Title of review (Protocol)

Team

[List team members]

Partner Organisations / Collaborators: delete if not applicable

Contact

[Name and contact details]

Date protocol completed

[dd/mm/yyyy]

Contents

[1. Background 3](#_Toc35873525)

[2. Objectives of the review 3](#_Toc35873529)

[3. Methods 4](#_Toc35873530)

[3.1. Criteria for considering studies for this review 4](#_Toc35873531)

[3.2. Search methods for identification of studies 5](#_Toc35873534)

[3.3. Data collection and analysis 6](#_Toc35873537)

[4. Acknowledgements 8](#_Toc35873543)

[5. Declarations of Interest 8](#_Toc35873544)

[6. References 8](#_Toc35873545)

[7. Appendices 8](#_Toc35873546)

[7.1. Search strategies 8](#_Toc35873547)

[7.2. Data extraction form 8](#_Toc35873548)

[7.3. Add as appropriate 8](#_Toc35873549)

IMPORTANT: This protocol template is only intended for questions that have been deemed high-priority and suitable for a rapid review to address urgent questions arising from the COVID-19 pandemic. All sections should be completed, and no inclusion/exclusion decisions made until the process is finalised.

Please refer to the associated COVID-19 Rapid Review workflow document before completing the protocol, which includes considerations for team composition and topic refinement.

The template was developed to maximise quality and efficiency in the review process and may be adapted or improved as reviews are published. It is primarily aimed at questions about effectiveness and will require adaptation for other types of review (e.g. diagnosis and prognosis).

The structure and methods are based on a template used by Cochrane Response and have been adapted in line with preliminary recommendations made by the Cochrane Rapid Reviews Method Group (RRMG March 2020). Recommended approaches from the Cochrane RRMG are indicated throughout the protocol but may be amended and tailored to the review question.

# Background

*[Keep to half a page]*

## Brief description of the condition / issue under consideration

[Add standard text about COVID-19]

## Description of the intervention / test

*[Heading can be amended depending on question type]*

## How the intervention / test might work

*[Heading can be amended depending on question type]*

# Objectives of the review

To assess the [effects/benefits/harms] of [intervention] for [health problem] in [population, disease, setting, etc].

*[Complete/delete as appropriate and amend as appropriate for non-intervention reviews. Aim for one succinct, well-formulated and commissioner-driven primary objective to guide the review process.]*

The review will also seek to address

*[add secondary objectives as required, e.g. to investigate different participant groups, comparisons or outcome measures*

# Methods

## Criteria for considering studies for this review

|  |  |
| --- | --- |
| Study and source eligibility | |
| Study design | [RCTs](#RCTs)  Quasi-RCTs  [Non-randomised controlled trials](#NRS)  [Prospective cohort studies](#Cohort)  [Retrospective cohort studies](#Cohort)  [Case-control studies](#Casecontrol" \o "A study that compares people with a specific outcome of interest (‘cases’) with people from the same source population but without that outcome (‘controls’), to examine the association between the outcome and prior exposure (e.g. having an intervention). )  [Cross-sectional studies](#crosssectional" \o "The study collects information on interventions (past or present) and current health outcomes, i.e. restricted to health states, for a group of people at a particular point in time, to examine associations between the outcomes and exposure to interventions)  [Controlled before-and-after studies](#Beforeandafter)  Modelling studies  Other (please specify) |
| Minimum duration | [free text] |
| ‘PICO’ eligibility | |
| Population | *[List/describe, including any relevant details about setting]*  Other considerations [delete as appropriate]:  Special populations of interest are *[list, e.g. adults over 75, those with pre-existing health conditions)]*  Studies including [*list ineligible populations*] will be excluded.  Studies with a subset of relevant participants will be *[excluded/included if]* |
| Intervention(s) | *[List/describe a restricted number of eligible interventions, including dose/frequency, mode of delivery etc.]*  Other considerations *[delete as applicable]:*  Studies assessing the intervention of interest in combination with another intervention will be *[excluded/included if].*  Studies comparing different brands or doses of the same intervention (e.g. vaccines) will be *[excluded/included if].* |
| Comparator(s) | *[List/describe a restricted number of eligible comparators, including dose/frequency, mode of delivery etc, and specify active or inactive control]* |
| Outcome(s) | *[List/describe a restricted number of outcomes place in priority order, with details of definitions, scale, measurements and timepoint]*  *[Consider the relevance of patient important benefits and harms (death, hospitalisation, adverse), incidence and prevalence, quality of life and economic outcomes]*  Studies will be included in the review irrespective of whether measured outcome data are reported in a ‘usable’ way. |

