

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

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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 are 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 haemoglobin (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 and trial 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 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 unrecognised sources of heterogeneity, missing data and less than three related studies, narrative synthesis approach will be used.

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 glycosylated haemoglobin control.
- Due to the limitation of language ability, some studies may be omitted, which may bias our findings.

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 organisations, and training meetings.

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INTRODUCTION

Diabetes is mainly characterised 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 years 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 WHO points out that patient-centred 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 behaviours, 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 behaviours and body weight; reduce fasting blood glucose, 2-hour postprandial blood glucose and glycosylated haemoglobin (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 hospitalisations, 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 (≥ 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 done 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, BMI 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 online supplemental file 1. The eligibility criteria will be guided in the form of 'PICOS' (Population, Intervention, Comparison, Outcomes and Study). 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 centres, hospitals, diabetes research centres and other institutions. Studies involving individuals with type 1 diabetes, gestational diabetes and hospitalisation 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 five topics:

- ▶ Knowledge acquisition.
- ▶ Self-sign or symptom monitoring.
- ▶ Medication management.
- ▶ Enhance problem-solving and decision-making skills.
- ▶ Change behaviours 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 the form of one-way education without interaction. For example, mutual help will be excluded for those studies that only describe lectures and courses with no mention of 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 glycaemic control—which represents average blood glucose over the previous 2–3 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) and death event. The study, including one of the outcomes above, will be considered.

Study design (S)

This review will consider randomly controlled trials (RCTs) and cluster RCTs (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 are 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 hospitalisation.
Intervention	Self-management is conducted in group. The number of activity more than once. Self-management involves the following five topics: 1. Knowledge acquisition 2. Self-sign or symptom monitoring 3. Medication management 4. Enhance problem-solving and decision-making skills 5. Change behaviours 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 through 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, TC, TG, HDL-C, LDL-C, SBP, DBP, BMI, WC, death event. The study including one of outcomes above will be considered.	No limitation
Study design	Randomised controlled trials and cluster randomised 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

BMI, body mass index; DBP, diastolic blood pressure; FPG, fasting plasma glucose; HbA1c, glycosylated haemoglobin; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; PBG, postprandial blood glucose; SBP, systolic blood pressure; TC, total cholesterol; T2DM, type 2 diabetes mellitus; TG, triglyceride; 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 and 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, and search Chinese Clinical Trial Registry (<http://www.chictr.org.cn>), US Clinical Trials Registry (<https://www.clinicaltrials.gov/>), and 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 online supplemental file 2.

Study selection

All identified articles will be managed by EndNote V.X8 software, and duplicates will be removed. Two reviewers (ZX and W-JS) will adapt a blind method to independently screen articles. The 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 are 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 (Y-YJ) to judge and resolve the issue. The screening process will be described by the PRISMA flow diagram.

Data extraction

One reviewer (ZX) will extract the characteristics of study with a data extraction form in Microsoft Excel 2019, including study design, participants’ characteristics, self-management activity, follow-up, study duration and outcomes. Another reviewer (W-JS) will check the

extraction result. A data extraction form will be designed based on Cochrane Collaboration data collection forms and piloted on 10 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 analysed 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 (Y-YJ) to judge and resolve the issue.

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 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 utilisation 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 T2DM (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 BMI. 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 and death event. We will also collect their units, measurement methods, measurement time, and 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 and other sources of bias. Each domain will be assessed as low risk of bias, high risk of bias or unclear risk of bias. The overall 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 WJS) 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 (YYJ) to judge and resolve the issue. 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 enrolment 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 and available outcome. Before meta-analysing 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 SDs, we will convert them into the form of mean and SD.³²

The size of the effect will be expressed as the mean difference (MD) if measurement methods are the same; if not, the standardised MD will be used, and their 95% CI 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 analyse 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 analyse pooled effect. We will analyse the study which has outcome difference at baseline in sensitivity analysis. For the outcomes of unrecognised sources of heterogeneity, missing data and less than three 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 V.16.0.

Meta-regression and subgroup analysis

Meta-regression and subgroup analysis will be used to identify sources of heterogeneity and analyse influencing factors. First, we will perform a meta-regression to screen out important factors that may lead to heterogeneity, and then perform subgroup analysis on the selected factors.³⁵

We will conduct meta-regression and subgroup analysis in the following seven aspects.

- ▶ Participant characteristics: gender, age, country, disease course.
- ▶ Basic level of HbA1c: less than 7.0% versus greater or equal to 7.0%.
- ▶ Insulin usage: use insulin versus not use.
- ▶ Comorbidities and serious complications: the study which excludes individuals of serious complications or other chronic diseases versus 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, 3–6 months, 6 months and more), whether the group activity lasted until the last follow-up (yes versus no), duration of each activity (less than 2 hours, 2 hours and more), the average number of patients in a group (10 and less, 10–20, more than 20), the number of self-management component, implementation site (community, primary healthcare centre, 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, 1–2 years and over 2 years.

Sensitivity analysis

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

- ▶ Study design: remove the cluster randomly controlled study to analyse the randomly controlled study.
- ▶ The risk of bias: remove studies with high risk of bias to analyse studies at low and unclear risk of bias.
- ▶ Baseline level: remove studies with outcome difference at baseline level to analyse studies with no difference.
- ▶ Lost to follow-up: remove the studies with a loss to follow-up rate greater than 10% to analyse the remaining studies.
- ▶ Language: remove studies published in Chinese to analyse English studies.
- ▶ Sample size: analyse 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 outcomes analysed in the meta-analysis. The GRADE method categorises the quality of evidence as very low, low, moderate and high. The RCT 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 V.3.6 software will be used.

Patient and public involvement

Patients or the public will not 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 organisations. In addition, we will present the findings to guide the diabetes self-management when training grass roots 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 behavioural 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 hospitalised patients as hospitalised patients may have more serious illness and are urgent to receive clinical treatment rather than self-management. Patients in the community have more time and energy to manage their own diseases. Consequently, this review will exclude hospitalised 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. Articles in other languages 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, and 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 behavioural 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 analysing the effect of different self-management characteristics, it will provide guidance for the improvement of diabetes self-management in the future.

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

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