Author:	06-Nov-2020
Complete List of Authors:	Xia, Zhang; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Jiang, Ying-ying; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Shang, Wei-jing; Chinese Center for Disease Control and Prevention, National Center for Women and Children's Health Guo, Hai-jun; Griffith University, Center for Environment and Population Health Mao, Fan; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Dong, Wen-lan; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Dong, Jian-qun; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention
Keywords:	DIABETES & ENDOCRINOLOGY, EDUCATION & TRAINING (see Medical Education & Training), Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Long-term effectiveness of group-based diabetes self-management for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis

Zhang Xia[1], Ying-ying Jiang[1], Wei-jing Shang[2], Hai-jun Guo[3], Fan Mao[1], Wen-lan Dong[1], Jian-qun Dong[1]

ZX and YJ contributed equally

Author Affiliations:

[1]National Center for Chronic and Non-communicable Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, China

[2]National Center for Women and Children's Health, Chinese Center for Disease Control and Prevention, Beijing, China

[3]Center for Environment and Population Health, Griffith University, Queensland, Australia

Corresponding Author:

Jian-qun Dong, Tel: +86 10 83136483, Fax: +86 10 63042350

E-mail: dongjianqun@ncncd.chinacdc.cn

Postal address: 27# Nanwei Road Xicheng District, Beijing, China 100050

Keywords：

Diabetes Mellitus, Type 2; Diabetes self-management education; Group; Systematic review

Word Count：3550

ABSTRACT

Introduction The prevalence of diabetes has been rising and posed a seriously negative impact on patients' quality of life. Diabetes self-management group activities are cost-effective and efficient for patients to control blood glucose. However, self-management group activity lacks consistent standards, and its' long-term effect (≥12 months) remains unclear. Moreover, few systematic reviews evaluate the long-term effects specifically. The objective of this review is to evaluate the long-term effect of self-management group activity, analyze effect of different self-management components on glycosylated hemoglobin (HbA1c).

Methods and analysis We will retrieve Chinese databases (Wanfang, Chinese Hospital Knowledge Warehouse) and English databases (PubMed, ScienceDirect, EMBASE, Web of Science, Bailian Platform, Cochrane Central Register of Controlled Trials, Google Scholar) for randomized controlled trials and cluster randomized controlled trials of which participants are adult patients with type 2 diabetes mellitus. We will manually search citation lists, trials registries, and consult authors to obtain relevant articles. The retrieval time range will be from the establishment of the database to July 2020. The primary outcome will be HbA1c. The secondary outcomes will be fasting plasma glucose, postprandial blood glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, systolic blood

pressure, diastolic blood pressure, body mass index, and waist circumference. Two reviewers will independently conduct article screening, data extraction and assessment of risk of bias, with a third reviewer arbitrating if necessary. We will give priority to the use of meta-analysis to evaluate the pooled effects of all outcomes. For the outcomes of unrecognized sources of heterogeneity, missing data, and less than 3 related studies, narrative synthesis approach will be used.

Ethics and dissemination Ethical approval is not required for this systematic review. We plan to present the findings in a peer-reviewed scientific journal, relevant and responsible organizations, and training meetings.

PROSPERO registration number CRD42020209011.

Strengths and limitations of this study

- This study will be the first systematic review to specifically evaluate the long-term effectiveness of group-based diabetes self-management activity.
- A clearly operable provision on self-management will be used in this study to exclude plausible studies so as to accurately reflect the effect of self-management.
- This study will focus on objective outcomes which can avoid unblinded biases to some extent, and provide more reliable evidence for diabetes self-management.

- Meta regression and subgroup analysis will provide an understanding of how different self-management components affect the long-term effect of HbA1c control.
- Due to the limitation of language ability, some studies may be omitted, which may bias our findings.

INTRODUCTION

Diabetes is mainly characterized by high blood glucose caused by insulin secretion defect or (and) its biological function disorder. In recent years, the number of diabetic patients has increased rapidly in developed and developing countries. According to data from the International Diabetes Federation, in the global, there were 463 million diabetic patients aged 20-79 in 2019, with the prevalence of diabetes at 9.3%, and it was estimated to reach at 578 million in 2030 and 700 million in 2045, with the prevalence of diabetes at 10.2% and 10.9%, respectively; in China, the number of diabetic patients of the same age was 116.4 million in 2019, ranking first in the world, and it predicted to increase to 140.5 million in 2030 and 147.2 million in 2045.[1] Diabetes can cause multiple complications such as coronary heart disease, peripheral neuritis, diabetic nephropathy and retinopathy, all of which the complication incidence gradually grows with the increase of disease duration, heavily leading to a negative impact on patients' quality of life.[2, 3]

The World Health Organization points out that patient-centered education is essential for the effective management of chronic diseases.[4] In the field of diabetes education, diabetes self-management education is a suitable technology to alleviate the burden of diabetes. Diabetes self-management refers to teaching patients the knowledge and skills needed for self-management through a series of health education courses, helping patients with the support of physicians to solve the various physical and emotional

problems caused by diseases in daily life.[5] At present, the main forms of self-management are group and individual form.[6] Compared with the individual form, the group form is relatively widely used because it can reduce time and capital investment required for education and has better cost-effectiveness and higher efficiency. Meanwhile, patients can communicate and share their experience with each other in a group, and decide whether to change their behaviors, which embodies the concept of 'empowerment'.[6, 7] Previous studies have shown that diabetes self-management group activity can improve patients' level of diabetes knowledge, self-efficacy, health behaviors and body weight, reduce fasting blood glucose, 2-hour postprandial blood glucose and glycosylated hemoglobin (HbA1c), and ultimately improve chronic condition.[8, 9] In addition, participating in self-management group activity can reduce the frequency of patients' outpatient visits and hospitalizations, and improve their quality of life.[10, 11]

However, there is still some weakness in diabetes self-management. First of all, the content of self-management activity still lacks consistent standards. Although the International Diabetes Federation has published the 'International Curriculum for Diabetes Health Professional Education' and 'International Standards for Diabetes Education', the self-management still differs in approach, content, form, and technology, which is not conducive to promote self-management and compare intervention effect. [7, 12] Additionally, existing studies have shown that patients can manage their blood glucose in a short

term after self-management intervention, but the long-term effect is still unclear.[13-17] And the long-term effects of other clinical indicators such as blood pressure and blood lipids have not formed a consistent conclusion.[18, 19] Furthermore, we have searched PubMed, ScienceDirect and Cochrane Library, and found that few systematic reviews have made clear provisions on the content of self-management, nor have they specifically evaluated the long-term effect of self-management (≥12 months), although some systematic reviews have evaluated the effect of self-management.[7, 20]

Hence, we present a protocol which describes how this systematic review will be designed and conducted, aiming to systematically and comprehensively evaluate the long-term effect of self-management group activity and explore the strategy of long-term blood glucose control. The protocol is presented in accordance with the guideline of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement.[21]

AIM AND RESEARCH QUESTION

The aim is to evaluate the long-term effect of self-management group activity (≥12 months) for patients with type 2 diabetes mellitus (T2DM) in community and identify what components of self-management benefit patients to control blood glucose. This review will attempt to answer following questions:

- What are the long-term effects of group-based diabetes self-management in control HbA1c for patients with T2DM in community compared with other interventions?
- What are the long-term effects of group-based diabetes self-management in control blood pressure, blood lipid and body weight?
- What are the effects of different components of group-based diabetes self-management on HbA1c?

METHODS

Systematic review design

The review will adopt methods described in the Cochrane Handbook for Systematic Reviews of Interventions guidelines and conform to the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[22, 23] The PRISMA-P checklist will be completed and attached as a supplementary file 1. The eligibility criteria will be guided in form of 'PICOS'. The review started on 1 May 2020 and will complete by 1 May 2021.

Eligibility criteria

Participants (P)

The review will include the study of which all participants are diagnosed with T2DM and 18 years old or older. All participants should be recruited from the

community through community health service centers, hospitals, diabetes research centers and other institutions. Studies involving patients with type 1 diabetes, gestational diabetes and hospitalization will be excluded.

Intervention (I)

The study will be included if it conducts a self-management intervention based on the group form. The number of activities is not less than once. The content of self-management activity involves the following 5 topics:

- Knowledge acquisition;
- Self-sign or symptom monitoring;
- Medication management;
- Enhance problem-solving and decision-making skills;
- Change behaviors such as physical activity, diet, smoking, etc.

