InSynQ (Intervention Synthesis Questions) checklist and guide for developing and reporting the questions addressed in systematic reviews of interventions

To cite this document. Sue E Brennan, Miranda S Cumpston, Rebecca Ryan, Joanne E McKenzie. InSynQ (Intervention Synthesis Questions) checklist and guide for developing and reporting the questions addressed in systematic reviews of interventions. Version 1.0, updated 29 April 2023. Available from InSynQ.info

Acknowledgements. We thank Cochrane for a grant that part-funded the development of InSynQ. We thank the following contributors for completing the online survey, piloting InSynQ or participating at consultation meetings and webinars. Their feedback informed the content of InSynQ: including Andrew Back, Soumyadeep Bhaumik, Mhairi Campbell, Lee Yee Chong, Jane Dennis, Jodie Doyle, Kerry Dwan, Ella Flemyng, Alix Hall, Ruaraidh Hill, Lee Hooper, Alexander Jarde, Renea Johnston, Kayleigh Kew, Theresa Moore, Luis Rafael Moscote-Salazar, Ani Movsisyan, Zachary Munn, Ivan Pérez-Neri, Anke Rohwer, Elizabeth Royle, Natalie Strobel, Anneliese Synnot, Pratibha Mary Thomas, Jacqueline Thompson, Jo Weldon and Melina Willson.

See InSynQ.info for additional information about funding and contributors.

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About this checklist

The aim of the InSynQ checklist and guide is to facilitate the development and *reporting of the questions* addressed in systematic reviews of interventions.

The checklist and guide was developed as part of a collaborative programme of work aimed at delivering practical resources to help authors and editors translate guidance from the Cochrane Handbook for Systematic Reviews of Interventions into practice.[1,2] The focus of the work was on resources to improve the planning, conduct and reporting of methods within high-priority public health reviews. However, InSynQ applies to any review that aims to evaluate the effects of health interventions.

Who is the InSynQ checklist for?

The checklist is framed for authors but should also be helpful to those editing or peer-reviewing systematic review protocols or reports. It may assist methodologists working with author teams to plan their synthesis, and commissioners seeking to ensure a planned synthesis aligns with their requirements. We expect the checklist will be most useful to less experienced author teams (or those new to reviews of interventions with complexity). This is because it aims to describe the steps that experienced authors take in developing and reporting their synthesis questions. However, in reviews of interventions with complexity, it is easy to overlook details that can enhance reporting for the reader, and so the checklist may be of use to more experienced authors.

Format and structure of the InSynQ checklist and guide.

The 11-item checklist follows the format of PRISMA 2020.[3] Each item includes ***essential elements*** (things that should be reported) and ***additional elements*** (things that enhance reporting but are not essential). In the elaboration, items are followed by an ***explanation*** of what to report and why. A list of related items from PRISMA,[3] SWiM[4] and Cochrane's MECIR standards[5] is included, as are links to the relevant sections of the Cochrane Handbook.[6] Examples of reporting each item are appended.

When to use the InSynQ checklist

The checklist can be used when planning a systematic review, writing a protocol for a review or reporting a review.

- *Items 1 to 9* should be reported in both the protocol and the review. These items cover the specification of the synthesis questions and the role of groups in the synthesis
- *Items 10 and 11* apply at review stage only, covering requirements for reporting any changes to the synthesis questions and the reporting of results.

The tabulated version of the checklist indicates which items apply to both the protocol and review, and which to the review only. For simplicity, a single checklist is presented. Items 1 to 9 are framed for reporting in a protocol but the interpretation is unchanged (except for tense) when reporting a review.

How does the InSynQ checklist relate to guidance in the Cochrane Handbook?

Guidance for systematic reviews typically requires authors to define their review 'question' (the objective) and develop criteria for including studies in the review using the PICO framework.[2,7,8] However, the results of a review are ultimately determined by the synthesis questions and the decisions authors take in deciding which studies are eligible to answer each synthesis question. Without changing the review eligibility criteria, the synthesis can be structured to address different questions (e.g. broader or narrower) simply by grouping the interventions, outcomes or populations differently (see **Box 1**). The concept of 'PICO for each synthesis' was introduced in Version 6 of the Cochrane Handbook[1,2] to bring greater focus on the need to plan and report details of the synthesis questions addressed in a systematic review. New guidance on defining the PICO for each synthesis was provided in Chapter 3.[1] This included a suggested process for planning intervention and outcomes groups, guidance on deciding on the role of these groups in the synthesis and on specifying comparisons. These decisions should be reported as part of the methods of a protocol and review, as the aim is to report enough information about how synthesis was done to allow replication by other review teams.

The InSynQ checklist augments the Handbook guidance by providing a practical guide to help authors increase the transparency of their synthesis plans and decisions. In turn, it is hoped that this will help ensure that reviews are replicable, trustworthy and relevant to decision-makers.

How does the InSynQ checklist relate to PRISMA, MECIR and SWiM?

The checklist is intended to complement rather than replace PRISMA 2020[3] and SWiM[4] reporting guidance and Cochrane's MECIR standards for the conduct of systematic reviews.[5] PRISMA 2020, SWiM and MECIR each include items about review questions with some considerations relating to the structure of the synthesis. This checklist elaborates on requirements for reporting the synthesis questions and how these questions are (or will be) operationalised in the review. Item 9 is reproduced from PRISMA 2020 (item 13a)[3] without change because it is integral to the reporting of how authors make decision about which studies contribute to each synthesis.

Will using InSynQ require more work or lengthen reports?

Taking a structured approach to question development need not require additional work, nor should the reporting requirements in InSynQ lengthen protocols or reviews. For example, providing a list of the comparisons addressed in the synthesis (i.e. intervention A vs control, intervention A vs intervention B, etc) will meet requirements of Item 5 and the first essential element of Item 4. Similarly, many reviews already identify and describe the different types of interventions eligible for the review. Addressing Item 1 may simply require an explicit statement that these groups will used in the synthesis (i.e. they are not just provided to illustrate the scope of the review) and, for Item 4, whether the groups will be used as the basis of comparisons (in meta-analysis or other), to examine potential effect modifiers, or something else. Some of this may seem self-evident, but it can be surprisingly difficult to identify the synthesis questions in many reviews, especially when meta-analysis is not possible for one or more comparisons.

Feedback

This is the first version of the checklist and feedback is welcome (insynq.cochrane@monash.edu). In line with the focus of the programme of work, the majority of examples appended to the checklist are from reviews of public health interventions. Over time, we expect to expand the examples to encompass a broader range of reviews so that all authors and editors have ready access to relevant best-practice examples. We welcome suggestions.

Core project team

Sue Brennan and Joanne McKenzie (principal investigators) are authors of Chapters 2 and 3 of the Cochrane Handbook. Rebecca Ryan is an author of Chapter 3 of the Cochrane Handbook. Miranda Cumpston is an Associate Editor of the Cochrane Handbook.

