International Journal of Global Health

Influence of Patient Care Provider on the Effect of Self-Management Education Program on Glycemic Control: A Systematic Review Protocol

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Abstract

Background: Type 2 diabetes accounts for approximately 95% of all diabetes cases, making the disease a global public health concern. The increasing prevalence of type 2 diabetes has highlighted the importance of evidence-based guidelines for effective prevention, management and treatment. Diabetes self-management education can produce positive effects on patient behaviors and health status.

Study objective: To synthesize findings from the existing studies to determine whether or not the effect of diabetes self-management education on glycemic control among adults with type 2 diabetes differ by the different models of diabetes care.

Methods: Electronic searches will be conducted on Web of Science, PubMed, Scopus, MEDLINE, EMBASE, PsychINFO and the Cochrane Central Register of Controlled Trials to identify relevant English language publications on diabetes self-management education from 2000 through 2020. In addition, reference lists of all eligible articles identified will be searched and screened for additional relevant studies. Titles and abstracts of the search results will be screened to select eligible papers for full text screening. All eligible papers will be retrieved and full text screening will be done by three independent reviewers to select studies for inclusion in the final analysis.

Discussion: The findings from this review will help in ascertaining whether diabetes self-management education programs implemented in patient populations with different clinical care models produce different effects on patients' levels of glycemic control. Our aim is to help policy makers understand whether or not the effects of diabetes self-management interventions could be influenced by the type of health professional providing usual care to patients. This information is vital in determining which type of patient care provider serves as a facilitator to the successful implementation of SME initiatives.

Introduction

One of the most life-threatening worldwide public health challenges is diabetes mellitus (DM) [1]. It is the fifth leading cause of death in high-income countries, and rapidly becoming epidemic in low and middle-income countries. The global number of people suffering from diabetes in 2013 was estimated at 382 million, and this number is expected to rise to 552 million by 2030. Diabetes care is expensive and the condition can lead to serious complications such as kidney failure, myocardial infarction, stroke, blindness and limb amputation [2]. It imposes a huge economic burden on national health care systems globally. Depending on the country, it can take up between 5 to 15% of total health expenditure.

Three main types of diabetes are known: 1) type 1 diabetes (caused by the body's failure to produce insulin), 2) type 2 diabetes (resulting from insulin resistance), and 3) gestational diabetes (which occurs in pregnant women without previous diagnosis of diabetes) [3]. Type 2 is the most common type of diabetes. It accounts for about 95% of all cases of diabetes. The prevalence varies with age, gender, ethnic background and genetic susceptibility. It is associated with environmental risk factors such as: lack of physical activity, nutritional status and obesity [3].

Available evidence indicates that early diagnosis and effective management increases the chances of preventing harmful and costly complications associated with diabetes [4]. Evidence has also been established regarding the benefits associated with glycemic control in reducing the risk for and delaying the progression of diabetes complications [5]. Achieving effective glycemic control requires a lifelong adherence to complex lifestyle management, involving regular blood glucose monitoring, self-adjustment of medications and a physically active lifestyle.

Self-Management Education (SME) is recognized globally as a tool that helps patients achieve optimum glucose control, through increasing knowledge and awareness, and learning behavioral strategies to manage diabetes. Diabetes SME involves a variety of educational programs, ranging from brief instructions by lay leaders, physicians, dietitians or nurses to more formal and comprehensive programs. In the 1960s and 1970s, diabetes self-management interventions were individually oriented, and mostly delivered in hospital settings by either nurses or dietitians. From 1980 onwards, more specific programs have been developed for diabetes patients and their families. Health professionals with different backgrounds educate patients in their own domain of expertise. In addition to individual education, more cost-effective interventions such as: group-based education (Duke, 2010), information technology-based education, and self-help and support group programs have been developed. Group-based education programs are often led by lay leaders (patients' peers trained as educators or health professionals, such as nurses and dietitians [6].

The success of a diabetes SME program depends on human factors, organizational processes, and intervention attributes. Given the demonstrated efficacy of existing strategies to improve health status, health behavior, and health care utilization, the current policy challenge is not to find new efficacious treatments, but to implement the proven programs more cost-effectively [7].

A key factor to the success of diabetes SME programs is the influence of patient's routine clinical care provider. The majority of the self-management interventions are organized separately from health systems, usually by voluntary organizations, and care providers' role - such as: serving as conduits for patients to enter the programs, guiding them through the process, and reinforcing what is learned during regular follow-up care - is critical to successfully implementing these initiatives. Different health care professionals are responsible for providing care to diabetes patients. However, evidence of whether or not there are differences in diabetes SME outcomes when participant's care provider is a general practitioner, a specialist, a nurse, or a combination of these health professionals has not yet been systematically established [8].

