Strengthening the Evidence in Exercise Sciences Initiative (SEES Initiative): Manual for Standardized Operational Procedures

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Pre-assessment

Search schedule

We conduct the searches in PubMed/MEDLINE between the 3rd to 7th day of each month. Our search strategies are built to retrieve systematic reviews with meta-analysis (SRMA) and randomized clinical trials (RCT) in a separate manner. Therefore, for each journal listed in our journals cohort, we carry out two searches (regarding the SRMA and RCT strategies). The periodicity of searches depends upon the journal category, occurring on a monthly basis for exercise sciences journals and at three-month intervals (every quarter) for general medicine journals. We apply date filters restricting the searches for the two past months, therefore overlapping two searches for a same given month (e.g., February is included in the search ran in March as well as in April). Although this strategy results in several duplicated references because each month is looked up twice, non-overlapped searches yielded loss of some references in out pilot tests using PubMed.

The full search queries for SRMA and RCT are presented at the following document: https://docs.google.com/document/d/19Jhc3KVQBLKNi6VzNGzqOX51MpZyKvC525NhWTML9IY/edit?usp=sharing

Files deposit

Files should be monthly archived at the SEES repository at the Open Science Framework (https://osf.io/ntw7d/) as raw non-manipulated csv files. Folder structure will be based on type of studies (SRMA and RCT) and individual files containing citations should display journal names and month of search in a consistent way.

Assessments

Note for RCT or SRMA articles: Whenever an article being assessed reports a publicly available protocol, registered record, or supplementary materials, please access such records. Although some contents must necessarily be within the articles (e.g., items reported in abstracts), additional information may be obtained from supplementary records/documents and should be taken into consideration at your discretion.

RCT

Journal Information

Journal Name

Check the box that describes the Journal name for the selected study.

What is the YEAR of publication for the study being assessed? (Note: the earliest appearance, such as 'ahead of print' versions should be primarily considered)

We recorded the year and month of the database search, not the year and month of publication ahead of print.

What is the MONTH of publication for the study being assessed? (Note: Consider the earliest appearance such as the 'ahead of print' version)

We recorded the year and month of the database search, not the year and month of publication ahead of print.

Study Information

Title

Copy and paste study's title.

Pubmed ID

Copy and paste study's PMID (EntrezUID).

Registration: Is the study registered in a clinical trial database?

Check "yes" if there is any mention of trial registration.

Registration: If the study is registered, provide the database together with the number of registry. (e.g., NCT01010101, ACTRN01010101010101, UMIN010101010, etc)

If the study is registered on a clinical trial database, copy and paste # of registry. If the study was not registered, please enter "NA".

Protocol: Is there referral of a publicly available methodological protocol? (Note: if so, you must also use the protocol to consult information about the trial)

Check "yes" if there is reference for a *publicly available* methodological protocol which could be published in a scientific journal, deposited in public repositories, Google Drive or others means.

Core assessment

This section refers to the selected items for identification, registration and reporting of structured sections of an individual study being assessed.
To note, there are article sections such and Introduction, Methods, Results before some questions. We highlight that such section names are a non-strict reference to an *expected* section to display the content addressed in the question. For example, if a question is framed as related to "Methods" and you do find the information in other section (say, in the Results), you must interpret that the required information is reported in the manuscript.

Title: Is the study identified as a randomized? (Note: "random allocation", "randomly assigned" should be considered as "Yes")

Check "yes" if there is any mention of random allocation procedures conducted within the study.

Abstract: Does the abstract list the study interventions?

Check “yes” if *all interventions (note: all study's arms)* are cited in the abstract.

Abstract: Does the abstract inform the primary outcome (variable of interest)?

Check “yes” if the primary outcome is clearly identified in the study’s abstract. If broadly/vaguely described (without clarity for the outcome measure, that is different inside the manuscript) will be rated as “no”. For example, generic terms such as “functional capacity”, “physical function”, “vascular health” may actually refer to several variables and therefore should not be considered as a primary outcomes specifically listed.

Abstract: If any quantitative result is reported, is it accompanied by the respective precision estimate (e.g., standard deviation, confidence intervals, etc)?