References

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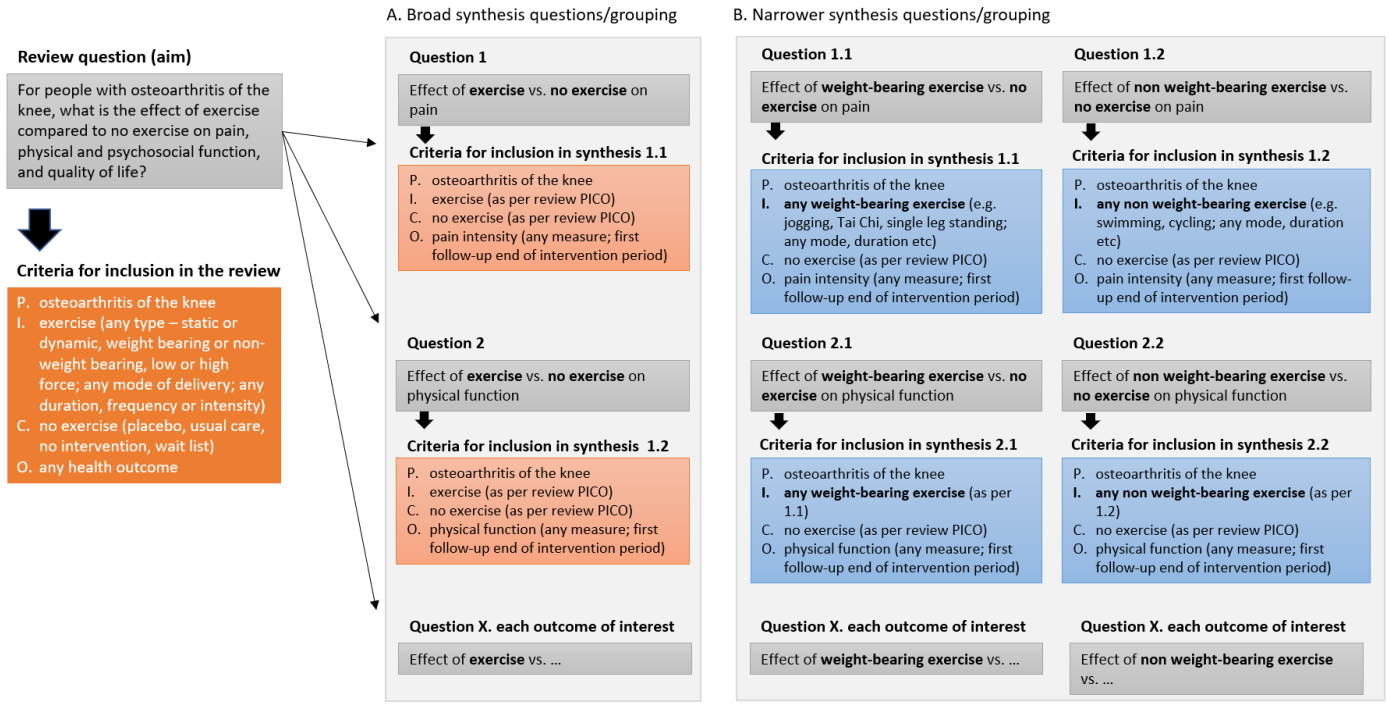
Box 1. An example illustrating why synthesis questions and criteria (PICO for each synthesis) should be specified

Historically, guidance for systematic reviews has focused on specifying questions and criteria for the review. The figure below (see InSynQ.info for enlarged version) illustrates why additional information is needed to articulate the questions addressed by each synthesis. The review question and a summary of the criteria for including studies in the review are shown on the left for a fictional example of a review of exercise for osteoarthritis of the knee. Panels A and B show two options for the questions that could be addressed in this review, focusing only on the intervention (many alternative questions are possible, including variants of questions and criteria for populations, comparators and outcomes).

In panel A, the questions addressed are broad and sufficiently similar to the overall review question that little additional information would be required to articulate the comparisons that will be made and how studies will be grouped within each. Taking question 1 for example, the questions addressed in the synthesis match the review question and the decision as to which subset of studies is eligible for each synthesis is determined only by whether the study measured the outcome of interest. While additional criteria are not required to operationalise these decisions, it should be clear to the reader that these are the planned synthesis questions and grouping of studies.

In contrast, panel B shows narrower questions that could be addressed in a review with the same overall question and review-level eligibility criteria. In this case, each synthesis includes only the subset of studies that examine one of two types of interventions (weight-bearing or non-weight-bearing). To decide which studies are eligible for each synthesis, the review authors will require criteria for 'weight-bearing' exercise and 'non-weight-bearing' exercise. Ideally, these synthesis questions and the comparisons and criteria required to operationalise the questions in the analysis will be reported in the protocol. At a minimum, they should be reported in the review.

Another possibility is that both the broad and narrower questions could be addressed in the same review. For example, the two types of interventions in panel B may be included in the one synthesis, presented as separate subgroups with an estimate for each subgroup and overall (i.e. a plan to group at more than one level). Alternatively, the broad question (panel A) might only be addressed if there is too little evidence to address the more specific (narrower) questions (i.e. a 'contingency' plan).



Checklist template

	Item	Essential and additional elements*	Location
What to report in the protocol and review			
1	Specify population and intervention groups to be used in the synthesis	● Label each group. ● Define each group in enough detail to replicate decisions about which intervention (or population) group(s) each study is eligible for. Where the definitions are based on an established source (e.g. a taxonomy of interventions), it may be sufficient to identify and reference the source. ● If your review includes studies with multi-component interventions, specify how these will be defined and grouped for each synthesis. ● If your review includes inactive comparators (e.g. usual care, no intervention), specify how they will be grouped for synthesis. ● Describe any plans to group at multiple levels, to address both broad and specific questions. ● Describe any contingency plans for accommodating the amount of available evidence (e.g. a plan to group more broadly if too few studies to address specific questions). ● *Consider presenting detailed definitions in boxes or tables.* ● *Consider using logic models or figures to provide a visual summary of groups, and the links between different PICO elements and the groups within each.*	
2	Specify outcome groups to be used in the synthesis.	● Label each outcome group. ● Define each outcome group (i.e. 'what is being measured') in enough detail to enable eligible outcomes from each included study to be categorised. ● Specify the measurement methods or tools/scales that provide an appropriate assessment of the domain (i.e. 'how the outcome is measured'). ● Specify the time frame of the outcome group (i.e. 'when the outcome is measured') (e.g. up to 12 weeks). ● Describe any plans to group outcomes at multiple levels, to address both broad and specific questions (e.g. 'what is the effect of anti-depressants on depression' versus 'what is the effect of anti-depressions on depression measured using the Hamilton Depression Rating Scale'). ● Describe any contingency plans for accommodating the amount of available evidence (e.g. a plan to group 'any health behaviour' outcome if there are too few studies to examine effects on specific health behaviours). ● *Consider presenting detailed information in tables.*	
3	Give a rationale for the groups	● For each PICO element, describe the basis for grouping with a rationale. ● If grouping is based on an existing system (e.g. a published conceptual framework, taxonomy or core outcome set, or other reviews), identify and reference the source, noting any adaptations made for the review. ● *Consider presenting a logic model or figure to provide a visual summary of the links between the different PICO elements and the groups within each, and the mechanisms (pathways) of action.*	
4	Identify the role of each group in the synthesis	● Identify which of the specified groups will form the basis of comparisons and any groups that will be used to stratify studies within the comparisons. ● If applicable, identify which of the specified groups will be used to explore possible causes of variation in the effects of an intervention (e.g. in subgroup analyses or meta-regression).	