For each eligible study, knowledge acquisition must be included, and at least 2 of other topics should be included.[24] The study will be excluded if it conducts self-management activities in form of one-way education without interaction. For example, studies which only describe lectures, courses but do not mention other interactive activities such as group discussion, experience sharing, mutual help will be excluded. Those conducting self-management group activities by Internet rather than face to face will also be excluded.

Comparison (C)

Comparisons will be made against any type of control. This may include, but not limited to, standard or usual care, usual education, waiting list control, paper educational materials and other interventions.

Outcomes (O)

The outcome will be reported as primary outcome and secondary outcome. Primary outcome is HbA1c, which is the gold standard for assessing glycemic control in diabetic patients and represents average blood glucose over the previous 2 to 3 months.[25] Secondary outcomes will include fasting plasma glucose (FPG), postprandial blood glucose (PBG), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), waist circumference (WC). The study including one of outcomes above will be considered.

Study design (S)

This review will consider randomized controlled trials (RCTs) and cluster randomized controlled trials (CRCTs). The time interval between baseline survey and follow-up survey should be at least 1 year or more. Reviews, qualitative research, observational research, comments, withdrawn research, government reports, book chapters, statements, guidelines, and the study of

which full text cannot be obtained will be excluded. The brief eligibility criteria are listed in Table 1.

Table 1 Predefined eligibility criteria in the systematic review

Item	Inclusion criteria	Exclusion criteria
Population	Patients with T2DM and aged 18 years old or older. They should be recruited from communities.	Patients with type 1 diabetes, gestational diabetes and hospitalization.
Intervention	Self-management is conducted in group. The activity is not less than once. Self-management involves the following 5 topics: 1. Knowledge acquisition 2. Self-sign or symptom monitoring 3. Medication management 4. Enhance problem-solving and decision-making skills 5. Change behaviors Knowledge acquisition must be included, and at least 2 of other topics should be included.	Self-management is conducted in form of one-way education without interaction. Self-management is carried out by Internet rather than face to face.
Comparison	This may include standard or usual care, usual education, waiting list control, paper educational materials and other interventions.	No limitation
Outcome	Primary outcome is HbA1c. Secondary outcomes include FPG, PBG, SBP, DBP, TC, TG, HDL-C, LDL-C, BMI, WC. The study including one of outcomes above will be considered.	No limitation
Study design	Randomized controlled trials and cluster randomized controlled trials. The time interval between baseline survey and follow-up survey should be at least 1 year or more.	Reviews, qualitative research, observational research, comments, withdrawn research, government reports, book chapters, statements, guidelines, and the study of which full text cannot be obtained

T2DM, type 2 diabetes mellitus; HbA1c, glycosylated hemoglobin; FPG, fasting plasma glucose; PBG, postprandial blood glucose; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; BMI, body mass index; WC, waist circumference.

Search strategy

We will conduct a systematic retrieval in Chinese databases with keywords such as ‘type 2 diabetes’, ‘self-management’, ‘randomized controlled trial’, ‘group’, ‘community’. Chinese databases will include Wanfang database and Chinese Hospital Knowledge Warehouse database. Only Chinese language articles will be retrieved in Chinese databases. Taking ‘Diabetes Mellitus, Type 2’, ‘T2DM’, ‘Self-Management’, ‘Randomized Controlled Trial’, ‘group-based’ as keywords, and adopting a combination of Mesh terms, free words and word variations, we will search English databases including PubMed, ScienceDirect, EMBASE, Web of Science, Bailian Platform (English language retrieval), Cochrane Central Register of Controlled Trials, Google Scholar. The language will be restricted to English. We will manually search the article in the citation list of published relevant reviews, consult field experts and authors to obtain published articles, search Chinese Clinical Trial Registry (http://www.chictr.org.cn), U.S. Clinical Trials Registry (https://www.clinicaltrials.gov/), EU Clinical Trials Registry (https://www.clinicaltrialsregister.eu/) to find articles. The literature retrieval time range will be from the establishment of the database to July 2020. We use PubMed as an example for retrieval, and the specific search strategy is shown in supplementary file 2.

Study selection

All identified articles will be managed by EndNote X8 software, and duplicates will be removed. Two reviewers (ZX and WS) will adapt a blind method to independently screen articles. Screening process will be made up of two stages. First stage, reviewers will read the title and abstract based on predefined eligibility criteria. The article will be included for further screening if the eligibility criteria is initially met. Stage two, they will read the full text to decide whether to include the article in the review. The reasons for article exclusion will be recorded during two stages. If the information related to the study is not available, they will contact the author at least three times by email. The study will be excluded if no response. After the study screening is completed, the screening results will be compared. Any disagreement will be resolved through discussion between two reviewers. If they cannot reach a consensus, they will invite a diabetes self-management expert (YJ) to judge and resolve. The screening process will be described by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Data extraction

Two reviewers (ZX and WS) will independently extract the characteristics of study with a data extraction form in Microsoft Excel2019, including study design, participants characteristics, self-management activities, follow-up, study duration and outcomes. Data extraction form will be designed based on

Cochrane Collaboration data collection forms and piloted on ten of the related studies.[26] Since outcomes such as blood glucose, blood pressure and blood lipids are mostly expressed as quantitative data, which cannot be analyzed together with categorical data, reviewers will contact the author to obtain quantitative data if the outcome is presented in categories. After the data extraction is completed, reviewers will compare the results with each other. Disagreement will be resolved through discussion. If a consensus cannot be reached, they will invite the diabetes self-management expert (YJ) to judge and resolve.

The following characteristics will be collected if reported in individual studies:

- Publication information: title, first author, publication year, author's contact information.
- Study characteristics: recruitment method, inclusion and exclusion criteria, study design type, follow-up time, loss to follow-up, conclusions.
- Participant characteristics: participant number, age, gender, nationality, course of disease, diabetes complications and complications, insulin usage.
- Intervention: name of the intervention, content, duration, frequency, implementer.
- Self-management components: referring to the study of Sarah Dineen-Griffin, components will include disease and self-management knowledge acquisition, encouragement of symptom monitoring, development of action plans for self-management, enhancement of resource utilization

capabilities, enhancement of problem solving and decision-making skills, enhancement of stress and emotional management capabilities, physical activity, diet management, smoking cessation, drug management and compliance, self-management compliance.[27]

- Outcomes: According to the 'Chinese guideline for the prevention and treatment of type 2 diabetes mellitus (2017 edition)', patients with diabetes should not only control blood glucose, but also blood pressure and blood lipids. The comprehensive diabetes control goals include blood glucose, blood pressure, blood lipids and body mass index.[28] Consequently, this review will collect information about HbA1c, FPG, PBG, TC, TG, HDL-C, LDL-C, SBP, DBP, BMI, WC. We will also collect their units, measurement methods, measurement time, data at baseline and endpoint.

Assessment of risk of bias in included studies

The Cochrane Risk of Bias Tool will be used to assess the risk of bias which contain random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other sources of bias. Each domain will be assessed as low risk of bias, high risk of bias or unclear risk of bias. The over risk of bias of each study will also be rated as low (if all domains are assessed as low risk of bias), high (if one or more domains are assessed as high risk of bias), or unclear (if one or more domains are assessed as unclear risk of

bias).[29] We will not consider assessing risk of bias at the outcome level because the outcome collected in this review are mostly obtained through laboratory tests and not easily affected by the subjectivity of participants and researchers.

Assessment will be conducted by two reviewers (ZX and WS) independently. After the assessment is completed, reviewers will compare the result, and resolve disagreement through discussion. If a consensus cannot be reached, they will invite the diabetes self-management expert (YJ) to judge and resolve. The risk of bias of included studies will be used to evaluate the robustness of the findings. A 'risk of bias graph' figure and 'risk of bias summary' figure will be attached.

Data synthesis

The characteristics of selected studies will be presented in a summary table, including publication (first author, year of publication, country), enrollment (enrollment time, number of patients enrolled), baseline (age, disease duration, gender, HbA1c value), study design type (RCTs/CRCTs), self-management intervention (contents, sites, duration, frequency, number of activities, educator), follow-up intervention (contents, duration, frequency, follow-up pattern, implementer), last follow-up (time, number of patients, outcomes), risk of bias. Before meta analyzing, if the unit of an outcome is inconsistent, we will convert it into a unified unit. For outcomes which are not represented by mean

and standard deviations, we will convert them into the form of mean and standard deviation.[30]

The size of the effect will be expressed as the mean difference (MD) if measurement methods are the same, if not, the standardized mean difference (SMD) will be used, and their 95% confidence interval will also be calculated. The heterogeneity will be evaluated by Cochrane Q test and inconsistency index test (using the I^2 statistic). If *P* value is larger than 0.1 and I^2 value is less than or equal to 40%, the heterogeneity will be considered small, and the fixed effects model will be used to analyze pooled effect for all outcomes, otherwise, the random effects model will be used. In this review, we assume that there is no difference in all outcomes between the intervention group and the control group at baseline. Consequently, only last follow-up data will be used to analyze pooled effect. We will analyze the study which has outcome difference at baseline in sensitivity analysis. For the outcomes of unrecognized sources of heterogeneity, missing data, and less than 3 related studies, narrative synthesis approach will be used.[20, 31, 32] The *P* value of no more than 0.05 will be considered as statistically significant. All the analyses will be conducted with Stata Statistical Software version16.0.

