REVEAL – prior evidence for new trials

Report Form with Example

Version 2.0 (September 2025) available at: https://doi.org/10.48341/REVEAL-reportform

Your feedback on this report form is very welcome. Just email us at office@cochrane.at with REVEAL in the subject line.

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Disclaimer:

This **structured report form** takes clinical researchers step-by-step through the process of planning and conducting a literature review for a new trial. Decisions regarding the review questions, scope and eligibility criteria for each literature review should be made *a priori*.

The report form provides a **template for documenting** all the relevant information needed to prepare the respective sections of funding proposals or trial protocols for submission for ethics review.

This report form is one of three documents in the REVEAL Guide:

- Find **all the background information** on the REVEAL literature review process **in the detailed guidance document**: https://doi.org/10.48341/REVEAL-guide.
- Find a **worked example with a completed report form** and sample text for a funding proposal or a trial protocol: https://doi.org/10.48341/REVEAL-example. The worked example will help you to understand what is required in each section of the report form.

EXAMPLE

The REVEAL literature review process is divided into two parts (see Figure 1 on the next page): In **Part A**, you will first search for **published systematic reviews (SRs)**. This is more efficient than searching for published trials first, and if you find one or more well-conducted and up-to-date SRs on the topic of your planned trial, you may not need to search for **published, unpublished or ongoing trials in Part B**.

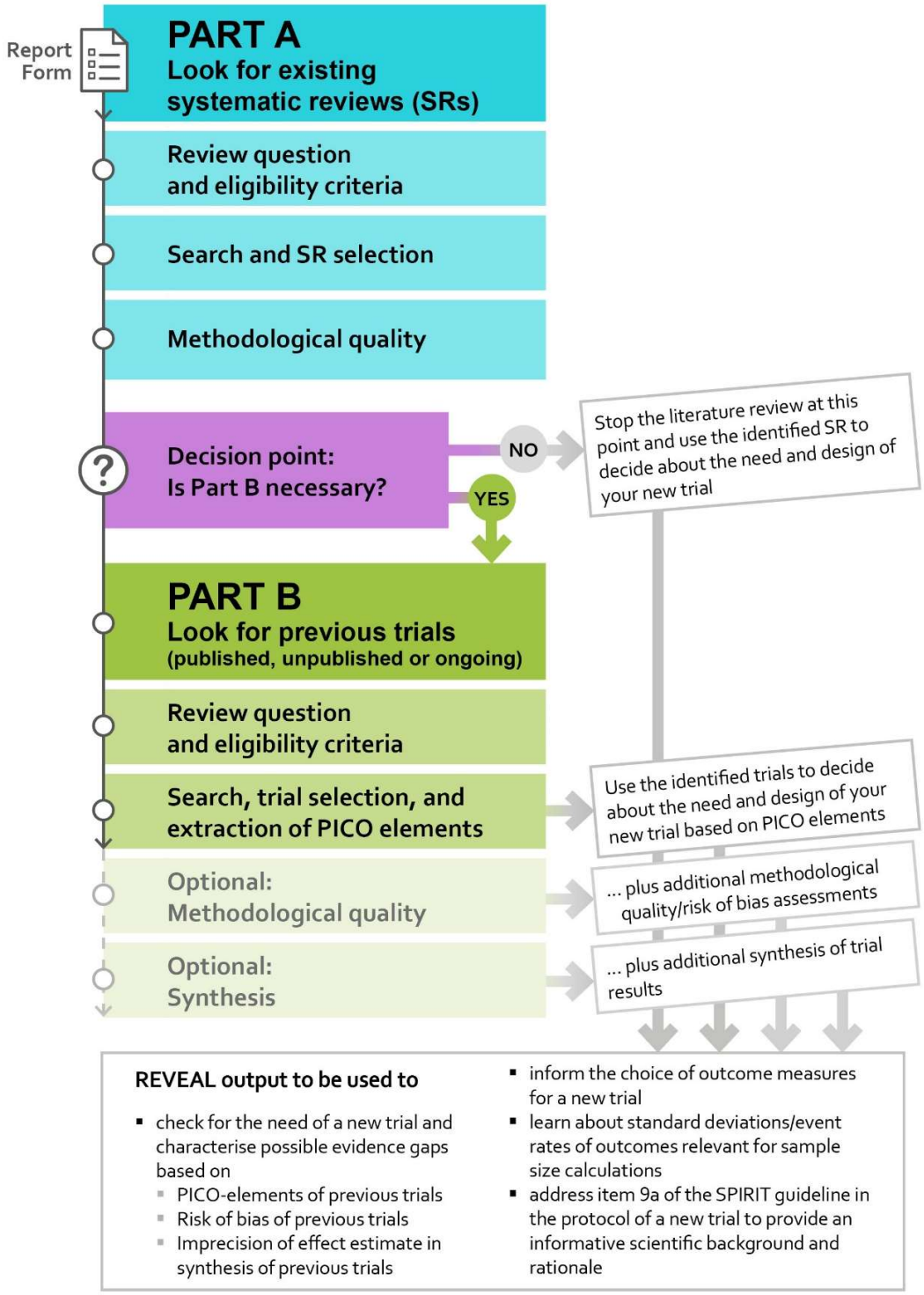

Figure 1: Schematic overview of the REVEAL literature review process

General information

Topic

Treatments for subacute cough in primary care*

*based on Speich et al., 2017 (https://bjgp.org/content/bjgp/68/675/e694.full.pdf), with minor adaptations for illustration purposes

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Start date

15.04.2017

PART A
Look for existing systematic reviews (SRs)

Step A1 | Review question

Where did you conduct your preliminary searches?

Preliminary searches are conducted during the preparation phase to get an idea of the available evidence on your topic. Results from preliminary searches help you to define and refine your review question and eligibility criteria.

Select all that apply

- ☒ Google
- ☐ Google Scholar
- ☐ PubMed
- ☐ Other *[write down which]*:

Which search terms were useful for your preliminary search?

Useful search terms identified during preliminary searching can help you construct your systematic search in Step A3.

- Population: "subacute cough"
- Study design: "systematic review"

What is your review question?