Study objective and research question

The objective of this study is to systematically review the literature to determine whether or not the effect of diabetes SME on glycemic control among adults with type 2 diabetes differ by the different models of diabetes care [9]. We define "model of diabetes care" in this study as the type of health professional providing clinical care to diabetes patients. The research question we seek to address is: Does the effect of diabetes SME program on glycemic control in adults with type 2 diabetes differ by the different models of diabetes care?

Models of diabetes care

Different models of diabetes care exist in different healthcare settings. One of such models is the specialist service delivery model, involving the use of diabetologists or endocrinologists as providers of diabetes care [10]. The most common model is the primary care physician-led model, where patients with diabetes are managed by primary care physicians. There is also the nurse and dietitian-led model in which nurses and dietitians, under the supervision of specialists, follow algorithms to deliver education and medical care to diabetic patients. Other models of diabetes care include advanced nurses and physicians-led model, nurses and pharmacists-led model, and nurses-led model.

Due to the complex nature of diabetes, recent literature emphasizes the application of a team approach to the delivery of care. This model of care enables a range of health care providers (primary care physicians, diabetologists, registered nurses, nurse practitioners, physician assistants, certified diabetes educators, dietitians and pharmacists) to integrate their skills to facilitate improved patient management and outcomes.

Methods

We will follow the Preferred Reporting for Systematic Review and Meta-Analysis (PRISMA) guidelines in conducting and reporting this study. However, since the review will exclude meta-analysis, not all of the PRISMA guidelines will be followed. Development of the review procedures will be also done in consultation with the Cochrane Handbook for Systematic Reviews of Interventions.

Search strategy and information source

The search strategy for this review has been drafted for pre-testing in (OVID) MEDLINE (Table 1). An expert health sciences librarian was consulted in drafting the search strategy, using key words medical subject headings (MeSH) terms and publication types based on the PICOS framing (Participants, Intervention, Comparison, Outcome and Study design). Participants are adults with type 2 DM. The intervention is diabetes SME program or intervention. The comparator is a control group in a randomized controlled trial (i.e. patients receiving "usual care" or "standard care"). The main outcome is glycemic control. Study designs to be considered will be randomized or clinical controlled trials. Once the MEDLINE strategy is pre-tested and finalized, it will be adapted to the syntax and subject headings of all other databases.

Electronic searches will be conducted on Web of Science, PubMed, Scopus, MEDLINE, EMBASE, PsychINFO and the Cochrane Central Register of Controlled Trials. In addition, reference lists of all eligible articles identified will be searched and screened for additional relevant studies. We will restrict the search to only English language medical literature published between January, 2000 and April, 2020.

Concept #	Search Terms
1	diabetes self management education or self management education or DSME or health education or diabetes education).af.or "Patient Education as Topic" or "Self Care" .sh.
2	(type 2 diabetes or type 2 diabetes mellitus or diabetes).af. or "Diabetes Mellitus" .sh. or "Diabetes Mellitus, Type 2" .sh. or Non-insulin dependent diabetes mellitus.af.
3	1 and 2
4	(randomized controlled trial or clinical controlled trial).pt. or randomly.af. or randomized.af. or control.af. or trial.af. or groups.af.
5	3 and 4
6	("glycemic control" or HbA1c or A1C).af. or "Hemoglobin A1C, glycosylated".sh. or "Haemoglobin A1C.af.
7	5 and 6

Table 1: Draft MEDLINE search strategy

Inclusion and exclusion criteria

Studies will be reviewed against pre-determined inclusion and exclusion criteria for eligibility in the final analysis. Included studies should be randomized-controlled trials with a matched control group, comparing diabetes SME to usual care. The definition of diabetes SME will be based on the American Association of Diabetes Educators' (AADEs') National Standards for Diabetes Self-Management Education and Support, i.e. a program to "facilitate the development of knowledge, skills and abilities that are required for successful self-management of diabetes". Also, to be included in the review, studies should evaluate the effectiveness of SME on glycemic control in adults with type 2 diabetes, as well as specifying the type of health professional responsible for patients' usual clinical care. All study settings (e.g. clinics, hospitals, communities, virtual/phone, etc.) will be included. Further, the study will not be restricted to a particular country or continent.

Studies will be excluded if they lack outcome assessment of program effectiveness, do not specify patient clinical care provider, focus on either type 1 or both type 1 and type 2 diabetes patients, and if they are review articles or reports. In addition, studies that compare two or more diabetes SME programs (e.g. group vs. individual education) will be excluded from the review.

