Life and Health Sciences Research Institute
Instituto de Investigação em Ciências da Vida e Saúde

ICVS/3B's
Associate Laboratory
University of Minho

Universidade do Minho
Escola de Ciências da Saúde

Introdução às Revisões Sistemáticas

Sessão Avaliação Qualidade

PhD4Moz
Fostering a sustainable platform to support PhD training in Health Sciences in Mozambique

Filipa Pinto Ribeiro

filiparibeiro@med.uminho.pt

Revisões sistemáticas - Principais passos

1. Desenvolvimento da pergunta de investigação
2. Pesquisa preliminar (Registos de RS e artigos)
3. Definição dos critérios de inclusão/exclusão
4. Definição da estratégia de pesquisa
5. Pesquisa nas bases de dados
6. Registo do protocolo de investigação
7. Triagem por título e resumo
8. Triagem do texto integral
9. Pesquisa manual das referências bibliográficas
10. Extração dos dados
11. Avaliação da qualidade
12. Verificação de dados e análise estatística
13. Meta-análise
14. Verificação das análises (e dados)
15. Redação do manuscrito
16. Submissão do manuscrito

Avaliação da qualidade

- A avaliação da qualidade dos estudos é uma componente essencial das revisões sistemáticas e meta-análises, embora nem todas as revisões a incluam.
- Existem várias ferramentas de avaliação da qualidade disponíveis, embora algumas sejam apenas listas de verificação simples ou não avaliem realmente a qualidade dos trabalhos
- Não existe orientação sobre a seleção de ferramentas de avaliação da qualidade adequadas, mas as equipas de revisão sistemática devem refletir cuidadosamente sobre isso.

Avaliação da qualidade

- Exemplos de ferramentas utilizadas nas revisões sistemáticas:
  - Escala de Newcastle-Ottawa (**NOS**),
  - Lista de verificação do Relatório de Estudos Observacionais em Epidemiologia (**STROBE**)
  - Lista de verificação do Programa de Competências de Avaliação Crítica (**CASP**).
- Estas ferramentas enfrentaram críticas, por serem subjetivas e não diretamente aplicáveis aos desenhos de estudo incluídos em revisões sistemáticas
- A **STROBE**, por exemplo, deve ser utilizado para avaliar a clareza dos relatórios e não a qualidade do estudo, como é praticado na literatura

Avaliação da qualidade

- A ausência de avaliação da evidência dificulta a capacidade de chegar a uma conclusão clara sobre o conjunto de evidências em relação à questão de investigação apresentada.
- A evidência é classificada considerando os pontos fortes e fracos de estudos com características de desenho de estudo semelhantes.
- Diferentes escalas utilizam diferentes abordagens para esta etapa, incluindo a classificação da confiança ou qualidade dos estudos e o nível ou força da evidência.

Avaliação da qualidade

Avaliação da Qualidade	Avaliação do Risco de Erro (Risk of bias)
Avalia a qualidade e fiabilidade geral dos estudos	Avalia a fiabilidade dos resultados com base na qualidade da metodologia
Determina a validade da evidência	Avalia a potencial ocorrência de erros sistemáticos que afetam os resultados
Quão apropriado é o desenho experimental	
Tamanho da amostra	Erros de seleção
Metodologia de colheita de dados	Erros de desempenho
Análise estatística	Deteção de erros/desvios na implementação
Consistência dos dados	Erros de atrição – dados incompletos
Generalização dos resultados	Erros de relato – relato de todos os dados
Adequação do follow-up	
Clareza e transparência dos dados	
Quantitativo	**Qualitativo**

Avaliação da qualidade – Componentes avaliadas

Avaliação da Qualidade	Avaliação do Risco de Erro (Risk of bias)
Alta	Sério
Moderada	Muito Sério
Baixa	Extremamente sério
Muito baixa	
	Inconsistência dos dados (Séria/muito séria)
	Risco de Imprecisão (Sério/muito sério)
	Erros indiretos (Sério/muito sério)

Avaliação da qualidade – Avaliação global

Table 2.4 Instructions on Downgrading for Risk of Bias (Mokkink et al., 2018)

