THE ANALYSIS OF DIABETES SELF-MANAGEMENT IMPLEMENTATION ON TYPE 2 DIABETES MELLITUS PATIENTS: A PROTOCOL FOR SYSTEMATIC REVIEW AND META-ANALYSIS

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Abstract

Diabetes is the fourth leading cause of death in the world. Ninety percent of the world's DM cases are dominated by type 2. International Diabetes Federation predicted the incidence and mortality rate of diabetes are increasing by 2045. Diabetes causes macrovascular complications that contribute to cardiovascular death, and microvascular which a risk factor for blindness, lower-extremity amputation, kidney failure, and death. One of the efforts to control complications from diabetes is done through diabetes self-management consists of education, medical nutrition therapy, pharmacological therapy, and physical exercise. The main purpose of implementing DSM is that patients can prevent or slow the onset of complications from diabetes itself. This study aims to summarize and systematically synthesize the clinical and non-clinical effectiveness and resume the cost-analysis of DSM implementation. Several electronic databases will be used: Medline via PubMed, and Embase. The complete evidence will be summarized and critically appraised using Cochrane guidelines and JBI Critical Appraisal Checklist for RCT and cohort studies. In terms of analysis, we will qualitative-quantitatively appraise and present the studies that meet our inclusion criteria. We are expected to summarize the quality and capture the valuable insights related to the study of effectiveness in implementing diabetes self-management of T2DM.

Keywords: diabetes self-management, DSM, T2DM, cost-effective

Abstrak

Diabetes melitus merupakan penyebab kematian nomor empat di dunia. Sembilan puluh persen kasus DM dunia didominasi oleh DM tipe 2. International Diabetes Federation memperkirakan insiden dan angka kematian diabetes akan terus meningkat hingga tahun 2045. Diabetes menyebabkan komplikasi makrovaskular yang berkontribusi terhadap kematian kardiovaskular, dan juga mikrovaskular yang merupakan faktor risiko penyebab kebutaan, amputasi ekstremitas bawah, gagal ginjal, dan kematian. Salah satu upaya pengendalian komplikasi akibat diabetes dilakukan melalui tata laksana mandiri diabetes yang terdiri dari edukasi, terapi nutrisi medik, terapi farmakologi, dan latihan fisik. Tujuan utama penerapan tata laksana mandiri diabetes ialah agar pasien dapat mencegah atau memperlambat timbulnya komplikasi dari diabetes itu sendiri. Penelitian ini bertujuan untuk merangkum, mensintesis, meninjau secara sistematis dan melakukan meta-analisis efektivitas klinis dan non klinis serta merangkum hasil analisis biaya dari penerapan tata laksana mandiri diabetes tersebut. Database elektronik yang akan digunakan: Medline via PubMed, dan Embase. Bukti efektivitas secara lengkap akan dirangkum dan dianalisis berdasarkan pedoman Cochrane serta menilai kualitas studi menggunakan JBI Critical Appraisal Checklist untuk RCT dan kohort. Artikel yang didapat akan kami telaah secara kualitatif-kuantitatif dan disajikan sesuai kriteria inklusi penelitian. Peneliti berekspektasi untuk menyimpulkan kualitas dan menangkap informasi yang berkaitan dengan studi efektifitas pada penerapan tata laksana mandiri diabetes.

***Kata kunci**: tata laksana mandiri, DSM, diabetes tipe 2, cost-effective*

INTRODUCTION

Non-communicable diseases are a major problem in every country, in 2020 WHO predicts that NCD will kill 41 million people each year, equivalent to 74% globally, 77% are in Low-Middle Income Countries (LMIC). More than 15 million deaths per year occur due to NCD in the age of 30-69 years, 85% of them are premature deaths in LMIC. Cardiovascular disease (heart attack and stroke) is the main cause of death for 17.9 million per year, followed by cancer (9.3 million), respiratory disorders (4.1 million), and diabetes (1.5 million) (WHO, 2021b). Diabetes Mellitus (DM) occurs when the pancreas does not produce enough insulin or when the body's metabolism is ineffective at using the insulin to its full potential, where insulin is a hormone that regulates blood sugar. Hyperglycemia is the effect of uncontrolled diabetes that can damage body systems, especially nerves and blood vessels. Almost 90% of all diabetes cases in the world are type 2 diabetes (Rygg *et al.*, 2012; Niknami *et al.*, 2018). Based on income group, diabetes is the 9th cause of death in LMIC, and the 6th position in Upper-Middle Income Countries (WHO, 2021). That's in line with the publication of the International Diabetes Federation (2021) which explains that 4 out of 5 people (81%) with DM come from LMIC. Around 240 million (44%) adults have lived with diabetes without realizing it, and almost 90% of them live in LMIC (International Diabetes Federation, 2021).

