Preferred Reporting Items For Systematic Review And Meta Analysis

PRISMA Checklist

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Item 1. Title

Essential elements

- ✓ Identify the report as a systematic review in the title.
- ✓ Report an informative title that provides key information about the main objective or question that the review addresses (e.g. the population and the intervention(s).)

Additional elements

✓ Consider providing additional information in the title, such as the method of analysis used (e.g. "a systematic review & meta-analysis"), the designs of included studies (e.g. "a systematic review of randomized trials"), or an indication that the review is an update of an existing review.

Item 2: Abstract - Use the PRISMA 2020 for Abstracts checklist

- An abstract providing key information about the main objective(s) or question(s) that the review addresses, methods, results, and implications of the findings should help readers decide whether to access the full report.
- □ For some readers, the abstract may be all that they have access to. Therefore, it is critical that results are presented for all main outcomes for the main review objective(s) or question(s) regardless of the statistical significance, magnitude, or direction of effect.
- □ Terms presented in the abstract will be used to index the systematic review in bibliographic databases. Therefore, reporting keywords that accurately describe the review question (such as population, interventions, outcomes) is recommended.

Item 3: Rationale

- ✓ Describe the current state of knowledge and its uncertainties.
- ✓ Articulate why it is important to do the review.
- ✓ If other systematic reviews addressing the same (or a largely similar) question are available, explain why the current review was considered necessary (for example, previous reviews are out of date or have discordant results).
- ✓ If the review is an update or replication of a particular systematic review, indicate this and cite the previous review.
- ✓ If the review examines the effects of interventions, also briefly describe how the intervention(s) examined might work.

Item 4: Objectives

An explicit and concise statement of the review objective(s) or question(s) will help readers understand the scope of the review and assess whether the methods used in the review (such as eligibility criteria, search methods, data items, and the comparisons used in the synthesis) adequately address the objective(s). Such statements may be written in the form of objectives ("the objectives of the review were to examine the effects of…") or as questions ("what are the effects of…?").

- ✓ Provide an explicit statement of all objective(s) or question(s) the review addresses
- ✓ If the purpose is to evaluate the effects of interventions, use the Population, Intervention, Comparator, Outcome (PICO) framework or one of its variants to state the comparisons that will be made.

Item 5. Eligibility criteria

- ✓ Specify all study characteristics used to decide whether a study was eligible for inclusion in the review, that is, components described in the PICO framework or one of its variants and other characteristics, such as eligible study design(s) and setting(s) and minimum duration of follow up.
- ✓ Specify eligibility criteria with regard to report characteristics, such as year of dissemination, language, and report status (for example, whether reports such as unpublished manuscripts and conference abstracts were eligible for inclusion).
- ✓ Clearly indicate if studies were ineligible because the outcomes of interest were not measured, or ineligible because the results for the outcome of interest were not reported. Reporting that studies were excluded because they had "no relevant outcome data" is ambiguous and should be avoided.
- ✓ Specify any groups used in the synthesis (such as intervention, outcome, and population groups) and link these to the comparisons specified in the objectives.

Item 5. Eligibility criteria (continue)

Example

"Objectives: To evaluate the benefits and harms of down-titration (dose reduction, discontinuation, or disease activity-guided dose tapering) of anti-tumour necrosis factor-blocking agents (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab) on disease activity, functioning, costs, safety, and radiographic damage compared with usual care in people with rheumatoid arthritis and low disease activity."

Item 6. Information sources

- ✓ Specify the date when each source (such as database, register, website, organisation) was last searched or consulted.
- ✓ If bibliographic databases were searched, specify for each database its name (such as MEDLINE, CINAHL), the interface or platform through which the database was searched (such as Ovid, EBSCOhost), and the dates of coverage (where this information is provided).
- ✓ If study registers (such as ClinicalTrials.gov) and other online repositories (such as SIDER Side Effect Resource) were searched, specify the name of each source and any date restrictions.
- ✓ If websites, search engines, or other online sources were browsed or searched, specify the name and URL (uniform resource locator) of each source.
- ✓ If organizations or manufacturers were contacted to identify studies, specify the name of each source.