Risk of bias	**Downgrading for Risk of Bias**
No	There are multiple studies of at least adequate quality, or there is one study of very good quality available.
Serious	There are multiple studies of doubtful quality available, or there is only one study of adequate quality
Very serious	There are multiple studies of inadequate quality, or there is only one study of doubtful quality available
Extremely serious	There is only one study of inadequate quality available

Avaliação da qualidade – Ferramentas e sua utilização

Desenho do estudo	Ferramenta	Descrição
RCTs	ROB2	Avalia Risk of Bias em Ensaios randomizados
Não-RCT	ROBIN-I	Avalia Risk of Bias em estudos intervencionais
Relatos de caso	COSMIM	Avalia a validade e adequação dos questionários
Modelos preditivos: Diagnóstico, prognóstico, monitorização	PROBAST	Estudos que desenvolvem modelos preditivos para a deteção de doenças ou sua ocorrência no futuro
Testes de diagnóstico	QUADAS-2	Usado para verificação de testes de diagnóstico

https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials

RoB

Signalling questions	Elaboration	Response options
1.1 Was the allocation sequence random?	Answer 'Yes' if a random component was used in the sequence generation process. Examples include computer-generated random numbers; reference to a random number table; coin tossing; shuffling cards or envelopes; throwing dice; or drawing lots. Minimization is generally implemented with a random element (at least when the scores are equal), so an allocation sequence that is generated using minimization should generally be considered to be random. Answer 'No' if no random element was used in generating the allocation sequence or the sequence is predictable. Examples include alternation; methods based on dates (of birth or admission); patient record numbers; allocation decisions made by clinicians or participants; allocation based on the availability of the intervention; or any other systematic or haphazard method. Answer 'No information' if the only information about randomization methods is a statement that the study is randomized. In some situations a judgement may be made to answer 'Probably no' or 'Probably yes'. For example, , in the context of a large trial run by an experienced clinical trials unit, absence of specific information about generation of the randomization sequence, in a paper published in a journal with rigorously enforced word count limits, is likely to result in a response of 'Probably yes' rather than 'No information'. Alternatively, if other (contemporary) trials by the same investigator team have clearly used non-random sequences, it might be reasonable to assume that the current study was done using similar methods.	Y/PY/PN/N/NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Answer 'Yes' if the trial used any form of remote or centrally administered method to allocate interventions to participants, where the process of allocation is controlled by an external unit or organization, independent of the enrolment personnel (e.g. independent central pharmacy, telephone or internet-based randomization service providers). Answer 'Yes' if envelopes or drug containers were used appropriately. Envelopes should be opaque, sequentially numbered, sealed with a tamper-proof seal and opened only after the envelope has been irreversibly assigned to the participant. Drug containers should be sequentially numbered and of identical appearance, and dispensed or administered only after they have been irreversibly assigned to the participant. This level of detail is rarely provided in reports, and a judgement may be required to justify an answer of 'Probably yes' or 'Probably no'. Answer 'No' if there is reason to suspect that the enrolling investigator or the participant had knowledge of the forthcoming allocation.	Y/PY/PN/N/NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	*Note that differences that are compatible with chance do not lead to a risk of bias. A small number of differences identified as 'statistically significant' at the conventional 0.05 threshold should usually be considered to be compatible with chance.* Answer 'No' if no imbalances are apparent or if any observed imbalances are compatible with chance. Answer 'Yes' if there are imbalances that indicate problems with the randomization process, including: (1) substantial differences between intervention group sizes, compared with the intended allocation ratio; or (2) a substantial excess in statistically significant differences in baseline characteristics between intervention groups, beyond that expected by chance; or	Y/PY/PN/N/NI