The International Diabetes Federation (2021), almost 537 million people in the world suffer from diabetes. The IDF shows a projection that in 2030 DM prevalence will be 643 million and continue to increase up to 784 million in 2045 due to population growth, aging, obesity, and lack of physical activity as the main causes of DM (International Diabetes Federation, 2021).

In 2014, 8.5% of the world's population aged over 18 years suffered from diabetes (WHO, 2021). Countries with the highest prevalence of DM are China, India, the USA, Pakistan, Brazil, Mexico, and Indonesia (Ernawati, Wihastuti and Utami, 2021). Based on the IDF publication (2021), Indonesia is the Western Pacific country that has the highest prevalence of DM after China in 2011 and 2021 (International Diabetes Federation, 2021). Total of 1.5 million people in the world in 2019 died from diabetes, 48% of them are under the age of 70 years (WHO, 2021). Diabetes causes death in 2.3 million people in the Western Pacific region (2021), this is the highest mortality of any state in the world.

Indonesia has a prevalence of people with diabetes in 2021 in the population aged 20–79 years reaching 10.8% of the total adult population (179,721 people) (International Diabetes Federation, 2019).

Economic expenses due to DM are direct costs (costs for treatment), and indirect costs (productivity losses due to suffering from DM). The American Diabetes Association showed the burden of disease due to diabetes in 2012 reached US$ 245 billion, this study showed the high costs for DM treatment, and productivity loss impacted 28% of the workforce's economy. Seuring, et al (2015), the economic burden has a major impact on LMICs, with annual direct costs from US$ 242 to US$ 4129 in 2011, and indirect costs reached US$ 45 to US$ 16,914 per capita (Seuring, Archangelidi and Suhrcke, 2015). Disease morbidity factors dominate the economic burden in High-Income Countries, while LMICs bear the indirect mortality costs from diabetes (Bommer *et al.*, 2017). Globally, health expenditure due to diabetes in 2021 has reached US$966 billion, a 316% increase over the last 15 years. This Economic evaluation compares the structure of resource expenditure (in the form of costs) with outcomes (whether clinical or other, even quality of life), including cost-effectiveness.

Most DM patients only seek medical treatment if the disease complications have been found (Ernawati, Wihastuti and Utami, 2021). Disease complications that occur if diabetes is not managed properly can cause macrovascular diseases (coronary heart disease, cerebrovascular disease, and peripheral vascular disease) that can contribute to cardiovascular death. Microvascular complications can also occur, such as retinopathy, nephropathy, and neuropathy. These complications are risk factors for blindness, kidney failure, and lower-extremity amputation, and also increase the individual burden of treatment (Carmienke *et al.*, 2020).

The incidence of COVID-19 is exacerbated by the presence of comorbidities, such as diabetes mellitus. Diabetes patients are at high risk of being infected with COVID-19 and will have the worst condition when infected (C. Shi *et al.*, 2020; Lukman, Sri and Ferdiana, 2020). Ten studies show the severity of COVID-19 patients with DM, including ARDS (acute respiratory distress syndrome), ICU admission, and increasing mortality (Apicella *et al.*, 2020; Brufsky, 2020; Erener, 2020; Huang, Lim and Pranata, 2020; Kumar *et al.*, 2020; Lukman, Sri and Ferdiana, 2020; Q. Shi *et al.*, 2020; Roncon *et al.*, 2020; Wang *et al.*, 2020; Zhang *et al.*, 2020).

Diabetes self-management (DSM) is an individual's effort to regulate or control the patient's health behavior. Through self-management, individuals can train themself, training to evaluate, monitor, regulate, and be responsible for themself. Self-management of patients with T2DM is a method to regulate diet, check blood sugar levels regularly (followed by pharmacological therapy), and exercise. Diet is the basis of treatment for individuals with DM. Through DSM, T2DM patients are expected to be skilled and able to monitor their blood sugar levels regularly, medication adherence, regulate a healthy diet accompanied by adequate physical activity, educational intervention (Diabetes self-management education), and reduce the risk of hypo/hyperglycemia incidence (Niknami *et al.*, 2018; Dahal and Hosseinzadeh, 2019; Represas-Carrera, Martínez-Ques and Clavería, 2021).