Write down your review question, ideally in a PICO structure: (i.e., Population, Intervention, Comparison, Outcome) and define the PICO elements under the following sub-headings.

What is the efficacy and safety of pharmacological interventions compared to placebo in patients with subacute cough (duration of 3-8 weeks) without chronic respiratory diseases on patient-relevant outcomes?

What is the population that you will investigate?

Outpatients aged ≥16 years with cough symptoms with a duration of 3–8 weeks (that is, subacute) and without known chronic respiratory diseases or other related diagnoses with overlapping symptoms (e.g., gastroesophageal reflux disease [GORD], chronic obstructive pulmonary disease [COPD], or asthma).

What is the intervention that you will investigate?

Any pharmacological intervention

What is the comparator intervention that you will investigate?

Placebo

What are the outcomes that you will investigate?

Cough severity, recovery, quality of life, adverse events

Step A1 | Review question (optional tasks)

Who is involved in determining the review question and PICO-elements?

Select all person groups that are involved in one or more steps of your review (e.g., discussing the topic of the review, determining the research question or choosing the outcomes that will be considered)

- ☐ Patients or patient representatives
- ☒ Clinicians (i.e., clinical experts in addition to the main author(s))
- ☒ Methodological experts (e.g., information specialist, statistician, systematic review expert)
- ☐ Others *[describe who]*:
- ☐ None of the above

What is your approach to defining the 3-5 most important outcomes?

Select all that apply

- ☒ I searched the COMET database, https://www.comet-initiative.org/
- ☐ I used the SPIRIT-PRO guideline (https://doi.org/10.1001/jama.2017.21903) or the 'Recommendations for including or reviewing patient reported outcome endpoints in grant applications' by Snyder et al. 2021 (https://doi.org/10.1136/bmj.n1367)
- ☐ I consulted guidance or other information by regulators (e.g., FDA, EMA)
- ☐ I involved patients and/or other clinicians
- ☐ Other *[describe]*:

Step A2 | Eligibility criteria

What are the main eligibility criteria for your literature review?

Fill out the table based on your review question. To improve the clarity of the eligibility criteria, also define exclusion criteria to contrast with the inclusion criteria. You may use the empty rows to add additional elements that are relevant for searching, study selection, data extraction, synthesis (e.g., document availability, study size, etc.)

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
POPULATION	Patients aged ≥16 years with subacute cough;	Patients with known chronic respiratory diseases or other related

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
	subacute cough with symptoms for 3–8 weeks and with slightly shorter or longer symptom duration (that is, a minimum of 2 weeks, a maximum of 10 weeks) or with a less specific definition (that is, no maximum duration reported; for example, '>2 weeks')	diagnoses with overlapping symptoms (for example, gastroesophageal reflux disease [GORD], chronic obstructive pulmonary disease [COPD], asthma or whooping cough [Pertussis]); patients already receiving pharmaceutical treatment for cough symptoms
INTERVENTION	Any pharmacological intervention (all administration routes: oral, inhalation, etc.; all dosages)	Combinations of different pharmacological interventions, Chinese or Asian herbal medicine, homestyle remedies without standardized preparation
COMPARATOR	Placebo	Head-to-head comparisons of different pharmacological and non-pharmacological interventions
OUTCOMES	Cough severity, recovery, quality of life, adverse events	Surrogate measures (e.g., lung function)

What are additional elements relevant for searching, study selection, data extraction, and synthesis?

Add any additional elements that may help you in the literature review process. You may use the empty rows to add additional elements or delete the predefined elements if they are not relevant for your review question.

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
STUDY DESIGN *[select all that apply]*	☒ Systematic reviews ☐ Other types of evidence synthesis:	☒ Non-systematic literature review (without any methods description) ☒ Any primary study
SETTING (e.g., hospital, outpatient clinic, etc.)	Outpatient clinics, GPs offices, any outpatient setting	Hospitals or other inpatient settings
DOCUMENT TYPE *[select all that apply]*	☒ Peer-reviewed articles ☐ Other published literature ☐ (Published) study protocols ☐ Preprints ☐ Conference abstracts ☐ Dissertations/Theses ☐ Other grey literature (e.g., webpages)	☐ Peer-reviewed articles ☐ Other published literature ☒ (Published) study protocols ☐ Preprints ☒ Conference abstracts ☐ Dissertations/Theses ☐ Other grey literature (e.g., webpages)
LANGUAGE	English, German, Italian, Spanish, or French	any other language
PUBLICATION YEARS	No restriction	
FULL-TEXT ACCESS	No restriction	

Step A3 | Search

Do you get input from an information specialist to construct your search strategy for existing SRs?

E.g., an information specialist designs and carries out your searches, or gives you advice about the search approach or does a peer review of your search strategy.

- ☐ No
- ☒ Yes

Which information sources do you use in your systematic search for SRs?

Select all that apply

We recommend searching at least one bibliographic database (e.g., MEDLINE/PubMed) and one additional source (e.g., academic search engines, such as Google Scholar, or other supplementary search methods, such as checking the reference lists of included SRs)

Bibliographic databases	**Search engines**	**Supplementary search methods**
☒ MEDLINE searched via PubMed ☐ MEDLINE searched via Ovid ☐ Epistemonikos.org ☒ Cochrane Database of Systematic Reviews (via Cochrane Library) ☐ Ovid Evidence-Based Medicine Reviews ☐ Other Database(s) *[List any databases + Interface or URL]*:	☒ Google Scholar *(e.g., screen only the first 20 results per query)* ☐ Other Search engines *[List any search engine used]*:	☐ Reference list checking ☐ Forward citation tracking ☐ Other supplementary search methods *[List any other methods used]*:

What are your search strategies to find SRs?

Record the date of your search and the names of the databases/search engines used, and copy and paste the exact search strings you used in each database/search engine. Also, document any filters or limits you applied to your search, e.g., selecting only the first 20 records for every Google Scholar search result. Document your search in sufficient detail to be reproducible (e.g., exact search terms, combinations with AND or OR).

Write down the numbers of records that you retrieved for each information source – you will need them to fill in the PRISMA flow chart.