	(3) imbalance in one or more key prognostic factors, or baseline measures of outcome variables, that is very unlikely to be due to chance and for which the between-group difference is big enough to result in bias in the intervention effect estimate. Also answer 'Yes' if there are other reasons to suspect that the randomization process was problematic: (4) excessive similarity in baseline characteristics that is not compatible with chance. Answer 'No information' when there is no *useful* baseline information available (e.g. abstracts, or studies that reported only baseline characteristics of participants in the final analysis). The answer to this question should not influence answers to questions 1.1 or 1.2. For example, if the trial has large baseline imbalances, but authors report adequate randomization methods, questions 1.1 and 1.2 should still be answered on the basis of the reported adequate methods, and any concerns about the imbalance should be raised in the answer to the question 1.3 and reflected in the domain-level risk-of-bias judgement. Trialists may undertake analyses that attempt to deal with flawed randomization by controlling for imbalances in prognostic factors at baseline. To remove the risk of bias caused by problems in the randomization process, it would be necessary to know, and measure, all the prognostic factors that were imbalanced at baseline. It is unlikely that all important prognostic factors are known and measured, so such analyses will at best reduce the risk of bias. If review authors wish to assess the risk of bias in a trial that controlled for baseline imbalances in order to mitigate failures of randomization, the study should be assessed using the ROBINS-I tool.	
Risk-of-bias judgement	See Table 3, Table 4 and Figure 1.	Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

RoB

Signalling questions	Elaboration	Response options
2.1. Were participants aware of their assigned intervention during the trial?	If participants are aware of their assigned intervention it is more likely that health-related behaviours will differ between the intervention groups. Blinding participants, most commonly through use of a placebo or sham intervention, may prevent such differences. If participants experienced side effects or toxicities that they knew to be specific to one of the interventions, answer this question 'Yes' or 'Probably yes'.	Y/PY/PN/N/NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	If carers or people delivering the interventions are aware of the assigned intervention then its implementation, or administration of non-protocol interventions, may differ between the intervention groups. Blinding may prevent such differences. If participants experienced side effects or toxicities that carers or people delivering the interventions knew to be specific to one of the interventions, answer question 'Yes' or 'Probably yes'. If randomized allocation was not concealed, then it is likely that carers and people delivering the interventions were aware of participants' assigned intervention during the trial.	Y/PY/PN/N/NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	For the effect of assignment to intervention, this domain assesses problems that arise when changes from assigned intervention that are inconsistent with the trial protocol arose because of the trial context. We use the term trial context to refer to effects of recruitment and engagement activities on trial participants and when trial personnel (carers or people delivering the interventions) undermine the implementation of the trial protocol in ways that would not happen outside the trial. For example, the process of securing informed consent may lead participants subsequently assigned to the comparator group to feel unlucky and therefore seek the experimental intervention, or other interventions that improve their prognosis. Answer 'Yes' or 'Probably yes' only if there is evidence, or strong reason to believe, that the trial context led to failure to implement the protocol interventions or to implementation of interventions not allowed by the protocol. Answer 'No' or 'Probably no' if there were changes from assigned intervention that are inconsistent with the trial protocol, such as non-adherence to intervention, but these are consistent with what could occur outside the trial context. Answer 'No' or 'Probably no' for changes to intervention that are consistent with the trial protocol, for example cessation of a drug intervention because of acute toxicity or use of additional interventions whose aim is to treat consequences of one of the intended interventions. If blinding is compromised because participants report side effects or toxicities that are specific to one of the interventions, answer 'Yes' or 'Probably yes' only if there were changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context. The answer 'No information' may be appropriate, because trialists do not always report whether deviations arose because of the trial context.	NA/Y/PY/PN/N/NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	Changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context will impact on the intervention effect estimate if they affect the outcome, but not otherwise.	NA/Y/PY/PN/N/NI