This study aims to conduct a systematic review and meta-analysis of DSM implementation both in clinical and non-clinical and review a partial-economic evaluation using cost-effectiveness and/or utility analysis (if supporting articles are found). Previous studies conducted to assess the clinical effectiveness and some cost-effectiveness analysis of DSM implementation with various methods and specific populations criteria (Brownson *et al.*, 2009; Khwakhong, Jiamjarasrangsi, Wiroj Sattayasomboon and Tuicompee, 2013; Mash *et al.*, 2015; Li *et al.*, 2018; Jiang *et al.*, 2021a). We plan to conduct a systematic review and meta-analysis that's potentially useful to gather the information to support DSM implementation in Indonesia, and to sharpen our appraisal skills.

METHOD

Operational definitions

Diabetes mellitus (DM) is the most common metabolic disorder caused by the defect of insulin secretion, insulin action, or

both (Bigdeli *et al.*, 2016). DM is a major public health concern worldwide, type 2 diabetes is the most common form of diabetes that constitutes about 90% of all diabetes cases worldwide (Rygg *et al.*, 2012; Bigdeli *et al.*, 2016). Type 2 diabetes mellitus (T2DM) is characterized by insulin resistance in peripheral tissues and subsequent declines in insulin production, leading to impaired blood glucose regulation. Due to chronic elevations in blood glucose, individuals with T2DM are at elevated risk of developing cardiovascular (ie, atherosclerotic coronary disease, diabetic cardiomyopathy), cerebrovascular, and microvascular (eg, nephropathy, neuropathy, and retinopathy) complications (Pirbaglou *et al.*, 2018). Diabetes-related complications such as retinopathy, nephropathy, peripheral neuropathy (PN), coronary heart diseases, peripheral vascular diseases (PVDs), amputation, and psychological impairment are also considered to be serious problems (Bigdeli *et al.*, 2016; Kurniawan and Yudianto, 2016).

Self-management is defined as the patient's ability to manage not only the symptoms inherent to a chronic condition but also its treatment and associated lifestyle changes (Ricci-Cabello *et al.*, 2014). Self-management support aims to give people with chronic disease confidence to actively manage their disease, in partnership with their healthcare provider (Captieux *et al.*, 2018). Diabetes self-management (DSM) is the primary means for controlling T2DM and its burden on healthcare systems and patients (Dahal and Hosseinzadeh, 2019). In this review, we search factors that influence the DSM implementation (using Lawrence Green theory: predisposing, reinforcing, enabling factor), the DSM activities (including DSM Education, nutritional diet, physical activity, and pharmacological therapy), and clinical and non-clinical outcomes (all the definition is in the Appendix 1). The self-management of DM optimizes metabolic control, prevents acute and chronic complications of DM, and optimizes quality of life (Gnanaselvam, Prathapan and Indrakumar, 2013). Ideally, diabetes self–care management is consistent and proportionate to the extent possible and consistent with the patient lifestyle, so that the patient can adhere to a self–care management (Salem *et al.*, 2017). A key goal of diabetes self-management is the control of Hemoglobin A1c (HbA1c), which is a measure of average blood glucose over several months. Poorly controlled HbA1c is associated with microvascular and macrovascular complications (Centers for Disease Control and Prevention, 2022). The demands of managing this complex illness also affect many dimensions of quality of life (QOL), which encompasses physical, emotional, and social well-being. Individuals with diabetes report lower QOL than individuals without chronic illness (Rubin and Peyrot, 1999; Cunningham *et al.*, 2018). We analyze the clinical laboratory result including HbA1c, FBG, BMI, Blood pressure, cholesterol (LDL, HDL, triglyceride), and non-clinical (including medical adherence, depression, anxiety disorder, self-efficacy, mental & physical component summary, and satisfaction with life), and resume the cost analysis of DSM implementation.

