Factors influencing self-management in adults with diabetes: an umbrella review protocol

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Review objectives: The aim of this umbrella review is to identify and describe factors influencing diabetes self-management (DSM) in adults with diabetes. More specifically, we will address DSM-related factors and their relationships, considering both qualitative and quantitative components of available literature.

The review question for the *qualitative component* of the umbrella review is:

i) Which are the factors which act as barriers to, or facilitators of, DSM among adults with diabetes?

The review questions for the *quantitative component* of the umbrella review are:

ii) What are the factors associated with DSM of adults with diabetes?

iii) What is the association between the identified factors and DSM in terms of strength and direction?

An additional question will be applied to *both the qualitative and quantitative components* of the overview:

iv) Do the identified factors (barriers or facilitators) vary according to patients' sociodemographic, illness and treatment characteristics, in terms of type of factors, direction and strength of association?

Keywords self-management; adults with diabetes; healthy behavior; monitoring of blood glucose; foot care

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Background

Diabetes is a public health burden worldwide.[1,2] According to the World Health Organization, the global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014.[3] With the combined effects of increased obesity and progressive aging, it is projected that the prevalence of diabetes will rise even more in the coming years.[3] This chronic disease is associated with high mortality, morbidity and disability, high economic costs, and loss of quality of life for both patients and their families.[1,2,4] The success of any treatment strategy largely relies on the patient's ability to perform DSM[5] which involves the performance of multiple interacting care activities embedded in everyday life.[6] Although the positive impact of DSM in patients' health-related outcomes is well established,[7-9] its actual daily application remains a challenge for most patients.[10] Indeed, patients' ability to perform DSM entails a complex process where key factors related to patients' health cognition as well as psychological, social, demographic and environmental factors exert a powerful influence.[11,12] For these reasons, having knowledge of and taking into account factors affecting DSM is fundamental to the work of diabetes health professionals because it enables them to be connected with patients' needs in performing DSM in their daily lives.

In the literature, the term self-management is used interchangeably with the term self-care.[13] In a recent conceptual analysis, self-care was defined as an activity initiated consciously which follows a learning process, and is appropriate to the situation and centered on a specific objective.[14] In the context of care for diabetes, DSM is also associated with the notion of patient adherence or compliance with self-management behaviors prescribed by health professionals.[15] While clinical differences among type I and type II diabetes diagnosis and illness trajectories exist, the suggested core Diabetes self-management care activities are similar for both types of diabetes.[6,15] In operational terms, DSM in adults refers to

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the accomplishment of therapeutic and health-monitoring behaviors, such as proper management of oral antidiabetic medication and/or insulin injections, self-monitoring of blood glucose and foot care. Diabetes self-management also includes healthy lifestyles, such as eating healthily, exercising regularly, achieving and maintaining a healthy body weight, limiting alcohol intake and smoking cessation/not smoking. In daily life, patients are expected to follow multiple DSM behaviors simultaneously in order to attain good diabetes health-related outcomes.[6] To accomplish these care activities, patients need to have knowledge, problem-solving, coping and practical skills.[6] Additionally, DSM also implies the adoption of new behaviors in patients' and families' everyday routines and/or the reconsideration of some habits deeply grounded in their traditions.[15] This requires long-term, proactive and continuous engagement by patients and their families because of the often-constant adjustments needed to maintain a balance between requirements of DSM and those of patients' lives in general.[16]

Diabetes self-management is influenced by a wide range of factors acting simultaneously and interfering with its actual application by patients.[11,12] These factors relate to patients' personal characteristics and experiences, and also include positive and negative cognitive, emotional and environmental factors.[11,12] Several models such as social cognition models and social ecological models highlight the role of these factors in the adoption of behaviors related to health such as DSM.[17,18] Specifically, these models detail the role of psychological and sociocognitive factors (e.g. emotions, knowledge, attitude, perceived social pressure and perceived capacity and control toward a behavior) in influencing the decision of an individual to adopt a specific DSM.[17] Similarly, they explain how patients' sociodemographic and environmental factors (e.g. age, gender, socioeconomic status and neighborhood) interfere with DSM application.[18] The characteristics of these factors are diverse. While some can be easily modified or controlled, others may represent a major limitation or facilitator for embracing DSM.[19] In order to develop strategies to support patients' actual performance and long-term maintenance of DSM, it is of paramount importance to identify such factors in diabetes patients' reality. This will help patients obtain good diabetes health-related outcomes.

