**PRISMA-P 2015 Checklist**

# **This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al**:**** Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 ****4****:1

| **Section/topic** | **#** | **Checklist item** | **Information reported**  | **Line number(s)** |
| --- | --- | --- | --- | --- |
| **Yes** | **No** |
| **ADMINISTRATIVE INFORMATION**  |
| **Title**  |
|   Identification  | 1a | Identify the report as a protocol of a systematic review | [x]  | [ ]  | 2, 44 |
|   Update  | 1b | If the protocol is for an update of a previous systematic review, identify as such | [ ]  | [x]  |  |
| **Registration**  | 2 | If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract | [x]  | [ ]  | 44-45 |
| **Authors**  |
|   Contact  | 3a | Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author | [x]  | [ ]  | 4-20 |
|   Contributions  | 3b | Describe contributions of protocol authors and identify the guarantor of the review | [x]  | [ ]  | 329-333 |
| **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 | [ ]  | [ ]  | N/A |
| **Support**  |
|   Sources  | 5a | Indicate sources of financial or other support for the review | [x]  | [ ]  | 46-47 |
|   Sponsor  | 5b | Provide name for the review funder and/or sponsor | [x]  | [ ]  | 46-47 |
|   Role of sponsor/funder  | 5c | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol | [x]  | [ ]  | 334-340 |
| **INTRODUCTION**  |
| **Rationale**  | 6 | Describe the rationale for the review in the context of what is already known | [x]  | [ ]  | 49-89 |
| **Objectives**  | 7 | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) | [ ]  | [ ]  | N/A |
| **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 | [x]  | [ ]  | 188-204 |
| **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 | [x]  | [ ]  | 167-187 |
| **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 | [ ]  | [x]  | Due to the nature of this realist review, the focus and scope of the searches is expected to be iterative (265-266). This is in line with RAMESES guidelines. |
| ***STUDY RECORDS*** |
|   Data management  | 11a | Describe the mechanism(s) that will be used to manage records and data throughout the review | [x]  | [ ]  | 213-214, 225, 236 |
|   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) | [x]  | [ ]  | 214-216, 223  |
|   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 | [x]  | [ ]  | 221-224, 236-237 |
| **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 | [x]  | [ ]  | 226-231, 234-236 |
| **Outcomes and prioritization**  | 13 | List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale | [x]  | [ ]  | 201-202, 227, 246, 248  |
| **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 | [ ]  | [ ]  | N/A for realist reviews. See 216-221 for comments on quality |
| ***DATA*** |
| **Synthesis**  | 15a | Describe criteria under which study data will be quantitatively synthesized | [ ]  | [ ]  | N/A |
| 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) | [ ]  | [ ]  | N/A |
| 15c | Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) | [ ]  | [ ]  | N/A |
| 15d | If quantitative synthesis is not appropriate, describe the type of summary planned | [x]  | [ ]  | 238-258 |
| **Meta-bias(es)**  | 16 | Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies) | [ ]  | [ ]  | N/A |
| **Confidence in cumulative evidence**  | 17 | Describe how the strength of the body of evidence will be assessed (e.g., GRADE) | [ ]  | [ ]  | N/A |