Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement.

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MAIN OBJECTIVES

- Systematic reviews (SR) are the reference standard for synthesizing evidence in health care because of their methodological rigor.
- SR are based on pre-defined eligibility criteria and conducted according to a pre-defined methodological approach.
- The preparation of a protocol is an essential component of the systematic review process; it ensures that a systematic review is carefully planned and that what is planned is explicitly documented before the review starts.

SCOPE

The PRISMA-P checklist is intended primarily for the preparation of protocols of systematic reviews and metaanalyses that summarize aggregate data from studies

PRISMA-P: Preferred Reporting Items for A guideline to help authors prepare protocols for planned systematic reviews and meta-analyses

- Provides a minimum set of items to be included in the protocol.
- A protocol is intended to Protocols provide the rationale for the review and pre-planned methodological and analytic approach, prior to embarking on a review.
- Investigators should prepare a review protocol in advance of registering it in PROSPERO or COCHRANE so that details requiring further consideration may be thought in advance, avoiding the need for multiple amendments to registration information

SYSTEMATIC REVIEW

- A systematic review attempts to collate all relevant evidences that fits pre-specified eligibility criteria to answer a specific research question.
- It uses explicit, systematic methods to minimize bias in the identification, selection, synthesis, and summary of studies.
- When done well, this provides reliable findings from which conclusions can be drawn and decisions made.
- The key characteristics of a systematic review are:
    - a clearly stated set of objectives with an explicit, reproducible methodology;
    - a systematic search that attempts to identify all studies that would meet the eligibility criteria;
    - an assessment of the validity of the findings of the included studies (assessment of risk of bias and confidence in cumulative estimates);
    - systematic presentation, and synthesis, of the characteristics and findings of the included studies

PROTOCOL

In the context of systematic reviews and meta-analyses, a protocol is a document that presents an explicit plan for a systematic review.
The protocol details the rationale and a priori methodological and analytical approach of the review.

PRISMA methodology

PRISMA-P does not contain a flow diagram documenting the flow of studies throughout the systematic review process. Such documentation is possible only after a review has been carried out and remains an essential component to include in the report of a completed systematic review or metanalysis; for further guidance, see the PRISMA Explanation and Elaboration document.

PRISMA-P 2015 checklist: recommended items to include in a systematic review protocol

Title		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number
Authors		
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor/ funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
METHODS		
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data		
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)