A preliminary search of the literature revealed that several factors associated with patients' performance of DSM have already been identified; it also showed that there has been a steady increase in reviews exploring this subject since 2000. More specifically, during this preliminary search, we found a variety of reviews on factors influencing DSM. While some of these reviews focused on a more comprehensive understanding of factors related to patients' daily DSM practices,[15,20-25] others addressed patients', families' and providers' perspectives qualitatively.[26,27] Additionally, a third category of reviews was summarizing the factors acting as facilitators or barriers to DSM,[24,28] and a fourth group focused on specific populations of patients with diabetes (e.g. older patients, ethnicity, type of diabetes).[28-31] In all these reviews, researchers used various methodology frameworks for collecting, analyzing and reporting data, as well as considering DSM as a whole or focusing on individual DSM components. Notwithstanding the fact that all these reviews contribute to enhancing knowledge about factors related to DSM, there is room for improvement in relation to the definition and classification of factors, and descriptions of their relative influence on DSM.

In that context, a systematic review of existing reviews, known as umbrella review, is necessary for considering the current breadth and depth of knowledge on these factors. The methodology chosen consists of an overall examination of the body of information available on a given topic for comparing the results of published systematic reviews.[32,33] Taking a more comprehensive look at factors influencing DSM by applying umbrella review strategies will contribute to our understanding of the patients' specificities and needs in the process of DSM and will assist intargeting interventions to support DSM in adults with diabetes.

Inclusion criteria

Types of participants

- Reviews that include primary studies focusing on adults ($\geq$18 years) with diabetes (type 1 or type 2) with no restrictions based on socio-demographic factors (e.g. age, ethnicity, socio-economic status) or general health and illness status (e.g. type of treatment, comorbidities, duration of diabetes).

Phenomena of interest/intervention

Qualitative component:

- Reviews focusing on barriers to and facilitators of DSM in general, or on individual DSM behaviors (i.e. management of oral antidiabetic medication and/or insulin injections, self-monitoring of blood glucose, foot care, eating healthily, exercising regularly and smoking cessation) reported by adults with diabetes.

Quantitative component:

- Effectiveness reviews (i.e. reviews of experimental or quasi experimental studies manipulating or identifying factors [barriers and facilitators] associated to DSM).
- Correlational reviews (i.e. reviews of observational studies reporting associations between barriers/facilitators and DSM).

Context/setting

- Reviews regarding any type of care context/setting including community, primary health care or acute care, any type of living or geographical settings (e.g. adults with diabetes living in rural region, patients with diabetes from Europe or Asia).

Outcomes

Quantitative component:

- Reviews focusing on DSM or on individual DSM behaviors as dependent variables with no restrictions regarding the measurement instrument.
- Reviews focusing on related factors (e.g. psychological, cognitive, social, demographic, and environmental variable) identified as determinants, predictors acting as barriers to, or facilitators of DSM or any of individual DSM behaviors with no restrictions regarding the measurement instrument.

Types of studies

This umbrella review will consider all systematic reviews that address factors influencing DSM. Reviews will be considered to be ''systematic'' if authors use an explicit and reproducible methodology, including a description of the search strategy, application of predefined eligibility criteria to select primary studies, and a synthesis of results.[34]

Qualitative component:

Among reviews that explore one or several barriers or facilitators (factors) influencing DSM or its individual components, we will specifically include:

- Reviews of qualitative primary studies
- Reviews including both quantitative and qualitative primary studies, where the quantitative components are described in narrative form
- Mixed-method reviews limited to the scope of the qualitative results therein.

Quantitative component:

Among reviews that explore one or several factors influencing DSM or its individual components, and whether they consider, or not, meta-analyses, we will specifically include:

- Reviews of quantitative primary studies (e.g. effectiveness studies of randomized controlled trial or quasi-experimental studies, and correlational studies)
- Mixed-method reviews limited to the scope of the quantitative results therein.