	Item	Essential and additional elements*	Location
		● If applicable, identify which of the specified groups will be used in sensitivity analyses to test the robustness of the findings to the decisions or assumptions made in the analysis. ● Identify any other roles the specified groups have in the synthesis or summary (e.g. to structure text, tables or figures). ● If a logic model or figure is used to display groups, be explicit about the role of these groups in the synthesis.	
5	Specify the pairwise comparisons that will be made between intervention groups	● Specify all of the comparisons to be made between intervention groups (including controls) ● Specify the order of importance of the comparisons or state that there is no order of importance. ● Specify whether co-interventions will be included in the same or separate comparisons. ● Provide a rationale for the selected comparisons (when these are a subset of all possible comparisons).	
6	Ensure that the Objectives align with the questions addressed in the synthesis	● Ensure that the objectives cover the questions addressed in the synthesis in sufficient detail to match the objectives to the corresponding syntheses. ● Use consistent wording (terminology) across all sections of the review where the questions addressed in the synthesis are reported, including in the objectives.	
7	Specify methodological groups to be used in the synthesis.	● Provide the basis for grouping with a rationale. ● Label each methodological group. ● Define each methodological group in enough detail to enable classification of studies into groups. ● Describe the role of the methodological groups in the synthesis.	
8	Identify how patients, the public and other stakeholders informed the development of questions to be addressed in the synthesis	● Describe how patients and the public, and other stakeholders, informed the development of questions (ideally using the constructs of the ACTIVE the framework). If there was no PPI or other stakeholder involvement, state this.	
9	Describe the processes used to decide which studies were eligible for each synthesis **	● Describe the processes to be 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.	
Additional information to report in the review			
10	Identify changes made at review stage to the groups or comparisons reported in the protocol	● Label and define any groups used in the review that were not reported in the protocol. ● List any comparisons made in the review that were not reported in the protocol. ● Provide a rationale for any changes made during the review to the planned groups or comparisons.	
11	Report the results in accordance with the groups and comparisons specified in the methods	● Report using the same groups and comparisons as specified in the methods. ● Report using the same group labels.	

* 'Additional elements' enhance reporting but are not essential. They appear in italics. ** Reproduced from PRISMA 2020 https://www.bmj.com/content/372/bmj.n160

Item elaborations

Item 1. Specify population and intervention groups to be used in the synthesis

Explanation

In any synthesis, studies with similar features are grouped in order to examine intervention effects, or factors that modify effects (see **Box 1**). Providing a clear label and definition for each of the intervention and population groups to be used in the synthesis will help readers understand the planned structure of the synthesis and assess whether the proposed groupings will appropriately address the objectives of the review. Such description will also help ensure methods are transparent and that decisions about which studies contribute to each synthesis are replicable.

Reporting of groups used in the synthesis should:

- be explicit (not implied);
- be presented as a complete list (not limited to examples);
- avoid using labels without definition (such as 'usual care' without stating 'as defined by trialists' or providing criteria to define usual care);
- cover all syntheses (i.e. comparisons, subgroups), structured summaries (e.g. text and results tables), and summaries of the review (e.g. Summary of Findings tables);
- cover any plans to group at more than one level in order to address both a broad question (e.g. what is the effect of 'any exercise intervention') and more specific questions (e.g. what is the effect of: 'weight-bearing exercise', 'non-weight-bearing exercise' …); and
- cover any contingencies, such as plans to group more broadly if there are insufficient studies to address specific questions (e.g. a plan to group 'all forms of exercise' if there are too few studies to examine specific types of exercise).

Where to report

Groups may be specified in different sections of the review (e.g. Background, Methods) and in different formats (e.g. dot point list, descriptive text, boxes or tables, logic models or figures) as long as it is clear to the reader that the specified groups are to be used in the synthesis. See examples.

Essential elements

- Label each group.
- Define each group in enough detail to replicate decisions about which intervention (or population) group(s) each study is eligible for. Where the definitions are based on an established source (e.g. a taxonomy of interventions), it may be sufficient to identify and reference the source.
- If your review includes studies with multi-component interventions, specify how these will be defined and grouped for each synthesis.
- If your review includes inactive comparators (e.g. usual care, no intervention), specify how they will be grouped for synthesis.
- Describe any plans to group at multiple levels, to address both broad and specific questions.

Describe any contingency plans for accommodating the amount of available evidence (e.g. a plan to group more broadly if too few studies to address specific questions).

Additional elements

- Consider presenting detailed definitions in boxes or tables.
- Consider using logic models or figures to provide a visual summary of groups, and the links between different PICO elements and the groups within each.

Reporting and conduct guidance

PRISMA 2020

Item 5 (essential element). 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 #4).

Item 13e (essential element): 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).

SWiM

Item 1a. Provide a description of, and rationale for, the groups used in the synthesis (eg, groupings of populations, interventions, outcomes, study design).

MECIR

Item C2 (Mandatory). Predefining objectives: Define in advance the objectives of the review, including participants, interventions, comparators and outcomes (PICO).
Item C4 (Highly desirable). Considering equity and specific populations: Consider in advance whether issues of equity and relevance of evidence to specific populations are important to the review, and plan for appropriate methods to address them if they are. Attention should be paid to the relevance of the review question to populations such as low-socioeconomic groups, low- or middle-income regions, women, children and older people.
Item C7 (Mandatory). Predefining unambiguous criteria for interventions and comparators: Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.
Item C62 (Mandatory). Ensuring meta-analyses are meaningful: Undertake (or display) a meta-analysis only if participants, interventions, comparisons and outcomes are judged to be sufficiently similar to ensure an answer that is clinically meaningful.

Handbook guidance

For population groups, see Chapter 3, Section 3.2.1.
For intervention groups, see Chapter 3, Section 3.2.2.
For inactive comparators, see Chapter 3, Section 3.2.3.

Additional resources

TIDieR checklist: Template for Intervention Description and Replication (reporting guideline)
TIDieR-PHP checklist: reporting guideline for population health and policy interventions

Item 2. Specify outcome groups to be used in the synthesis

Explanation

Fully specifying outcome groups (domains) to be used in each synthesis allows readers to understand the specific research questions addressed in the review (i.e. the review objectives); for example, whether a review of new generation antidepressants will examine the effects of antidepressants on 'depression at any time point', 'depression in the short term (up to 12 weeks)', 'depression in the longer term (up to 12 months)', or all three outcome groups. Moreover, fully specifying each outcome group enables readers to confirm whether the groups use in the synthesis were planned or were driven by what was reported in the studies. Providing sufficient detail also aids in replication of the decisions about which studies contribute to each synthesis. This is particularly important for outcomes assessed by measurement scales, where different scales are used across the studies, and decisions are needed as to whether the scales provide a measure of the review outcome, and thus should contribute to the synthesis.

A scenario to avoid is providing a list of outcomes in the 'Types of outcome measures' section, without clearly specifying the level at which the outcomes will be grouped for synthesis. For example, by having a heading 'depression' under which are listed 'Hamilton Depression Rating Scale (HAM-D)', 'Montgomery-Asberg Depression Rating Scale (MADRS)', 'Children's Depression Rating Scale (CDRS-R)', it is not clear if the planned group for synthesis is 'depression', or if separate syntheses will be undertaken for each of the measurement scales.

Where to report

Essential elements of the outcome groups to be used in the synthesis are often reported in the 'Types of outcome measures' section within the Cochrane protocol or review template. Detailed definitions may be reported in tables See examples.

Essential elements

- Label each outcome group.
- Define each outcome group (i.e. 'what is being measured') in enough detail to enable eligible outcomes from each included study to be categorised.
- Specify the measurement methods or tools/scales that provide an appropriate assessment of the domain (i.e. 'how the outcome is measured').
- Specify the time frame of the outcome group (i.e. 'when the outcome is measured') (e.g. up to 12 weeks).
- Describe any plans to group outcomes at multiple levels, to address both broad and specific questions (e.g. 'what is the effect of anti-depressants on depression' versus 'what is the effect of anti-depressions on depression measured using the HAM-D' 'what is the effect … using the CDRS-R' etc).
- Describe any contingency plans for accommodating the amount of available evidence (e.g. a plan to group 'any health behaviour' outcome if there are too few studies to examine effects on specific health behaviours).

Additional elements

- Consider presenting detailed information in tables.

Reporting and conduct guidance

PRISMA 2020

Item 10a (essential element). List and define the outcome domains and time frame of measurement for which data were sought.