Item 6. Information sources (continue)

- ✓ If individuals were contacted to identify studies, specify the types of individuals contacted (such as authors of studies included in the review or researchers with expertise in the area).
- ✓ If reference lists were examined, specify the types of references examined (such as references cited in study reports included in the systematic review, or references cited in systematic review reports on the same or a similar topic).
- ✓ If cited or citing reference searches (also called backwards and forward citation searching) were conducted, specify the bibliographic details of the reports to which citation searching was applied, the citation index or platform used (such as Web of Science), and the date the citation searching.
- ✓ If journals or conference proceedings were consulted, specify the names of each source, the dates covered and how they were searched (such as hand searching or browsing online).

Item 7: Search strategy

- ✓ Provide the full line by line search strategy as run in each database with a sophisticated interface (such as Ovid), or the sequence of terms that were used to search simpler interfaces, such as search engines or websites.
- ✓ Describe any limits applied to the search strategy (such as date or language) and justify these by linking back to the review's eligibility criteria.
- ✓ If published approaches such as search filters designed to retrieve specific types of records (for example, filter for randomized trials) or search strategies from other systematic reviews, were used, cite them. If published approaches were adapted—for example, if existing search filters were amended—note the changes made.

Item 8: Selection process

- ✓ Report how many reviewers screened each record (title/abstract) and each report retrieved, whether multiple reviewers worked independently (that is, were unaware of each other's decisions) at each stage of screening or not (for example, records screened by one reviewer and exclusions verified by another), and any processes used to resolve disagreements between screeners (for example, referral to a third reviewer or by consensus).
- ✓ Report any processes used to obtain or confirm relevant information from study investigators.
- ✓ If abstracts or articles required translation into another language to determine their eligibility, report how these were translated (for example, by asking a native speaker or by using software programs).

Item 9: Data collection process

- ✓ Report how many reviewers collected data from each report, whether multiple reviewers worked independently or not (for example, data collected by one reviewer and checked by another), and any processes used to resolve disagreements between data collectors.
- ✓ Report any processes used to obtain or confirm relevant data from study investigators (such as how they were contacted, what data were sought, and success in obtaining the necessary information).
- ✓ If any automation tools were used to collect data, report how the tool was used (such as machine learning models to extract sentences from articles relevant to the PICO characteristics), how the tool was trained, and what internal or external validation was done to understand the risk of incorrect extractions.

Item 9: Data collection process (continue)

- ✓ If articles required translation into another language to enable data collection, report how these articles were translated (for example, by asking a native speaker or by using software programs).
- ✓ If any software was used to extract data from figures, specify the software used.
- ✓ If any decision rules were used to select data from multiple reports corresponding to a study, and any steps were taken to resolve inconsistencies across reports, report the rules and steps used.

Item 10 (a): Data Item

- ✓ List and define the outcome domains and time frame of measurement for which data were sought.
- ✓ Specify whether all results that were compatible with each outcome domain in each study were sought, and, if not, what process was used to select results within eligible domains.
- ✓ If any changes were made to the inclusion or definition of the outcome domains or to the importance given to them in the review, specify the changes, along with a rationale.
- ✓ If any changes were made to the processes used to select results within eligible outcome domains, specify the changes, along with a rationale

Item 10 (b): Data Item

- ✓ List and define all other variables for which data were sought. It may be sufficient to report a brief summary of information collected if the data collection and dictionary forms are made available (for example, as additional files or deposited in a publicly available repository).
- Describe any assumptions made about any missing or unclear information from the studies. For example, in a study that includes "children and adolescents," for which the investigators did not specify the age range, authors might assume that the oldest participants would be 18 years, based on what was observed in similar studies included in the review, and should report that assumption.

Item 11:Study risk of bias assessment

- ✓ Specify the tool(s) (and version) used to assess risk of bias in the included studies.
- ✓ Specify the methodological domains/components/items of the risk of bias tool(s) used.
- ✓ Report whether an overall risk of bias judgment that summarized across domains/components/ items was made, and if so, what rules were used to reach an overall judgment.
- ✓ If any adaptations to an existing tool to assess risk of bias in studies were made (such as omitting or modifying items), specify the adaptations.
- ✓ If a new risk of bias tool was developed for use in the review, describe the content of the tool and make it publicly accessible.

