



Con il Patrocinio di



STUDI CLINICI: METODOLOGIA

Coordinatore
Dr.ssa Stefania Gori

Evento ECM MODULO 4

REVISIONI SISTEMATICHE E METANALISI



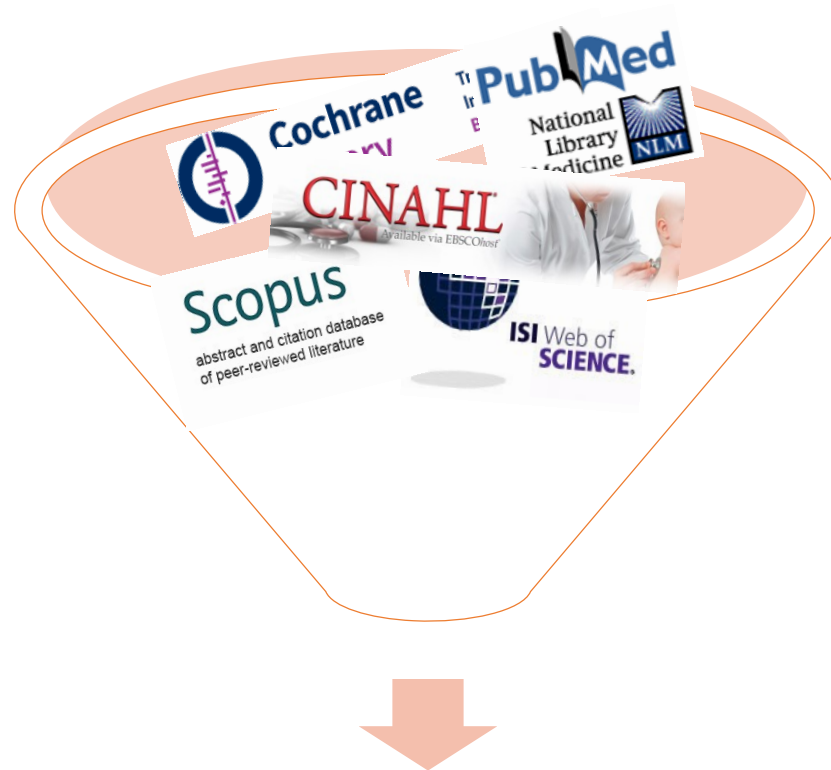
NEGRAR
5/6 Aprile
2019

Centro Formazione
IRCCS Ospedale Sacro Cuore
Don Calabria

**Definizione della strategia
di ricerca e di selezione
degli studi; *study flow***

Negrar, 5 aprile 2019

Output della strategia di ricerca



RISULTATO

Lista di studi potenzialmente includibili

List of records

Summary ▾ 20 per page ▾ Sort by Most Recent ▾

Search results

Items: 1 to 20 of 22772 Selected: 3

<< First < Prev

- ☒ [Evaluation of a new tablet formulation of deferasirox to reduce chronic blood transfusions.](#)
Chalmers AW, Shammo JM.
Ther Clin Risk Manag. 2016 Feb 15;12:201-8. doi: 10.2147/TCRM.S82449. eCollection PMID: 26929633
- ☒ [Plasma levels of TGF- \$\beta\$ 1 in homeostasis of the inflammation in sickle cell disease.](#)
Torres LS, Okumura JV, Silva DG, Belini Júnior É, Oliveira RG, Mimouni Bonini Domingos CR.
Cytokine. 2016 Feb 26;80:18-25. doi: 10.1016/j.cyto.2016.02.012. [Epub ahead of print] PMID: 26928604
- ☒ [Sofosbuvir and Simeprevir Treatment of a Stem Cell Transplanted Teenager with Chronic Hepatitis C Infection.](#)
Fischler B, Priftakis P, Sundin M.
Pediatr Infect Dis J. 2016 Feb 26. [Epub ahead of print] PMID: 26928522
- ☐ [Numerical simulation of healthy and defective red blood cell settling in blood plasma.](#)
Hashemi Z, Rahnama M, Jafari S.
J Biomech Eng. 2016 Feb 29. doi: 10.1115/1.4032851. [Epub ahead of print] PMID: 26926169

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Related searches

sickle cell disease review
management sickle cell disease

PMID- 26929633

OWN - NLM

STAT- PubMed-not-MEDLINE

DA - 20160301

DCOM- 20160301

IS - 1176-6336 (Print)

IS - 1176-6336 (Linking)

VI - 12

DP - 2016

TI - Evaluation of a new tablet formulation of deferasirox to reduce chronic iron overload after long-term blood transfusions.

PG - 201-8

LID - 10.2147/TCRM.S82449 [doi]

AB - Transfusion-dependent anemia is a common feature in a wide array of hematological disorders, including thalassemia, sickle cell disease, aplastic anemia, myelofibrosis, and myelo-dysplastic syndromes. In the absence of a physiological mechanism to excrete excess iron, chronic transfusions ultimately cause iron overload. Without correction, iron overload can lead to end-organ damage, resulting in cardiac, hepatic, and endocrine dysfunction/failure. Iron chelating agents are utilized to reduce iron overload, as they form a complex with iron, leading to its clearance. Iron chelation has been proven to decrease organ dysfunction and improve survival in certain transfusion-dependent anemias, such as beta-thalassemia. Several chelating agents have been approved by the United States Food and Drug Administration for the treatment of iron overload, including deferoxamine, deferiprone, and deferasirox. A variety of factors have to be considered when choosing an iron chelator, including dosing schedule, route of administration, tolerability, and side effect profile. Deferasirox is an orally administered iron chelator with proven efficacy and safety in multiple hematological disorders. There are two formulations of deferasirox, a tablet for suspension, and a new tablet form. This paper is intended to provide an overview of iron overload, with a focus on deferasirox, and its recently approved formulation Jadenu((R)) for the reduction of transfusional iron overload in hematological disorders.