## Search methods for identification of studies

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Search methods | | | | | |
| Expertise | The searches will be [informed/verified] by a content expert, conducted by an information specialist [initials], and independently peer reviewed. | | | | |
| Electronic databases | Database [minimum checked – please specify one other]  MEDLINE  CENTRAL  EMBASE  Other (please specify, e.g. PsycINFO)  Clinical Trial Registry (please specify) | From:  *[e.g. inception or limited to last X years]* | | To: | |
| Other searches | Systematic review references  Reference lists of included studies  Grey literature (please specify)  Citation tracking  Data from the pharmaceutical industry  Contact experts for references  Other (please specify) | *[provide details]* | | | |
| Approach to ongoing and unpublished studies | Include ongoing studies  Unpublished studies  Studies in press  Exclude all studies that are ongoing, unpublished, or in press | *[specify how these will be sought]* | | | |
| Methods for screening search results | | | | | |
| Expertise | Screening will be performed by *[specify content expert/methodologist etc and initials]* in *[specify software]* | | | | |
| Screening methods | Dual; second reviewer checks all excluded records  Dual; second reviewer checks *[X%]* of excluded records  Dual; independent screen and cross check | | *Abstract* | | *Full text* |
| Discrepancy resolution | Consensus and/or third reviewer  Other (please specify) | | | | |
| Excluded studies | All decisions taken during screening will be documented and outlined in the final report with a list of excluded studies | | | | |
| Inclusion of abstracts and conference proceedings | Exclude all  Include if clearly eligible and have usable data  Include if clearly eligible regardless of usable data  Include if eligibility is unclear and add to section in report | | | | |
| Inclusion of non-English language studies | Include abstracts and full texts *[in Chinese/any language]*  Include full texts only *[in Chinese only/ language]*  Exclude | | | | |
| All potentially relevant abstracts will progress to full text screen  [Single/dual] title/abstract screen by foreign-language speaker(s)  [Abstract/methods/full text] will be translated for abstract/full text screen  Listed as non-English language and not assessed further | | | | |

## Data collection and analysis

|  |  |  |
| --- | --- | --- |
| Data extraction | | |
| Expertise | Data extraction will be performed by [specify content expert/methodologist etc and initials]. | |
| Software | Data will be extracted using pilot-tested data extraction forms in [*software*] | |
| Data to be extracted | Study design [including methods, location, sites, groups]  Setting  Participant characteristics [specify, with a particular focus on effect modifiers and prognostic factors] any disease severity and age)  Intervention characteristics [specify details]  Comparator characteristics  Outcomes assessed  Numerical data for outcomes of interest | |
| Data extraction methods | Single, no second reviewer  Dual; second reviewer checks all data  Dual; second reviewer checks [add proportion]  Dual; independent screen and cross check | |
| Risk of bias tool | *[specify for each study design]*  No risk of bias assessment  Cochrane RCT risk of bias tool  ROBINS-I tool for non-randomised studies  Adapted-hybrid of the RCT-ROBINS-I tools  Newcastle-Ottawa Scale  Another tool [*please specify]* | |
| Method of risk of bias assessment | Single, no second reviewer  Dual; second reviewer checks all judgements  Dual; second reviewer checks [add proportion]  Dual; independent screen and cross check | All outcomes  Primary only |
| Discrepancy resolution | Consensus and/or third reviewer  Other (please specify) | |
| Contacting study authors | Authors will be contacted for missing information and data  Authors will be contacted for missing outcome data only  Authors will not be contacted | |
| Data management | | |
| Software | State any additional software (and version) that might be used for data management. | |
| Standardisation | Where necessary, outcome data will be standardised to the same unit of measurement. If these require scaling / conversion factors [*cite in protocol and review]*, these will be sourced, and their use confirmed (a priori) with a content expert. | |
| Resolving conflicts between sources | If there is a conflict between data reported across multiple sources for a single study (e.g. between a published article and a trial registry record), we will *[specify approach].* | |

