The Effect of Patient Empowerment on Anxiety, Depression or Health-Related Quality of Life in Patients With Type 2 Diabetes: A Systematic Review Protocol

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Abstract

Background. Type 2 Diabetes Mellitus (T2DM) is one of the most prevalent health problems worldwide. Besides metabolic and cardiovascular complications, nearly one in four patients with T2DM suffer from comorbid depression and it has been reported higher incidence and prevalence of anxiety disorders. Beyond metabolic and cardiovascular risk improvement, empowering patients could contribute to mental health and quality of life enhancement. This Systematic Review (SR) aims to analyze and synthetize the evidence about the effect of patient empowerment on anxiety, depression and health-related quality of life (HRQOL).

Methods. A SR of the literature will be conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) guidelines. The review will include studies reporting the effect of patient empowerment on anxiety, depression or HRQOL in patients with a T2DM diagnosis. We will use the following databases: Medline, Embase, PsycInfo and Cochrane Library, from inception through July 2020. Additionally, the database searches will be supplemented by searching through citations and references. Literature searches, identification of eligible studies, data extraction, and bias assessment will be undertaken independently by at least two researchers. All disagreements will be resolved by an independent third reviewer. If heterogeneity between studies is too high or it is not possible to conduct a meta-analysis, a narrative analysis of the study results will be provided.

Discussion. Existing evidence suggest that empowerment-based strategies significantly improve knowledge, anxiety and depressive levels, self-care, and motivation; contributing to increase HRQOL in patients with T2DM. The results of this SR will provide a deeper understanding on the relationship between patient empowerment and psychosocial outcomes in T2DM.

Systematic review registration: PROSPERO CRD42020192429.

Background

Diabetes Mellitus (DM) is a major public health problem (1) with a large and increasing frequency and socio-economic burden worldwide (2). In 2017, the International Diabetes Foundation estimated that 451 million people all around the world had diabetes, and it is expected that this number will increase to 693 million by 2045 (2). This rise can be explained by different factors including a growth in the life expectancy of the population, together with an increase of risk factors of DM development such as obesity and sedentary lifestyles (3, 4).

DM is a chronic disease characterized by hyperglycemia, due to a scarcity of insulin (absolute or relative). It can be classified in four general categories: type 1 diabetes mellitus (T1DM), due to autoimmune β-cell destruction that leads to an absolute insulin deficiency; type 2 diabetes mellitus (T2DM), due to a progressive loss of adequate β-cell insulin secretion; gestational diabetes mellitus (GDM) and other specific types of diabetes triggered by different causes such as monogenic diabetes syndromes, exocrine pancreas diseases or chemical-induced diabetes (5). T2DM, also called noninsulin-dependent diabetes or adult-onset diabetes, accounts for approximately 90–95% of all diagnosed cases of DM (5) and is one of the most prevalent health problems nowadays (6). T2DM imposes a considerable burden on patients health and health-related quality of life (HRQOL), as well as on socioeconomic issues (7, 8).

Treatment management of T2DM is complex, requiring continuous and long-term involvement of patients to maintain daily adherence to recommendations regarding diet, physical activity and medication (9, 10). There's a large consensus on the importance of self-care behaviors for the successful management of T2DM. However, there are several barriers, both individual and environmentally related, associated with a low adherence to treatment recommendations (11).

Nearly one in four patients with T2DM suffer from comorbid depression (12). Besides, compared to the general population, a higher incidence and prevalence of anxiety disorders has also been reported among people with T2DM (13, 14). Several authors have reported that patients with T2DM and comorbid mental health problems, such as anxiety and depression, are more likely to have diabetes complications (15) and less likely to meet the guidelines for healthy habits and self-care recommendations (16–18), with higher difficulties to achieve and maintain diabetes control.

With the aim of optimizing health outcomes and promote HRQOL, the American Diabetes Association, in its 2016 position statement about psychosocial care for people with diabetes, highlighted the need to integrate psychosocial care with person-centered medical care for people with diabetes, (19).

Person-centered care has a holistic view on patients care; focusing on the need of seeing people beyond the illness, valuing their needs and respecting their rights and dignity. One of the core elements of person-centered care is patient empowerment. The World Health Organization defines "empowerment" as a process through which people can gain control over decisions and actions affecting their health (20). Accordingly, the aim of patient empowerment is to provide them with critical thinking, skills and tools to take responsibility for their health and wellbeing, develop autonomy and self-confidence, make autonomous informed decisions and influence their own behavior in order to improve health outcomes and quality of life.

The aim of this study is to provide evidence on the effect of patient empowerment on anxiety and depressive symptoms and on the HRQOL of T2DM patients.

Methods

A SR of the literature will be conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) statement (21), from a protocol based on the PRISMA guidelines for systematic review's design, conducting and reporting (PRISMA-P) (22). The detail of the PRISMA-P checklist can be found in **Additional file 1**. This SR was registered in the International Prospective Register of Systematic Reviews (PROSPERO) on July 16th 2020 with the registration number CRD42020192429.