FAU - Chalmers, Anna W

AU - Chalmers AW

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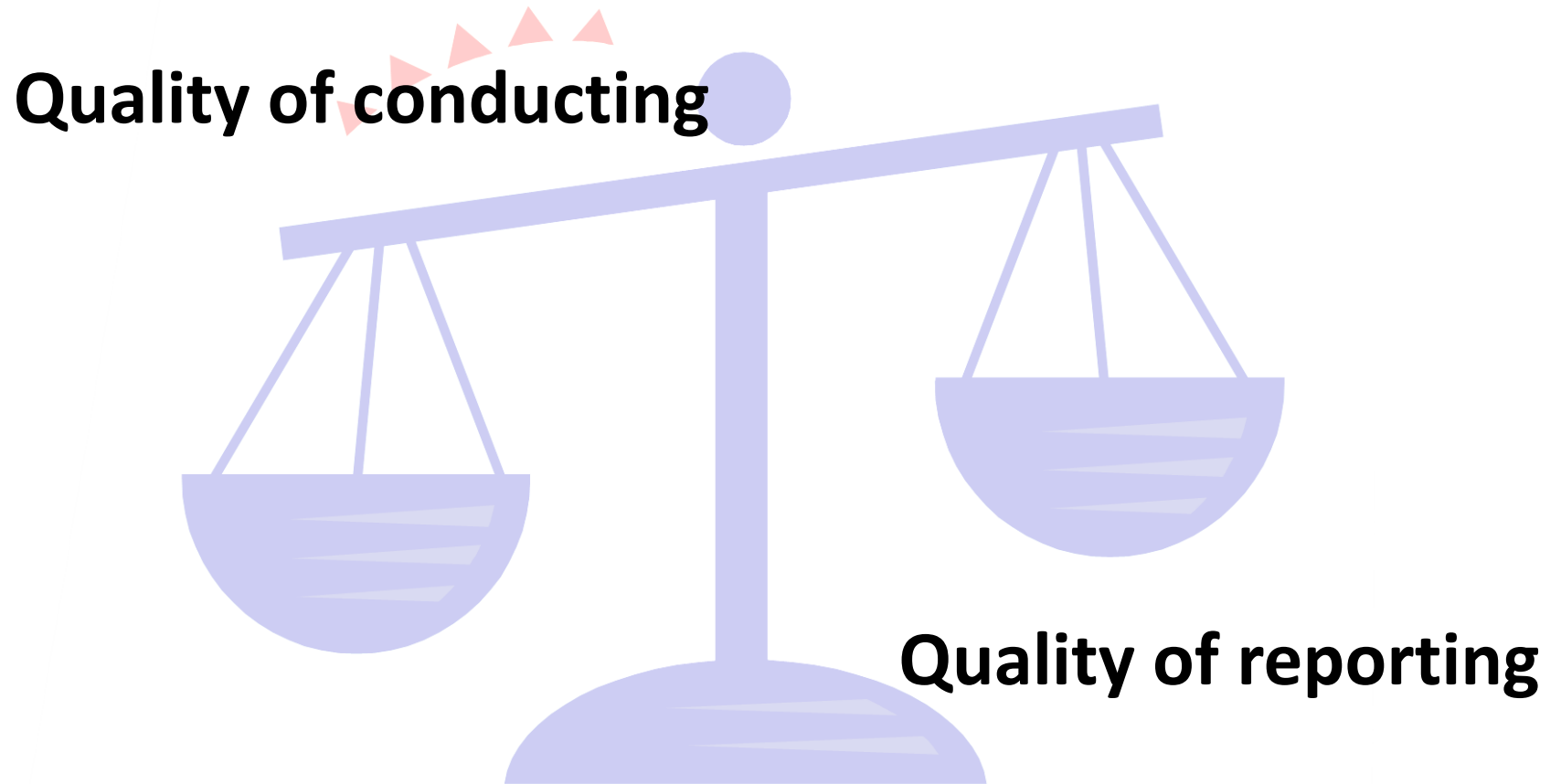
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AU - Chalmers AW



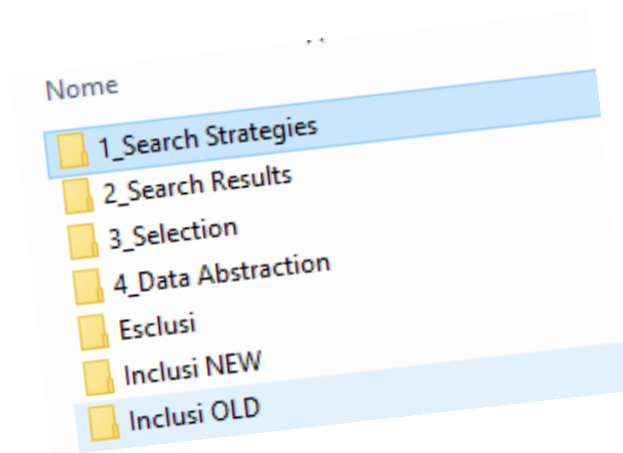
What and How?



Conducting

Document

the selection process in sufficient detail to complete a PRISMA flow chart



Included or excluded?

Was a list of studies (included and excluded) provided?

- A list of included and excluded studies should be provided.
- Provide justification for each exclusion.

AMSTAR - A measurement tool for the 'assessment of multiple systematic reviews'

Duplicate selection

Was there duplicate study selection?

There should be at least two independent data extractors and a consensus procedure for disagreements should be in place

AMSTAR - A measurement tool for the 'assessment of multiple systematic reviews'

Conducting

Reporting

In pratica..