Item 11:Study risk of bias assessment

- ✓ Report how many reviewers assessed risk of bias in each study, whether multiple reviewers worked independently (such as assessments performed by one reviewer and checked by another), and any processes used to resolve disagreements between assessors.
- ✓ Report any processes used to obtain or confirm relevant information from study investigators.
- ✓ If an automation tool was used to assess risk of bias in studies, report how the automation tool was used (such as machine learning models to extract sentences from articles relevant to risk of bias), how the tool was trained, and details on the tool's performance and internal validation.

Item 12: Effect measures

- ✓ Specify for each outcome or type of outcome (such as binary, continuous) the effect measure(s) (such as risk ratio, mean difference) used in the synthesis or presentation of results.
- ✓ State any thresholds or ranges used to interpret the size of effect (such as minimally important difference; ranges for no/trivial, small, moderate, and large effects) and the rationale for these thresholds.
- ✓ If synthesized results were re-expressed to a different effect measure, report the methods used to re-express results (such as meta-analyzing risk ratios and computing an absolute risk reduction based on an assumed comparator risk).

Item 13a: Synthesis methods

Essential elements

✓ Describe the processes used to decide which studies were eligible for each synthesis. (such as tabulating the study intervention characteristics and comparing against the planned groups for each synthesis)

Item 13b: Synthesis methods

Essential elements

✓ Report any methods required to prepare the data collected from studies for presentation or synthesis, such as handling of missing summary statistics or data conversions.

Item 13c: Synthesis methods

Essential elements

- ✓ Report chosen tabular structure(s) used to display results of individual studies and syntheses, along with details of the data presented.
- ✓ Report chosen graphical methods used to visually display results of individual studies and syntheses.

Additional elements

- ✓ If studies are ordered or grouped within tables or graphs based on study characteristics (such as by size of the study effect, year of publication), consider reporting the basis for the chosen ordering/grouping.
- ✓ If non-standard graphs were used, consider reporting the rationale for selecting the chosen graph.

Item 13d: Synthesis methods

- ✓ If statistical synthesis methods were used, reference the software, packages, and version numbers used to implement synthesis methods (such as metan in Stata 16,117 metafor (version 2.1-0) in R118).
- ✓ If it was not possible to conduct a meta-analysis, describe and justify the synthesis methods (such as combining P values was used because no or minimal information beyond P values and direction of effect was reported in the studies) or summary approach used.

Item 13d: Synthesis methods (continue)

- ✓ If meta-analysis was done, specify:
 - the meta-analysis model (fixed or random-effects) and provide rationale for the selected model.
 - the method used (such as Mantel-Haenszel, inverse-variance).
 - any methods used to identify or quantify statistical heterogeneity (such as visual inspection of results, a formal statistical test for heterogeneity, heterogeneity variance $(\tau 2)$, inconsistency (such as I2), and prediction intervals).
- ✓ If a random-effects meta-analysis model was used, specify:
 - the between-study (heterogeneity) variance estimator used (such as DerSimonian and Laird)
 - the method used to calculate the confidence interval for the summary effect

Item 13e: Synthesis methods (continue)

- ✓ If methods were used to explore possible causes of statistical heterogeneity, specify the method used (such as subgroup analysis, meta-regression).
- ✓ If other methods were used to explore heterogeneity because data were not amenable to metaanalysis of effect estimates, describe the methods used (such as structuring tables to examine variation in results across studies based on subpopulation, key intervention components, or contextual factors) along with the factors and levels.
- ✓ If any analyses used to explore heterogeneity were not pre-specified, identify them as such

Item 13e: Synthesis methods

- ✓ If subgroup analysis or meta-regression was performed, specify for each:
 - which factors were explored, levels of those factors, and which direction of effect modification was expected and why (where possible).
 - whether analyses were conducted using study-level variables (where each study is included in one subgroup only), within study contrasts (where data on subsets of participants within a study are available, allowing the study to be included in more than one subgroup), or some combination of the above.
 - how subgroup effects were compared (such as statistical test for interaction for subgroup analyses).

Item 13f: Synthesis methods (continue)

- ✓ If subgroup analysis or meta-regression was performed, specify for each:
 - which factors were explored, levels of those factors, and which direction of effect modification was expected and why (where possible).
 - whether analyses were conducted using study-level variables (where each study is included in one subgroup only), within study contrasts (where data on subsets of participants within a study are available, allowing the study to be included in more than one subgroup), or some combination of the above.
 - how subgroup effects were compared (such as statistical test for interaction for subgroup analyses).