Essential: Medline via Pubmed, searched 10.02.2017:

Search number	Query	Results
1	"cough"[MeSH Terms] OR cough[tiab]	61,962
2	Subacute[tiab] OR sub-acute[tiab] OR persistent[tiab] OR post[tiab] OR postviral[tiab] OR post-viral[tiab] OR postcold[tiab] OR post-cold[tiab] OR post-infectious[tiab] OR postinfectious[tiab]	1,334,093
3	#1 AND #2	6,071
4	#1 AND #2 Filters: Systematic Review	36

Essential: Cochrane Library, searched 10.2.2017

ID	Search	Hits
#1	MeSH descriptor: [Cough] explode all trees	1602
#2	cough:ti,ab,kw	11591
#3	#1 or #2	11591
#4	(Subacute OR sub-acute OR persistent OR post OR postviral OR post-viral OR postcold OR post-cold OR post-infectious OR postinfectious):ti,ab,kw	247766
#5	#3 and #4 in Cochrane Reviews, Cochrane Protocols	48

Optional: further supplementary search methods: Google Scholar, searched 10.2.2017
"Subacute cough systematic", screened first 20 hits

Step A3 | Search (optional tasks)

Do you use a reference management software or a SR support platform to collect search results and document the data selection process?

- ☐ No
- ☒ Yes, I use [*mark all that apply*]
  - ☒ EndNote
  - ☐ Zotero
  - ☐ Mendeley
  - ☐ Citavi
  - ☐ Rayyan
  - ☐ SR Accelerator
  - ☐ Covidence
  - ☐ DistillerSR
  - ☐ EPPI-Reviewer
  - ☐ JBI SUMARI
  - ☐ Other [*write down which*]: ___

Step A4 | SR selection – abstract level

What is your approach for title and abstract screening?

Select one option

- ☒ Essential: One person screens all records at titles/abstract level on their own (i.e., single screening)
- ☐ Optional: More than one person screens titles/abstracts, but each title/abstract is screened only once (i.e., single screening)
- ☐ Optional: Single screening, but a second researcher helps with uncertain screening decisions
- ☐ Optional: A second researcher cross-checks a subset of abstracts or all excluded titles/abstracts
- ☐ Optional: Each abstract is screened by two or more persons (i.e., dual screening)
- ☐ Other *[Please explain your approach here]*:

Did you first screen a subset of abstracts (e.g., 30-50) to fine-tune your eligibility criteria?

If you are screening your titles/abstracts alone, it is helpful to refine your eligibility criteria after screening the first batch. If two or more researchers are involved, discuss the uncertainties of the first batch to get everyone on the same page.

- ☒ Yes
- ☐ No

How many titles/abstracts did you include and exclude?

It is enough to document the numbers. You will need them in the PRISMA flow chart.

Number of included titles/abstracts: 9

Number of excluded titles/abstracts: 63

Step A5 | SR selection – full-text level

Were you able to retrieve the full texts of all potentially relevant abstracts?

- ☐ Yes
- ☒ No

If no, how many records could you not find? 1 (*You will need the number in the PRISMA flow chart*)

What is your approach for full-text screening?

Select one option

- ☒ Essential: One person screens all full texts on their own (i.e., single screening)
- ☐ Optional: More than one person screens full texts, but each full text will be screened only once (i.e., single screening)
- ☐ Optional: Single screening, but a second researcher helps with uncertain screening decisions
- ☐ Optional: A second researcher crosschecks a subset of full texts or all excluded full texts
- ☐ Optional: Each full text is screened by two or more persons (i.e., dual screening)

☐ Other *[Please explain your approach here]*:

How many full-text articles did you include and exclude?

Write the numbers of included and excluded full texts in the PRISMA chart on the next page.

Number of included full texts: 1

Number of excluded full texts: 7

Reasons for exclusion:

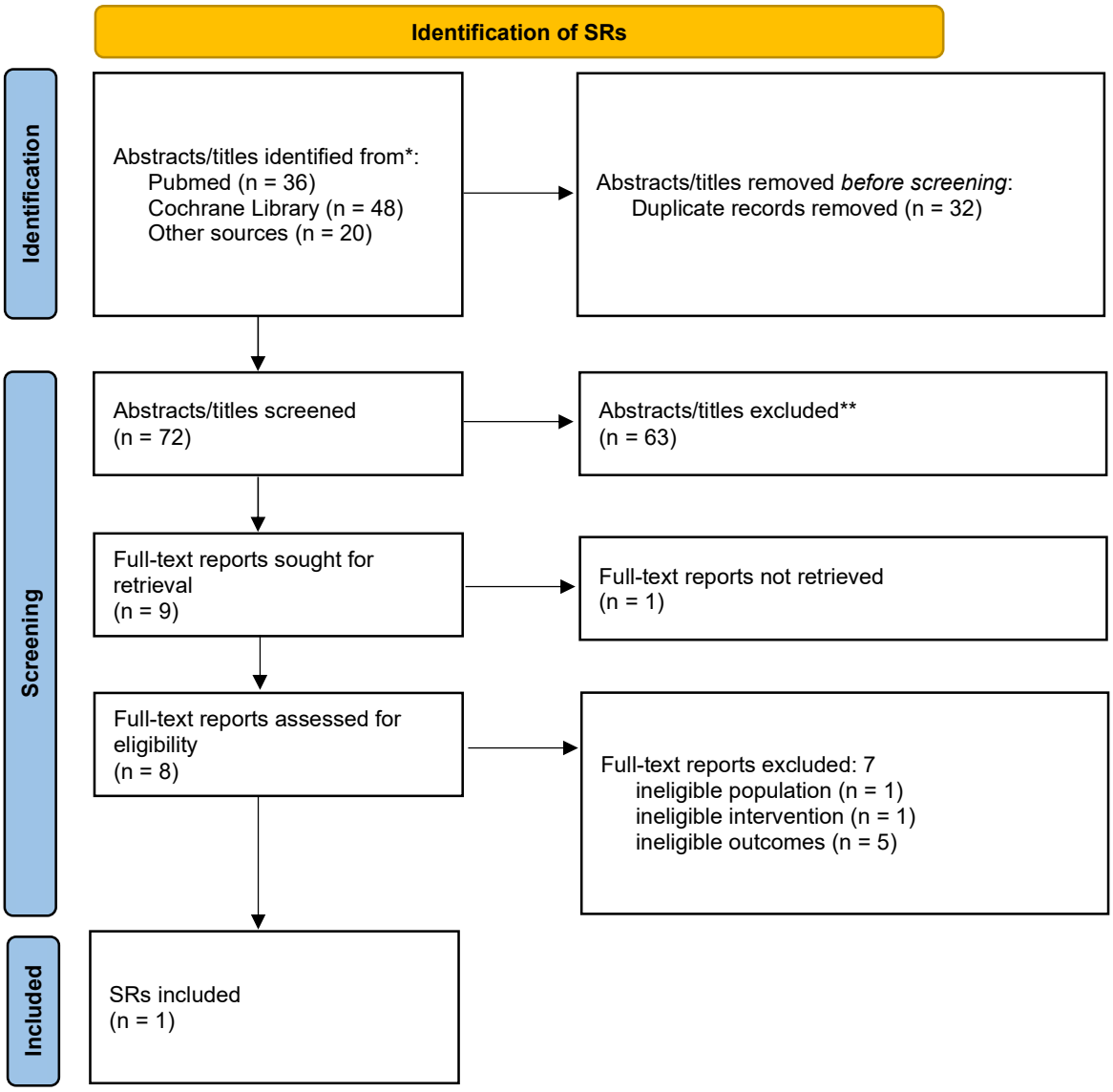
ineligible population: 1

ineligible intervention: 1

ineligible outcomes: 5

What are the results of the search and selection process for SRs (Part A)?

To be filled out stepwise, after searching, abstract and full text screening: Use this PRISMA flow chart to document how many SRs you found, excluded and included. For documents that you assessed in full text, also document the reasons for exclusion, optionally by coding the reasons (e.g., ineligible population).



*Consider, if feasible to do so, reporting the number of records identified from each database and other sources searched separately (rather than the total number across all databases/sources).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Adapted From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

How to proceed from here?

Did you find eligible SRs?

- ☐ **NO** → skip Step A6 proceed directly to Part B
- ☒ **YES** → proceed with Step A6

Eligible SRs that meet our inclusion criteria:

Johnstone KJ, Chang AB, Fong KM, Bowman RV, Yang IA. Inhaled corticosteroids for subacute and chronic cough in adults. Cochrane Database Syst Rev. 2013 Mar 28;2013(3):CD009305. doi: 10.1002/14651858.CD009305.pub2. PMID: 23543575; PMCID: PMC8934584.

Step A6 | Methodological quality of eligible SRs

Which tool do you use to assess the methodological quality of eligible SRs?

Select one tool

- ☐ "Fast and frugal" decision tree for rapid critical appraisal of SRs based on AMSTAR 2 (https://doi.org/10.1002/jrsm.1754)
- ☒ AMSTAR 2 (https://amstar.ca/Amstar_Checklist.php)
- ☐ Other:

What is your approach for assessing the methodological quality of eligible SRs?

Select the number of researchers involved in assessing methodological quality

- ☒ Essential: A single researcher assesses the methodological quality
- ☒ Optional: A second researcher verifies the quality assessments
- ☐ Optional: Two researchers assess the quality independently
- ☐ Optional: Other *[Please explain your approach here]*:

What is the result of your quality assessment of included SRs?

Reference (authors, title, year)	Overall quality rating for the SR with explanations
Johnstone et al., 2013: Inhaled corticosteroids for subacute and chronic cough in adults	Low risk of bias; concerns regarding eligibility criteria, methods to identify and select studies, data collection and quality appraisal of included studies and synthesis were all rated as low.

What were your findings from the searches for SRs?

Now it is time to document the results of Part A. Use the table below to help you remember why you stopped here or moved on to Part B. If you found any eligible SRs, write down the most important information about them here (e.g., quality rating, main findings). Write a short justification for stopping here or moving on to Part B.

Systematic reviews	
Number of eligible SRs	1
Overall quality rating of SRs	Low risk of bias
Summary of the SR findings	Very heterogenous findings. SR recommends that a trial of inhaled corticosteroids (ICS) should only be considered in patients after thorough evaluation including chest X-ray and consideration of spirometry and other appropriate investigations.
Justification for stopping or moving on to Part B	Only one outdated SR was found. There is a need to look for more recent evidence on the research question.

Decision point – Is Part B necessary?

Based on your findings from Part A: Will you search for previous trials (published and unpublished)?

Select one option

- ☐ **NO,** because I found at least one recent and good-quality SR that addresses my review question
- ☒ **YES,** because I only found outdated good-quality SRs that address my review question. I will look for more recent evidence on my research question → proceed to Part B
- ☐ **YES,** because I found no recent and good-quality SR and will look for previous trials → proceed to Part B

Infobox: 'recent' and 'good-quality' systematic review

Whether a SR can be considered '**recent**' or 'up-to-date' depends on the topic under investigation. In a fast-changing field, a SR with a search date of 2 years ago may be already out of date. In a field where developments are slower, a SR with a search date of, e.g., 5 years ago maybe still be usable; in particular, if a research question has been settled. As a rule of thumb, if you know already 1 or more RCTs not included in a SR due to an older search date, the SR should be considered 'outdated', but a SR with a search date of 1 year ago or less is typically considered 'recent'. In any case, we recommend consulting a content expert to judge whether the SR is outdated.

We consider a SR to be '**good-quality**' if it is useful for the purpose of REVEAL. To qualify as 'good-quality', a SR should meet the following criteria (based on reasoning from AMSTAR2 and the "fast and frugal" decision tree): The search covered at least 2 databases and a trial register, the search strategy was reported, the risk of bias of included trials was systematically assessed, and the results were synthesized qualitatively or quantitatively.

PART B
Look for previous trials (published, unpublished or ongoing)

If you found an outdated SR on your review question or a SR that has a similar topic but does not answer your review question, you can use the information from these SRs to inform your search for previous trials: e.g., to update an outdated SR, to choose relevant information sources or to specify eligible outcome measures.