1. Ottenere una unica lista di referenze

- I risultati della ricerca di ogni database vanno importati su un programma di gestione delle referenze (endnote, excel)
- Eliminare i doppioni (stesso articolo indicizzato su più di una banca dati e quindi trovato più volte)

In pratica..

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- Eliminare i doppioni (stesso articolo indicizzato su più di una banca dati e quindi trovato più volte)

2. Selezionare gli articoli potenzialmente rilevanti da acquisire in full text

- Scriversi su un foglio i criteri di inclusione sotto forma di PICOS
- Valutare ogni titolo e abstract rispetto al PICOS

3. Obiettivo è non perdere nulla

- Fare il lavoro in due in modo indipendente
- In caso di dubbio, disaccordo o mancanza di abstract il titolo si seleziona lo stesso

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4. Procurarsi i full text

3. Obiettivo è non perdere nulla

- Fare il lavoro in due in modo indipendente
- In caso di dubbio, disaccordo o mancanza di abstract il titolo si seleziona lo stesso

4. Procurarsi i full text

5. Rivalutare ogni articolo leggendo il full text rispetto al PICOS

- Fare il lavoro in due in modo indipendente
- Confrontarsi sui risultati
- In questa fase vanno presi solo gli articoli realmente pertinenti
In caso di differenze:
 - Risolvere il disaccordo tramite discussione
 - Rivolgersi a terzo revisore

6. Fare lista di studi esclusi

- Indicare ragione dell'esclusione sempre in base al PICOS
- Es: studi esclusi perché partecipanti non nei criteri di inclusione, intervento non nei criteri di inclusione, disegno di studio non nei criteri di inclusione
- Questo lavoro va fatto solo sui full text, non per gli studi esclusi sulla base dell' abstract

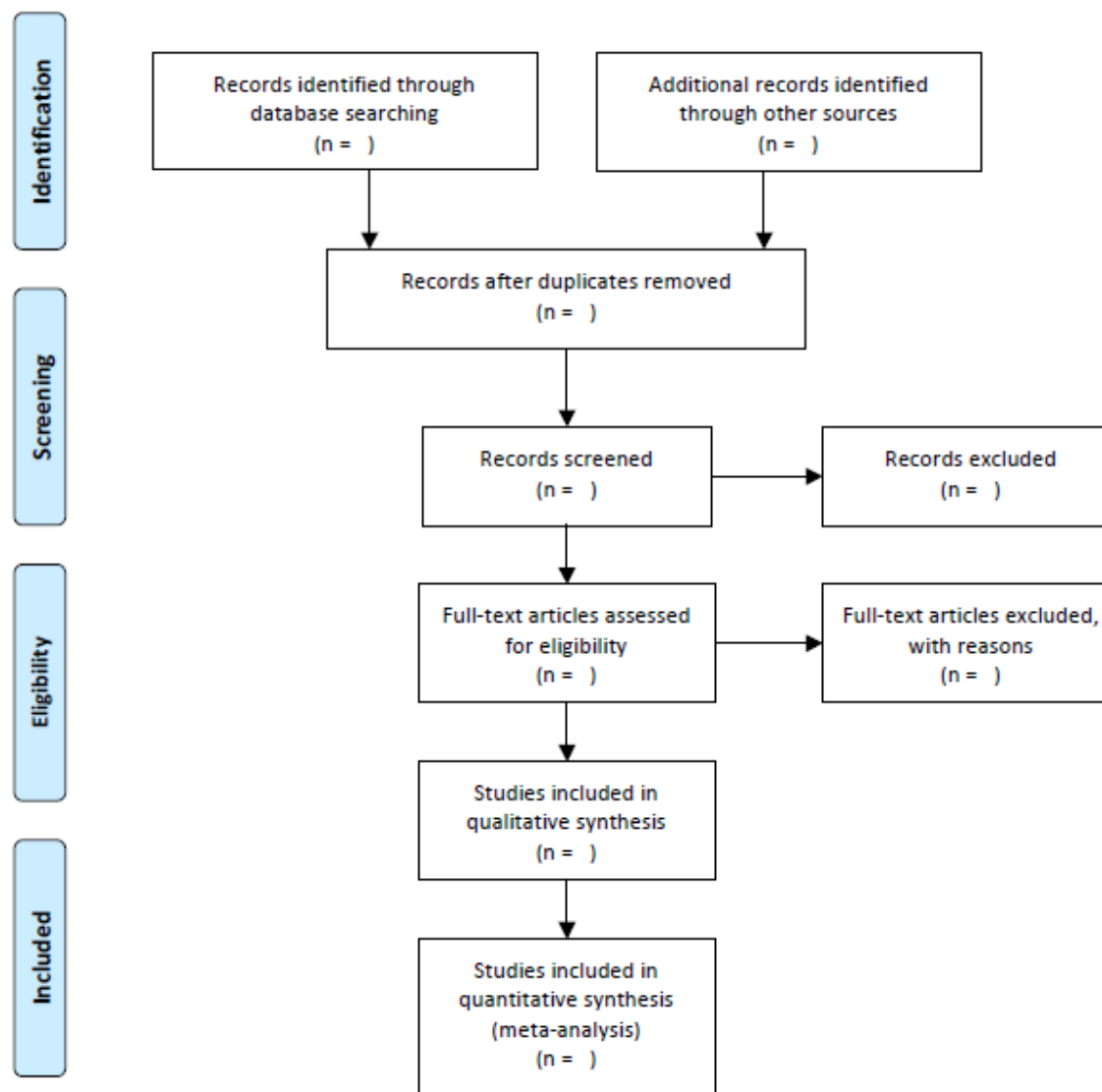
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- Questo lavoro va fatto solo sui full text, non per gli studi esclusi sulla base dell' abstract