Study selection

Selection and inclusion of papers for this review will involve a two-stage process: screening of abstracts and titles; and full text reading to select eligible papers for final inclusion. Three independent reviewers (EK, SEA and CA) will conduct the selection process through each stage of the review. All publications retrieved through the search will be imported into a shared bibliography for duplicate records to be removed. After removing the duplicates, the reviewers will apply the pre-determined inclusion and exclusion criteria and independently assess the titles and abstracts for full-text review eligibility. Following this process, articles will be selected for full-text screening. Again, the reviewers will apply the inclusion and exclusion criteria and independently assess the full-text articles to select the final set of publications eligible for inclusion in the study. After each stage of the selection process, the reviewers will compare results and reach a consensus, with a fourth reviewer (FOK) serving as a tiebreaker should the three reviewers fail to reach an agreement.

Data extraction

Data extraction from the selected publications will be done by two members of the research team (EK and SEA). The abstractors will discuss differences that may arise and reach a consensus. To ensure data consistency and accuracy, two other members of the research team (FOK and CA) will verify all the extracted information against each of the selected papers. Information to be collected include: authors and year of publication, study sample, study site (country), participant demographic details, study aim/objective, setting of diabetes care (clinic, general medical practice, hospital etc.), provider of patients usual clinical care (general practitioner, specialist etc.), SME leader (dietitian, nurse, peer educator, physician etc.), description of SME intervention, study outcome (i.e. effect on A1C) and conclusions drawn from the findings.

Validity assessment

Internal validity will be assessed across the selected studies using the Cochrane Collaboration Criteria for four types of bias: selection bias (systematic differences between baseline characteristics of the study and the control groups), performance bias (systematic differences between study and control groups in the care that is provided, apart from the intervention being evaluated), attrition bias (systematic difference between study groups in withdrawals from a study), and detection biases (systematic difference between study groups in how outcomes are assessed)[39]. Studies will be judged to have a high or low risk of bias for each of these criteria.

Categorization of interventions and evaluation of program effectiveness

Based on the setting of care and patients' routine clinical care provider, we will classify the diabetes SME programs into different models of diabetes care and assess the effectiveness of each of these interventions across the groups. Each program's effectiveness will be judged based on the level of significance of A1C mean difference between the intervention and the control groups, as reported by the studies. Programs with significant A1C mean difference between the intervention. group and the control group will be considered effective. The results will then be compared to find out if some models of diabetes care will have more programs showing significantly positive effects than others. This will help us to determine whether or not there are differences in diabetes SME outcomes when patients have different types of routine clinical care providers.

Discussion

The findings from this systematic review will help in ascertaining whether diabetes SME programs implemented in patient populations with different clinical care models produce different effects on patients' levels of glycemic control. Our aim is to help policy makers understand whether or not the effects of diabetes SMEs could be influenced by the type of health professional providing usual care to patients. This information is vital in determining which type of patient care provider serves as a facilitator to the successful implementation of SME initiatives. At the end of the study, we will be able to recommend to clinicians, health researchers and policy makers whether or not it is necessary to take into consideration the professional providing routine clinical care to diabetes patients during the design and implementation of SME programs. As no universal patient education that can be standardized and recognized as effective for all individuals has been defined [20], and countries are finding ways of providing more cost effective SME interventions, findings from this systematic review will be more valuable. The study will contribute to the optimal design, implementation and evaluation of effective self-management interventions. It will add to and extend the existing knowledge on factors influencing the effectiveness of diabetes SME programs.

Our conclusions will be based on high quality evidence as only randomized controlled trials, considered the strongest research design for evaluating the effects of health interventions, will be included in the analysis. However, we do recognize two principal factors which might serve as limitations to our review: First, restricting the search strategy to only studies published in peer-reviewed English journals

between 2000 and 2020 may pose the risk of evidence selection bias. For instance, we may risk excluding useful information that may not have been peer-reviewed, may be in other languages or published before 2000. Second, we recognize that our final set of included articles may not be studies directly measuring the association between the influence of patient care provider and the effect of diabetes SME program on glycemic control, as such studies do not exist currently. Thus, the conclusions we will draw on the influence of patient care provider on the effects of SME programs may be suggestive rather than being conclusive. This will, however, not defeat the purpose of the study as we aim to use the findings to provide a thought-provoking research topic for further quantitative studies to produce empirical evidence on the influence of diabetes patient care provider on the success of SME interventions, particularly the ones that are organized outside the traditional healthcare system. We intend publishing the final output of this research in International Journal of Global Health, open access option, to make the findings freely accessible to healthcare policy makers, clinicians, the academia and the rest of the scientific community.

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