Step B1 | Review question and eligibility criteria

Based on the results of Part A, are any changes to the review question needed? (e.g., specifying eligible population sub-groups, outcomes or outcome measures)

Select one option

- ☐ Yes, I need to modify my review question
- ☒ No, my review question is still valid

What is your review question?

Copy and paste your review question from Part A and make any changes or modifications here.

Your review question should ideally be formulated in a PICO structure: (i.e., Population, Intervention, Comparison, Outcome). Define the PICO elements under the following sub-headings.

What is the efficacy and safety of pharmacological interventions compared to placebo in patients with subacute cough (duration of 3-8 weeks) without chronic respiratory diseases on patient-relevant outcomes?

What is the population that you will investigate? *(e.g., specify eligible population sub-groups)*

Outpatients aged ≥16 years with cough symptoms with a duration of 3–8 weeks (that is, subacute) and without known chronic respiratory diseases or other related diagnoses with overlapping symptoms (e.g., gastroesophageal reflux disease [GORD], chronic obstructive pulmonary disease [COPD], or asthma).

What is the intervention that you will investigate?

Any pharmacological intervention

What is the comparator intervention that you will investigate?

Placebo

What are the outcomes that you will investigate?

Cough severity, recovery, quality of life, adverse events

Are any changes to the main eligibility criteria needed? (e.g., specifying eligible population sub-groups, outcomes or outcome measures)

Select one option

- ☐ Yes, I need to modify my eligibility criteria
- ☒ No, there is no need for changes in my eligibility criteria

What are the main eligibility criteria for your literature review?

Copy and paste the table with your main eligibility criteria from Part A and make any changes or modifications here.

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
POPULATION	Patients aged ≥16 years with subacute cough; subacute cough with symptoms for 3–8 weeks and with slightly shorter or longer symptom duration (that is, a minimum of 2 weeks, a maximum of 10 weeks) or with a less specific definition (that is, no maximum duration reported; for example, '>2 weeks')	Patients with known chronic respiratory diseases or other related diagnoses with overlapping symptoms (for example, gastroesophageal reflux disease [GORD], chronic obstructive pulmonary disease [COPD], asthma or whooping cough [Pertussis]); patients already receiving pharmaceutical treatment for cough symptoms;
INTERVENTION	Any pharmacological intervention (all administration routes: oral, inhalation, etc.; all dosages)	Combinations of different pharmacological interventions, Chinese or Asian herbal medicine, homestyle remedies without standardized preparation
COMPARATOR	Placebo	Head-to-head comparisons of different pharmacological and non-pharmacological interventions
OUTCOMES	Cough severity, recovery, quality of life, adverse events	Surrogate measures (e.g., lung function)

What are additional elements relevant for searching, study selection, data extraction, synthesis?

Copy and paste the table with your main eligibility criteria from Part A and make any changes or modifications that are necessary for the review of previous trials. E.g., changing eligible study designs to RCTs, limiting to publication dates starting from the search date of an identified SR, etc.

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
STUDY DESIGN *[select all that apply]*	☒ RCT ☐ Other design [*which*]:	Non-randomised trials, observational studies
SETTING (e.g., hospital, outpatient clinic, etc.)	Outpatient setting	Inpatient setting

Category	INCLUSION CRITERIA	EXCLUSION CRITERIA
DOCUMENT TYPE *[select all that apply]*	☒ Peer-reviewed articles ☐ Other published literature ☒ Trials register entries ☐ (Published) study protocols ☐ Preprints ☐ Conference abstracts ☐ Dissertations/Theses ☐ Other grey literature (e.g., webpages)	☐ Peer-reviewed articles ☐ Other published literature ☐ Trials register entries ☒ (Published) study protocols ☐ Preprints ☒ Conference abstracts ☐ Dissertations/Theses ☐ Other grey literature (e.g., webpages)
LANGUAGE	English, German, Italian, Spanish, or French	
PUBLICATION DATE *[select all that apply]*	☒ Starting from the last search date of an included SR: Dec 2012 ☐ Other time limit: ☐ no time limit	
FULL-TEXT ACCESS	No restriction	

Step B2 | Search

Do you get input from an information specialist to construct your search strategy for published and unpublished trials?

E.g., an information specialist designs and carries out your searches, or gives you advice about the search approach or does a peer review of your search strategy.

☐ No
☒ Yes

Which information sources do you use in your search for published trials?

Select all that apply

We recommend searching at least the bibliographic database MEDLINE (e.g., via PubMed) and one additional source (e.g., academic search engines, such as Google Scholar, or other supplementary search methods, such as checking the reference lists of included SRs or included trials)

Bibliographic databases	Search engines	Supplementary search methods
☒ MEDLINE searched via PubMed ☐ MEDLINE searched via Ovid ☒ Cochrane Central Register of Controlled Trials (CENTRAL) searched via the Cochrane Library	☐ Google Scholar *(e.g., screen only the first 20 results per query)* ☐ Other Search engines *[List any search engine used]*:	☒ Reference list checking of SRs found in Part A ☐ Reference list checking of included trials ☐ Forward citation tracking ☐ Other supplementary search methods *[List any other methods used]*:

Bibliographic databases	Search engines	Supplementary search methods
☐ Cochrane Central Register of Controlled Trials (CENTRAL) searched via Ovid ☐ Embase searched via Embase.com (Elsevier) ☐ Embase searched via Ovid ☐ Other Database(s) *[List any databases + Interface or URL]*:		

Which information sources do you use to find ongoing/unpublished trials?

Select all that apply

- ☒ Essential: ClinicalTrials.gov
- ☒ Optional: WHO International Clinical Trials Registry Platform (ICTRP)
- ☐ Optional: Other trials registers, e.g., national trials registers *[List any other registers you are searching and provide their URL]*:

What are your search strategies to find previous trials?

Record the date of your search and the names of the databases/search engines/trials registers used, and copy and paste the exact search strings you used in each database/search engine/trials register. Also, document any filters or limits you applied to your search, e.g., selecting only the first 20 records for every Google Scholar search result. Document your search in sufficient detail to be reproducible (e.g., exact search terms, combinations with AND or OR). For reference list checking, note the articles you used.