|  |  |
| --- | --- |
| Data synthesis | |
| Measures of treatment effect | Continuous outcome: mean difference and 95% confidence intervals (CIs)  Continuous outcome: standardised mean difference  Dichotomous outcome: risk ratio / relative risk (RR) and 95% CIs  Dichotomous outcome: odds ratio (OR) and 95% CIs  Dichotomous outcome: risk difference (absolute risk reduction)  Peto odds ratio method  Other (please specify)  *[Specify what data processing would be undertaken to calculate the required effect measures using the data extracted from the individual studies]* |
| Unit of analysis issues | Advice from a statistician will be sought to address issues relating to double counting, correlation or unit of analysis posed by the following:  Cluster RCTs  Crossover trials  Body part randomised trials  Episodes of disease  Multi-arm studies  Other (please specify) |
| Assessment of heterogeneity | Inspecting forest plots  Statistical test (chi-squared) for heterogeneity *[specify p-value]*  I2 statistic *[state how values of I2 will be interpreted]*  Explore potential sources of the heterogeneity among study results *[state which characteristics will be used]*  Sensitivity analysis by excluding outlying studies |
| Assessment of reporting biases | Funnel plots  Test for funnel plot asymmetry (e.g. Begg, Egger test)  Trim and fill technique |
| Data synthesis | Forest plots  Qualitative synthesis  Synthesis without meta-analysis  *[Specify data type and study designs, interventions to be pooled*  *If non-randomised and observational studies are included, describe how these studies will be analysed]* |
| Model | Fixed-effect meta-analyses  Random-effects meta-analyses (DerSimonian and Laird method)  Other *[please specify]* |
| Subgroup analyses | The following subgroups will be explored: *[limit the number]*  *[List/describe]* |
| Sensitivity analysis | Excluding studies at high risk of bias *[specify domains]*  Excluding studies with dubious eligibility  Alternative analysis methods *[specify]*  Other *[please specify]*  Any *post hoc* sensitivity analyses that arise during the review process will be justified in the final report. |
| GRADE approach | GRADE will be used for *[all outcomes/the primary outcome(s)]* and results presented in a summary of findings table |

# Acknowledgements

*Report the contribution of people not listed in the ‘Team’ and briefly describe their contribution to the protocol.*

# Declarations of Interest

*[For each member of the team, report relevant present or recent affiliations or other involvement in any organisation or entity with an interest in the review’s findings that might lead to a real or perceived conflict of interest]*

# References

# Appendices

## Search strategies

## Data extraction form

## [Add as appropriate]

# Supporting information [delete before submission]

## Rapid review methods with support from the Rapid Reviews Method Group survey:

* Place emphasis on higher-quality study designs
* Restrict the number of eligible interventions, comparators, outcomes, or settings
* Restrict the search by date, English-language only (or prioritise Chinese for COVID-19 questions)
* Limit main database searches to CENTRAL, MEDLINE (e.g., via PubMed) and Embase
* Limit grey literature and supplemental searching to trials registries and bibliographies
* Single reviewer screening with a second reviewer to screen all studies excluded by the first reviewer (ranked first in survey). It should be noted that this adheres to MECIR for title abstract sift but not for full text review.
* Single reviewer data extraction with full verification by a second reviewer (including study characteristics and outcomes data). It should be noted that this does not adhere to MECIR C45 and C46. Single extraction; with verification by a second reviewer of a proportion of study characteristics and all outcome data was ranked second.
* Streamline the data to be extracted about study characteristics, interventions, and outcome details (existing high-quality SRs and experienced reviewers may reduce time spent extracting)