SWiM

Item 1a. Provide a description of, and rationale for, the groups used in the synthesis (e.g., groupings of populations, interventions, outcomes, study design).

Item 2. Describe the standardised metric and transformation methods used. Describe the standardised metric for each outcome. Explain why the metric(s) was chosen, and describe any methods used to transform the intervention effects, as reported in the study, to the standardised metric, citing any methodological guidance consulted.

MECIR

Item C14 (Mandatory). Predefining outcome domains: Define in advance outcomes that are critical to the review, and any additional important outcomes.
Item C18 (Highly desirable). Predefining time points of interest: Define in advance the timing of outcome measurement.
Item C62 (Mandatory). Ensuring meta-analyses are meaningful: Undertake (or display) a meta-analysis only if participants, interventions, comparisons and outcomes are judged to be sufficiently similar to ensure an answer that is clinically meaningful.

Handbook guidance

See Chapter 3, Section 3.2.4.
Outcomes (from Table 3.2.c)

- 1. Fully specific outcome domains ('what is measured', 'when' and 'how' the outcome is measured)
- 3. Define the outcome time points
- 4. Specify the measurement tool or measurement method

Item 3. Give a rationale for the groups

Explanation

The groups used in a synthesis can be based on a variety of characteristics (e.g. intervention content, purpose or mode of delivery; outcome measurement method or timing; population characteristics associated with inequitable health outcomes). Decisions about grouping may be underpinned by a theoretical rationale (e.g. the possible mechanism(s) of action), an existing system, empirical evidence, current practice, the priorities of decision-makers (see Item 8) or other factors. Decisions should also account for practical issues that impact on the synthesis. For example, the amount of available evidence will determine whether it is possible to answer specific or more general questions (reflected in narrow or broader groupings).

Reporting the basis for the groups used in the synthesis and the associated rationale helps the reader understand what options were considered and why particular decisions were made. Such decisions may seem self-evident to the review authors, but may not be evident to readers of the review unless reported. This includes the special case where all types or variants of a seemingly diverse category of interventions (or other PICO element) are included in a single broad group for synthesis (e.g. any exercise, any psychosocial intervention, any health behaviour outcome). Providing an explicit rationale for the groups used in the synthesis enables readers to verify that the approach aligns with the review objectives, rather than being driven by available studies. This is especially important for analyses that examine whether particular characteristics modify the intervention effects (e.g. intervention intensity or setting), the credibility of which is increased by pre-specifying a scientific rationale for the hypothesised direction of effect modification.

Where to report

In general, the rationale for grouping should be reported with the description of the groups for synthesis. In some instances, for example where more detailed explanation is required or a logic model is used, it may be more practical to present the rationale elsewhere (e.g. in the Background) and cross-reference from the methods. See examples.

Essential elements

- For each PICO element, describe the basis for grouping with a rationale.
- If grouping is based on an existing system (e.g. a published conceptual framework, taxonomy or core outcome set, or other reviews), identify and reference the source, noting any adaptations.

Additional elements

- Consider presenting a logic model or figure to provide a visual summary of the links between the different PICO elements and the groups within each, and the mechanisms (pathways) of action.

Reporting and conduct guidance

PRISMA 2020

No related item for providing a rationale for the groups used in comparisons
Item 13e (essential element): 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).

SWiM

Item 1a. Provide a description of, and rationale for, the groups used in the synthesis (eg, groupings of populations, interventions, outcomes, study design)

MECIR

Item C22 (Mandatory). Planning sub-group analyses: Predefine potential effect modifiers (e.g. for subgroup analyses) at the protocol stage; restrict these in number, and provide rationale for each.

Handbook guidance

For population groups, see Chapter 3, Section 3.2.1.
For intervention groups, see Chapter 3, Section 3.2.2.
For inactive comparators, see Chapter 3, Section 3.2.3.
For outcome groups, see Chapter 3, Section 3.2.4.

Item 4. Identify the role of each group in the synthesis

Explanation

Specifying how groups will be used in the synthesis enables readers to understand how the synthesis is structured. It should be clear to readers whether the groups will be used:

- as the basis of comparisons (i.e. intervention groups and outcomes specified for each meta-analysis or other synthesis);
- to structure text, tables or figures (e.g. to stratify studies in a forest plot according to population or intervention characteristics, or by methodological characteristics);
- to explore possible causes of variation in the effects of an intervention (i.e. in subgroup analyses or meta-regression used to explore possible causes of statistical heterogeneity);
- to assess the robustness of the results of the synthesis to the decisions or assumptions made in the analysis (i.e. in sensitivity analyses); or
- to convey the scope of the review, for example the range of populations or interventions included in the review, with no intended role in the synthesis.

Identifying the role of each group in the synthesis is especially important in the common scenario where specific interventions or outcomes are listed under broad categories. Take for example a review where the authors report that "eligible interventions include 'relational approaches' (e.g. parent-child interventions, family-focused interventions) and 'mind-body approaches' (e.g. group music therapy, trauma-focused art therapy, yoga)" and "eligible comparators are 'any inactive control'." Further detail is needed so that readers can tell how the authors will structure their synthesis. For example,

- use the broad categories as the basis for separate comparisons (relational approaches vs. control; mind-body approaches vs. control)
- use the broad categories as the basis for separate comparisons and within these stratify by the specific types of intervention;
- use the specific types of interventions as the basis for separate comparisons (e.g. parent-child intervention vs. control; yoga vs. control), and the broad categories as headings in the text; or
- use the specific interventions only to convey the scope of interventions eligible for the review, and include all intervention types in the same synthesis.

Where to report

Judgement is needed about the most appropriate section of the review in which to report the role of the groups in the synthesis. For example, addressing Item 5 would identify the role of groups used for comparisons without further explanation. Groups used to investigate heterogeneity or in sensitivity analysis are often reported in subsections of the 'Data synthesis' section (i.e. 'Subgroup analysis and investigation of heterogeneity', 'Sensitivity analysis') within the Cochrane protocol or review template. See examples.

Essential elements

- Identify which of the specified groups will form the basis of comparisons and any groups that will be used to stratify studies within the comparisons.
- If applicable, identify which of the specified groups will be used to explore possible causes of variation in the effects of an intervention (e.g. in subgroup analyses or meta-regression).
- If applicable, identify which of the specified groups will be used in sensitivity analyses to test the robustness of the findings to the decisions or assumptions made in the analysis.
- Identify any other roles the specified groups have in the synthesis or summary (e.g. to structure text, tables or figures).
- If a logic model or figure is used to display groups, be explicit about the role of these groups in the synthesis.

Reporting and conduct guidance

MECIR

Item C2 (Mandatory) Predefining objectives: Define in advance the objectives of the review, including participants, interventions, comparators and outcomes (PICO).
Item C22 (Mandatory). Planning sub-group analyses: Predefine potential effect modifiers (e.g. for subgroup analyses) at the protocol stage; restrict these in number, and provide rationale for each.

Handbook guidance

For specifying the eligibility for synthesis, see Chapter 3.
For investigating heterogeneity, see Chapter 10, Section 10.11.
For sensitivity analysis, see Chapter 10, Section 10.14.

Item 5. Specify the pairwise comparisons that will be made between intervention groups

Explanation

Specifying the pairwise comparisons that will be made between intervention groups allows readers to understand the planned syntheses and assess whether they align with the review objectives. In reviews with only two intervention groups (e.g. cognitive behaviour therapy (CBT), wait-list (WL) control) the pairwise comparison is self-evident (CBT versus WL). This is not the case when there are multiple intervention groups. For example, in a review including the intervention groups CBT, behaviour therapy (BT), cognitive therapy (CT), and WL, there are six possible comparisons; however, only a subset of comparisons may be of interest in the review (e.g. CBT versus WL, BT versus WL, CT versus WL). Furthermore, within the set of comparisons of interest, some may be considered more important than others for decision making. Pre-specifying the comparisons, whether there is an order of importance (and, if so, what that order is) reassures readers that the comparisons as presented were planned, and are not just those showing 'interesting' or 'favourable' results.