Write down the numbers of records that you retrieved for each information source – you will need them to fill in the PRISMA flow chart.

Essential: MEDLINE via PubMed, searched 10.02.2017

Search number	Query	Results
1	"cough"[MeSH Terms] OR cough[tiab]	61,962
2	Subacute[tiab] OR sub-acute[tiab] OR persistent[tiab] OR post[tiab] OR postviral[tiab] OR post-viral[tiab] OR postcold[tiab] OR post-cold[tiab] OR post-infectious[tiab] OR postinfectious[tiab]	1,334,093
3	(randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR "clinical trials as topic"[MeSH Terms:noexp] OR randomly[tiab] OR trial[ti]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])	1,404,989
4	#1 AND #2 AND #3	468

Essential: Cochrane CENTRAL, searched 16.03.2017

ID	Search terms	Hits
#1	MeSH descriptor: [Cough] this term only	1096
#2	cough:ti,ab	4180
#3	{or #1-#2}	4503
#4	(Subacute or sub-acute or persistent or post or postviral or post-viral or postcold or post-cold or post-infectious or postinfectious):ti,ab	89307
#5	1-#4 in Trials	568

Essential: ClinicalTrials.gov, searched 10.02.2017

Condition: (Subacute OR sub-acute OR persistent OR post OR postviral OR post-viral OR postcold OR post-cold OR post-infectious OR postinfectious) AND cough

Hits: 109, combined searching and screening

Optional: further supplementary search methods: ICTRP, searched 10.2.2017

Subacute cough OR sub-acute cough OR persistent cough OR post cough OR postviral cough OR post-viral cough OR postcold cough OR post-cold cough OR post-infectious cough OR postinfectious cough

Hits: 187, combined searching and screening

Step B3 | Study selection – abstract level

What is your approach for title and abstract screening for published trials?

Select one option

- ☒ Essential: One person screens all records at titles/abstract level on their own (i.e., single screening)
- ☐ Optional: More than one person screens titles/abstracts, but each title/abstract is screened only once (i.e., single screening)
- ☐ Optional: Single screening, but a second researcher helps with uncertain screening decisions
- ☐ Optional: A second researcher cross-checks a subset of abstracts or all excluded titles/abstracts
- ☐ Optional: Each abstract is screened by two or more persons (i.e., dual screening)
- ☐ Other *[Please explain your approach here]*:

Did you first screen a subset of abstracts (e.g., 30-50) to fine-tune your eligibility criteria?

If you are screening your titles/abstracts alone, it is helpful to refine your eligibility criteria after screening the first batch. If two or more researchers are involved, discuss the uncertainties of the first batch to get everyone on the same page.

- ☒ Yes
- ☐ No

How many titles/abstracts from the search for published trials did you include and exclude?

It is enough to document the numbers. You will need them in the PRISMA flow chart.

Number of included titles/abstracts: 50

Number of excluded titles/abstracts: 641

What is your approach to looking for ongoing/unpublished trials?

Select one option

- ☒ Essential: Pragmatic approach: One person conducts simple search(es) in ClinicalTrials.gov, screens the titles and full records on screen during the search ("Google"-like approach, combined searching and screening)
- ☐ Optional: Systematic approach: An information specialist searches ClinicalTrials.gov using a systematic search strategy, exports the results in bulk and researcher(s) screen them separately from the search (either by one person or dually)

How many ClinicalTrials.gov records did you include and exclude?

Write down the numbers of retrieved, screened and included references. You will need these numbers in the PRISMA flow chart.

Number of initially retrieved records: Clinicaltrials.gov 109

Number of initially retrieved records: ICTRP 187

Number of full records screened: 26

Number of included records: 0

Reasons for exclusion:

ineligible population: 16

ineligible intervention: 6

ineligible comparison: 4

Step B4 | Study selection – full-text level

Were you able to retrieve the full texts of all potentially relevant abstracts of published trials?

- ☐ Yes
- ☒ No

If no, how many records could you not find? 1

What is your approach for full text screening of published trials?

Select one option

- ☒ Essential: One person screens all full texts on their own (i.e., single screening)
- ☐ Optional: More than one person screens full texts, but each full text will be screened only once (i.e., single screening)
- ☐ Optional: Single screening, but a second researcher helps with uncertain screening decisions
- ☐ Optional: A second researcher cross-checks a subset of full texts or all excluded full texts
- ☐ Optional: Each full text is screened by two or more persons (i.e., dual screening)
- ☐ Other *[Please explain your approach here]*:

How many full-text articles of published trials did you include and exclude?

Write the numbers of included and excluded full texts in the PRISMA chart on the next page.

Number of included full texts: 6

Number of excluded full texts: 43

Reasons for exclusion:

ineligible population: 18

ineligible study design (e.g., other than RCT): 15

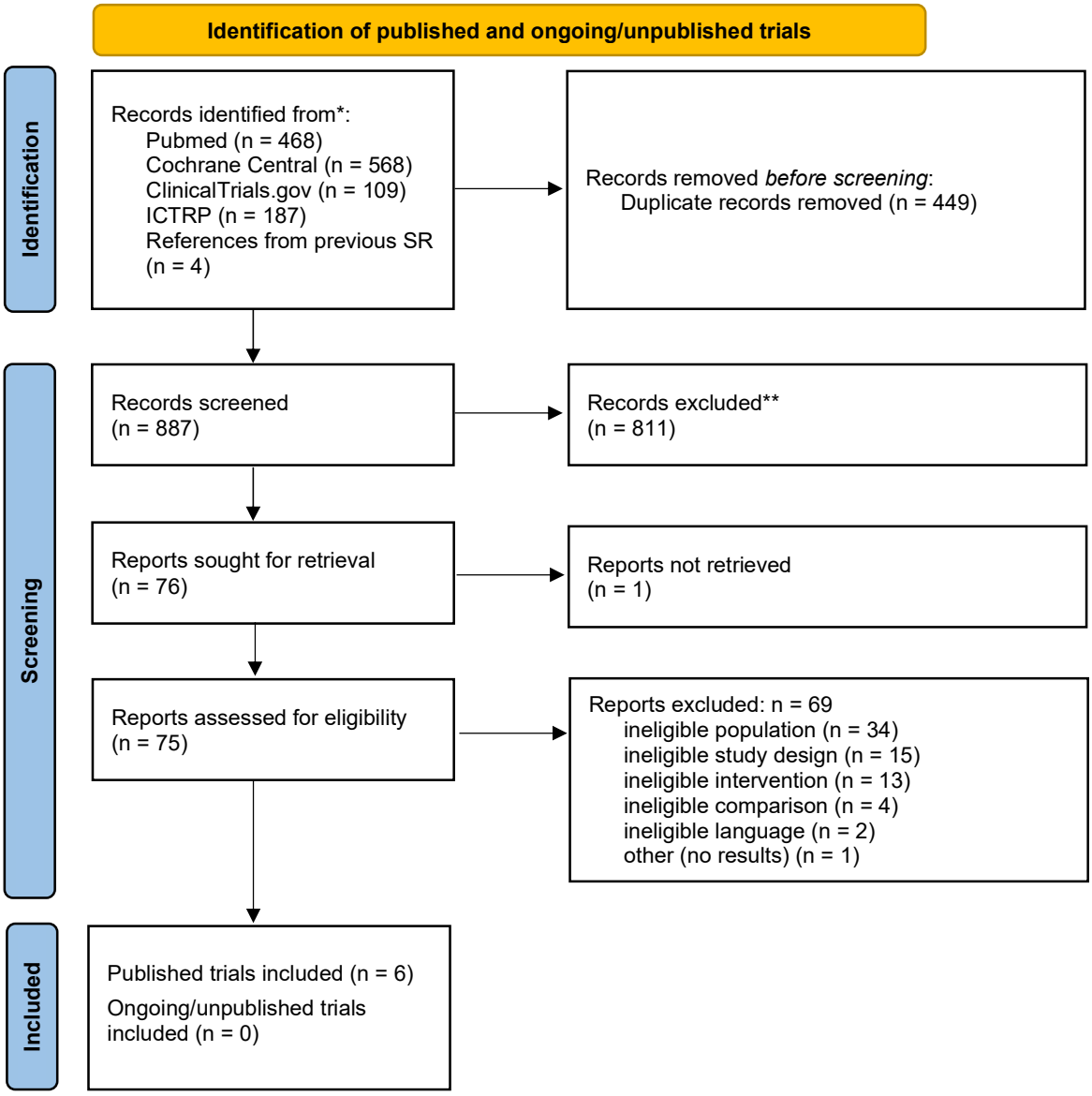
ineligible intervention: 7

ineligible language: 2

no result: 1

What are the results of the search and selection process for published and ongoing/unpublished trials?

To be filled out stepwise, after searching, abstract and full text screening: Use this PRISMA flow chart to document how many published and ongoing/unpublished trials you found, excluded and included. For documents that you assessed in full text, also document the reasons for exclusion, optionally by coding the reasons (e.g., ineligible population).



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched separately (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Adapted From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

How to proceed from here?

Did you find published, ongoing or completed unpublished trials similar to the one you are planning?

- ☐ **NO** → Stop the literature review and go on with planning your own trial: Use the fact that there are no similar trials available as justification for your trial. Report the results of your literature review using REVEAL in the study protocol of your own clinical trial
- ☒ **YES** → Proceed to Step B5: Data extraction of PICO-elements

Step B5 | Data extraction of PICO elements

What is your approach for data extraction?

Select one option

- ☒ Essential: One person extracts relevant data per study, without checking by another person
- ☐ Optional: One person extracts relevant data per study, a second person checks data extractions of a subset of studies (e.g., a random 25%)
- ☐ Optional: One person extracts relevant data per study, a second person checks data extractions of all studies
- ☐ Other *[Please explain your approach here]*:

What data items will you extract?

Note that the trial characteristics and PICO elements in black font are essential to extract in this step (Step B5), outcome data and subgroup results are needed only for the optional Step B7 – Synthesis.

Select all that apply

- ☒ Name of first author and year and trial acronym (if applicable)
- ☐ Trial identifier or publication reference
- ☐ Study design
- ☐ Year(s) of study conduct
- ☐ Country
- ☐ Setting
- ☒ Patient population
- ☒ Intervention(s)
- ☒ Comparison intervention(s)
- ☒ Outcomes
- ☐ Outcome measures
- ☐ Relevant results
- ☐ Subgroup results
- ☐ Other *[please specify]*:

Where did you save your completed data extraction?

We recommend conducting the data extraction in a separate document (e.g., Excel) or in a review platform (e.g., Covidence). For future reference, note here where to find the completed extraction form.

Excel spreadsheets on servers of our institution ((Z:\Users\Researcher\ProjectCough\Dataextraction)

Published trials that meet our inclusion criteria:

Trials found by update search:

(1) Wang K, Birring SS, Taylor K, Fry NK, Hay AD, Moore M, et al. Montelukast for postinfectious cough in adults: a double-blind randomised placebo-controlled trial. Lancet Respir Med. 2014;2(1):35-43.
(2) Zanasi A, Lecchi M, Del Forno M, Fabbri E, Mastroroberto M, Mazzolini M, et al. A randomised, placebo-controlled, double-blind trial on the management of post-infective cough by inhaled ipratropium and salbutamol administered in combination. Pulm Pharmacol Ther. 2014;29(2):224-32.

Trials included in the previous SR:

(3) Woodcock A, McLeod RL, Sadeh J, Smith JA. The efficacy of a NOP1 agonist (SCH486757) in subacute cough. Lung. 2010;188 Suppl 1:S47-52.
(4) Zolghadrasli AA. The effect of orally administered gelatin on sympton resolution in chronic persistent cough: a randomised clinical trial study. Iranian Red Crescent Medical Journal [Internet]. 2009; 11(2):[145-8 pp.]. Available from: http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/461/CN-00754461/frame.html.
(5) Ponsioen BP, Hop WC, Vermue NA, Dekhuijzen PN, Bohnen AM. Efficacy of fluticasone on cough: a randomised controlled trial. Eur Respir J. 2005;25(1):147-52.
(6) Pornsuriyasak P, Charoenpan P, Vongvivat K, Thakkinstian A. Inhaled corticosteroid for persistent cough following upper respiratory tract infection. Respirology. 2005;10(4):520-4.