Check “yes” if numerical results are accompanied by any form(s) of precision estimates.

Abstract: Is a P-value reported in the abstract?

Check “yes” if at least one P-value is reported for the study’s results in the abstract.

Intro/Methods-TID2: Is there a rationale, theory, or goals described to present the essential elements of the intervention?

Check “yes” if the study’s introduction (or methods) gives a satisfactory theoretical explanation for the trial conduction.

Introduction: Is there a hypothesis stated for the outcomes of interest? (Note: if there is not a directional hypothesis, but there is explanation for an exploratory approach, answer "Yes")

Check “yes” if the study’s hypothesis (or it’s exploratory nature) is clearly stated. It can be stated in the abstract or inside the manuscript and needs a direction such as "more effective", "superior", "non-inferior", etc.

Methods: Is there a description for the trial design (e.g., parallel, factorial, cluster)?

Check “yes” if there is a description for the trial design.

Methods: Is there a detailed description of eligibility criteria for participants? (i.e., information that would allow to replicate the inclusion and exclusion decisions)

Check “yes” if sufficient detail of eligibility criteria is given (in order to replicate the experiment). Generic terms such as "elderly" will be rated as “no”.

Methods: Are primary and secondary outcomes listed as well as their measurements specified?

Check “yes” if primary and secondary outcomes are clearly listed *and* if sufficient detail of the data acquisition procedures is given.

Methods: Is the type of randomization sufficiently described? (Note: (i) type, such as computer; (ii) allocation ratio; and (iii) methods of restriction (if any) such as stratification or blocking should be considered)

Check “yes” if randomization procedures were mentioned with minimally reasonable detail.

Methods: Is there a mention regarding the mechanism for allocation concealment?

Check “yes” if any methods of allocation concealment are described.

Methods: Is there a description of blinding/masking for measurements or analysis of outcomes?

Check “yes” if any methods of blinding/masking are mentioned and sufficiently described. If the trial design does not present blinding/masking at any step, but provides a rationale for not doing so check “yes”.

Methods: Is there a description of sample size calculation?

Check “yes” if authors reported the (i)outcome(s) measure(s) (e.g., body weight), AND (ii) the difference sought (e.g., 1.0 kg change), AND (ii) probabilities of type I and type II errors. If the outcome was continuous, the anticipated value for the measure of variability (e.g., standard deviation) should also be reported.

Methods/Intro-TID1: Is there a brief name or a phrase that describes the intervention?

Check "yes" if authors provide a name or a statement to identify the nature of the intervention.

Methods-TID3: Is there a description of physical and information materials used as part of the intervention? (i.e., information that would allow to replicate the intervention with materials for participants or intervention providers)

Check "yes" if any material is available to provide a description of the intervention. Note that it could be also an external source, such as a website.

Methods-TID4: Is there a description of activities or procedures used to carry out the intervention? (i.e., information that would allow to replicate the necessary steps to run the intervention)

Check "yes" if the authors reported interventions' details (personnel, facilities, resources etc). Lack of information (ie. that would need to be retrieved by contacting the authors) will make the question to be rated as "no".

Methods-TID5: Is there a description of individuals involved in providing the intervention? (i.e., information that would allow to replicate the necessary workforce to run the intervention)

Check "yes" if there is a reasonable amount of information of who provided the intervention (e.g., number of providers; their background, etc).

Methods-TID7: Is there a description of location(s) where the intervention occurred? (Note: infrastructure and relevant features should be considered)

Check "yes" if the authors provide the settings in which the interventions were carried out.

Methods/Results-TID8: Is there a description regarding the period, amount, intensity and schedule of delivery? (i.e., information that would allow to replicate 'when' and 'how much')

Check "yes" if there is a partial reporting of the above items (not necessarily all of them).

Methods/Results-TID9: If any form of individual tailoring for the intervention was used (such as, variable exercise intensity), is there a description for the rationale and guide for tailoring?

Check "yes" if the interventions were tailored, by which mechanism, with guidance and rationale. Partial descriptions will be also rated as "yes".