Meta regression and subgroup analysis

Meta regression and subgroup analysis will be used only for HbA1c in order to identify sources of heterogeneity and analyze influencing factors. Firstly, we will

perform a meta regression to screen out important factors that lead to heterogeneity, and then perform subgroup analysis on the selected factors.[33] We will conduct meta regression and subgroup analysis in following seven aspects.

- Participant characteristics: gender, age, region, disease course.
- Basic level of HbA1c: less than 7.0% vs greater or equal to 7.0%.
- Insulin usage: use insulin vs not use.
- Comorbidities and serious complications: the study which excludes patients of serious complications or other chronic diseases vs the study which does not exclude them.
- Characteristics of self-management activity: participant types (patient only, patient + families/friends, others), educator types (patient only, doctor/nurse only, specialist only, patient + doctor/nurse/specialist, others), theories (involve theories, not involve), group activity time (3 months and less, 3 to 6 months, 6 months and more), duration of each activity (less than 1 hour, 1 hour and more), the number of self-management component, implementation site (community, hospital).
- Characteristics of follow-up: pattern (face-to-face, online form, combination of both), frequency (at least once every 3 months, at least once every 6 months, at least once every year).
- Study duration: 1 year, 1 to 2 year and over 2 year.

Sensitivity analysis

If sufficient studies are available, we will conduct a sensitivity analysis for HbA1c in following five aspects to assess the robustness of results.

- Study design: remove the cluster randomized controlled study to analyze the randomized controlled study.
- The risk of bias: remove studies with high risk of bias to analyze studies at low and unclear risk of bias.
- Baseline level: remove studies with outcome difference at baseline level to analyze studies with no difference.
- Lost to follow-up: remove the studies with a loss to follow-up rate greater than 20% to analyze the remaining studies.
- Language: remove studies published in Chinese to analyze English studies.
- Sample size: analyze studies of which sample size is larger than the median of sample size of all included studies.

Assessment of publication biases

For each outcome, if more than 10 studies are included in the meta-analysis, we will use a funnel plot to check publication bias, and use Egger method, trim and fill method to test publication bias.[34, 35]

Quality of evidence

The grading of recommendations assessment, development and evaluation (GRADE) approach will be used to evaluate the quality of evidence for each outcome. The GRADE method categorizes the quality of evidence as very low, low, moderate and high. The randomized controlled trial is designated as the highest level of evidence. There are five factors that may lower the quality of evidence, including study limitations, inconsistency of results, indirectness of evidence, imprecision, and reporting bias.[36] GRADE Profiler 3.6 software will be used.

Patient and public involvement

No patients or public will participate in the study.

ETHICS AND DISSEMINATION

Ethical approval is not required for this study, given that the study does not involve direct data collection from patients. We will submit our manuscript to a peer-reviewed journal for publication. Likewise, we will share the findings with relevant and responsible organizations. In addition, we will present the findings to guide the diabetes self-management when training grassroots chronic disease workers.

DISCUSSION

In this review, we make a clearly operable provision on self-management, and many studies similar to self-management but do not meet the requirements of self-management will be excluded, which ensure that the finding of the review can accurately reflect the effects of self-management. Moreover, compared with previous systematic reviews, the finding can provide more information about different self-management components and is more reliable because the outcomes collected are not easily affected by unblinded assessment.[32] Additionally, this review focuses on community patients instead of hospitalized patients as hospitalized patients may have more serious illness and are urgent to receive clinic treatment rather than self-management. Patients in the community have more time and energy to manage their own diseases. As a consequence, this review will exclude hospitalized patients to focus on those who need self-management most.

There are a few limitations. We might exclude some relevant studies mistakenly, which will influence the quality of evidence. Actually, some studies might be carried out in accordance with the self-management standards, but they fail to describe the detail in the published article. In addition to this, due to the limitation of language ability, we may omit some related studies. This review will only retrieve Chinese and English articles. Other languages articles will not be searched because we could not read these languages, which indicates that more articles in different languages need to be included for future research.

This review will provide a reference for the long-term effect of diabetes self-management. At the same time, by analyzing the effect of different self-management components, it will provide guidance for the improvement of diabetes self-management in the future.

Author details

Zhang Xia[1], e-mail: 1140706612@qq.com

Yingying Jiang[1], e-mail: jiangyingying@ncncd.chinacdc.cn

Weijing Shang[2], e-mail: shangweij@163.com

Haijun Guo[3], e-mail: haijun.guo@griffithuni.edu.au

Fan Mao[1], e-mail: manfan@ncncd.chinacdc.cn

Wenlan Dong[1], e-mail: dongwenlan@ncncd.chinacdc.cn

Corresponding author: Jianqun Dong[1], e-mail: dongjianqun@ncncd.chinacdc.cn, Tel: +86 10 83136483, Postal address: 27# Nanwei Road Xicheng District, Beijing, China 100050

[1]National Center for Chronic and Non-communicable Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, China

[2]National Center for Women and Children's Health, Chinese Center for Disease Control and Prevention, Beijing, China

[3]Center for Environment and Population Health, Griffith University, Queensland, Australia

Acknowledgements We sincerely appreciate the assistance from MS. Qian Xu at West China School of Pharmacy Sichuan University, with developing the study selection and data synthesis for this study, and also thank Huang Qiu-min from National Institute for Nutrition and Health Chinese Center for Disease Control and Prevention for reviewing the draft of this protocol.

Contributors ZX conceived the study, developed the methodology, designed search strategy and drafted the manuscript. YJ determined the scope of the review, reviewed methodology and revised the manuscript. HG reviewed methodology and revised the manuscript. WS contributed to the design of search strategy, data extraction form, and also revised the manuscript. FM, WD and JD reviewed methodology and revised the manuscript. JD acts as guarantor for the study. All authors have read and approved the final version of the manuscript.

Funding

This study was supported by grant from the National Key Research and Development Project of China (2020YFC2006403).

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract*. 2019;157:107843. doi: 10.1016/j.diabres.2019.107843
2. Liu Y， Chen Z， Zhang Q， et al. The clinical epidemiological analysis of 1433 cases of type 2 diabetes and their diabetic complications. *Journal of Chinese Physician*. 2005;7(5):607-9. doi:10.3760/cma.j.issn.1008-1372.2005.05.012
3. Wu J, Su H, He L, et al. Study on the risk factors of chronic complications and quality of life among inpatients with type 2 diabetes mellitus. *Modern Preventive Medicine*. 2010;37(8):1411-4.
4. World Health Organisation: Therapeutic Patient Education: Continuing Education Programmes for Healthcare Providers in the Field of Prevention of Chronic Diseases. Report of a WHO Working Group. 1998.
5. Tan P, Dong J. Research progress on diabetes mellitus self-management. *Chinese Journal of Prevention and Control of Chronic Diseases*. 2011;19(4):435-9. doi:10.16386/j.cjpccd.issn.1004-6194.2011.04.036
6. Mensing C, Norris S. Group education in diabetes: effectiveness and implementation. *Diabetes Spectr*. 2003;16(2):96–103. doi:10.2337/diaspect.16.2.96
7. Steinsbekk A, Rygg L, Lisulo M, et al. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Serv Res*. 2012;12:213. doi:10.1186/1472-6963-12-213
8. Yao J, Wang J, Li X. Analysis of the effect of self-management group activities in community diabetes management. *Chinese Journal of Prevention and Control of Chronic Diseases*. 2018;26(8):635-7. doi:10.16386/j.cjpccd.issn.1004-6194.2018.08.020
9. Jiang Y, Zhang X, Mao F, Dong W, Dong J. The impact evaluation of a community‐based intervention supporting type 2 diabetes mellitus patients in their self‐management of the disease.