In the special case of co-interventions, where the same supplementary intervention is delivered in both intervention groups (e.g. CBT + antidepressant versus WL + antidepressant), it is important to specify whether these studies will contribute to the same comparison (e.g. CBT versus WL), or be considered a different comparison. If the first option is taken, an additional consideration to report is whether there will be subgrouping by the comparisons involving co-interventions and those without.

Where to report

Currently there is no specific 'Comparisons' section within the Cochrane protocol or review template; however, a user-specified subheading can be created. This may most appropriately be placed under the 'Data synthesis' section of the Methods, although there may be reasons for preferring placement under the 'Criteria for considering studies for this review - Types of interventions' section. See examples.

Essential elements

- Specify all of the comparisons to be made between intervention groups (including controls).
- Specify the order of importance of the comparisons (or state that there is no order).
- Specify whether co-interventions will be included in the same or separate comparisons.
- Provide a rationale for the selected comparisons (when these are a subset of all possible comparisons).

Reporting and conduct guidance

MECIR

Item C2 (Mandatory) Predefining objectives: Define in advance the objectives of the review, including participants, interventions, comparators and outcomes (PICO).

Handbook guidance

For defining comparisons, see Chapter 3, Section 3.2.3.
For co-interventions, see Chapter 3, Section 3.2.3.1.
For broader questions as contingencies, see Chapter 2, Section 2.5.3.

Item 6. Ensure that the Objectives align with the questions addressed in the synthesis

Explanation

While authors are encouraged to define the objectives of their review before developing detailed PICO criteria, ultimately it is important to ensure that there is alignment between the reporting of the review objectives and the specific questions defined in the PICO for each synthesis. These PICO are articulated through the specification of groups and their role in the synthesis (Items 1 to 5) and can be considered an operationalisation of the review objectives. As a final step in reporting, authors should ensure that the objectives cover the questions (to be) addressed in the synthesis using consistent wording. Doing so enables readers to understand the purpose of the review and match the objectives to the corresponding syntheses and findings.

Take, for example, a review of school-based interventions to promote physical activity. After defining the intervention, outcome and population groups to be used in the synthesis, the authors should ensure that their objectives capture the defined groups and how these will be used in the synthesis.

For example, the objectives might be:

1. to estimate the pooled effect of school-based interventions on physical activity, fitness and body composition and whether this effect is modified by type of intervention and age (children versus adolescents); and
2. to estimate the effect of each type of school-based intervention (i.e. before or after school physical activity, enhanced physical education classes, school time physical activity, multi-component), compared with usual practice, on physical activity, fitness and body composition.

Note in this example, the authors plan to synthesise at two levels; in the first, examining 'any' school-based interventions to promote physical activity versus usual practice, and in the second examining the effects of four specific types of interventions (each need to be defined). We would expect all five intervention groups and their role in the synthesis to be identified in detail later in the review, and the same for the outcome and population groups. If the authors had elected to examine the effects of 'any' school-based intervention, then we would expect a rationale so that it is clear to the reader that the objectives and synthesis questions align.

Where to report

In the Objectives section.

Essential elements

- Ensure that the objectives cover the questions addressed in the synthesis in sufficient detail to match the objectives to the corresponding syntheses.
- Use consistent wording (terminology) across all sections of the review where the questions addressed in the synthesis are reported, including in the objectives.

Reporting and conduct guidance

PRISMA 2020

Item 4 (essential element).

- Provide an explicit statement of all objective(s) or question(s) the review addresses, expressed in terms of a relevant question formulation framework.
- 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.

MECIR

Item C2 (Mandatory) Predefining objectives: Define in advance the objectives of the review, including participants, interventions, comparators and outcomes (PICO).

Handbook guidance

See Chapter 2, Section 2.3.

Item 7. Specify methodological groups to be used in the synthesis

Explanation

The focus of systematic reviews of interventions is to address research questions about the benefits and harms of interventions; items 1 -5 guide review authors in articulating these. A common secondary focus will be to examine whether the findings from analyses addressing these research questions are robust to methodological factors (e.g. risk of bias (RoB), study design features, outcome assessment methods). Such analyses can reassure readers, and thus provide them with confidence in the findings or, conversely, raise concerns.

Similar to populations, interventions and outcomes, it is important to provide a clear label and definition of each methodological group to be used in the synthesis (e.g. low RoB studies, some concerns / high RoB studies; OR low / some concerns RoB studies, high RoB studies), the basis for grouping with a rationale (item 3), and role of the group in each synthesis (e.g. sensitivity analysis, subgroup analysis) (item 4).

Providing readers with sufficient detail of the methodological factors, groups and role in the synthesis, allows readers to:

- assess whether all important factors have been investigated;
- verify that the analyses are not data driven to obtain a desired result; and
- replicate decisions about which studies contribute to each methodological group.

Where to report

Essential elements of methodological groups to be used in the synthesis are often reported in subsections of the 'Data synthesis' section (i.e. 'Subgroup analysis and investigation of heterogeneity', 'Sensitivity analysis') within the Cochrane protocol or review template. See examples.

Essential elements

- Provide the basis for grouping with a rationale.
- Label each methodological group.
- Define each methodological group in enough detail to enable classification of studies into groups.
- Describe the role of the methodological groups in the synthesis.

Reporting and conduct guidance

MECIR

Item C57 (Highly desirable). Addressing risk of bias in the synthesis: Address risk of bias in the synthesis (whether quantitative or non-quantitative). For example, present analyses stratified according to summary risk of bias, or restricted to studies at low risk of bias.

Handbook guidance

For groups based on study designs, see Chapter 3, Section 3.3.
For groups based on risk of bias, see Chapter 7, Section 7.6.2.

Item 8. Identify how patients, the public and other stakeholders informed the development of questions to be addressed in the synthesis

Explanation

Patient and public involvement (PPI) in research, including development of review questions, can improve the relevance of research to patients.[1,2] PPI may include involving patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services.[3] Other stakeholders, including health professionals, health decision makers and funders, may also be involved in the development of the questions.

Stakeholders (including patients and public) can be involved in any aspect of the development of questions; for example, identifying patient important outcomes (see Item 2) or prioritising pairwise comparisons (see Item 5). The 'ACTIVE (Authors and Consumers Together Impacting on eVidencE) framework' provides a structure for guiding and describing stakeholders' involvement in systematic reviews.[4] Constructs of the framework include 'who was involved?', 'how were stakeholders recruited?', 'what was the mode of involvement?', 'at what stage in the review process did involvement occur?' and 'what was the level of involvement?'. Reporting the development of review questions against these constructs may help end users assess the likely relevance of the review.

Where to report

Stakeholders' involvement across the review stages (including development of the review questions) should ideally be reported in its own section. This could be a section in the Methods or included as additional supplementary materials. When the rationale for adopting specific methods choices (e.g. choice of outcome domains) is influenced by stakeholders, this might also be reported in the corresponding Methods section (e.g. Types of outcome measures). See examples.

Essential elements

- Describe how patients and the public, and other stakeholders, informed the development of questions (ideally using the constructs of the ACTIVE the framework). If there was no PPI or stakeholder involvement, state this.