7. Fare lista finali di studi inclusi

- Se presenti più record di un articolo tenerli per eventuali dati
Es: diversi periodi di follow up, analisi di sottogruppi; doppie pubblicazioni (stesso studio pubblicato più volte su riviste diverse con titolo diverso e/o diverso ordine degli autori)

8. Fare flow chart (es: PRISMA)



Reporting of systematic reviews

Good reporting of primary studies is crucial for SR development



The reporting need to be
clear, explicit and transparent

Reporting

METHOD SECTION

RESULTS SECTION


Conducting

Reporting

Method section

Search methods for identification of studies

We searched the Cochrane Central Register of Controlled Trials (Issue 3, 2004) and these electronic databases: MEDLINE and EMBASE (up to October 2004), PsychInfo and CINAHL (1999 to October 2004). We conducted citation searches, screened cited references of exercise reviews and contacted content experts for additional trials. We did not restrict the searches or inclusion criteria to any specific language (see Appendix 1; Appendix 2 for full strategy).



**Riportate per esteso per
permettere
RIPRODUCIBILITA' e
UPDATE**

**Salvare le strategie di
ricerca per poter includerle
nella review**

Hyden et al. 2011

Appendix

Appendix I. CENTRAL search strategy

1. #1 MeSH descriptor Back explode all trees
2. #2 MeSH descriptor Buttocks, this term only
3. #3 MeSH descriptor Leg, this term only
4. #4 MeSH descriptor Back Pain explode tree 1
5. #5 MeSH descriptor Back Injuries explode all trees
6. #6 MeSH descriptor Low Back Pain, this term only
7. #7 MeSH descriptor Sciatica, this term only
8. #8 (low next back next pain)
9. #9 (lbp)
10. #10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
11. #11 MeSH descriptor Musculoskeletal Manipulations explode all trees
12. #12 MeSH descriptor Chiropractic explode all trees
13. #13 manip*
14. #14 MeSH descriptor Osteopathic Medicine explode all trees
15. #15 osteopath*
16. #16 chiropract*
17. #17 (#11 OR #12 OR #13 OR #14 OR #15 OR #16)
18. #18 (#17 AND #10)
19. #19 (#18)

**RIPRODUCIBILITA'
e UPDATE**

Update della strategia di ricerca

- La ricerca bibliografica è il primo processo da eseguire dopo aver scritto il protocollo
- È probabile che quando si sottomette la review per la pubblicazione la ricerca sia «vecchia»
- Le riviste sono più interessate a studi aggiornati...

Rerun or update searches for all relevant databases within 12 months before publication of the review or review update, and screen the results for potentially eligible studies.

Mandatory

Incorporate fully any studies identified in the rerun or update of the search within 12 months before publication of the review or review update.

Highly desirable

Method section

Study selection

- State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)
- How many people are involved
- Did they work independently?
- Describe how disagreements were handled

..in the text

Selecting trials for inclusion:

All the citations identified by the above searches were downloaded into a reference manager database. Two authors (ES and RYN), non-blinded to authors and publication journals, independently screened for inclusion, using the pre-specified criteria. If it was clear from the abstract that the study did not meet the selection criteria, it was excluded. If it was unclear from the abstract whether the study met the selection criteria, the full paper was retrieved. Two authors (MAK and SAMH), using the same selection criteria used for the abstract screening, read the full paper and made final selection decisions. Any discrepancies were resolved by discussion, followed, if necessary, by a third reviewer (RYN) if disagreement persisted.

For studies that were excluded following review of the full text, reasons for exclusion were detailed in the Characteristics of Excluded Studies table, with a summary provided in the text of the review.

Yousefi-Nooraie et al. 2011

Results section

Study selection

- Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram

Studies awaiting classification

- List the characteristics of any studies that have been identified as potentially eligible but have not been incorporated into the review - Studies about which an inclusion or exclusion decision cannot be made because sufficient information is not currently available.