Zhonghua Yu Fang Yi Xue Za Zhi. 2019;53(2):206-11. doi: 10.3760/cma.j.issn.0253-9624.2019.02.016

10. Qian Y, Wang L, Chen H, et al. Effectiveness of peer‐supported self‐management group intervention in patients with type 2 diabetes. *Zhonghua Yu Fang Yi Xue Za Zhi*. 2020;54(4):406-10. doi:10.3760/cma.j.cn112150-20190329-00229
11. Lv S, Zhang Y, Hu W, et al. Evaluation on self-efficacy and quality of life among patients with diabetes before and after community self-management activities. *Chinese Journal of Disease Control & Prevention*. 2015;19(9):890-3. doi:10.16462/j.cnki.zhjbkz.2015.09.008
12. Chatterjee S, Davies M, Heller S, et al. Diabetes structured self-management education programmes: a narrative review and current innovations. *Lancet Diabetes Endocrinol*. 2018;6(2):130-42. doi:10.1016/S2213-8587(17)30239-5
13. Samuel-Hodge C, Keyserling T, Park S, et al. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. *Diabetes Educ*. 2009;35(3):439-54. doi:10.1177/0145721709333270
14. Rygg L, Rise M, Gronning K, et al. Efficacy of ongoing group based diabetes self-management education for patients with type 2 diabetes mellitus. A randomised controlled trial. *Patient Educ Couns*. 2012;86(1):98-105. doi: 10.1016/j.pec.2011.04.008
15. Lorig K, Ritter P, Villa F, et al. Community-based peer-led diabetes self-management: a randomized trial. *Diabetes Educ*. 2009;35(4):641-51. doi:10.1177/0145721709335006
16. Debussche X, Besançon S, Balcou-Debussche M, et al. Structured peer-led diabetes self-management and support in a low-income country: The ST2EP randomised controlled trial in Mali. *PLoS One*. 2018;13(1):e0191262. doi:10.1371/journal.pone.0191262
17. Spencer M, Kieffer E, Sinco B, et al. Outcomes at 18 Months From a Community Health Worker and Peer Leader Diabetes Self-Management Program for Latino Adults. *Diabetes Care*. 2018;41(7):1414-22. doi:10.2337/dc17-0978
18. Captieux M, Pearce G, Parke H, et al. Supported self-management for people with type 2 diabetes: a meta-review of quantitative systematic reviews. *BMJ Open*. 2018;8(12):e024262. doi:10.1136/bmjopen-2018-024262
19. Norris S, Engelgau M, Narayan K. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care*. 2001;24(3):561-87. doi:10.2337/diacare.24.3.561
20. Odgers-Jewell K, Ball L, Kelly J, et al. Effectiveness of group-based self-management education for individuals with Type 2 diabetes: a systematic review with meta-analyses and meta-regression. *Diabet Med*. 2017;34(8):1027-39. doi:10.1111/dme.13340
21. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4(1):1. doi:10.1186/2046-4053-4-1
22. Higgins J, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
23. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Int J Surg*. 2010;8(5):336-41. doi:10.1016/j.ijsu.2010.02.007
24. Jonkman N, Schuurmans M, Jaarsma T, et al. Self-management interventions: Proposal and validation of a new operational definition. *J Clin Epidemiol*. 2016;80:34-42. doi:10.1016/j.jclinepi.2016.08.001

25. Bene B, O'Connor S, Mastellos N, et al. Impact of mobile health applications on self-management in patients with type 2 diabetes mellitus: protocol of a systematic review. *BMJ Open*. 2019;9(6):e025714. doi:10.1136/bmjopen-2018-025714
26. Higgins J, Deeks J (editors). Chapter 7: Selecting studies and collecting data. In: Higgins JPT, Green S (editors), *Cochrane Handbook for Systematic Reviews of Interventions.* Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
27. Leroyer C, Dineen-Griffin S, Garcia-Cardenas V, et al. Helping patients help themselves: A systematic review of self-management support strategies in primary health care practice. *PLoS One*. 2019;14(8):e0220116. doi:10.1371/journal.pone.0220116
28. Chinese Diabetes Society. Chinese guideline for the prevention and treatment of type 2 diabetes mellitus (2017 edition). *Chinese Journal of Diabetes Mellitus*. 2018;10(1):4-67. doi:10.3760/cma.j.issn.1674-5809.2018.01.003
29. Higgins J, Altman D, Sterne J (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Churchill R, Chandler J, Cumpston MS (editors), *Cochrane Handbook for Systematic Review of Interventions* version 5.2.0 (updated June 2017), Cochrane, 2017. Available from www.training.cochrane.org/handbook.
30. Liu H, Wu H, Yao C, et al. Advanced methods of data extraction for continuous outcomes in meta-analysis. *Chinese Journal of Evidence-Based Medicine*. 2017;17(1):117-21. doi:10.7507/1672-2531.201612004
31. Zeng X, Ren X. Use STATA for Meta analysis. Beijing: China Union Medical University Press 2017:64.
32. Zimbudzi E, Lo C, Misso M, et al. Effectiveness of self-management support interventions for people with comorbid diabetes and chronic kidney disease: a systematic review and meta-analysis. *Syst Rev*. 2018;7(1):84. doi:10.1186/s13643-018-0748-z
33. Shi X, Wang Z. Application of Meta-regression and subgroup analyses of heterogeneity disposal in Meta-analysis. *Zhonghua Liu Xing Bing Xue Za Zhi*. 2008;29(5):497-501. doi:10.3321/j.issn:0254-6450.2008.05.018
34. Sterne J, Egger M, Moher D (editors). Chapter 10: Addressing reporting biases. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions*. Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
35. Kang D, Hong Q, Liu G, et al. Investigating and dealing with publication bias in Meta analysis. *Chinese Journal of Evidence-Based Medicine*. 2003;3(1):45-9. doi:10.3969/j.issn.1672-2531.2003.01.010
36. Guyatt G, Oxman A, Vist G, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650):924-6. doi:10.1136/bmj.39489.470347.AD

Search Strategy for PubMed
Research date:26/07/2020.
Mesh=Medical Subject Heading.
mp=Title, Abstract.
Ptyp=Publication Type.

Retrieval order	**Retrieval word**	**Retrieval scope**	**Retrieval results**
# 1	"Diabetes Mellitus, Type 2"	Mesh	134,593
# 2	diabet* AND ("type II" OR "type 2")	mp	151,627
# 3	T2DM	mp	20,936
# 4	# 1 OR # 2 OR # 3		194,469
# 5	neighborhood* OR communit*	mp	586,771
# 6	"Adult"	Mesh	7,250,646
# 7	"Infant" OR "Child" OR "Adolescent"	Mesh	3,578,519
# 8	# 6 NOT # 7		5,561,112
# 9	# 4 AND # 5 AND # 8		3,175
# 10	"Self-Management"	Mesh	2,458
# 11	Self?care OR Self?help OR Self?manag* OR Self?admin* OR Self?concept OR self?monitor* OR self?medicat*	mp	103,347
# 12	# 10 OR # 11		103,695
# 13	group OR groups OR group-based		4,384,977
# 14	random*	mp	1,147,385
# 15	"Randomized Controlled Trial"	Ptyp	
# 16	# 14 AND # 15		390,384
# 17	# 9 AND # 12 AND # 13 AND # 16		108

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	22
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	23
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			
Sources	5a	Indicate sources of financial or other support for the review	23
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	6-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-12
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	12
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	12

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	13
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	13-14
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	14-15
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	15-16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	16-17
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	17-19
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	17
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	19
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	19-20

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Long-term effectiveness of group-based diabetes self-management on glycated hemoglobin for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-046692.R1
Article Type:	Protocol
Date Submitted by the Author:	01-Jun-2021
Complete List of Authors:	Xia, Zhang; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Jiang, Ying-ying; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Shang, Wei-jing; Chinese Center for Disease Control and Prevention, National Center for Women and Children's Health Guo, Hai-jun; Griffith University, Center for Environment and Population Health Mao, Fan; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Dong, Wen-lan; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention Dong, Jian-qun; Chinese Center for Disease Control and Prevention, National Center for Chronic and Non-communicable Disease Control and Prevention
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Diabetes and endocrinology, Evidence based practice
Keywords:	DIABETES & ENDOCRINOLOGY, EDUCATION & TRAINING (see Medical Education & Training), Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Long-term effectiveness of group-based diabetes self-management on glycated hemoglobin for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis

Zhang Xia[1], Ying-ying Jiang[1], Wei-jing Shang[2], Hai-jun Guo[3], Fan Mao[1], Wen-lan Dong[1], Jian-qun Dong[1]