Reporting and conduct guidance

MECIR

Item C1 (Mandatory). Formulating review questions: Ensure that the review question and particularly the outcomes of interest, address issues that are important to review users such as consumers, health professionals and policy makers.
Item C15 (Mandatory). Choosing outcomes: Choose only outcomes that are critical or important to users of the review such as healthcare consumers, health professionals and policy makers.

Handbook guidance

For engaging stakeholders to define the review questions, see Chapter 2, Section 2.4.2.
For outcomes, see Chapter 3, Section 3.2.4.

Additional resources

[1] Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ*. 2017;358:j3453.
[2] Kreis J, Puhan MA, Schünemann HJ, Dickersin K. Consumer involvement in systematic reviews of comparative effectiveness research. *Health Expectations*. 2013;16(4):323-337.
[3] INVOLVE. *Briefing notes for researchers: involving the public in NHS, public health and social care research*. INVOLVE; 2021.
[4] Pollock A, Campbell P, Struthers C, et al. Development of the ACTIVE framework to describe stakeholder involvement in systematic reviews. *Journal of Health Services Research & Policy*. 2019;24(4):245-255.

Cochrane Engaging Stakeholders framework
Cochrane Consumer Network, *Involving consumers (patients and public) in your Cochrane review – a brief guide for authors*
ACTIVE (Authors and Consumers Together Impacting on eVidencE) framework
GRIPP2 reporting checklists

Item 9. [Reproduced from PRISMA 2020 item 13a] Describe the processes used to decide which studies were eligible for each synthesis

Explanation

Before undertaking any statistical synthesis ([PRISMA 2020] item #13d), decisions must be made about which studies are eligible for each planned synthesis ([PRISMA 2020] item #5. These decisions will likely involve subjective judgments that could alter the result of a synthesis, yet the processes used and information to support the decisions are often absent from reviews. Reporting the processes (whether formal or informal) and any supporting information is recommended for transparency of the decisions made in grouping studies for synthesis. Structured approaches may involve the tabulation and coding of the main characteristics of the populations, interventions, and outcomes. For example, in a review examining the effects of psychological interventions for smoking cessation in pregnancy, the main intervention component of each study was coded as one of the following based on pre-specified criteria: counselling, health education, feedback, incentive-based interventions, social support, and exercise.[5] This coding provided the basis for determining which studies were eligible for each planned synthesis (such as incentive-based interventions versus usual care). Similar coding processes can be applied to populations and outcomes.

Where to report

Report in either the 'Data extraction and management' section or the 'Data synthesis' section within the Cochrane protocol or review template. The location will depend on the approach authors take to the coding and analysis of the PICO elements of studies (i.e. whether part of the data extraction/coding, the qualitative synthesis of study characteristics or a mix). See examples.

Essential elements

- Describe the processes to be 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.

Reporting and conduct guidance

PRISMA 2020

Item 13a (essential element). 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)

Handbook guidance

See Chapter 9, Section 9.3.

[5] Note: Reference in PRISMA 2020 paper removed. See https://doi.org/10.1136/bmj.n160 for complete text.

Item 10. Identify changes made at review stage to the groups or comparisons reported in the protocol

Explanation

When conducting a review, especially one involving intervention complexity, authors may need to change the groups or comparisons reported in the protocol in order to make best use of available data. Examples include:

- where insufficient studies are found for a planned comparison a decision may be taken to group more broadly (including the decision to include 'any' intervention in a single group);
- where insufficient information is available to decide which studies are eligible for a planned group;
- where a group emerges but was not identified at planning stage; or
- where an important potential effect modifier has been overlooked at the planning stage.

Any changes from what was planned should be reported with a rationale and the new approach described.

Where to report

Any new groups or comparisons should be reported in the Methods section (e.g. a new comparison should be added to the list of comparisons). All changes, including methods not used should also be described in the 'Differences between protocol and review' section. See examples.

Essential elements

- Label and define any groups used in the review that were not reported in the protocol.
- List any comparisons made in the review that were not reported in the protocol.
- Provide a rationale for any changes made during the review to the planned groups or comparisons.

Reporting and conduct guidance

PRISMA 2020

Item 24c (essential element). 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.

SWiM

Item 1b. Detail and provide rationale for any changes made subsequent to the protocol in the groups used in the synthesis.

Item R107 (mandatory). Changes from the Protocol: Explain and justify any changes from the protocol (including any post hoc decisions about eligibility criteria or the addition of subgroup analyses).
Item R108 (mandatory). Methods not implemented: Document aspects of the protocol that were not implemented (e.g. because no studies, or few studies, were found) in the section 'Differences between protocol and review', rather than in the Methods section.

Handbook guidance

See Chapter 1, Section 1.5.

Item 11. Report the results in accordance with the groups and comparisons specified in the methods

Explanation

The reporting of the results should be consistent with the final PICO for each synthesis reported in the objectives and methods. Consistency helps readers navigate the review and enables easy matching of the results to the questions. Consistency can be achieved in a number of ways; for example, by:

- using the same groups and comparisons as specified in the methods;
- using the same group labels (i.e. using consistent terminology);
- presenting the results in the same order as the objectives are presented;
- including headings in the results to indicate which objectives are being addressed.

In the circumstance where syntheses cannot be undertaken, the groups and comparisons specified in the methods can still be used to structure the text of the review, tables and figures, as well as summary versions of the review (Summary of Findings Tables, Abstract, Plain language summary).

Essential elements

- Report using the same groups and comparisons as specified in the methods.
- Report using the same group labels.

Reporting and conduct guidance

PRISMA 2020

Item 20b (essential element). Report results of all statistical syntheses described in the protocol and all syntheses conducted that were not pre-specified.

SWiM

Item 8. Reporting results: For each comparison and outcome, provide a description of the synthesised findings, and the certainty of the findings. Describe the result in language that is consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis.

MECIR

Item C68 **(Mandatory)**. Interpreting subgroup analyses: *If subgroup analyses are conducted*, follow the subgroup analysis plan specified in the protocol without undue emphasis on particular findings.

Handbook guidance

For Summary of Findings Tables, see Chapter 14, Section 14.1

Appendix: Examples

Item	Complete reporting example	Incomplete reporting example
Item 1. Specify population and intervention groups to be used in the synthesis	We stratified each primary outcome by country under-five mortality rates taken from the UNICEF report on levels and trends in child mortality (UNICEF 2019), as follows: ● Low-mortality countries: those in the lowest quartile of under-five child mortality rates ● Medium-mortality countries: those in the second quartile of under-five child mortality rates ● High-mortality countries: those in the highest two quartiles of under-five child mortality rates. *Source: Bergman H, et al. Vaccines for preventing rotavirus diarrhoea: vaccines in use. Cochrane Database of Systematic Reviews 2021, Issue 11.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008521.pub6/full*	We sought to compare the effectiveness of rotavirus vaccines in countries with low and high child mortality rates.
	Comparisons are based on the following interventions. 1. Counselling interventions are those which provide motivation to quit, support to increase problem solving and coping skills (Ortendahl 2007c; Ortendahl 2008a; Ortendahl 2009b), and may incorporate 'transtheoretical' models of change (Prochaska 1992; Prochaska 2007). This includes interventions such as motivational interviewing, cognitive behaviour therapy, psychotherapy, relaxation, problem solving facilitation, and other strategies. Counselling interventions may be provided face-to-face, by telephone, via interactive computer programs, or using audiovisual equipment. The duration of counselling may range from brief interventions (less than five minutes) to more intensive interventions, which can last for up to an hour and be repeated over multiple sessions. Counselling may be provided by a range of personnel, including pregnancy care providers, trained counsellors, or others, on-site or by referral to specialist stop smoking services. Interventions that involved provision of videos with personal stories were included as counselling in this review. 2. Health education interventions are defined as those where women are provided with information about the risks of smoking and advice to quit, but are not given further support or advice about how to make this change. Interventions where the woman was provided with automated support such as self-help manuals or automated text messaging (e.g. Naughton 2012), but there was no personal interaction at all, were coded as health education in this review. 3. Feedback interventions are those where the mother is provided with feedback with information about the fetal health status or measurement of by-products of tobacco smoking to the mother. This includes interventions such as ultrasound monitoring and carbon monoxide or urine cotinine measurements, with results fed back to the mother. We did not include studies or interventions where measurements were used for confirming smoking abstinence in the study, provided for participants in both intervention and control arms. *Source: Chamberlain C, O'Mara-Eves A, Porter J, Coleman T, Perlen SM, Thomas J, McKenzie JE. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews 2017, Issue 2. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub5/full*	We included any interventions based on counselling, education or feedback to women about smoking cessation during pregnancy, with information provided online or in person, for any duration.