Methods/Results-TID11: Is there a description of materials/strategies used in regard to intervention adherence?

Check "yes" if materials/strategies to improve/control adherence were described or provided in external sources (e.g., protocols, website, etc).

Methods/Results-TID12: Is there a description of results of intervention adherence? (i.e., attrition rates)?

Check "yes" if authors provide any *qualitative or quantitative* information about intervention adherence.

Methods: Is there a description of statistical methods used to compare groups for primary and secondary outcomes?

Check "yes" if the statistical approach was minimally described. If partially described (only for primary/index outcome), please also check "yes".

Results: Is there a participant flow (in text or diagram) reporting the numbers of participants who were assigned, received intervention, and were analyzed for the primary outcome?

Check "yes" authors report the above information about the participant flow accordingly (in format of text or a CONSORT-like flow diagram).

Results: Is there a description regarding the dates/periods of recruitment? (Note: if the follow-up has a variable length, the min-median-max durations should be considered)

Wherever you find this information (methods, results, etc), please check "yes".

Results: Are baseline data for each group presented?

Check "yes" if authors report baseline data (in text or table). The reporting (or lack thereof) of P-values for baseline variables should not affect rating.

Results: Is there a description on the actual number of participants analyzed? (Note: if numbers are reported only for the primary outcome, please choose "Yes")

Check "yes" if authors present the number of participants analyzed (as numbers within the text, in tables or graphs).

Results: Are the effect sizes described along with their precision measures? (e.g., continuous outcomes with standard deviation and binary outcomes with risk measures and absolute numbers)

Check "yes" if authors provided any precision/dispersion/amplitude measures for effect sizes (e.g., standard deviation, standard error, range, interquartile range, variation coefficient etc.) in any form. In graphs, check “yes” if there are numerical values (e.g., group average or individual values) with close correspondence in the axes AND lines/bars of dispersions whenever AND number of individual analyzed for the presented outcome.

Results-TID10: Is there a description for non-planned modifications to the intervention during the course of the study? (Note: regards to the study level, and what-why-when for changes should be considered).

Check "yes" if authors provide informations about protocol deviations (or whether the intervention plan was followed). For this question you should not consult study's protocol/register/supplementary materials, if available.

Results: Is there a description for harm outcomes or adverse events? (Note: whether related or unrelated to interventions)

Check "yes" if authors quantitatively or qualitatively describe harm outcomes/adverse events.

Discussion: Is there a discussion of potential bias, imprecision, multiplicity of analyses or other limitations?

Check "yes" if authors interpreted/discussed their findings in light of the study's limitations (by any nature).

Discussion: Is there a potential spin bias based on a specific reporting strategy to highlight that the experimental treatment is beneficial?

Check "yes" if there is a specific reporting that could distort the interpretation of results and mislead readers. For example, we will consider distorted presentation and interpretation if the authors assessed more than one outcome but asymmetrically discuss or emphasize only outcome(s) with hypothesized or "positive" results.

Is there a statement regarding the data availability (data sharing plan)?

Check "yes" if authors provided a data-sharing plan statement. If authors are not willing to share their data but clearly disclose this intention, check "yes". Details of data-sharing mechanisms are not needed.

Is there a statement regarding the sources of funding?

Check "yes" if authors inform whether the study or involved personnel were funded by grant agencies. Scholarships for students should be also considered.

If any type of funding was reported, list the agency(ies) and institution(s) that supported the study or researchers. (Note: comma-separated)

In the case of the absence of the information, please state as unclear.

Did the trial authors declare whether they had any conflicts of interest (COI)?

Please check yes if the authors disclosed to have financial and non-financial conflicts of interest or not. The absence of a statement, regardless of the presence or not, should be rated as "no".

SRMA

Note for RCT or SRMA articles: Whenever an article being assessed reports a publicly available protocol, registered record, or supplementary materials, please access such records. Although some contents must necessarily be within the articles (e.g., items reported in abstracts), additional information may be obtained from supplementary records/documents and should be taken into consideration at your discretion.

Journal Information

Journal Name

Check the box that describes the Journal name for the selected study.