ZX and YJ contributed equally

Author Affiliations:

[1]National Center for Chronic and Non-communicable Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, China

[2]National Center for Women and Children's Health, Chinese Center for Disease Control and Prevention, Beijing, China

[3]Center for Environment and Population Health, Griffith University, Queensland, Australia

Corresponding Author:

Jian-qun Dong, Tel: +86 10 83136483, Fax: +86 10 63042350

E-mail: dongjianqun@ncncd.chinacdc.cn

Postal address: 27# Nanwei Road Xicheng District, Beijing, China 100050

Keywords:

Diabetes Mellitus, Type 2; Diabetes self-management education; Group; Systematic review

Word Count：3748

ABSTRACT

Introduction The rapid rise in the prevalence of diabetes has a negative impact on patients' quality of life. Diabetes self-management group education is cost-effective and efficient for patients to control blood glucose. However, there is no consistent standards for self-management group education, and its long-term effects (⩾ 12 months) are unclear. Although a few systematic reviews evaluated the long-term effects, they did not make clear provisions on the content of self-management, and the number and sample size of included studies were small, which may lead to misclassification bias and reporting bias. Therefore, we plan to conduct this systematic review to evaluate the long-term effects of self-management group education and determine the effects of different self-management characteristics on glycosylated hemoglobin (HbA1c).

Methods and analysis We will retrieve Chinese databases (Wanfang, Chinese Hospital Knowledge Warehouse) and English databases (PubMed, ScienceDirect, EMBASE, Web of Science, Bailian Platform, Cochrane Central Register of Controlled Trials, Google Scholar) for randomly-controlled trials and cluster randomly-controlled trials of which participants are adults with type 2 diabetes mellitus. We will manually search citation lists, trials registries, and consult authors to obtain relevant articles. The retrieval time range will be from the establishment of the database to July 2020 to avoid omitting relevant studies. The primary outcome will be HbA1c. The secondary outcomes will be

fasting plasma glucose, postprandial blood glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, systolic blood pressure, diastolic blood pressure, body mass index, waist circumference, and death event. Two reviewers will independently conduct article screening, assessment of risk of bias, with a third reviewer arbitrating if necessary. We will give priority to the use of meta-analysis to evaluate the pooled effects of all outcomes. For the outcomes of unrecognized sources of heterogeneity, missing data, and less than 3 related studies, narrative synthesis approach will be used.

Ethics and dissemination Ethical approval is not required for this systematic review. We plan to present the findings in a peer-reviewed scientific journal, relevant and responsible organizations, and training meetings.

PROSPERO registration number CRD42020209011.

Strengths and limitations of this study

- This study will be the first systematic review to specifically evaluate the long-term effectiveness of group-based diabetes self-management education.
- A clearly operable provision on self-management will be used in this study to exclude plausible studies so as to accurately reflect the effect of self-management.

- This study will focus on objective outcomes which can avoid unblinded biases to some extent, and provide more reliable evidence for diabetes self-management.
- Meta regression and subgroup analysis will provide an understanding of how different self-management characteristics affect the long-term effect of HbA1c control.
- Due to the limitation of language ability, some studies may be omitted, which may bias our findings.

INTRODUCTION

Diabetes is mainly characterized by high blood glucose caused by insulin secretion defect or (and) its biological function disorder. In recent years, the number of people with diabetes has increased rapidly in developed and developing countries. According to data from the International Diabetes Federation, there were 463 million patients aged 20-79 in 2019 globally, with the prevalence of diabetes at 9.3%, and it was estimated to reach at 578 million in 2030 and 700 million in 2045, with the prevalence of diabetes at 10.2% and 10.9%, respectively; in China, this number was 116.4 million in 2019, ranking first in the world, and it predicted to increase to 140.5 million in 2030 and 147.2 million in 2045.[1] Diabetes can cause multiple complications such as coronary heart disease, peripheral neuritis, diabetic nephropathy and retinopathy, all of which the complication incidence gradually grows with the increase of disease duration, heavily leading to a negative impact on patients' quality of life.[2, 3]

The World Health Organization points out that patient-centered education is essential for the effective management of chronic diseases.[4] In the field of diabetes education, diabetes self-management education is a suitable technology to alleviate the burden of diabetes. Diabetes self-management refers to teaching patients the knowledge and skills needed for self-management through a series of health education courses, helping patients with the support of physicians to solve the various physical and emotional problems caused by diseases in daily life.[5] At present, the main formats of

self-management are group and individual format.[6] Compared with the individual format, the group format is relatively widely used because it can reduce time and capital investment and has better cost-effectiveness and higher efficiency. Meanwhile, people can communicate and share their experience with each other in a group, and decide whether to change their behaviors, which embodies the concept of 'empowerment'.[6, 7] Previous studies have shown that diabetes self-management group education can improve patients' level of diabetes knowledge, self-efficacy, health behaviors and body weight, reduce fasting blood glucose, 2-hour postprandial blood glucose and glycosylated hemoglobin (HbA1c), and ultimately improve chronic condition.[8, 9] In addition, participating in self-management group education can reduce the frequency of patients' outpatient visits and hospitalizations, and improve their quality of life.[10, 11]

However, there is still some weakness in diabetes self-management. Primarily, self-management education lacks consistent standards. Although the International Diabetes Federation has published the 'International Curriculum for Diabetes Health Professional Education' and 'International Standards for Diabetes Education', the self-management still differs in approach, content, form, and technology, which is not conducive to promote self-management and compare intervention effect.[7, 12] Additionally, existing studies have shown that patients can manage their blood glucose in a short term after self-management intervention, but the long-term effect is still unclear.[13-17] For

other clinical indicators such as blood pressure and blood lipids, there is no consistent conclusion with respect to the long-term effects either.[18, 19] Furthermore, we have searched PubMed, ScienceDirect and Cochrane Library, and found that a few systematic reviews evaluated the effect of self-management, but there are some deficiencies.[7, 20, 21] For example, they did not make clear provisions on the content of self-management, which may lead to misclassification bias; furthermore, for the long-term effect ($\geqslant$12 months) evaluation, the number and sample size of included studies were small, which may introduce reporting bias.[22]

Hence, we present a protocol which describes how this systematic review will be designed and conducted, with the aim to systematically and comprehensively evaluate the long-term effect of self-management group education and to explore the strategy of long-term blood glucose control. Since participants may attempt to carry out self-management after the first group activity or continue to carry out self-management on their own after the end of all group activities, the time interval between the baseline survey and the last follow-up survey was defined as the influence period of self-management group education. According to previous studies, the self-management effect with a time interval of 12 months or more is defined as long-term effect in this study.[7, 20, 21] The protocol is presented in accordance with the guideline of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement.[23]

AIM AND RESEARCH QUESTION

The aim is to evaluate the long-term effect of self-management group education (≥12 months) for focused group with type 2 diabetes mellitus (T2DM) in community and to identify what characteristics of self-management benefit patients to control blood glucose. This review is with the attempt to answer the following questions:

- What are the long-term effects of group-based diabetes self-management education on HbA1c, blood pressure, blood lipid, body weight and death event?
- What are the effects of different self-management characteristics on HbA1c?

METHODS

Systematic review design

The review will adopt methods described in the Cochrane Handbook for Systematic Reviews of Interventions guidelines and conform to the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[24, 25] The PRISMA-P checklist will be completed and attached as a supplementary file 1. The eligibility criteria will be guided in form of 'PICOS'. The review started on 1 May 2020 and will complete by 1 May 2021.

Eligibility criteria

Participants (P)

The review will include the study of which all participants are diagnosed with T2DM and 18 years old or older. All participants should be recruited from the community through community health service centers, hospitals, diabetes research centers and other institutions. Studies involving individuals with type 1 diabetes, gestational diabetes and hospitalization will be excluded.

Intervention (I)

The study will be included if it conducts a self-management intervention based on the group format. The group activity should be carried out more than once. The content of self-management activity involves the following 5 topics:

- Knowledge acquisition;
- Self-sign or symptom monitoring;
- Medication management;
- Enhance problem-solving and decision-making skills;
- Change behaviors such as physical activity, diet, smoking, etc.

For each eligible study, knowledge acquisition must be included, and at least two of other topics should be included.[26] The study will be excluded if it conducts self-management activity in form of one-way education without interaction. For example, mutual help will be excluded for those studies that

only describe lectures, courses with no mention on other interactive activities such as group discussion or experience sharing. Online or virtual group activities instead of face-to-face will also be excluded.