Item 14: Reporting bias assessment

- Specify the methods (tool, graphical, statistical, or other) used to assess the risk of bias due
- to missing results in a synthesis (arising from reporting biases).
- If risk of bias due to missing results was assessed using an existing tool, specify the methodological components/domains/items of the tool, and the process used to reach a judgment of overall risk of bias.
- If any adaptations to an existing tool to assess risk of bias due to missing results were made (such as omitting or modifying items), specify the adaptations.
- If a new tool to assess risk of bias due to missing results was developed for use in the review, describe the content of the tool and make it publicly accessible.

Item 14: Reporting bias assessment (continue)

- Report how many reviewers assessed risk of bias due to missing results in a synthesis, whether multiple reviewers worked independently, and any processes used to resolve disagreements between assessors.
- Report any processes used to obtain or confirm relevant information from study investigators.
- If an automation tool was used to assess risk of bias due to missing results, report how the tool was used, how the tool was trained, and details on the tool's performance and internal validation.

Item 15: Certainty assessment

- Specify the tool or system (and version) used to assess certainty in the body of evidence.
- Report the factors considered (such as precision of the effect estimate, consistency of findings across studies) and the criteria used to assess each factor when assessing certainty in the body of evidence.
- Describe the decision rules used to arrive at an overall judgment of the level of certainty (such as high, moderate, low, very low), together with the intended interpretation (or definition) of each level of certainty.

Item 15: Certainty assessment (continue)

- If applicable, report any review-specific considerations for assessing certainty, such as thresholds used to assess imprecision and ranges of magnitude of effect that might be considered trivial, moderate or large, and the rationale for these thresholds and ranges (item #12).
- If any adaptations to an existing tool or system to assess certainty were made, specify the adaptations in sufficient detail that the approach is replicable.
- Report how many reviewers assessed the certainty of evidence, whether multiple reviewers worked independently, and any processes used to resolve disagreements between assessors.
- Report any processes used to obtain or confirm relevant information from investigators.

Item 15: Certainty assessment (continue)

- If an automation tool was used to support the assessment of certainty, report how the automation tool was used, how the tool was trained, and details on the tool's performance and internal validation.
- Describe methods for reporting the results of assessments of certainty, such as the use of Summary of Findings tables (see item #22).
- If standard phrases that incorporate the certainty of evidence were used (such as "hip protectors probably reduce the risk of hip fracture slightly"), report the intended interpretation of each phrase and the reference for the source guidance.

Item 16a: Study selection

- Report, ideally using a flow diagram, the number of: records identified; records excluded before the number of ongoing studies and associated reports identified.
- If the review is an update of a previous review, report results of the search and selection process for the current review and specify the number of studies included in the previous review. An additional box could be added to the flow diagram indicating the number of studies included in the previous review.
- If applicable, indicate in the PRISMA flow diagram how many records were excluded by a human and how many by automation tools.

Item 16b: Study selection

Essential elements

• Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.

Item 17: Study characteristics

Essential elements

• Present the key characteristics of each study in a table or figure (considering a format that will facilitate comparison of characteristics across the studies).

Additional elements

If the review examines the effects of interventions, consider presenting an additional table that summarizes the intervention details for each study.

Item 18: Risk of bias in studies

Essential elements

- Present tables or figures indicating for each study the risk of bias in each domain/component/item assessed and overall study-level risk of bias.
- Present justification for each risk of bias judgment—for example, in the form of relevant quotations from reports of included studies.

Additional elements

• If assessments of risk of bias were done for specific outcomes or results in each study, consider displaying risk of bias judgments on a forest plot, next to the study results, so that the limitations of studies contributing to a particular meta-analysis are evident.

Item 19: Results of individual studies

- For all outcomes, irrespective of whether statistical synthesis was undertaken, present for each study summary statistics for each group (where appropriate). For dichotomous outcomes, report the number of participants with and without the events for each group; or the number with the event and the total for each group (such as 12/45). For continuous outcomes, report the mean, standard deviation, and sample size of each group.
- For all outcomes, irrespective of whether statistical synthesis was undertaken, present for each study an effect estimate and its precision (such as standard error or 95% confidence/credible interval). For example, for time-toevent outcomes, present a hazard ratio and its confidence interval.