Exclusion criteria

Diagnostic and prognostic reviews, as well as reviews that incorporate theoretical studies or text and opinion as their primary source of evidence will be excluded. We will not include reviews reporting solely the effect of behavior change interventions (i.e. intervention reviews not examining or reporting factors, predicting or determining DSM). Reviews related to DSM during pregnancy or in case of gestational diabetes will be also excluded.

Search strategy

The search strategy for this umbrella review will be developed in order to find both published and unpublished reviews (i.e. gray literature reviews).

Electronic databases

The search strategy will consider the following key words: ''Diabetes'' AND (''self-management'' (self-care, self-management) OR ''compliance'' (adherence) OR ''health behaviors'' OR ''Diet'' OR ''Exercise'' OR ''Self-monitoring of blood glucose'' OR ''Foot care'' OR ''Medication taking'' OR ''Tobacco cessation'') AND ''review''. The search databases/sources will include: MEDLINE, CINAHL, PsychINFO, Embase, *JBI Database of Systematic Reviews and Implementation Reports*, Cochrane Database of Systematic Reviews (CDSR), Centre for Reviews and Dissemination Databases (Database of Reviews of Effects [DARE]), and the PROSPERO register. We will start with a comprehensive search

strategy for MEDLINE, using all identified keywords and subject headings terms, and adapt the search strategies to the other databases. The search strategy will not be extending prior to 1990 since very few systematic reviews was published prior to that time.[35]

Others sources

The search for unpublished studies will include: ProQuest Dissertations and Theses Database and DART Europe E-theses portal. The reference lists of all full-text papers and all identified reports will also be examined for additional studies.

Study selection

All identified reviews will be first screened by two independent reviewers for inclusion and exclusion criteria using titles and abstracts. Articles obviously not meeting our inclusion criteria or not being a systematic review (e.g. letter to the editor, comment) will be discarded. Second, full-text examination of the remaining reviews will be undertaken to assess eligibility. The process will be summarized in a flowchart as recommended by the Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA).[36] This flowchart will appear in the results section of this umbrella review report.

Assessment of methodological quality

A critical appraisal of the methodological validity of the included reviews will be made by two independent reviewers using the JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses adapted for this umbrella review.[32] This tool includes criteria to ensure that the correct search methods and a systematic methodology of reviewing data have been employed for data extraction and synthesis.[32] We will also apply a criterion extracted from the assessment of multiple systematic reviews AMSTAR (A MeaSurement Tool to Assess systematic Reviews) instrument[37] that seems appropriate for this umbrella review, namely, point 6 of the AMSTAR grid: Were the characteristics of the included studies provided?.[37] All these criteria will be critically appraised as being ''met'' or ''not met'' or unclear'' and ''not applicable''. The purpose of the latter procedure is to provide a methodological quality assessment of each review included in this umbrella review which is relevant for the successive results interpretation and implications for practice and research. This means that this assessment will not be used to decide whether or not a review is to be included in this umbrella review. Any disagreement arising between the reviewers will be solved through discussion; if consensus is not reached, a third reviewer will be consulted for a third opinion. The presentation of the results of this assessment will include a narrative summary of the overall methodological quality of each included review. If necessary, these results will be described in a table that will appear in the results section of this umbrella review report.

Data extraction

Data of the included reviews will be extracted using the JBI data extraction tool for review for systematic reviews and research syntheses adapted for this umbrella review (Appendix I). Extraction will be undertaken by two independent reviewers for each paper. The extraction strategy will be first critically discussed among reviewers and tested on selected items before its application to minimize the risk of errors in the procedure. Any disagreement between the reviewers will be solved through discussion; if consensus is not reached, a third reviewer will be consulted for a third opinion. Data regarding key findings from each of the included reviews, particularly relevant for this umbrella review questions, will be extracted in detail (see Appendix I).

Data summary

All findings will be presented using a narrative form and displayed in tables appearing in the result section of this umbrella review report. The main characteristics of all included reviews will be described in a table, which will include the following information: author, year of publication, type of review, search details, objectives of the review, characteristics of primary studies included in the review (population [type of diabetes, age, gender, ethnicity], presence of comorbidities, diabetes duration and treatment [if available], quality evaluation applied), and main findings of the review. Any overlap of original research studies in the included systematic reviews (i.e. one study covered by multiple reviews) will be clearly indicated.