Comparison (C)

Comparisons will be made against any type of control. This may include, but not limited to, standard or usual care, usual education, waiting list control, paper educational materials and other interventions.

Outcomes (O)

The outcome will be reported as primary outcome and secondary outcome. Primary outcome is HbA1c – the gold standard for assessing glycemic control – which represents average blood glucose over the previous 2 to 3 months.[27] Secondary outcomes include fasting plasma glucose (FPG), postprandial blood glucose (PBG), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), systolic blood pressure (SBP), diastolic blood pressure (DBP), body mass index (BMI), waist circumference (WC), death event. The study including one of outcomes above will be considered.

Study design (S)

This review will consider randomly-controlled trials (RCTs) and cluster randomly-controlled trials (CRCTs). The time interval between the baseline survey and the last follow-up survey should be at least 12 months. Reviews, qualitative research, observational research, comments, withdrawn research, government reports, book chapters, statements, guidelines, and the study of which full text cannot be obtained will be excluded. The brief eligibility criteria is listed in Table 1.

Table 1 Predefined eligibility criteria in the systematic review

Item	Inclusion criteria	Exclusion criteria
Population	People with T2DM and aged 18 years old or older. They should be recruited from communities.	People with type 1 diabetes, gestational diabetes, and hospitalization.
Intervention	Self-management is conducted in group. The number of activity more than once. Self-management involves the following 5 topics: 1. Knowledge acquisition 2. Self-sign or symptom monitoring 3. Medication management 4. Enhance problem-solving and decision-making skills 5. Change behaviors Knowledge acquisition must be included, and at least 2 of other topics should be included.	Self-management is conducted in form of one-way education without interaction. Self-management is carried out by Internet rather than face to face.
Comparison	This may include standard or usual care, usual education, waiting list control, paper educational materials and other interventions.	No limitation
Outcome	Primary outcome is HbA1c. Secondary outcomes include FPG, PBG, SBP, DBP, TC, TG, HDL-C, LDL-C, BMI, WC, death event. The study including one of outcomes above will be considered.	No limitation

Study design	Randomized controlled trials and cluster randomized controlled trials. The time interval between baseline survey and the last follow-up survey should be at least 12 months.	Reviews, qualitative research, observational research, comments, withdrawn research, government reports, book chapters, statements, guidelines, and the study of which full text cannot be obtained

T2DM, type 2 diabetes mellitus; HbA1c, glycosylated hemoglobin; FPG, fasting plasma glucose; PBG, postprandial blood glucose; SBP, systolic blood pressure; DBP, diastolic blood pressure; TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; BMI, body mass index; WC, waist circumference.

Search strategy

We will conduct a systematic retrieval in Chinese databases with keywords such as 'type 2 diabetes', 'self-management', 'randomized controlled trial', 'group', 'community'. Chinese databases will include Wanfang database and Chinese Hospital Knowledge Warehouse database. Only Chinese language articles will be retrieved in Chinese databases. Taking 'Diabetes Mellitus, Type 2', 'T2DM', 'Self-Management', 'Randomized Controlled Trial', 'group-based' as keywords, and adopting a combination of Mesh terms, free words, and word variations, we will search English databases including PubMed, ScienceDirect, EMBASE, Web of Science, Bailian Platform (English language retrieval), Cochrane Central Register of Controlled Trials, Google Scholar. The language will be restricted to English. We will manually search the article in the citation list of published relevant reviews, consult field experts and authors to obtain published articles, search Chinese Clinical Trial Registry (http://www.chictr.org.cn), U.S. Clinical Trials Registry (https://www.clinicaltrials.gov/), EU Clinical Trials Registry

(https://www.clinicaltrialsregister.eu/) to find articles. The literature retrieval time range will be from the establishment of the database to July 2020 to avoid omitting relevant studies. We use PubMed as an example for retrieval, and the specific search strategy is shown in supplementary file 2.

Study selection

All identified articles will be managed by EndNote X8 software, and duplicates will be removed. Two reviewers (ZX and WS) will adapt a blind method to independently screen articles. Screening process will be made up of two stages:

1) Stage one: reviewers will read the title and abstract based on predefined eligibility criteria. The article will be included for further screening if the eligibility criteria is initially met.
2) Stage two: they will read the full text to decide whether to include the article in the review. The reasons for article exclusion will be recorded during two stages. If the information related to the study is not available, they will contact the author by email. The study will be excluded if no response.

After the study screening is completed, the screening results will be compared. Any disagreement will be resolved through discussion between two reviewers. If they cannot reach a consensus, they will invite a diabetes self-management expert (YJ) to judge and resolve. The screening process will be described by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Data extraction

One reviewer (ZX) will extract the characteristics of study with a data extraction form in Microsoft Excel2019, including study design, participants' characteristics, self-management activity, follow-up, study duration and outcomes. Another reviewer (WS) will check the extraction result. Data extraction form will be designed based on Cochrane Collaboration data collection forms and piloted on ten of the related studies.[28] Since outcomes – such as blood glucose, blood pressure and blood lipids – are mostly expressed as continuous data, which cannot be analyzed together with categorical data, reviewers will contact the author to obtain continuous data if the outcome is presented in categories. Disagreement will be resolved through discussion. If a consensus cannot be reached, they will invite the diabetes self-management expert (YJ) to judge and resolve.

The following characteristics will be collected if reported in individual studies:

- Publication information: title, first author, publication year, author's contact information.
- Study characteristics: recruitment method, inclusion and exclusion criteria, study design type, follow-up time, loss to follow-up, conclusions.
- Participant characteristics: participant number, age, gender, nationality, course of disease, diabetes complications and complications, insulin usage.

- Intervention: name of the intervention, content, duration, frequency, facilitator.
- Self-management components: referring to the study of Sarah Dineen-Griffin, components will include disease and self-management knowledge acquisition, encouragement of symptom monitoring, development of action plans for self-management, enhancement of resource utilization capabilities, enhancement of problem solving and decision-making skills, enhancement of stress and emotional management capabilities, physical activity, diet management, smoking cessation, drug management and compliance, self-management compliance.[29]
- Outcomes: According to the 'Chinese guideline for the prevention and treatment of type 2 diabetes mellitus (2017 edition)', people with diabetes should control not only blood glucose, but also blood pressure and blood lipids. The comprehensive diabetes control indicators include blood glucose, blood pressure, blood lipids and body mass index. And the comprehensive diabetes control goal is to prevent death and to reduce mortality.[30] Consequently, this review will collect information about HbA1c, FPG, PBG, TC, TG, HDL-C, LDL-C, SBP, DBP, BMI, WC, death event. We will also collect their units, measurement methods, measurement time, data at baseline and endpoint.

Assessment of risk of bias in included studies

The Cochrane Risk of Bias Tool will be used to assess the risk of bias which contains random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, other sources of bias. Each domain will be assessed as low risk of bias, high risk of bias or unclear risk of bias. The over risk of bias of each study will also be rated as low (if all domains are assessed as low risk of bias), high (if one or more domains are assessed as high risk of bias), or unclear (if one or more domains are assessed as unclear risk of bias).[31] We will not consider assessing risk of bias at the outcome level because the outcome collected in this review is mostly obtained through laboratory tests and is not easily affected by the subjectivity of participants and researchers.

Assessment will be conducted by two reviewers (ZX and WS) independently. After the assessment is completed, reviewers will compare the result, and resolve disagreement through discussion. If a consensus cannot be reached, they will invite the diabetes self-management expert (YJ) to judge and resolve. The risk of bias of included studies will be used to evaluate the robustness of the findings. A 'risk of bias graph' figure and 'risk of bias summary' figure will be attached.

Data synthesis

The characteristics of selected studies will be presented in a summary table, including publication (first author, year of publication, country), number of enrollment and follow-up, baseline (age, disease duration, gender, HbA1c value), study design type (RCTs/CRCTs), self-management intervention (mode/theory, educator, site, number of activity, frequency, duration, number of self-management component), follow-up intervention, control group intervention, study duration, available outcome. Before meta analyzing, if the unit of an outcome is inconsistent, we will convert it into a unified unit. For outcomes which are not represented by mean and standard deviations, we will convert them into the form of mean and standard deviation.[32]

The size of the effect will be expressed as the mean difference (MD) if measurement methods are the same; if not, the standardized mean difference (SMD) will be used, and their 95% confidence interval will also be calculated. The heterogeneity will be evaluated by Cochrane Q test and inconsistency index test (using the I^2 statistic). If P value is larger than 0.1 and I^2 value is less than or equal to 40%, the heterogeneity will be considered small, and the fixed effects model will be used to analyze pooled effect for all outcomes; otherwise, the random effects model will be used. In this review, we assume that there is no difference in all outcomes between the intervention group and the control group at baseline. Consequently, only last follow-up data will be used to analyze pooled effect. We will analyze the study which has outcome difference at baseline in sensitivity analysis. For the outcomes of unrecognized sources of

heterogeneity, missing data, and less than 3 related studies, narrative synthesis approach will be used.[20, 33, 34] The *P* value of no more than 0.05 will be considered as statistically significant. All the analyses will be conducted with Stata Statistical Software version16.0.