What is the YEAR of publication for the study being assessed? (Note: the earliest appearance, such as 'ahead of print' versions should be primarily considered)

We recorded the year and month of the database search, not the year and month of publication ahead of print.

What is the MONTH of publication for the study being assessed? (Note: Consider the earliest appearance such as the 'ahead of print' version)

We recorded the year and month of the database search, not the year and month of publication ahead of print.

Study Information

Title

Copy and paste study's title.

Pubmed ID

Copy and paste study's PMID (EntrezUID).

Registration: Is the review registered in a public database?

Check “yes” if authors describe a registration in a publicly available registry in the manuscript (such as PROSPERO).

Registration: If the review is registered, insert the number of registry. (e.g., CRD010101)

If the review is not registered, write: “no registry”.

Protocol: Is there referral of a publicly available methodological protocol? (Note: if so, you must also use the protocol to consult information about the review)

Check “yes” if authors mentioned a study protocol, including its reference.

Core assessment

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To note, there are article sections such and Introduction, Methods, Results before some questions. We highlight that such section names are a non-strict reference to an *expected* section to display the content addressed in the question. For example, if a question is framed as related to “Methods” and you do find the information in other section (say, in the Results), you must interpret that the required information is reported in the manuscript.

Title: Is the study identified as a systematic review, meta-analysis, or both?

Check “yes” if there is a clear identification of intended study design in the title, as mentioned above.

Abstract: Does the abstract list the data sources used in the review? (Note: if more than five databases were used, simplified or partial referral should be considered as "Yes")

Check “yes” if authors sufficiently described the databases.

Abstract: Does the abstract inform key eligibility criteria for study selection?

Check “yes” if authors minimally inform key eligibility criteria in the abstract.

Abstract: Is there a description regarding the population (participants) or main condition(s) addressed in the review?

Check “yes” if there’s a simple reference to these components in the abstract.

Abstract: Is there a description regarding the interventions/exposures (or, broadly, independent variables) addressed in the review?

Check “yes” if there’s a simple reference to these components in the abstract.

Abstract: Is an effect estimate reported in the abstract?

Check “yes” if authors presented a estimative measure (alone or with a precision measure).

Abstract: Is there a description of the number of included studies?

Check “yes” if authors clearly stated the number of included studies.

Abstract: Is there a result description for the main outcome of interest?

Check “yes” if authors described the result of at least one of outcome of interest.

Introduction: Is there a description for the research question (with PICOS elements) or precisely stated objectives (with PICOS) ?

Check “yes” if authors described the PICOS elements of the study in the introduction or objectives.

Methods: How many databases of PUBLISHED evidence were searched?

Databases for grey literature and study registration (e.g., Clinical Trials.gov) should not be accounted for.

Methods: Is there at least one search query fully available? (Note: a full search query should allow complete replication)

A full search query with all search terms and combinations must be available. This is usually available as a supplementary material.

Methods: Did the search strategy include non-published evidence? ("grey literature")

Check “yes” if authors clearly state that grey literature was searched or when databases for study registration (e.g., Clinical Trials.gov) were also consulted.

Methods: If the search is restricted for evidence generated after 1980, is there an indirect or direct justification related to the time range?

Check “yes” if authors state and justify any time range restrictions in the search.

Methods: How many languages were considered for study eligibility?

When authors not report a language restriction for study eligibility our answer will be “no restriction”.

Methods: Is there a detailed explanation of eligibility criteria for PICOS elements? (Note: detailed explanation should allow complete replication)

We consider yes when authors described in detail each one of the PICOS elements.

Methods: Was the study selection carried out in duplicate?

We consider no when authors not report the study selection in duplicate or when only one reviewer performed the selection and another one independently verified it.

Methods: Was the data extraction carried out in duplicate?

We consider no when authors not report the study extraction in duplicate or when only one reviewer performed the extraction and another one independently verified it.

Methods: Is there a description of the assessment of risk of biases?

We consider yes when authors described if there was an assessment of risk of biases.

Methods: Was the assessment of risk of biases carried out in duplicate?