As we will be considering all types of reviews, data describing the types of barriers and facilitators (first objective of this umbrella review), which will

come from reviews including qualitative primary studies, and data presenting association results (i.e. correlational or effectiveness studies – second objective of this umbrella review), which will come from quantitative primary studies, will be summarized separately.

The types of barrier and facilitators (first objective – qualitative component) will be classified into the following five categories: i) demographic/biological; ii) psychological (cognitive, personality, affects); iii) behavioral attributes/skills; iv) social/cultural; and v) physical environment (see Appendix I). These categories have already been considered in previous umbrella reviews examining factors influencing health behaviors. These findings will be summarized in a table where factors will be presented by category, type (barrier or facilitator) and review of origin.

Data extracted from quantitative reviews of correlational or effectiveness studies (second objective – quantitative component) will also be classified into the five categories mentioned above. Both the direction and strength of the association of each factor will be classified according to the statistical significance reported by their review of origin (see Appendix II). The rules for this assessment are based on previous umbrella reviews examining factors influencing health behaviors.[38,39] These findings will also be summarized in a table, with factors presented by direction and strength of association, category and review of origin. Finally, both quantitative and qualitative findings will be analyzed and critically compared using a discussion approach where results are either assimilated, either considered complementary or divergent.

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Appendix I: JBI data extraction tool for systematic reviews and research syntheses adapted for the present umbrella review

Review details	
Citation details	
Objectives	
Type of review	
Participants details (type of diabetes, age, gender, and ethnicity)	
Setting/context or geographic location	
Search strategy and primary studies details	
Number and type of databases searched	
Search years range of each database searching	
Publication year range of included studies	
Number of studies included	
Type of study design of included studies	
Country of origin of included studies	
Appraisal	
Instrument used to appraise the primary studies and the rating of their quality	
Analysis	
Type of research synthesis	
Method of analysis/synthesis	
Findings relevant to the present umbrella review **For each included review:** ***Reviews with qualitative components*** – *Factor(s) reported by the review* – *Classification of each factor into one of the following categories: (i) demographic/biological; (ii) psychological (cognitive, personality, affects); (iii) behavioral attributes/skills;(iv) social/cultural factors, and (v) physical environment* ***Reviews with quantitative components*** – *Factor(s) reported by the review* – *Classification for each factor reported by the review: (i) demographic/biological; (ii) psychological (cognitive, personality, affects); (iii) behavioral attributes/skills;(iv) social/cultural factors, and (v) physical environment* – *If meta-analysis: effect size measure (e.g., odds ratio or relative risk) of the association (negative or positive) between reported factors and DSM* – *If quantitative review (not meta-analysis): number and percentage of primary studies indicating a statistically significant association (negative or positive) between the factor and DSM*	
Comments	

Appendix II: Rules for classifying the strength of the direction of association with DSM factors

Strength of association Codes	Definition of the rules
+ OR –	*Strong support for the role of the factor if*: • Results of *meta-analyses* (e.g., odds ratio or relative risk): statistically significant for an association between the factor and DSM; or/and • Results of *quantitative reviews* (no meta-analyses): at least 50% of the identified reviews reporting supportive findings with at least 50% of the primary studies indicating a statistically significant association between the factor and DSM. + positive association/– negative association
?	*Indeterminate support for the role of the factor if*: • Results of *meta-analyses* (e.g., odds ratio or relative risk): contrasted findings, for an association between the factor and DSM, neither +/– nor 0 (according to their respective definitions); or/and • Results of *quantitative reviews* (no meta-analyses): 30% to 49% of the identified reviews reporting supportive findings with 30% to 49% of the primary studies indicating a statistically significant association between the factor and DSM.
0	*No support for the role of the factor if:* • Results of *meta-analyses* (e.g., odds ratio or relative risk): no statistically significant for an association between the factor and DSM; or/and • Results of *quantitative reviews* (no meta-analyses): more than 70% of the identified reviews reporting non supportive findings with more than 70% of the primary refuting a statistically significant association between the factor and DSM.