Item	Complete reporting example	Incomplete reporting example
Item 2. **Specify outcome groups to be used in the synthesis**	We grouped outcomes into three sets of time points. 1. T1: short term/immediate post intervention (defined as 0 to 1 month post intervention) to detect illness recovery/symptom reduction of the intervention. 2. T2: intermediate term (defined as 1 to 6 months post intervention) to detect sustained illness recovery/symptom reduction. 3. T3: longer term (defined as 7 to 24 months post intervention) as a measure of medium- to long-term avoidance of recurrence and chronicity. Subgroup analyses were performed for 1- to 2-year outcomes if available. If an outcome was reported more than once during any of the above time points, we used the latest time point within that category (e.g. if there was a measure at 3 months and at 6 months, we used the results at 6 months for T2) or the time point that correlated best with other studies compared within each outcome. *Source: van Ginneken N, et al. Primary-level worker interventions for the care of people living with mental disorders and distress in low- and middle-income countries. Cochrane Database of Systematic Reviews 2021, Issue 8. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009149.pub3/full*	We considered outcomes measured immediately post-intervention, as well as longer term follow-up.
	For an example of outcomes and measures displayed in table format, see Table 5 in: *Source: Petkovic J, et al. Behavioural interventions delivered through interactive social media for health behaviour change, health outcomes, and health equity in the adult population. Cochrane Database of Systematic Reviews 2021, Issue 5.* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012932.pub2/full	
Item 3. **Give a rationale for the groups**	Mental disorders included are in accordance with the ICD-11 classification of mental disorders (WHO 2019), and include common mental disorders, severe mental disorders, perinatal mental disorders, disorders specifically associated with stress, disorders associated with substance abuse, neurocognitive disorders such as dementia, as well as all mental developmental (e.g. autism), emotional (e.g. mood disorders) and behavioural (e.g. ADHD) disorders associated with childhood (based on those included in the Mental Health Gap Action Programme (mhGAP) guide (WHO 2016). (See Table 1 for further definitions of participants, 'LMIC', and 'primary care', and for the list of included mental disorders, as well as a definition of mental distress.) *Adapted from: van Ginneken, et al. Primary-level worker interventions for the care of people living with mental disorders and distress in low- and middle-income countries. Cochrane Database of Systematic Reviews 2021, Issue 8. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009149.pub3/full*	Mental disorders included are common mental disorders, severe mental disorders, perinatal mental disorders, disorders specifically associated with stress, disorders associated with substance abuse, neurocognitive disorders such as dementia, as well as all mental developmental (e.g. autism), emotional (e.g. mood disorders) and behavioural (e.g. ADHD) disorders associated with childhood (See Table 1 for further definitions of included mental disorders, as well as a definition of mental distress.)
	[W]e have differentiated between interventions that: ● have a sole aim of supporting smoking cessation in pregnancy; ● aim to improve broader maternal health outcomes, but include a smoking cessation component or module.	[W]e have differentiated between interventions that:

Item	Complete reporting example	Incomplete reporting example
	This is because women enrolling in these different types of trials may have different motivations for participating in interventions and characteristics in relation to smoking that are difficult to quantify. Trials that aimed to improve broader maternal health outcomes included only smoking cessation and reduction outcomes, but not infant outcome measures such as birthweight, preterm birth, breastfeeding and perinatal mortality, which might be attributable to other components of the intervention package. *Source: Chamberlain C, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews 2017, Issue 2.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub5/full*	• have a sole aim of supporting smoking cessation in pregnancy; • aim to improve broader maternal health outcomes, but include a smoking cessation component or module.
	Based on a preliminary scoping of the literature, we developed an a priori process-based logic model to display the relationships between intervention domains and outcomes (Figure 1), and a system-based logic model to describe and classify relevant interventions in relation to broader contextual factors (Figure 2). These models represent the authors' evidence-informed understanding of the system in which the measures to protect residents of long-term care facilities were implemented during the present SARS-CoV-2 pandemic. Based on this, we have distinguished four domains of measures that focus on: 1. entry regulations; 2. regulating contacts and reducing transmission; 3. surveillance; and 4. outbreak control measures. *Source: Strati, et al. Non-pharmacological measures implemented in the setting of long-term care facilities to prevent SARS-CoV-2 infections and their consequences: a rapid review. Cochrane Database of Systematic Reviews 2021, Issue 9. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015085.pub2/full*	
Item 4. Identify the role of each group in the synthesis	We performed separate analyses determined by the participant's HPV status as defined by the result of an HPV DNA tests at enrolment. Three groups were distinguished: a) initially hrHPV DNA negative, b) initially HPV16/18 DNA negative, and c) regardless of initial HPV DNA test results. Subgroup analyses were performed, if possible, using age group as a stratifying variable. We distinguished younger (15 to 26 years) from mid-adult women (24 to 45 years), which were the two age groups assessed in the available randomised trials. *Adapted from: Arbyn M, et al. Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors. Cochrane Database of Systematic Reviews 2018, Issue 5.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009069.pub3/full*	We grouped studies by the participant's HPV status as defined by the result of an HPV DNA tests at enrolment (initially hrHPV DNA negative, initially HPV16/18 DNA negative, and regardless of initial HPV DNA test results), and by age group (15 to 26 years, and 24 to 45 years).

Item	Complete reporting example	Incomplete reporting example
Item 5. **Specify the pairwise comparisons that will be made between intervention groups**	We conducted separate comparisons based on the type of control group. We classified control groups as non-interactive social media control when the control was no intervention or a non-interactive social media control, and we classified those which included an interactive social media comparator in the control arm as having 'active social media controls'. For these studies, we considered the most intense intervention (e.g. social media plus other components) to be the 'intervention' (e.g. compared to social media alone). Finally, for studies in which the same social media intervention was provided in both arms, we considered the control to be non-interactive social media (e.g. a Facebook group addressing the health condition of interest compared to a different Facebook group on another topic). In these studies, the outcomes of interest were related to the content for the intervention arm, and participants needed to be active on the social media platform of interest to be eligible. Therefore, the content provided in the control group would be similar to what the participants would be exposed to through their usual social media use so classifying the control groups as non-interactive social media is appropriate. *Source: Petkovic J, et al. Behavioural interventions delivered through interactive social media for health behaviour change, health outcomes, and health equity in the adult population. Cochrane Database of Systematic Reviews 2021, Issue 5.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012932.pub2/full*	We included studies that compared interactive social media interventions to any comparator group, including no intervention, non-interactive social media, or alternative social media interventions.
	We included studies of self-management interventions delivered in any form (e.g. Internet, mobile device, face-to-face, paper) with the following comparisons. 1. Self-management versus usual care 2. Self-management versus an alternate form of self-management (e.g. paper-based booklet versus mobile app) For comparisons between different types of self-management programmes we included co-interventions, including types of exercise interventions, provided that they were evenly distributed between groups. *Source: Kelly C, et al. Self-management for bronchiectasis. Cochrane Database of Systematic Reviews 2018, Issue 2.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012528.pub2/full* [Note that it would be good practice for the authors to define 'usual care'.]	
Item 6. **Ensure that the Objectives align with the questions addressed in the synthesis**	Primary objectives: ● To identify whether psychosocial interventions can support women to stop smoking in pregnancy. ● To compare the effectiveness of the main psychosocial intervention strategies in supporting women to stop smoking in pregnancy (i.e. counselling, health education, feedback, social support, incentives, exercise). *Source: Chamberlain C, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews 2017, Issue 2.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001055.pub5/full*	This review evaluated the effect of psychosocial interventions designed to support women to stop smoking in pregnancy.
Item 7. **Specify methodological groups**	To ensure that we captured all relevant study types, we considered a broad range of empirical studies of any size that provided a quantitative measure of impact, including experimental and quasi-experimental studies, observational studies, and mathematical modelling studies. Given that empirical and observational studies provide a measured	To ensure that we captured all relevant study types, we considered a broad range of empirical studies of any size that provided a quantitative measure