We consider no when authors not report the assessment of risk of biases in duplicate or when only one reviewer performed the assessment and another one independently verified it.

Methods: Is there a description of the statistical combination (meta-analysis) regarding the effect measure (e.g., relative risk or mean difference), statistical method (e.g., inverse variance), and effects approach (fixed or random)?

We consider yes if authors described all these three elements in the statistical analysis section.

Methods: Is there a description regarding the assessment of statistical heterogeneity?

We consider yes when authors described if there was an assessment of heterogeneity.

Results: Is there a full description regarding the numbers of references (retrieval, eligibility, synthesis)?

We consider yes when authors describe these numbers in the text or in the diagram.

Results: Is there a description about the sample sizes of individual studies?

We consider yes when authors describe the sample sizes of individual studies in the text or in a table. Usually, this information is in a supplementary material.

Results: Is there a full description of characteristics? (Note: the available PICOS elements should be considered)

We consider yes when author described in the text or in a table the study characteristics according to PICOS.

Results: Is there a description of study duration (follow-up lengths)?

We consider yes when author described a time frame of interventions/expositions of the studies.

Results: Is there a minimally recommended description of meta-analytic summary estimates? (Note: binary outcomes as frequencies with and without the event (or as proportions such as 12/45); continuous outcomes as the mean, standard deviation, and sample size for each group)

We consider no if authors not presented a full description of meta-analytic summary estimates as indicated in the question.

Results: Is there a full description of individual results for studies composing the meta-analysis? (Note: effects size, imprecision measure and percentage weight should be considered)

We consider yes if authors presented a full description of individual results for studies composing the meta-analysis as indicated in the question. Usually, this information is in the forest plot.

Results: Is there a description of risk of bias within studies? (Note: your assessment should be based on the characteristic of the RoB tool)

We consider yes if authors describe the specific domains of the tool used for risk of bias assessment and partial yes if authors report only a total risk of bias.

Results: Is there a description for non-planned modifications to the synthesis during the course of the review? (e.g.: change in eligibility criteria or RoB tools; please, what was changed and its justification [why] should be considered).

We consider:
a) Yes, if authors did a non-planned modifications and justified clearly.
b) Yes partial, if authors did a non-planned modification but not justified it clearly.
c) No, if authors did a non-planned modification but not justified it.
d) Unclear, if the SRMA does not have a protocol registration and thus it was not possible to verify whether or not a non-planned modification occurred.
e) Does not apply, if the SRMA did not perform a non-planned modification (confirmation at the protocol registration site)

Discussion: Is there a potential spin bias based on a specific reporting strategy to highlight that the experimental treatment (or condition of interest) leads to the hypothesized result?

Check “yes” if there is a specific reporting that could distort the interpretation of results and mislead readers. For example, we will consider distorted presentation and interpretation if the authors assessed more than one outcome but asymmetrically discuss or emphasize only outcome(s) with hypothesized or “positive” results.

Discussion: Are the results discussed in light of the risk of biases in individual studies?

We consider yes if authors took into account risk of bias of individual studies in the discussion of the results found.

Discussion: Are limitations discussed at the study/outcome and/or at the review level?

We consider if author reported the limitations in the primary study level, in the review level or both.

Is there a statement regarding the data availability (data sharing plan)?

We consider yes when author clearly described if there was or not some data sharing plan.

Is there a statement regarding the sources of funding? (Note: funding for the review itself)

We consider yes when author stated if there was or not a source of funding for the review or for the researchers.

If any type of funding was reported, list the agency(ies) and institution(s) that supported the study or researchers. (Note: comma-separated; for review authors only)

We reported literally the agency(ies) and institution(s) that supported the study or researchers as stated in the manuscript.
If there is not any type of funding, we just write “no funding”.

Did the review authors declare whether they had any conflicts of interest (COI)?

We consider yes when author declared if there was or not a financial, non-financial or both conflicts of interest.

To read about the rationale and references for our methods, please access our website and refer to our Protocol: www.sees-initiative.org

We welcome feedback and self-correction.
If you have any corrections or suggestions for improving our procedures, please email us at: sees.initiative@gmail.com