..in the text



Good quality of reporting

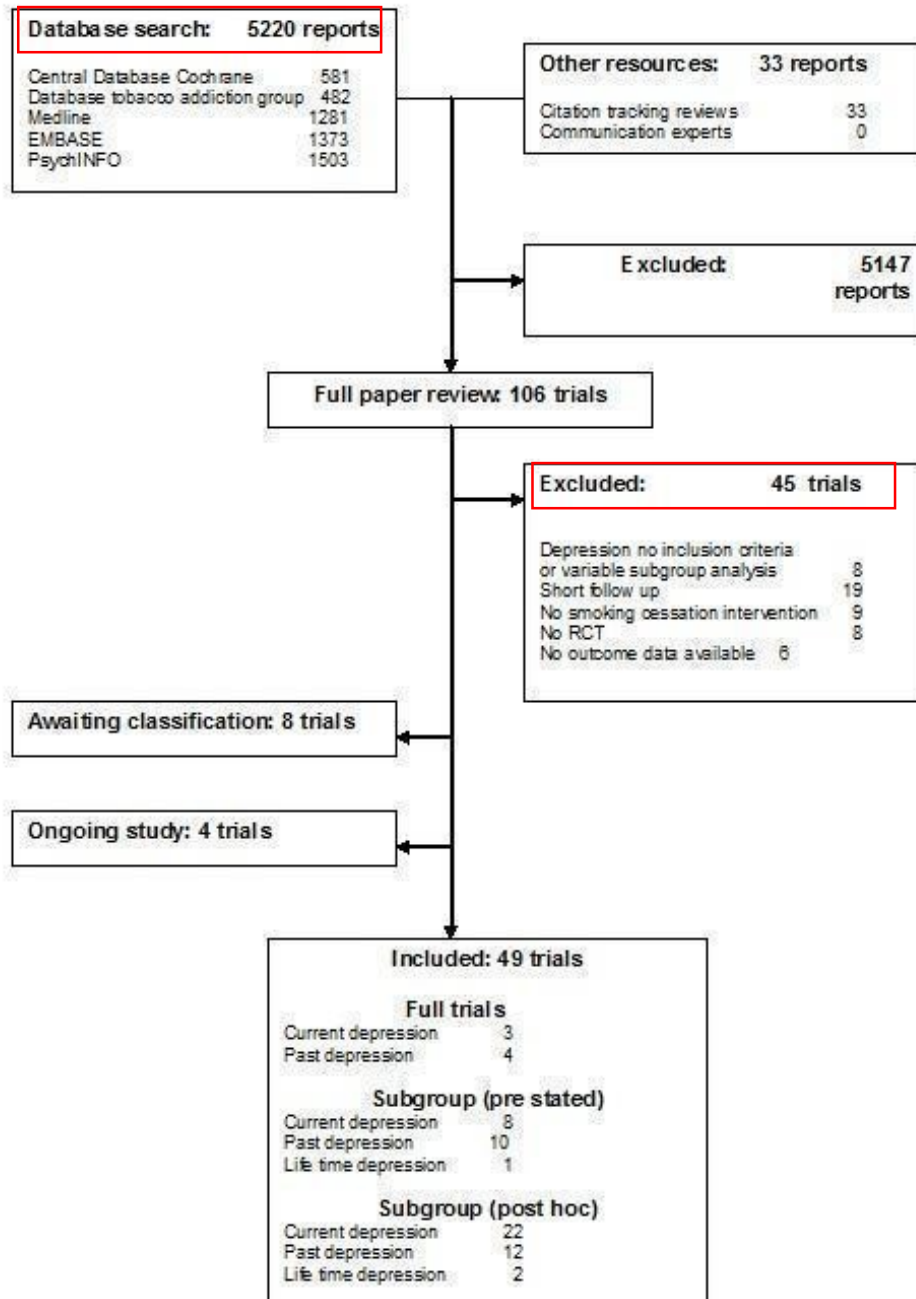
We identified 5220 reports from the electronic search of the databases. See [Figure 1](#) for a summary of the process for identifying trials for inclusion. We identified 33 reports by checking the reference lists of relevant reviews and through communication with experts in the tobacco control and depression field. After screening, we reviewed the full text of 106 trials that were considered potentially eligible. Of these, 45 trials were excluded after reviewing the full text (see Characteristics of excluded studies). Four studies were ongoing and the outcomes are expected in 2013 to 2014 (see Characteristics of ongoing studies). Eight studies are awaiting classification. We asked the authors for additional data, which they have not yet supplied (see Characteristics of studies awaiting classification).

(Van der Meer RM 2013 Rev Cochrane Database)



Poor quality of reporting

We identified and included 21 reports of 7 trials with a total of 260 participants.
(Tsoi 2010)



..in the text

(Van der Meer RM 2013 Rev Cochrane Database)

AMSTAR CHECKLIST

- Valuta il **QUALITY OF CONDUCT**: la misura in cui la revisione è esente da errori sistematici
- Per aiutare chi legge a capire se la SR è affidabile e valida
- Composta di 11 items
- [Shea BJ et al.](#) Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol. 2007 Feb 15;7:10.

AMSTAR – a measurement tool to assess the methodological quality of systematic reviews.

1. Was an 'a priori' design provided?

The research question and inclusion criteria should be established before the conduct of the review.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a "yes."

2. Was there duplicate study selection and data extraction?

There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

- ☐ Yes
- ☐ No
- ☐ Can't answer
- ☐ Not applicable

Note: 2 people do study selection, 2 people do data extraction, consensus process or one person checks the other's work.

3. Was a comprehensive literature search performed?

At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized

- ☐ Yes
- ☐ No

AMSTAR CHECKLIST II

- *“... The original AMSTAR instrument did not include an assessment of the risk of bias in non-randomised studies included in a review, which is a key issue given the diversity of designs that such studies may use and the biases that may affect them”.*
- [Shea BJ et al.](#) AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008
- 16 items

AMSTAR CHECKLIST II

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:

- ☐ Population
- ☐ Intervention
- ☐ Comparator group
- ☐ Outcome

Optional (recommended)

- ☐ Timeframe for follow-up
- ☐ Yes
- ☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:

The authors state that they had a written protocol or guide that included ALL the following:

- ☐ review question(s)
- ☐ a search strategy
- ☐ inclusion/exclusion criteria
- ☐ a risk of bias assessment

For Yes:

As for partial yes, plus the protocol should be registered and should also have specified:

- ☐ a meta-analysis/synthesis plan, if appropriate, *and*
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

- ☐ Yes
- ☐ Partial Yes
- ☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:

- ☐ *Explanation for* including only RCTs
- ☐ OR *Explanation for* including only NRSI
- ☐ OR *Explanation for* including both RCTs and NRSI
- ☐ Yes
- ☐ No

AMSTAR CHECKLIST II

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):

- ☐ searched at least 2 databases (relevant to research question)
- ☐ provided key word and/or search strategy
- ☐ justified publication restrictions (eg, language)

For Yes, should also have (all the following):

- ☐ searched the reference lists/bibliographies of included studies
- ☐ searched trial/study registries
- ☐ included/consulted content experts in the field
- ☐ where relevant, searched for grey literature
- ☐ conducted search within 24 months of completion of the review

- ☐ Yes
- ☐ Partial Yes
- ☐ No

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:

- ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
- ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 per cent), with the remainder selected by one reviewer

- ☐ Yes
- ☐ No

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

- ☐ at least two reviewers achieved consensus on which data to extract from included studies
- ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 per cent), with the remainder extracted by one reviewer

- ☐ Yes
- ☐ No

AMSTAR CHECKLIST II

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes:

- ☐ provided a list of all potentially relevant studies that were read in full text form but excluded from the review

For Yes, must also have:

- ☐ Justified the exclusion from the review of each potentially relevant study

- ☐ Yes
- ☐ Partial Yes
- ☐ No

8. Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):

- ☐ described populations
- ☐ described interventions
- ☐ described comparators
- ☐ described outcomes
- ☐ described research designs

For Yes, should also have ALL the following:

- ☐ described population in detail
- ☐ described intervention and comparator in detail (including doses where relevant)
- ☐ described study's setting
- ☐ timeframe for follow-up

- ☐ Yes
- ☐ Partial Yes
- ☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from

- ☐ unconcealed allocation, and
- ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all cause mortality)

For Yes, must also have assessed RoB from:

- ☐ allocation sequence that was not truly random, and
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☐ Yes
- ☐ Partial Yes
- ☐ No
- ☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:

- ☐ from confounding, and
- ☐ from selection bias

For Yes, must also have assessed RoB:

- ☐ methods used to ascertain exposures and outcomes, and
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☐ Yes
- ☐ Partial Yes
- ☐ No
- ☐ Includes only RCTs

AMSTAR CHECKLIST II

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes

- | | |
|---|------------------------------|
| <input type="checkbox"/> Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information but it was not reported by study authors also qualifies | <input type="checkbox"/> Yes |
| | <input type="checkbox"/> No |

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- | | |
|---|---|
| <input type="checkbox"/> The authors justified combining the data in a meta-analysis | <input type="checkbox"/> Yes |
| <input type="checkbox"/> AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present | <input type="checkbox"/> No |
| | <input type="checkbox"/> No meta-analysis |

For NRSI

For Yes:

- | | |
|---|---|
| <input type="checkbox"/> The authors justified combining the data in a meta-analysis | <input type="checkbox"/> Yes |
| <input type="checkbox"/> AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present | <input type="checkbox"/> No |
| <input type="checkbox"/> AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available | <input type="checkbox"/> No meta-analysis conducted |
| <input type="checkbox"/> AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review | |

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- | | |
|--|---|
| <input type="checkbox"/> included only low risk of bias RCTs | <input type="checkbox"/> Yes |
| <input type="checkbox"/> OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect | <input type="checkbox"/> No |
| | <input type="checkbox"/> No meta-analysis conducted |

AMSTAR CHECKLIST II

13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?

For Yes:

- | | |
|---|------------------------------|
| <input type="checkbox"/> included only low risk of bias RCTs | <input type="checkbox"/> Yes |
| <input type="checkbox"/> OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results | <input type="checkbox"/> No |

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- | | |
|--|---|
| <input type="checkbox"/> There was no significant heterogeneity in the results | |
| <input type="checkbox"/> OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review | <input type="checkbox"/> Yes
<input type="checkbox"/> No |

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- | | |
|---|--|
| <input type="checkbox"/> performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias | <input type="checkbox"/> Yes
<input type="checkbox"/> No
<input type="checkbox"/> No meta-analysis conducted |
|---|--|

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- | | |
|---|------------------------------|
| <input type="checkbox"/> The authors reported no competing interests OR | <input type="checkbox"/> Yes |
| <input type="checkbox"/> The authors described their funding sources and how they managed potential conflicts of interest | <input type="checkbox"/> No |

ROBIS: A new tool to assess risk of bias in systematic reviews was developed

Penny Whiting^{a,b,c,*}, Jelena Savović^{a,b}, Julian P.T. Higgins^{a,d}, Deborah M. Caldwell^a, Barnaby C. Reeves^e, Beverley Shea^f, Philippa Davies^{a,b}, Jos Kleijnen^{c,g}, Rachel Churchill^a, the ROBIS group

^aSchool of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, UK

^bThe National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West at University Hospitals Bristol NHS Foundation Trust, 9th Floor, Whitefriars, Lewins Mead, Bristol BS1 2NT

^cKleijnen Systematic Reviews Ltd, Unit 6, Escrik Busi

^dCentre for Reviews and Dissemination, I

^eSchool of Clinical Sciences, University of Bristol, Bristol Royal Infirmary

^fCommunity Information and Epidemiological Technologies Institute of Popula

^gSchool for Public Health and Primary Care (CAPRI), Maastrich

Accepted 5 June 2015; Publi

Phase 2: Identifying concerns with the review process

DOMAIN 1: STUDY ELIGIBILITY CRITERIA

Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified:

1.1 Did the review adhere to pre-defined objectives and eligibility criteria?	Y/PY/PN/N/NI
1.2 Were the eligibility criteria appropriate for the review question?	Y/PY/PN/N/NI
1.3 Were eligibility criteria unambiguous?	Y/PY/PN/N/NI
1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?	Y/PY/PN/N/NI
1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	Y/PY/PN/N/NI

Concerns regarding specification of study eligibility criteria LOW/HIGH/UNCLEAR

Rationale for concern:

DOMAIN 2: IDENTIFICATION AND SELECTION OF STUDIES

Describe methods of study identification and selection (e.g. number of reviewers involved):

2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?	Y/PY/PN/N/NI
2.2 Were methods additional to database searching used to identify	Y/PY/PN/N/NI

Abstract

Objective: To develop ROBIS, a new tool for assessing the risk

Study Design and Setting: We used four-stage approach to develop face meeting, and refine the tool through piloting.