Diabetes was one of the high-cost-expenditure illnesses globally, health spending due to diabetes in 2021 was US$966 billion, an increase of 316% over the last 15 years, while the total health expenditure due to diabetes in the Western Pacific Countries (2021) is US$ 241 billion, 25% of global health expenditure. This cost is predicted to soar in 2030 by US$ 262.4 billion and in by 2045 US$ 269.5 billion (International Diabetes Federation, 2021). We conducted a review of the cost-effectiveness and/or utility analysis of DSM implementation. CEA or cost-effectiveness analysis compares two or more health interventions that provide different outcomes. With an analysis that measures costs and effects, researchers can determine the most efficient form of health intervention to obtain the intended results. Besides that, the cost-utility analysis is similar to CEA, but the outcomes expressed the utility related to improving the quality of life and/or changes in quality of life due to the intervention (Nadjib, 2020). The result of these analyses will show QALY gained (the cost to add one year of healthy life based on calculations using the utility approach)

Inclusion and Exclusion Criteria

In terms of inclusion criteria, we will include full diabetes self-management

effectiveness: influence factors, quality of life and the costs-analysis from DSM implementation, particularly that performing decision analytic or mathematical model. We remain including the evaluation alongside the randomized clinical trial, clinical trial, and cohort method (Table 1).

Table 1: PICOS search strategy and sources for the review

Parameter	Definition
Populatin	T2DM patient, age ≥20–79 years
Intervention	Diabetes self-management • DSM is a self-management that helps individuals with T2DM can prevent or slow the onset of complications • The application of DSM consists of: self-efficacy, medical management to prevent complications, emotional management of patients.
Comparator	Usual care
Outcomes	Primary: HbA1c Secondary: BMI, cholesterols, complications Patient reported: quality of life, self-efficacy, self-management behaviors
Study design	*Randomized control trial, clinical trial, cohort*
Date	Initial database search: January 2012 to August 2022; Update search November 2022.
Exclusion	• T2DM patient age <20 or >79 years • Papers not published in English or Indonesia.

The population is the T2DM patients (age ≥20–79 years old, with no restriction on gender characteristics and race) who had applied diabetes self-management. No limitations regarding the medical nutrition or pharmacological therapy, administration frequency, and treatment duration. The primary outcomes of this study include factors related to DSM, the clinical and non-clinical outcomes, and also the cost analysis of DSM implementation (if supporting articles are found). The PICO criteria and literature search method adopted by Turini are listed in appendix (Turrini *et al.*, 2010).

We adapted Cochrane guidelines to conduct a systematic review and meta-analysis of diabetes self-management implementation in people with type 2 diabetes, only RCT and cohort methodology will review. Reporting follows the PRISMA 2020 *flow diagram for new systematic reviews* (Page *et al.*, 2021). The published articles start from March 2012 to November 2022, this protocol only provided the information and stages regarding our review plan. The result of the systematic review after applying the searching strategy will correspond with each stage (plan when conducting the review) below:

Study Selection

We have two independent reviewers, ZS will screen the title and abstracts, selecting the studies that potentially meet our eligibility criteria. Another reviewer ACS will be working together with ZS for rechecking the screening stage before the critical review process. The disagreements between reviewers will be resolved by discussion. The details of this selection process will be reported using PRISMA 2020 *flow diagram for new systematic reviews* (Page *et al.*, 2021).

Data Extraction

We will use a standardized sheet in Microsoft Excel ZS will extract the data. The sheet will be used to summarize the important characteristics of studies that meet our eligibility criteria, there are including the author and year of publication, factors that influence diabetes self-management, type of cost analysis, method, perspective, and result (clinical and/or non-clinical). To keep our transparency and consistency, another reviewer (ACS) will re-check the completed extraction form.

Quality Assessment

The quality assessment would be assessed by the author (ZS) and reviewed by a second author (ACS). We will use JBI Critical Appraisal for RCT and Cohort (Appendix 3). The tools contain 11-13 questions regarding the quality of the review. All systematic reviews incorporate a process of critique or appraisal of the research evidence. The purpose of this appraisal is to assess the methodological quality of a study and to determine the extent to which a study has addressed the possibility of bias in its design, conduct, and analysis. All papers selected for inclusion in the systematic review (that is – those that meet the inclusion criteria described in the protocol) need to be subjected to rigorous appraisal by two critical appraisers. The results of this appraisal can be used to inform the article's quality (Tufanaru *et al.*, 2020).