Item 19: Results of individual studies (continue)

- If study-level data are presented visually or reported in the text (or both), also present a tabular display of the results.
- If results were obtained from multiple sources (such as journal article, study register entry, clinical study report, correspondence with authors), report the source of the data. This need not be overly burdensome. For example, a statement indicating that, unless otherwise specified, all data came from the primary reference for each included study would suffice. Alternatively, this could be achieved by, for example, presenting the origin of each data point in footnotes, in a column of the data table, or as a hyperlink to relevant text highlighted in reports
- If applicable, indicate which results were not reported directly and had to be computed or estimated from other information

Item 20a: Results of syntheses

- Provide a brief summary of the characteristics and risk of bias among studies contributing to each synthesis (meta-analysis or other). The summary should focus only on study characteristics that help in interpreting the results (especially those that suggest the evidence addresses only a restricted part of the review question, or indirectly addresses the question). If the same set of studies contribute to more than one synthesis, or if the same risk of bias issues are relevant across studies for different syntheses, such a summary need be provided once only.
- Indicate which studies were included in each synthesis (such as by listing each study in a forest plot or table or citing studies in the text).

Item 20b: Results of syntheses

- Report results of all statistical syntheses described in the protocol and all syntheses conducted that were not pre-specified.
- If meta-analysis was conducted, report for each:
 - ✓ the summary estimate and its precision (such as standard error or 95% confidence interval).
 - \checkmark measures of statistical heterogeneity (such as τ 2, I2, prediction interval).
- If other statistical synthesis methods were used (such as summarizing effect estimates, combining P values), report the synthesized result and a measure of precision (or equivalent information, for example, the number of studies and total sample size).
- If comparing groups, describe the direction of effect (such as fewer events in the intervention group, or higher pain in the comparator group).

Item 20b: Results of syntheses

- If the statistical synthesis method does not yield an estimate of effect (such as when P values are combined), report the relevant statistics (such as P value from the statistical test), along with an interpretation of the result that is consistent with the question addressed by the synthesis method (for example, "There was strong evidence of benefit of the intervention in at least one study (P < 0.001, 10 studies)" when P values have been combined).
- If synthesizing mean differences, specify for each synthesis, where applicable, the unit of measurement (such as kilograms or pounds for weight), the upper and lower limits of the measurement scale (for example, anchors range from 0 to 10), direction of benefit (for example, higher scores denote higher severity of pain), and the minimally important difference, if known. If synthesizing standardized mean differences and the effect estimate is being re-expressed to a particular instrument, details of the instrument, as per the mean difference, should be reported.

Item 20c: Results of syntheses

- If investigations of possible causes of heterogeneity were conducted:
 - ✓ present results regardless of the statistical significance, magnitude, or direction of effect modification.
 - ✓ identify the studies contributing to each subgroup.
 - ✓ report results with due consideration to the observational nature of the analysis and risk of confounding due to other factors.
- If subgroup analysis was conducted, report for each analysis the exact P value for a test for interaction as well as, within each subgroup, the summary estimates, their precision (such as standard error or 95% confidence/credible interval) and measures of heterogeneity. Results from subgroup analyses might usefully be presented graphically.

Item 20c: Results of syntheses (continue)

- If meta-regression was conducted, report for each analysis the exact P value for the regression coefficient and its precision.
- If informal methods (that is, those that do not involve a formal statistical test) were used to investigate heterogeneity-which may arise particularly when the data are not amenable to meta-analysis-describe the results observed. For example, present a table that groups study results by dose or overall risk of bias and comment on any patterns observed.

Item 20d: Results of syntheses

Essential elements

- If any sensitivity analyses were conducted:
 - ✓ report the results for each sensitivity analysis.
 - ✓ comment on how robust the main analysis was given the results of all corresponding sensitivity analyses

Additional elements

- If any sensitivity analyses were conducted, consider:
 - ✓ presenting results in tables that indicate: (i) the summary effect estimate, a measure of precision (and potentially other relevant statistics, for example, I2 statistic) and contributing studies for the original meta-analysis; (ii) the same information for the sensitivity analysis; and (iii) details of the original and sensitivity analysis assumptions.
 - ✓ presenting results of sensitivity analyses visually using forest plots.

