Preregistration – Systematic review (Vorlage: PROSPERO)

Name:
E-Mail:
Date:

Please note that you can submit the exposé and the thesis in ***English*** as well as in ***German***.

Introduction

Rationale: Shortly describe the relevance and theoretical framework of your study (500-1,000 words).

Review questions: Please list each research question included in this study derived from the study rationale. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS (see, e.g., Huang et al., 2006) where relevant.

Hypotheses: For each of the research questions listed in the previous section, provide one or multiple specific and testable hypotheses (e.g., H1, H2a, H2b, …. A figure or table may be helpful to describe complex interactions.

Exploratory research questions (optional, e.g., E1, E2, …)

Control variables: If applicable, please indicate which control variables are considered for the analyses.

Method

Participants: Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Intervention(s), exposure(s): Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed. This is particularly important for reviews of complex interventions (interventions involving the interaction of several elements). If appropriate, an operational definition describing the content and delivery of the intervention should be given. Ideally, an intervention should be reported in enough detail that others could reproduce it or assess its applicability to their own setting. The preferred format includes details of both inclusion and exclusion criteria. For synthesis of correlative evidence and reviews of qualitative studies give details of the focus of the review.

Comparator(s)/control: Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g., another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria. Control or comparison interventions should be described in as much detail as the intervention being reviewed. If the comparator is 'treatment as usual' or 'standard care', this should be described, with attention being paid to whether it is 'standard care' at

the time that an eligible study was done, or at the time the review is done. Synthesis of correlative evidence or systematic reviews of qualitative studies rarely have a comparator or control, therefore, if applicable, this paragraph can be omitted.

Types of study to be included: Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria. If different study designs are needed for different parts of the review, this should be made clear. Where qualitative evidence will be incorporated in or alongside a review of quantitative data, this should be stated.

Searches: State the sources that will be searched. Give the search dates, and any restrictions. The full search strategy may be provided in the appendix. The search strategy reported in systematic review protocols should include:

- name all sources that will be used to identify studies for the systematic review (e.g., bibliographic databases, reference lists of eligible studies and review articles, key journals, conferences proceedings, trial registers, internet resources, contact with experts)
- search dates (from and to)
- restrictions on the search including language and publication period
- whether unpublished studies will be sought

Study records

Selection process: Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded. Data extraction methods reported in systematic review protocols should include the study selection process itself and the software system or mechanism for recording decisions.

Data extraction:

- List which data will be extracted from study documents, including information about study design and methodology, participant demographics and baseline characteristics, numbers of events or measures of effect (where applicable). Alternatively, state how this information will be obtained from study investigators. It is possible to include the coding scheme in the appendix.
- Explain how missing data will be handled including whether study investigators will be contacted for unreported data or additional details.
- State the means of recording data (e.g., in an Excel spreadsheet, in a software system such as Eppi Reviewer).

Risk of bias in individual studies: Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used. Methods for assessing risk of bias reported in systematic review protocols should include:

- Which characteristics will be assessed (e.g. methods of randomization, treatment allocation, blinding).
- Whether assessment will be done at study or outcome level.

- The criteria used to assess internal validity, if a formal risk of bias assessment is planned (e.g., the Cochrane risk of bias tool, DIAD, ROBINS, QUADAS).
- How the results of the assessment will inform data synthesis (where applicable).

Data

Data synthesis: Provide details of the planned synthesis including a rationale for the methods selected. This must not be generic text but should be specific to your review and describe how the proposed analysis will be applied to your data. Data synthesis methods reported in systematic review protocols should be specific about how they apply to the review and data in question and include:

- Criteria under which the data will be synthesized (e.g., the minimum number of studies or level of consistency required for synthesis)
- Which data will be synthesized including outcomes and summary effect measures (e.g., risk ratios for progression free survival at 2 years)
- The formal method of combining individual study data including, as applicable, information about statistical models that will be fitted (e.g., risk ratios for individual studies will be combined using a random-effects meta-analysis) or methods of synthesizing qualitative data.

Meta-bias(es): Please describe how meta-biases (e.g., publication bias or reporting bias) will be assessed.

Confidence in cumulative evidence: Please indicate whether and how the overall quality of the body of evidence will be assessed and rated (e.g., GRADE - for more information see, e.g., GRADE working group or Santesso et al., 2020).