Meta regression and subgroup analysis

Meta regression and subgroup analysis will be used to identify sources of heterogeneity and analyze influencing factors. Firstly, we will perform a meta regression to screen out important factors that lead to heterogeneity, and then perform subgroup analysis on the selected factors.[35] We will conduct meta regression and subgroup analysis in following seven aspects.

- Participant characteristics: gender, age, country, disease course.
- Basic level of HbA1c: less than 7.0% vs greater or equal to 7.0%.
- Insulin usage: use insulin vs not use.
- Comorbidities and serious complications: the study which excludes individuals of serious complications or other chronic diseases vs the study which does not exclude them.
- Characteristics of self-management activity: participant types (patient only, patient + families/friends), educator types (patient only, doctor/nurse/specialist only, patient + doctor/nurse/specialist), theories (involve theories, not involve), group activity time (3 months and less, 3 to 6 months, 6 months and more), duration of each activity (less than 2 hours,

2 hours and more), the number of self-management component, implementation site (community, primary health care center, others).

- Characteristics of follow-up: pattern (face-to-face, online form, combination of both), frequency (at least once every 3 months, at least once every 6 months, at least once every year).
- Study duration: 1 year, 1 to 2 year and over 2 year.

Sensitivity analysis

If sufficient studies are available, we will conduct a sensitivity analysis for each outcome in following five aspects to assess the robustness of results.

- Study design: remove the cluster randomly controlled study to analyze the randomly controlled study.
- The risk of bias: remove studies with high risk of bias to analyze studies at low and unclear risk of bias.
- Baseline level: remove studies with outcome difference at baseline level to analyze studies with no difference.
- Lost to follow-up: remove the studies with a loss to follow-up rate greater than 10% to analyze the remaining studies.
- Language: remove studies published in Chinese to analyze English studies.
- Sample size: analyze studies of which sample size is larger than the median of sample size of all included studies.

Assessment of publication biases

For each outcome, if more than 10 studies are included in the meta-analysis, we will use a funnel plot to check publication bias, and use Egger method, trim and fill method to test publication bias.[36, 37]

Quality of evidence

The grading of recommendations assessment, development and evaluation (GRADE) approach will be used to evaluate the quality of evidence for each outcome. The GRADE method categorizes the quality of evidence as very low, low, moderate and high. The randomized controlled trial is designated as the highest level of evidence. There are five factors that may lower the quality of evidence, including study limitations, inconsistency of results, indirectness of evidence, imprecision, and reporting bias.[38] GRADE Profiler 3.6 software will be used.

Patient and public involvement

No patients or public will participate in the study.

ETHICS AND DISSEMINATION

Ethical approval is not required for this study, given that the study does not involve direct data collection from people. We will submit our manuscript to a peer-reviewed journal for publication. Likewise, we will share the findings with

relevant and responsible organizations. In addition, we will present the findings to guide the diabetes self-management when training grassroots chronic disease workers.

DISCUSSION

In this review, we use a clearly operable definition of self-management interventions to carry out the study because this definition has some strengths.[26] First, the definition proposed explicit content that self-management interventions should be involved, which helps us to easily distinguish self-management from any other form of education or behavioral intervention. Second, the definition can be used to make a distinct selection of self-management interventions without being too restrictive because it only set boundaries for intervention content but not intensity, duration, mode of delivery and so forth. Third, the definition was generated by consensus meetings with self-management experts and practitioners, which may guarantee its external validity. Adopting this definition can exclude studies whose interventions are similar to self-management but do not meet the requirements of self-management, and ensure that the finding of the review can accurately reflect the effects of self-management. Moreover, compared with previous systematic reviews, the finding can provide more information about different self-management characteristics and is more reliable because the outcomes collected are not easily affected by unblinded assessment.[34] Additionally, this

review focuses on community patients instead of hospitalized patients as hospitalized patients may have more serious illness and are urgent to receive clinic treatment rather than self-management. Patients in the community have more time and energy to manage their own diseases. Consequently, this review will exclude hospitalized patients to focus on those who need self-management most.

There are a few limitations. We might exclude some relevant studies mistakenly, which will influence the quality of evidence. Some studies might be carried out in accordance with the self-management standards, but they fail to describe the detail in the published article. In addition to this, due to the limitation of language ability, we may omit some related studies. This review will only retrieve Chinese and English articles. Other languages articles will not be searched because we could not read these languages, which indicates that more articles in different languages need to be included for future research. Some important outcomes such as quality of life, self-efficacy, reduced distress, mental health, cessation of smoking, reducing alcohol are not covered in the study because the definitions and measurement methods for these outcomes are various, which may cause great heterogeneity and even cannot be used for meta-analysis. Therefore, this study cannot answer the questions about the psychological and behavioral effects of self-management, and more separate reviews are needed to determine these effects.

This review will provide a reference for the long-term effect of diabetes self-

management. At the same time, by analyzing the effect of different self-management characteristics, it will provide guidance for the improvement of diabetes self-management in the future.

Author details

Zhang Xia[1], e-mail: 1140706612@qq.com

Yingying Jiang[1], e-mail: jiangyingying@ncncd.chinacdc.cn

Weijing Shang[2], e-mail: shangweij@163.com

Haijun Guo[3], e-mail: haijun.guo@griffithuni.edu.au

Fan Mao[1], e-mail: manfan@ncncd.chinacdc.cn

Wenlan Dong[1], e-mail: dongwenlan@ncncd.chinacdc.cn

Corresponding author: Jianqun Dong[1], e-mail: dongjianqun@ncncd.chinacdc.cn, Tel: +86 10 83136483, Postal address: 27# Nanwei Road Xicheng District, Beijing, China 100050

[1]National Center for Chronic and Non-communicable Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, China

[2]National Center for Women and Children's Health, Chinese Center for Disease Control and Prevention, Beijing, China

[3]Center for Environment and Population Health, Griffith University, Queensland, Australia

Acknowledgements We sincerely appreciate the assistance from MS. Qian Xu at West China School of Pharmacy Sichuan University, with developing the

study selection and data synthesis for this study, and also thank Huang Qiu-min from National Institute for Nutrition and Health Chinese Center for Disease Control and Prevention for reviewing the draft of this protocol.

Contributors ZX conceived the study, developed the methodology, designed search strategy, and drafted the manuscript. YJ determined the scope of the review, reviewed methodology and revised the manuscript. HG reviewed methodology and revised the manuscript. WS contributed to the design of search strategy, data extraction form, and also revised the manuscript. FM, WD and JD reviewed methodology and revised the manuscript. JD acts as guarantor for the study. All authors have read and approved the final version of the manuscript.

Funding

This study was supported by grant from the National Key Research and Development Project of China (2020YFC2006403).