Ongoing or completed unpublished trials that meet our inclusion criteria:

No ongoing or completed unpublished trials found that meet our inclusion criteria.

How to proceed from here?

After extracting important characteristics and PICO elements of eligible trials you have the following 2 options:

→ **Option 1**: Proceed to Step B6: Methodological quality/Risk of Bias

→ **Option 2** (with no further time and other resources): **Stop the literature review here** and **characterize identified evidence gaps** based on the PICO elements of eligible trials to justify your new trial

Did you find sufficient evidence of good quality that answers your review question?

Select one option

- ☐ **YES** → Re-evaluate the need for your trial with your team or supervisor, and decide whether the research question of your planned trial should be modified to close an evidence gap. Your planned trial may not be needed in its current form.
- ☒ **NO** → Start your own trial and justify it using the fact that there is insufficient evidence available.

Summarisze why your trial is still needed based on the information about methodological aspects, the population studied or other characteristics of completed unpublished trials.

In addition to the 4 trials identified by a previous SR (Johnstone et al 2013, see part A) we found 2 newer published RCTs. We found no ongoing or unpublished trials. None of the individual RCTs found clear patient-relevant benefits for patients with post-infectious cough lasting 3 to 8 weeks.

We will conduct Risk of Bias assessment and a more detailed data extraction, but findings so far indicate that further trials are necessary to answer the research question.

Step B6 | Methodological quality/Risk of Bias (RoB)

Which tool do you use to assess the methodological quality/risk of bias of included published trials?

Select one tool

- ☐ ROBUST-RCT tool (https://www.bmj.com/content/388/bmj-2024-081199)
- ☐ RoB 2 Tool for RCTs (https://www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2)
- ☐ ROBINS-I (Risk Of Bias In Non-randomised Studies - of Interventions) (https://www.riskofbias.info/welcome/home/current-version-of-robins-i)
- ☒ Other: *RoB 1*

What is your approach for assessing the risk of bias of included published trials?

Select the number of researchers involved in assessing the risk of bias of published trials

- ☐ Essential: A single researcher assesses risk of bias
- ☐ Optional: A second researcher verifies the risk of bias assessments for a subset of trials
- ☒ Optional: A second researcher verifies risk of bias assessments for all included trials
- ☐ Optional: Two researchers assess the risk of bias independently
- ☐ Optional: Other *[Please explain your approach here]*:

What is the result of your risk of bias assessment of included published?

	Random sequence generation	Allocation concealment	Blinding of patients and personnel	Blinding of outcome assessment	Analysed as randomised	Attrition bias and missing data (>10%)
Wang 2014	+	+	+	+	+	-
Zanasi 2014	+	?	+	?	+	-
Woodcock 2010	?	?	+	?	+	(+)
Zolghadrasli 2009	?	?	-	-	?	+
Ponsioen 2005	+	+	+	?	+	+
Pornsuriyasak 2005	?	?	+	+	?	(-)

How to proceed from here?

After assessing the methodological quality/risk of bias of included published trials you have the following 2 options:

→ Option 1: Proceed to Step B7: Synthesis of trial results to additionally check for evidence gaps based on imprecision of effect estimates of important outcomes
→ Option 2 (with no further time and other resources): **Stop the literature review here** and **characterize identified evidence gaps based on PICO elements and RoB assessment** (RoB domains rated as high or unclear risk-of-bias for several trials) of eligible trials to justify your new trial.

Did you find sufficient evidence of good quality that answers your review question?

Select one option

- ☐ **YES** → Re-evaluate the need for your trial with your team or supervisor, and decide whether the research question of your planned trial should be modified to close an evidence gap. Your planned trial may not be needed in its current form.
- ☒ **NO** → Start your own trial and justify it using the fact that there is insufficient evidence available

Summarise why your trial is still needed based on the information about methodological aspects, the PICO elements and RoB assessments.

No previous trial tested oral corticosteroids for post-infectious cough (only 1 trial actually focused on patients with post-infectious cough but tested a different intervention). Most previous trials had high or unclear risk of bias.

How to proceed from here?

Do you have further time and other resources?

Select one option

- ☒ Yes → Proceed to Step B7: Data synthesis
- ☐ No → Stop the literature review and report the results from your literature review in the study protocol of your clinical trial.

Step B7 | Synthesis

What is your approach for synthesis?

Select all that apply

- ☒ I will synthesize the results narratively
- ☒ I will present the results in tables
- ☐ I will perform meta-analysis for some or all outcomes
- ☐ I will assess the certainty of evidence for the most important outcomes
- ☐ I will assess the applicability of included trials' results and the purpose of my planned trial using the PRECIS-2 tool (https://www.precis-2.org/)
- ☐ Other *[Please explain your approach here]*:

What are the synthesized findings from the searches for published trials?

To be filled out at the end of the literature review process: This is the summary of the literature review of previous trials. It provides a synthesis of your findings and helps to justify your next steps. Note whether you found any trials that are relevant to your research question, the most important information about the trials you selected (e.g., study design, study arms, number of participants), and any other considerations that are relevant for your decision about whether to proceed with your own trial.

Published trials	
Number of eligible published trials	6
Overall risk of bias of published trials	Four of the six trials that were included had a high risk of bias in at least one domain, and the risk of bias was often unclear due to poor reporting.
Summary of the findings	Evidence on treatment options for subacute cough is weak. There is no treatment showing clear patient-relevant benefits in clinical trials
Other relevant considerations	None

Where did you save your complete data synthesis?

Depending on your approach, you may have a more extensive synthesis than the table above. For future reference, note here where to find any additional documents (e.g., meta-analysis, certainty of evidence, etc.).

All additional documents are stored in the project folders (Z:\Users\Researcher\ProjectCough\) at the servers of our institution.

How to proceed from here?

Did you find sufficient evidence of good quality that answers your review question?

Select one option

☐ **YES** → Re-evaluate the need for your trial, because your planned trial may not be necessary in its current form

☒ **NO** → Start your own trial and justify it using the fact that there is insufficient evidence available