Item	Complete reporting example	Incomplete reporting example
to be used in the synthesis	estimate of effect whereas modelling studies predict such an effect, we treated these as two separate bodies of evidence in the synthesis. *Adapted from Burns J, et al. International travel-related control measures to contain the COVID-19 pandemic: a rapid review. Cochrane Database of Systematic Reviews 2021, Issue 3.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013717.pub2/full*	of impact, including experimental and quasi-experimental studies, observational studies, and mathematical modelling studies.
Item 8. **Identify how patients, the public and other stakeholders informed the development of questions**	**Ensuring relevance to decisions in health care** The protocol received feedback from health providers and family members who receive a family-centred intervention through Apunipima Cape York Health Service (Australia) about the meaning and relevance of family-centred interventions for them (McCalman 2016). We intended to conduct further pre-planned meetings using formal group methods to reach consensus decisions on key issues relating to the structure and methods of the review; however, this was not possible. *Source: Strobel NA, et al. Family-centred interventions for Indigenous early childhood well-being by primary healthcare services. Cochrane Database of Systematic Reviews 2022, Issue 12.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012463.pub2/full*	
	Justification of outcome measures Our recent research to define and prioritise core outcome domains for the evaluation of vaccination communication interventions informed the selection of outcomes for this review (Kaufman 2017; Kaufman 2017a). First, we developed a taxonomy of potential vaccination communication outcomes that were derived from trials, non-vaccination health communication studies, and focus groups with stakeholders (parents, healthcare providers, researchers, and policymakers; Kaufman 2017). This taxonomy organised outcomes into eight domains: 1) knowledge or understanding, 2) attitudes or beliefs, 3) vaccination status and behaviours, 4) communication delivery and design, 5) community participation, 6) decision making, 7) health status and well-being, and 8) cost. Using a Delphi survey, we asked representatives from each stakeholder group to rate the relative importance of each of these outcome domains when evaluating a communication intervention to inform or educate about vaccination (Kaufman 2017a). The top four domains for this type of intervention, according to stakeholders, were 'knowledge or understanding', 'attitudes or beliefs', 'vaccination status and behaviours', and 'communication delivery and design'. Therefore, we ensured that outcomes from each of these domains were captured by this review. *Source: Kaufman J, et al. Face-to-face interventions for informing or educating parents about early childhood vaccination. Cochrane Database of Systematic Reviews 2018, Issue 5.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010038.pub3/full*	
	The review protocol was developed with input from an international advisory group. This group comprised people who proactively contacted the lead review author to offer support to the review (either after seeing the registered title for a Cochrane rapid review, or seeing Scottish Government funding announcement), and members recruited though the Cochrane Consumers COVID-19 rapid review panel. This group represents diverse professional and geographical backgrounds, including frontline healthcare professionals within the COVID-19 pandemic and earlier	

Item	Complete reporting example	Incomplete reporting example
	epidemics (e.g. Ebola). All members of the team had an interest in synthesising the evidence in relation to the impact of COVID-19 on the mental health and well-being of health and social care professionals, in order to urgently identify optimal ways of supporting frontline workers who are working in highly stressful circumstances. However, while there was engagement and involvement of this group at the start of the review, with considerable input at the protocol stage, and with some individual members providing substantial input during the searching and selection of studies stage, the involvement during stages of data extraction and synthesis was considerably less. This was due to the review team lacking the time to maintain communication and involvement with this group of people. However, all group members were invited to comment on a pre-publication version of the review, and a number of changes were made in response to these peer-review comments. *Adapted from: Pollock A, et al. Interventions to support the resilience and mental health of frontline health and social care professionals during and after a disease outbreak, epidemic or pandemic: a mixed methods systematic review. Cochrane Database of Systematic Reviews 2020, Issue 11.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013779/full*	
Item 9. Describe the processes used to decide which studies were eligible for each synthesis	Given the complexity of the interventions being investigated, we attempted to categorize the included interventions along four dimensions: (1) was housing provided to the participants as part of the intervention; (2) to what degree was the tenants' residence in the provided housing dependent on, for example, sobriety, treatment attendance, etc.; (3) if housing was provided, was it segregated from the larger community, or scattered around the city; and (4) if case management services were provided as part of the intervention, to what degree of intensity. We created categories of interventions based on the above dimensions: 1) Case management only, 2) Abstinence-contingent housing, 3) Non-abstinence-contingent housing, 4) Housing voucher, 5) Residential treatment with case management. Some of the interventions had multiple components (e.g. abstinence-contingent housing with case management). These interventions were categorized according to the main component (the component that the primary authors emphasized). They were also placed in separate analyses. We then organized the studies according to which comparison intervention was used (any of the above interventions, or usual services). *Source: Munthe-Kaas HM, et al. Effectiveness of interventions to reduce homelessness: a systematic review and meta-analysis. Campbell Syst Rev 2018;14:1-281. https://onlinelibrary.wiley.com/doi/10.4073/csr.2018.3*.	
	We identified 10 individual components in the interventions (see Figure 4). Except those in UK ERA 2011, control group respondents were also subject to many of these components, such as employment requirements and earnings disregards, to varying degrees. Thus, we describe only those intervention components that represent an incentive, sanction or service over and above what the control group received. *Source: Gibson M, et al. Welfare-to-work interventions and their effects on the mental and physical health of lone parents and their children. Cochrane Database of Systematic Reviews 2018, Issue 2.* *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009820.pub3/full*	

Item	Complete reporting example	Incomplete reporting example
Item 10. Identify changes made at review stage to the groups or comparisons reported in the protocol	Within each comparison, we planned the following subgroups. 1. Categories of health workers: primary health professionals (PHPs) (e.g. doctors, nurses); community professionals (CPs) (e.g. teachers); and non-professional lay workers (LHWs). 2. Types of interventions (e.g. collaborative versus psychological interventions). 3. Settings (e.g. government versus non-government). After considering the studies included in this review, we revised the comparisons, so that separate analyses would be performed for categories of health workers and types of community interventions as the main analyses - not as subgroups. We were not able to perform other subgroup analyses to check if the intervention effect varied with different population characteristics, as the number of included studies for each comparison was insufficient. *Source: van Ginneken N, et al. Primary-level worker interventions for the care of people living with mental disorders and distress in low- and middle-income countries. Cochrane Database of Systematic Reviews 2021, Issue 8. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009149.pub3/full*	