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. Saeedi P, Petersohn I, Salpea P, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract. 2019;157:107843. doi: 10.1016/j.diabres.2019.107843
2. Liu Y， Chen Z， Zhang Q， et al. The clinical epidemiological analysis of 1433 cases of type 2 diabetes and their diabetic complications. Journal of Chinese Physician. 2005;7(5):607-9. doi:10.3760/cma.j.issn.1008-1372.2005.05.012
3. Wu J, Su H, He L, et al. Study on the risk factors of chronic complications and quality of life among inpatients with type 2 diabetes mellitus. Modern Preventive Medicine. 2010;37(8):1411-4.
4. World Health Organisation: Therapeutic Patient Education: Continuing Education Programmes for Healthcare Providers in the Field of Prevention of Chronic Diseases. Report of a WHO Working Group. 1998.
5. Tan P, Dong J. Research progress on diabetes mellitus self-management. Chinese Journal of Prevention and Control of Chronic Diseases. 2011;19(4):435-9. doi:10.16386/j.cjpccd.issn.1004-6194.2011.04.036
6. Mensing C, Norris S. Group education in diabetes: effectiveness and implementation. Diabetes Spectr. 2003;16(2):96–103. doi:10.2337/diaspect.16.2.96
7. Steinsbekk A, Rygg L, Lisulo M, et al. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Serv Res. 2012;12:213. doi:10.1186/1472-6963-12-213
8. Yao J, Wang J, Li X. Analysis of the effect of self-management group activities in community diabetes management. Chinese Journal of Prevention and Control of Chronic Diseases. 2018;26(8):635-7. doi:10.16386/j.cjpccd.issn.1004-6194.2018.08.020
9. Jiang Y, Zhang X, Mao F, Dong W, Dong J. The impact evaluation of a community‐based intervention supporting type 2 diabetes mellitus patients in their self‐management of the disease. Zhonghua Yu Fang Yi Xue Za Zhi. 2019;53(2):206-11. doi: 10.3760/cma.j.issn.0253-9624.2019.02.016
10. Qian Y, Wang L, Chen H, et al. Effectiveness of peer‐supported self‐management group intervention in patients with type 2 diabetes. Zhonghua Yu Fang Yi Xue Za Zhi. 2020;54(4):406-

10. doi:10.3760/cma.j.cn112150-20190329-00229
11. Lv S, Zhang Y, Hu W, et al. Evaluation on self-efficacy and quality of life among patients with diabetes before and after community self-management activities. Chinese Journal of Disease Control & Prevention. 2015;19(9):890-3. doi:10.16462/j.cnki.zhjbkz.2015.09.008
12. Chatterjee S, Davies M, Heller S, et al. Diabetes structured self-management education programmes: a narrative review and current innovations. Lancet Diabetes Endocrinol. 2018;6(2):130-42. doi:10.1016/S2213-8587(17)30239-5
13. Samuel-Hodge C, Keyserling T, Park S, et al. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. Diabetes Educ. 2009;35(3):439-54. doi:10.1177/0145721709333270
14. Rygg L, Rise M, Gronning K, et al. Efficacy of ongoing group based diabetes self-management education for patients with type 2 diabetes mellitus. A randomised controlled trial. Patient Educ Couns. 2012;86(1):98-105. doi: 10.1016/j.pec.2011.04.008
15. Lorig K, Ritter P, Villa F, et al. Community-based peer-led diabetes self-management: a randomized trial. Diabetes Educ. 2009;35(4):641-51. doi:10.1177/0145721709335006
16. Debussche X, Besançon S, Balcou-Debussche M, et al. Structured peer-led diabetes self-management and support in a low-income country: The ST2EP randomised controlled trial in Mali. PLoS One. 2018;13(1):e0191262. doi:10.1371/journal.pone.0191262
17. Spencer M, Kieffer E, Sinco B, et al. Outcomes at 18 Months From a Community Health Worker and Peer Leader Diabetes Self-Management Program for Latino Adults. Diabetes Care. 2018;41(7):1414-22. doi:10.2337/dc17-0978
18. Captieux M, Pearce G, Parke H, et al. Supported self-management for people with type 2 diabetes: a meta-review of quantitative systematic reviews. BMJ Open. 2018;8(12):e024262. doi:10.1136/bmjopen-2018-024262
19. Norris S, Engelgau M, Narayan K. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. Diabetes Care. 2001;24(3):561-87. doi:10.2337/diacare.24.3.561
20. Odgers-Jewell K, Ball L, Kelly J, et al. Effectiveness of group-based self-management education for individuals with Type 2 diabetes: a systematic review with meta-analyses and meta-regression. Diabet Med. 2017;34(8):1027-39. doi:10.1111/dme.13340
21. Deakin T, Mcshane C E, Cade J E, et al. Group based training for self-management strategies in people with type 2 diabetes mellitus [J]. The Cochrane database of systematic reviews, 2005, 2: CD003417. doi:10.1002/14651858.CD003417.pub2
22. Sterne J, Egger M, Moher D, Boutron I. Chapter 10: Addressing reporting biases. In: Higgins JPT, Churchill R, Chandler J, Cumpston MS (editors), Cochrane Handbook for Systematic Reviews of Interventions version 5.2.0 [updated June 2017]. Cochrane 2017: 10.17-10.18.
23. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1. doi:10.1186/2046-4053-4-1
24. Higgins J, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
25. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg. 2010;8(5):336-41. doi:10.1016/j.ijsu.2010.02.007

26. Jonkman N, Schuurmans M, Jaarsma T, et al. Self-management interventions: Proposal and validation of a new operational definition. J Clin Epidemiol. 2016;80:34-42. doi:10.1016/j.jclinepi.2016.08.001
27. Bene B, O'Connor S, Mastellos N, et al. Impact of mobile health applications on self-management in patients with type 2 diabetes mellitus: protocol of a systematic review. BMJ Open. 2019;9(6):e025714. doi:10.1136/bmjopen-2018-025714
28. Higgins J, Deeks J (editors). Chapter 7: Selecting studies and collecting data. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
29. Leroyer C, Dineen-Griffin S, Garcia-Cardenas V, et al. Helping patients help themselves: A systematic review of self-management support strategies in primary health care practice. PLoS One. 2019;14(8):e0220116. doi:10.1371/journal.pone.0220116
30. Chinese Diabetes Society. Chinese guideline for the prevention and treatment of type 2 diabetes mellitus (2017 edition). Chinese Journal of Diabetes Mellitus. 2018;10(1):4-67. doi:10.3760/cma.j.issn.1674-5809.2018.01.003
31. Higgins J, Altman D, Sterne J (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Churchill R, Chandler J, Cumpston MS (editors), Cochrane Handbook for Systematic Review of Interventions version 5.2.0 (updated June 2017), Cochrane, 2017. Available from www.training.cochrane.org/handbook.
32. Liu H, Wu H, Yao C, et al. Advanced methods of data extraction for continuous outcomes in meta-analysis. Chinese Journal of Evidence-Based Medicine. 2017;17(1):117-21. doi:10.7507/1672-2531.201612004
33. Zeng X, Ren X. Use STATA for Meta analysis. Beijing: China Union Medical University Press 2017:64.
34. Zimbudzi E, Lo C, Misso M, et al. Effectiveness of self-management support interventions for people with comorbid diabetes and chronic kidney disease: a systematic review and meta-analysis. Syst Rev. 2018;7(1):84. doi:10.1186/s13643-018-0748-z
35. Shi X, Wang Z. Application of Meta-regression and subgroup analyses of heterogeneity disposal in Meta-analysis. Zhonghua Liu Xing Bing Xue Za Zhi. 2008;29(5):497-501. doi:10.3321/j.issn:0254-6450.2008.05.018
36. Sterne J, Egger M, Moher D (editors). Chapter 10: Addressing reporting biases. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.
37. Kang D, Hong Q, Liu G, et al. Investigating and dealing with publication bias in Meta analysis. Chinese Journal of Evidence-Based Medicine. 2003;3(1):45-9. doi:10.3969/j.issn.1672-2531.2003.01.010
38. Guyatt G, Oxman A, Vist G, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-6. doi:10.1136/bmj.39489.470347.AD

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	22
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	23
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			
Sources	5a	Indicate sources of financial or other support for the review	23
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	6-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-12
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	12
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	12

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	13
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	13-14
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	14-15
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	15
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	15-16
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	17
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	16-17
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	17-19
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	17
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	19
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	19-20

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Search Strategy for PubMed
Research date:26/07/2020.
Mesh=Medical Subject Heading.
mp=Title, Abstract.
Ptyp=Publication Type.

Retrieval order	**Retrieval word**	**Retrieval scope**	**Retrieval results**
# 1	"Diabetes Mellitus, Type 2"	Mesh	134,593
# 2	diabet* AND ("type II" OR "type 2")	mp	151,627
# 3	T2DM	mp	20,936
# 4	# 1 OR # 2 OR # 3		194,469
# 5	neighborhood* OR communit*	mp	586,771
# 6	"Adult"	Mesh	7,250,646
# 7	"Infant" OR "Child" OR "Adolescent"	Mesh	3,578,519
# 8	# 6 NOT # 7		5,561,112
# 9	# 4 AND # 5 AND # 8		3,175
# 10	"Self-Management"	Mesh	2,458
# 11	Self?care OR Self?help OR Self?manag* OR Self?admin* OR Self?concept OR self?monitor* OR self?medicat*	mp	103,347
# 12	# 10 OR # 11		103,695
# 13	group OR groups OR group-based		4,384,977
# 14	random*	mp	1,147,385
# 15	"Randomized Controlled Trial"	Ptyp	
# 16	# 14 AND # 15		390,384
# 17	# 9 AND # 12 AND # 13 AND # 16		108