Eligibility criteria

Population

Studies addressing patients with T2DM, aged 18 years or older, will be included. Studies involving children or adolescents, patients with T1DM, GDM or participants with pre-diabetes will be excluded.

Exposure

Studies analyzing the effect of patient empowerment on anxiety, depression or HRQOL, will be included. Despite patient empowerment has been defined in many different ways, a consensus definition is still lacking (23,24). In order to be exhaustive, this review will consider patient empowerment as an exposure factor, adding two other theoretical related concepts such as self-efficacy and patient activation (25,26).

Outcomes

We will include all outcomes related to anxiety and/or depressive symptomatology, including measures of distress (i.e., combination of anxiety and depression symptoms), as well as measures of general or diabetes-specific HRQOL. These outcomes are usually assessed by means of self-reported questionnaires or standardized interviews. Studies will be excluded if they did not report on anxiety, depression or HRQOL as outcome measures.

Design

All studies assessing the effect of patient empowerment (or one of its two theoretical related concepts, self-efficacy and patient activation) on anxiety, depression or HRQOL will be included regardless its design. Clinical trials not including a specific measure of patient empowerment, self-efficacy or patient activation will be excluded, even if the intervention is based on person-centered or shared decision-making principles. Conference abstracts, letters, commentaries, essays, book chapters, qualitative studies, study protocols and reviews will also be excluded. No language or publication year restrictions will be applied.

Data source and search strategy

A set of keywords on the topics of interest were identified from a previous scoping literature search. The following terms will be used individually or combined according to the Medical Subject Heading (MeSH) terms to design the search strategy: “diabetes”, “anxiety”, “depression”, “quality of life” as well as “empowerment”, “self-efficacy” and “patient activation”. Four electronic databases will be consulted: Medline, Embase, PsycInfo and Cochrane Library. We will execute monthly Medline searches until the study submission. Boolean operators, such as “AND”, “OR” and “NOT” and proximity operators like “NEAR” or “WITHIN” will be incorporated into the search strategy. Additionally, the reference list of all eligible studies will be screened in order to identify additional studies meeting our inclusion criteria. As an example, the full Medline search strategy is presented in **Table 1.** The same search strategy, with the required modifications, will be used for the other three electronic databases.

Study selection

All citations extracted from the different electronic databases will be imported into a standardized Microsoft Excel data sheet and duplicates will be removed. First, two members of the research team will independently review all titles and abstracts in order to pre-select those meeting the inclusion criteria. If disagreement, a third reviewer will be contacted. Secondly, the full-text of the potentially relevant studies will be again screened for eligibility by two reviewers. Any disagreement will be solved by discussion and consensus and a third reviewer will be consulted if needed. The studies selection process and the exclusion reasons will be documented and documented following the PRISMA’s flowchart format (21).

Data extraction

From each included study, two reviewers will independently extract data on the following variables according to a standardized data extraction form in Microsoft Excel: first author, year of publication, country, number of participants, mean age, study design, setting, study population, outcomes, effect estimates for the main outcomes (i.e., Pearson's correlation, beta coefficient, risk ratio, odds ratio) and results. In case of missing data, the corresponding authors will be contacted by e-mail in order to ask them to provide the needed details.

Risk of bias assessment

To evaluate the quality of cross-sectional studies, the Joanna Briggs Institute critical appraisal checklist will be used (27). Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2) (28) will be used to assess the risk of bias in randomized trials. Quality assessment will be undertaken by two independent reviewers and disagreements will be solved by discussion and consensus or after consulting a third reviewer in case consensus isn't achieved.

Data analysis

In case of having two or more combinable studies evaluating the same (or comparable) variable, a meta-analysis (MA) will be conducted, combining the results by using the inverse variance method (29). If MA is not appropriate, a narrative synthesis of the evidence will be carried out. Statistical heterogeneity between the different studies included in the MA will be evaluated with the Q and I^2 statistics (30). If Q-value is significant ($p < 0.010$) or $I^2 > 50\%$, a random effects model will be applied (29) and the following variables will be explored as sources of heterogeneity: type of study (experimental/observational; prospective/retrospective); theoretical concept (empowerment, self-efficacy or patient activation), mean age and HbA1c levels at baseline, and follow-up duration. Subgroup analyses for categorical variables or meta-regression for continuous variables will be performed. Publication bias will be analyzed if there are 10 or more studies per variable, visually using funnel plots, and statistically by means of the Egger test (31).

Discussion

T2DM is one of the most prevalent chronic health conditions worldwide. Its incidence and prevalence has risen dramatically in the past decades and is expected to keep increasing over the next ten years, with the greatest growth in the lower-income countries (32). T2DM is a complex health condition that limits autonomy, HRQOL, and health expectancy, at individual level; besides a substantial socioeconomic burden. Although there is no cure for T2DM, it is possible to improve disease control to delay clinical complications and mortality by means of personalized and complex therapeutic strategies that always include empowerment and behavior change interventions, to build effective self-management capacities among patients. Adherence to self-care behaviors is not always an easy task but they are needed to achieve sustained long-term control and improve health outcomes. Psychosocial problems such as anxiety and depression have shown to be related with less self-care behaviors, so it seems necessary to address those problems and determine their potential predictive role and magnitude in T2DM patients.