Data Synthesis

The substantial heterogeneity between studies such as study setting, analysis, perspective, method, and result, we do attempt to synthesize all included studies, narratively. The objective of this narrative presentation is to identify, critically appraise and compare all studies. In addition, we also try to explore the strengths as well as the weaknesses of each study, with expectation to gain insight for our meta-analysis. Results from a meta-analysis could include more precise estimates of treatment effects or disease risk factors, or other outcomes (Wibowo and Putri, 2021). The clinical outcomes of this study are numerical, so authors need a method to estimate the outcomes quantitatively using meta-analysis with RevMan 5.4 software. The purpose of meta-analysis in this study is to estimate the value of benefits from combining the results of quantitative data on clinical outcomes. Meta-analysis produces an overall statistic (along with its confidence interval) that summarizes the effectiveness of an experimental intervention compared to a control group. The data synthesis and level of evidence are presented based on the checklist. The interpretation of the quantitative result of the meta-analysis process can be seen from the meta-forest plot.

CONCLUSION

This protocol attempts to describe our initial stage for conducting DSM effectiveness in systematic reviews and meta-analysis. Furthermore, the review of this study is intended to inform and provide a description for researchers in our team and the audience about systematic steps in our studies. The evidence from DSM effectiveness and costs of the health care expenditure that can be saved from DSM implementation (if supporting articles are found) are expected to provide us with beneficial information and obtain more comprehensive input in understanding the method, model development, results, and as well as research gap.

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Appendix 1: Operational Definitions

Variabel	Definition
Type 2 DM	Type of diabetes, characterized by insulin resistance in peripheral tissues and subsequent declines in insulin production, leading to impaired blood glucose regulation
Diabetes Self Management	The patient's ability to manage not only the symptoms inherent to a chronic condition but also its treatment and associated lifestyle changes
Predisposing factors	Factors that can facilitate behavior's changes within individuals that include knowledge, attitudes, beliefs, values and norms
Reinforcing factors	Factors that can strengthen the behavior of T2DM in DSM implementation: health workers, community leaders, or influential people in decision makers
Enabling factors	Factors that enable the behavior or action: health facilities, access to health facilities, health rule, and skills related to health
Diabetes self-management education	Provide educational counseling and/or coaching behavior to increase health knowledge, minimize disease complications and improve the health status of T2DM patients
Nutritional diet	Meal arrangements for T2DM patients according to individual calorie and nutritional needs (as recommended by a doctor/ nutritionist), with an emphasis on the regularity of the meal schedule, type, and amount of calorie content
Physical activity	Physical activity (excluding daily routine activities) as recommended by the American Diabetes Association and/or PERKENI (the Indonesia Endocrinologist association): 3–5 days/week (@30–45 minutes), with a total of 150 minutes/week, no more than 2 consecutive days. The goal is to maintain fitness, lose weight and improve insulin sensitivity.
Pharmacology therapy	Pharmacological administration of antihyperglycemic drugs orally or through injections is carried out concurrently with clinical nutrition management and physical exercise.
Quality of Life	The quality of life of T2DM patients based on clinical or non-clinical results of a medical examination by a doctor/health worker
HbA1c	The levels of glycated hemoglobin or glucose-associated hemoglobin
BMI	Measure of body fat based on height and weight that applies to adult men and women
Cholesterols	The total amount of cholesterol in blood includes low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol
Complication	The risk of developing cardiovascular, cerebrovascular, microvascular, psychological impairment and other complications.
Self-efficacy	An individual's belief in their capacity to act in the ways necessary to reach specific goals
Cost-analysis	Economic evaluation analysis that compares the resources (costs) with the quantity/quality of the outcomes achieved (generally Quality Adjusted Life Year/QALY)

Appendix 2: Method Adopted for Literature Review

Keyword	Diabetes self-management OR Diabetes mellitus self-management, diabetes mellitus self-care, diabetes self-care, self-management, self-care, quality of life, QOL, cost effective, cost effectiveness, health care expenditure, health expenditure AND Diabetes type 2, type 2 diabetes mellitus, diabetes mellitus type 2, T2DM
Databases	MEDLINE (via PubMed), EMBASE, GOOGLE SCHOLAR
Search criteria	Topic/ Engish/ Indonesia/ clinical trial/ systematic review/ meta-analysis/ randomized controlled trial/ controlled clinical trial/ cohort English/ article/ full text/ free full text/ open access/2012-2022
Result	Total no. of articles retrieved: Total no. of articles screened as relevant: Total no. of empirical studies: Total no. of normative/ theoretical papers:

Appendix 3: JBI Critical Appraisal Checklist for RCT Studies

Reviewer_____ Date_____

Author_____ Year_____Record Number_____

		es	No	Unclear	NA
1.	Was true randomization used for assignment of participants to treatment groups?			□	□
2.	Was allocation to treatment groups concealed?			□	□
3.	Were treatment groups similar at the baseline?			□	□
4.	Were participants blind to treatment assignment?			□	□
5.	Were those delivering treatment blind to treatment assignment?			□	□
6.	Were outcomes assessors blind to treatment assignment?			□	□
7.	Were treatment groups treated identically other than the intervention of interest?			□	□
8.	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?			□	□
9.	Were participants analyzed in the groups to which they were randomized?			□	□
10.	Were outcomes measured in the same way for treatment groups?			□	□
11.	Were outcomes measured in a reliable way?			□	□
12.	Was appropriate statistical analysis used?			□	□
13.	Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?			□	□

Overall appraisal: Include □ Exclude □ Seek further info □

Comments (Including reason for exclusion)

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Appendix 4: JBI Critical Appraisal Checklist for Cohort Studies

Reviewer_____Date_____

Author_____ Year_____Record Number_____

	es	No	Unclear	Not applicable
1. Were the two groups similar and recruited from the same population?		□	□	
2. Were the exposures measured similarly to assign people to both exposed and unexposed groups?		□	□	
3. Was the exposure measured in a valid and reliable way?		□	□	
4. Were confounding factors identified?		□	□	
5. Were strategies to deal with confounding factors stated?		□	□	
6. Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?		□	□	
7. Were the outcomes measured in a valid and reliable way?		□	□	
8. Was the follow up time reported and sufficient to be long enough for outcomes to occur?		□	□	
9. Was follow up complete, and if not, were the reasons to loss to follow up described and explored?		□	□	
10. Were strategies to address incomplete follow up utilized?		□	□	
11. Was appropriate statistical analysis used?		□	□	

Overall appraisal: Include □ Exclude □ Seek further info □

Comments (Including reason for exclusion)

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Appendix 5: PRISMA 2020 Item Checklist

Section and topic	tem#	Checklist item	Location where item is reported
Title		Identify the report as a systematic review	
Abstract		See the PRISMA 2020 *flow diagram for new systematic reviews*	
Introduction			
Rationale		Describe the rationale for the review in the context of existing knowledge.	
Objectives		Provide an explicit statement of the objective(s) or question(s) the review addresses.	
Methods			
Eligibility criteria		Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses	
Information sources		Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy		Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process		Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process	
Data collection process		Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items		List and define all outcomes for which data were sought.	
	0a	Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect	
	0b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	1	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	2	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results	
Synthesis methods	3a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)	
		Describe any methods required to prepare the data for	

Section and topic	tem#	Checklist item	Location where item is reported
	3b	presentation or synthesis, such as handling of missing summary statistics, or data conversions	
	3c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	3d	Describe any methods used to synthesise results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	3e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	3f	Describe any sensitivity analyses conducted to assess robustness of the synthesised results.	
Reporting bias assessment	4	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	5	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	
Results			
Study selection	6a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	6b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded	
Study characteristics	7	Cite each included study and present its characteristics.	
Risk of bias in studies	8	Present assessments of risk of bias for each included study.	
Results of individual studies	9	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	0a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	0b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	0c	Present results of all investigations of possible causes of heterogeneity among study results	
	0d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesised results.	
Reporting biases	1	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	2	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed	
Discussion		Provide a general interpretation of the results in the	

Section and topic	tem#	Checklist item	Location where item is reported
	3a	context of other evidence.	
	3b	Discuss any limitations of the evidence included in the review.	
	3c	Discuss any limitations of the review processes used.	
	3d	Discuss implications of the results for practice, policy, and future research	
Other information			
Registration and protocol	4a	Provide registration information for the review, including register name and registration number, or state that the review was not registered	
	4b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	4c	Describe and explain any amendments to information provided at registration or in the protocol	
Support	5	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	6	Declare any competing interests of review authors.	
Availability of data, code, and other materials	7	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review	