Item 21: Risk of reporting biases in syntheses

- Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.
- If a tool was used to assess risk of bias due to missing results in a synthesis, present responses to questions in the tool, judgments about risk of bias, and any information used to support such judgments to help readers understand why particular judgments were made.
- If a funnel plot was generated to evaluate small study effects (one cause of which is reporting biases), present the plot and specify the effect estimate and measure of precision used in the plot (presented typically on the horizontal axis and vertical axis respectively106). If a contour-enhanced funnel plot was generated, specify the "milestones" of statistical significance that the plotted contour lines represent (P=0.01, 0.05, 0.1, etc).

Item 21: Risk of reporting biases in syntheses (continue)

- If a test for funnel plot asymmetry was used, report the exact P value observed for the test and potentially other relevant statistics, such as the standardised normal deviate, from which the P value is derived.
- If any sensitivity analyses seeking to explore the potential impact of missing results on the synthesis were conducted, present results of each analysis (see item #20d), compare them with results of the primary analysis, and report results with due consideration of the limitations of the statistical method.

Item 22: Certainty of evidence

- Report the overall level of certainty in the body of evidence (such as high, moderate, low, or very low) for each important outcome. Provide an explanation of reasons for rating down (or rating up) the certainty of evidence (such as in footnotes to an evidence summary table). Explanations for each judgment should be concise, informative, relevant to the target audience, easy to understand, and accurate (that is, addressing criteria specified in the methods guidance).
- Communicate certainty in the evidence wherever results are reported (that is, abstract, evidence summary tables, results, conclusions). Use a format appropriate for the section of the review. For example, in text, certainty might be reported explicitly in a sentence (such as "Moderate certainty evidence (downgraded for bias) indicates that…") or in brackets alongside an effect estimate (such as "[RR 1.17, 95% CI 0.81 to 1.68; 4 studies, 1781 participants; moderate certainty evidence]").

Item 23a: Discussion

Essential elements

Provide a general interpretation of the results in the context of other evidence.

Item 23b: Discussion

Essential elements

Discuss any limitations of the evidence included in the review..

Item 23c: Discussion

Essential elements

• Discuss any limitations of the review processes used and comment on the potential impact of each limitation.

Item 23d: Discussion

- Discuss implications of the results for practice and policy.
- Make explicit recommendations for future research.

Item 24a: Registration and protocol

Essential elements

• Provide registration information for the review, including register name and registration number, or state that the review was not registered.

Item 24b: Registration and protocol

Essential elements

• Indicate where the review protocol can be accessed (such as by providing a citation, DOI, or link) or state that a protocol was not prepared.

Item 24c: Registration and protocol

Essential elements

• Report details of any amendments to information provided at registration or in the protocol, noting: (a) the amendment itself, (b) the reason for the amendment, and (c) the stage of the review process at which the amendment was implemented.

Item 25: Support

- Describe sources of financial or non-financial support for the review, specifying relevant grant ID numbers for each funder. If no specific financial or non-financial support was received, this should be stated.
- Describe the role of the funders or sponsors (or both) in the review. If funders or sponsors had no role in the review, this should be declared—for example, by stating, "The funders had no role in the design of the review, data collection and analysis, decision to publish, or preparation of the manuscript."

Item 26: Competing interests

- Disclose any of the authors' relationships or activities that readers could consider pertinent or to have influenced the review.
- If any authors had competing interests, report how they were managed for particular review processes.

Item 27: Availability of data, code, and other materials

- Report which of the following are publicly available: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.
- If any of the above materials are publicly available, report where they can be found (such as provide a link to files deposited in a public repository).
- If data, analytic code, or other materials will be made available upon request, provide the contact details of the author responsible for sharing the materials and describe the circumstances under which such materials will be shared.

Reference

Matthew J Page, David Moher, Patrick M Bossuyt, Isabelle Boutron, Tammy C Hoffmann, Cynthia D Mulrow et al. PRISMA 2020 explanation and elaboration: updated guidance and exemplars for reporting systematic reviews. BMJ 2021;372:n160.

http://dx.doi.org/10.1136/bmj.n160