Promoting the participation of people in their own healthcare is considered an ethical imperative included in the Declaration of Salzburg (33) and implies professionals providing knowledge and abilities, as well as recognizing and facilitating patient's self-determination with regard to their autonomy as well as joining them in the decision-making process (34). Existing evidence suggest that empowering patients and helping them to get involved in their healthcare decisions could also improve their anxiety and depression symptoms (35) as well as enhance their quality of life (36). Furthermore, two SRs published in the last five years (37, 38) have shown that empowerment-based strategies may improve clinical, behavioral and psychological outcomes in patients with T2DM. More specifically, Baldoni et al. (37) reported that programs based on collective empowerment strategies lead to an increase in confidence and DM knowledge, better attitudes toward the disease and more healthy eating patterns. Likewise, Aquino et al. (38) concluded that individual empowerment-based strategies present several psychosocial benefits such as more self-care behaviors, an increase in motivation, self-efficacy and DM knowledge and better quality of life. In both SRs, MAs were also conducted to combine the results of different studies and evaluate the effectiveness of empowerment strategies in reducing HbA1c. Whereas Baldoni et al. (37) found significant evidence indicating beneficial effects of collective empowerment programs in the reduction of HbA1c, in Aquino et al. (38) no statistically significant improvement for HbA1c was found.

Even though previous SRs have highlighted the effectiveness of empowerment-based interventions in the context of DM, to our knowledge, this is the first SR to summarize current evidence about the specific relation of patient empowerment interventions, with anxiety, depression and HRQOL outcomes in patients with T2DM. Nevertheless, there could be several potential limitations in this planned SR. First, although we will perform our search in four different electronic databases and hand-searches also will be executed; potential non-identified studies cannot be discarded. The heterogeneity between studies in the terminology used to label and define patient empowerment may further increase this risk. Finally, as we won't apply design restrictions, observational studies might be included and it is possible, therefore, that this review could not provide a conclusive answer on causality.

The results of this SR are expected to provide a deeper understanding on the relationship between patient empowerment and anxiety, depression and HRQOL in patients with T2DM, and thus help to focus on what person-centered care programs should be applied in order to provide a more ethical and effective attention to these patients.

List Of Abbreviations

DM: Diabetes Mellitus; GDM: Gestational Diabetes Mellitus; HbA1C: Glycated haemoglobin; HRQOL: Health-related quality of life; MA: Meta-analysis; MeSH: Medical Subject Heading; PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analysis; PROSPERO: International Prospective Register of Systematic Reviews; RoB 2: Version 2 of the Cochrane risk-of-bias tool for randomized trials; ROBINS-I: Risk of bias in non-randomized studies of interventions; SR: Systematic Review; T1DM: Type 1 Diabetes Mellitus; T2DM: Type 2 Diabetes Mellitus.

Declarations

Ethics approval and consent to participate

No ethics approval is required as this protocol is based on information from previously published data.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

ADD and LPP conceived and designed the study. WP helped to define and formulate the inclusion criteria and search strategy. ARS, HGP and YRF provided statistical expertise. ADD, YAP and VRG wrote the initial draft of the protocol. LGA, MBB and SGM reviewed the whole manuscript and provided substantial comments. PSA oversaw all stages of the manuscript. All authors have read, provided critical revisions and approved the final version of the final protocol.

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Tables

Table 1. Medline search strategy

#	Searches	Results
1	Diabetes Mellitus, Type 2/	132045
2	(non insulin* depend* or noninsulin* depend* or noninsulin?depend* or non insulin? depend*).tw.	12281
3	((typ? 2 or typ? II or typ?2 or typ?II) adj3 diabet*).tw.	144639
4	(MODY or NIDDM or T2D*).tw.	38228
5	(((late or adult* or matur* or slow or stabl*) adj3 onset) and diabet*).tw.	4607
6	1 or 2 or 3 or 4 or 5	194887
7	exp Diabetes Insipidus/	7854
8	diabet* insipidus.tw.	8499
9	7 or 8	10780
10	6 not 9	194779
11	((patient$ or adult$ or client$ or participant$ or individual$) adj3 empower$).tw.	4981
12	Self Efficacy/ or (self efficacy or self-efficacy).tw.	35629
13	patient activation.mp. or Patient Participation/	26372
14	Empowerment/	179
15	11 or 12 or 13 or 14	65516
16	6 and 15	1579
17	Anxiety/ or Anxiety Disorders/ or anxiety.tw.	218044
18	depression.mp. or Depression/ or Depressive disorders/ or depressive disorder*.mp.	435656
19	"Quality of Life"/ or quality of life.tw.	335184
20	17 or 18 or 19	848114
21	16 and 20	359

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