ROBIS QUALITY OF CONDUCT Checklist

PRISMA Statement

OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

David Moher^{1,2*}, Alessandro Liberati^{3,4}, Jennifer Tetzlaff¹, Douglas G. Altman⁵, The PRISMA Group[¶]

¹ Ottawa Methods Centre, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, ² Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada, ³ Università di Modena e Reggio Emilia, Modena, Italy, ⁴ Centro Cochrane Italiano, Istituto Ricerche Farmacologiche Mario Negri, Milan, Italy, ⁵ Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom





PRISMA

- PRISMA is an evidence-based **minimum set of items** for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.

<http://www.prisma-statement.org/>

PRISMA

- Pubblicato nel 2009, evoluzione del QUOROM statement (guida, pubblicata nel 1999, per migliorare il reporting di meta-analisi di RCT).
- Valuta il ***QUALITY OF REPORTING***
- Pubblicato in Annals of Internal Medicine, PLoS Medicine, Open Medicine, the British Medical Journal and the Journal of Clinical Epidemiology.

KEY DOCUMENTS

- [PRISMA Statement](#)
- [PRISMA Checklist](#)
- [PRISMA flow diagram](#)
- [PRISMA E&E](#)

PRISMA Checklist

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants; and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2 for each meta-analysis).	

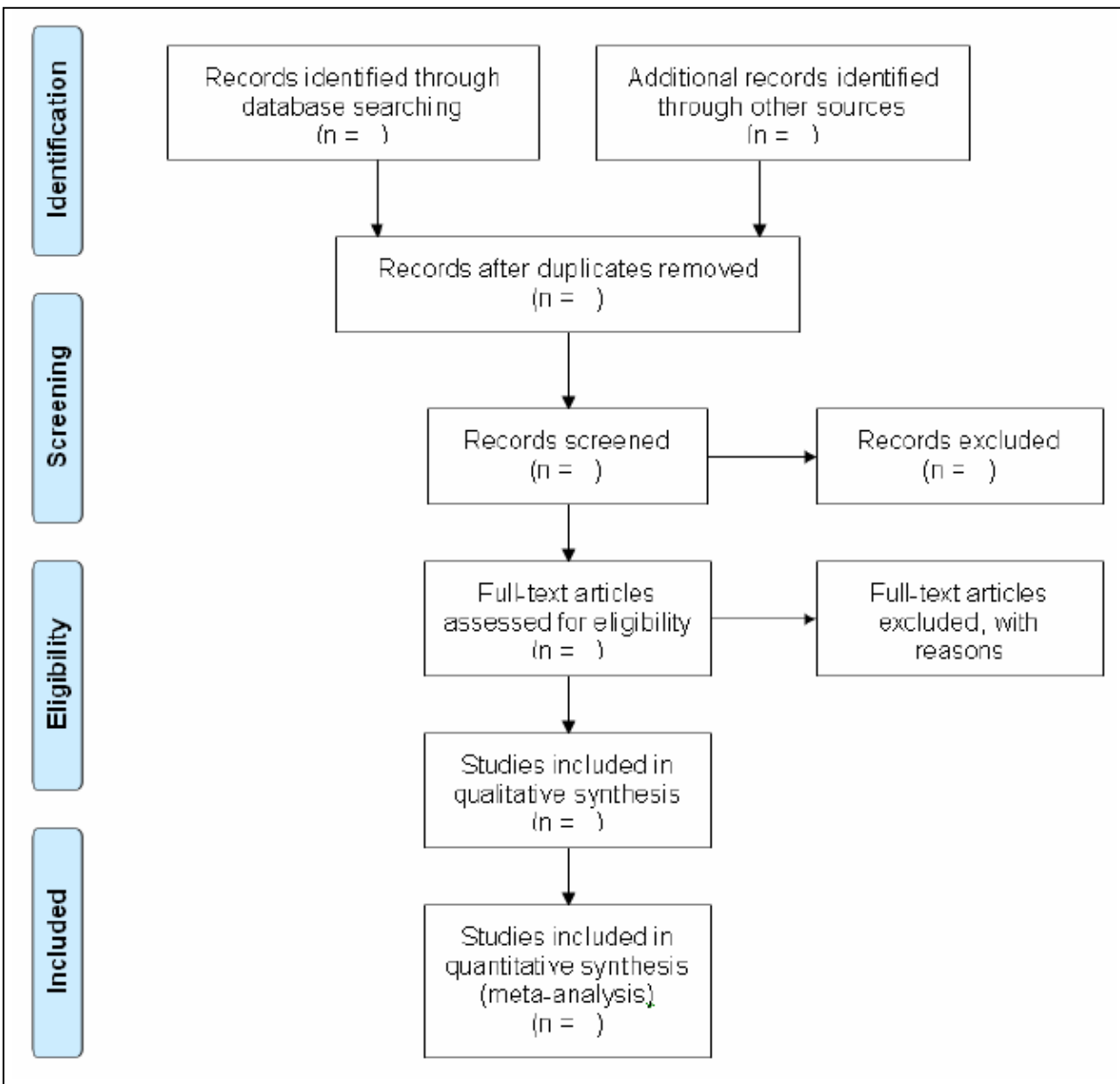
PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression (see item 16)).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome, consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2006). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed.0060097

For more information, visit: www.prisma-statement.org

PRISMA Flow diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Style and Format

[File format](#)

[Length](#)

[Font](#)

[Headings](#)

[Layout](#)

[Page and line numbers](#)

[Footnotes](#)

Submission Guidelines

PLOS Medicine publishes original research articles of outstanding medical importance. We will consider manuscripts of any length; we encourage the submission of both substantial full-length bodies of work and shorter manuscripts that report novel findings that might be based on a more limited range of experiments.

The writing style should be concise and accessible, avoiding jargon so that the paper is understandable for readers outside a specialty or those whose first language is not English. Editors will make suggestions for how to achieve this, as well as suggestions for deletions or additions that could be made to the article to strengthen the argument. Our aim is to make the editorial process rigorous and consistent, but not intrusive or overbearing. Authors are encouraged to use their own voice and to decide how best to present their ideas, results, and conclusions.

Systematic reviews and meta-analyses

Reports of systematic reviews and meta-analyses must adhere to the [PRISMA Statement](#) or alternative guidelines appropriate to the study design, and include the completed checklist and flow diagram to accompany the main text. Authors must complete the appropriate reporting checklist not only with page references, but also with sufficient text excerpted from the manuscript to explain how they accomplished all applicable items.



Download blank templates of the checklist and flow diagram from the [EQUATOR web site](#).

Abstracts should follow [PRISMA for Abstracts](#), using the PLOS abstract format. Authors must also state within the Methods section of their paper whether a protocol exists for their systematic review, and if so, provide a copy of the protocol as supporting information.

Esempio

PLOS ONE

Efficacy of muscle exercise in patients with muscular dystrophy: a systematic review showing a missed opportunity to improve outcomes

Section/topic	#	Checklist item	Reported on page #
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INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page #2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page #2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	None
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page #2-3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page #3
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Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page #4

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The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



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guideline to use?**



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under development**



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[Quality improvement studies](#)

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[PRISMA](#)

[SPIRIT](#)

[STARD](#)

[CARE](#)

[AGREE](#)

[SRQR](#)

[ARRIVE](#)

[SQUIRE](#)

[Extensions](#)

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[Extensions](#)

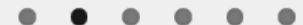
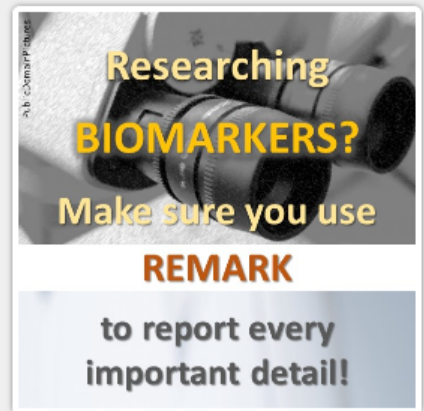
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Example of bad reporting

[Hip Int.](#) 2012 Jul-Aug;22 Suppl 8:S19-24. doi: 10.5301/HIP.2012.9566.

Value of debridement and irrigation for the treatment of peri-prosthetic infections. A systematic review.

Abstract

Debridement and irrigation has been proposed as a salvage procedure for early post-operative and late acute haematogenous periprosthetic hip and knee infections, however the effective ability of this procedure to avoid recurrent infection is still debated. In this systematic review of the literature we reviewed full-text papers published from 1970 through 2011, that reported the success rate of infection eradication after debridement and irrigation with prosthesis retention for the treatment of early septic complications (within six weeks from surgery) or late acute haematogenous infections after hip or knee prosthesis. In all, 14 original articles, reporting the results of 710 patients were retrieved. The average success rate has been, respectively, 45.9% and 52% after a single or repeated debridement and irrigation procedures, at a mean follow-up of 53.3 months. The methodological limitations of this study and the heterogeneous material in the reviewed papers notwithstanding, this systematic review shows that debridement and irrigation procedure is associated with a rather poor outcome, even in a population of patients selected on the basis of symptoms' duration and patients should be adequately informed prior to undergo this salvage procedure.

- ✓ **ABSTRACT NON STRUTTURATO IN INTRODUZIONE, OBIETTIVI, RISORSE RICERCA, CRITERI DI ELIGIBILITA', INTERVENTI, CRITICAL APPRISAL, SINTESI DEI METODI, RISULTATI, LIMITAZIONI CONCLUSIONI, IMPLICAZIONI**
- ✓ **SYSTEMATIC REVIEW REGISTRATION NUMBER**
- ✓ **MANCANO BANCHE DATI**

Example of good reporting

Virtual Reality Therapy for Adults Post-Stroke: A Systematic Review and Meta-Analysis Exploring Virtual Environments and Commercial Games in Therapy

Abstract

Background: The objective of this analysis was to systematically review the evidence for virtual reality (VR) therapy in an adult post-stroke population in both custom built virtual environments (VE) and commercially available gaming systems (CG).

Methods: MEDLINE, CINAHL, EMBASE, ERIC, PSYCInfo, DARE, PEDro, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews were systematically searched from the earliest available date until April 4, 2013. Controlled trials that compared VR to conventional therapy were included. Population criteria included adults (>18) post-stroke, excluding children, cerebral palsy, and other neurological disorders. Included studies were reported in English. Quality of studies was assessed with the Physiotherapy Evidence Database Scale (PEDro).

Results: 32 studies were included. The mean PEDro score was 8.52 (range 0.85-10.0). The overall effect size was moderate to large (Cohen's d = 0.85). The results of the meta-analysis showed that VR rehabilitation moderately improves outcomes compared to conventional therapy in adults post-stroke. Current CG interventions have been too few and too small to assess potential benefits of CG. Future research in this area should aim to clearly define conventional therapy, report on participation measures, consider motivational components of therapy, and investigate commercially available systems in larger RCTs.

Discussion: VR rehabilitation moderately improves outcomes compared to conventional therapy in adults post-stroke. Current CG interventions have been too few and too small to assess potential benefits of CG. Future research in this area should aim to clearly define conventional therapy, report on participation measures, consider motivational components of therapy, and investigate commercially available systems in larger RCTs.

Trial Registration: Prospero CRD42013004338