RoB

2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	Changes from assigned intervention that are inconsistent with the trial protocol and arose because of the trial context are more likely to impact on intervention effect estimate if they are not balanced between the intervention groups.	NA/Y/PY/PN/N/NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Both intention-to-treat (ITT) analyses and modified intention-to-treat (mITT) analyses excluding participants with missing outcome data should be considered appropriate. Both naïve 'per-protocol' analyses (excluding trial participants who did not receive their assigned intervention) and 'as treated' analyses (in which trial participants are grouped according to the intervention that they received, rather than according to their assigned intervention) should be considered inappropriate. Analyses excluding eligible trial participants post-randomization should also be considered inappropriate, but post-randomization exclusions of ineligible participants (when eligibility was not confirmed until after randomization, and could not have been influenced by intervention group assignment) can be considered appropriate.	Y/PY/PN/N/NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	This question addresses whether the number of participants who were analysed in the wrong intervention group, or excluded from the analysis, was sufficient that there could have been a substantial impact on the result. It is not possible to specify a precise rule: there may be potential for substantial impact even if fewer than 5% of participants were analysed in the wrong group or excluded, if the outcome is rare or if exclusions are strongly related to prognostic factors.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See Table 5, Table 6 and Figure 2.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

RoB

Signalling questions	Elaboration	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	The appropriate study population for an analysis of the intention to treat effect is all randomized participants. "Nearly all" should be interpreted as that the number of participants with missing outcome data is sufficiently small that their outcomes, whatever they were, could have made no important difference to the estimated effect of intervention. For continuous outcomes, availability of data from 95% of the participants will often be sufficient. For dichotomous outcomes, the proportion required is directly linked to the risk of the event. If the observed number of events is much greater than the number of participants with missing outcome data, the bias would necessarily be small. Only answer 'No information' if the trial report provides no information about the extent of missing outcome data. This situation will usually lead to a judgement that there is a high risk of bias due to missing outcome data. Note that imputed data should be regarded as missing data, and not considered as 'outcome data' in the context of this question.	Y/PY/PN/N/NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Evidence that the result was not biased by missing outcome data may come from: (1) analysis methods that correct for bias; or (2) sensitivity analyses showing that results are little changed under a range of plausible assumptions about the relationship between missingness in the outcome and its true value. However, imputing the outcome variable, either through methods such as 'last-observation-carried-forward' or via multiple imputation based only on intervention group, should not be assumed to correct for bias due to missing outcome data.	NA/Y/PY/PN/N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	If loss to follow up, or withdrawal from the study, could be related to participants' health status, then it is possible that missingness in the outcome was influenced by its true value. However, if all missing outcome data occurred for documented reasons that are unrelated to the outcome then the risk of bias due to missing outcome data will be low (for example, failure of a measuring device or interruptions to routine data collection). In time-to-event analyses, participants censored during trial follow-up, for example because they withdrew from the study, should be regarded as having missing outcome data, even though some of their follow up is included in the analysis. Note that such participants may be shown as included in analyses in CONSORT flow diagrams.	NA/Y/PY/PN/N/NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	This question distinguishes between situations in which (i) missingness in the outcome could depend on its true value (assessed as 'Some concerns') from those in which (ii) it is likely that missingness in the outcome depended on its true value (assessed as 'High risk of bias'). Five reasons for answering 'Yes' are: 1. Differences between intervention groups in the proportions of missing outcome data. If there is a difference between the effects of the experimental and comparator interventions on the outcome, and the missingness in the outcome is influenced by its true value, then the proportions of missing outcome data are likely to differ between intervention groups. Such a difference suggests a risk of bias due to missing outcome data, because the trial result will be sensitive to missingness in the outcome being related to its true value. For time-to-event-data, the analogue is that rates of censoring (loss to follow-up) differ between the intervention groups. 2. Reported reasons for missing outcome data provide evidence that missingness in the outcome depends on its true value;	NA/Y/PY/PN/N/NI

RoB

	3. Reported reasons for missing outcome data differ between the intervention groups; 4. The circumstances of the trial make it likely that missingness in the outcome depends on its true value. For example, in trials of interventions to treat schizophrenia it is widely understood that continuing symptoms make drop out more likely. 5. In time-to-event analyses, participants' follow up is censored when they stop or change their assigned intervention, for example because of drug toxicity or, in cancer trials, when participants switch to second-line chemotherapy. Answer 'No' if the analysis accounted for participant characteristics that are likely to explain the relationship between missingness in the outcome and its true value.	
Risk-of-bias judgement	See Table 9, Table 10 and Figure 4.	Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

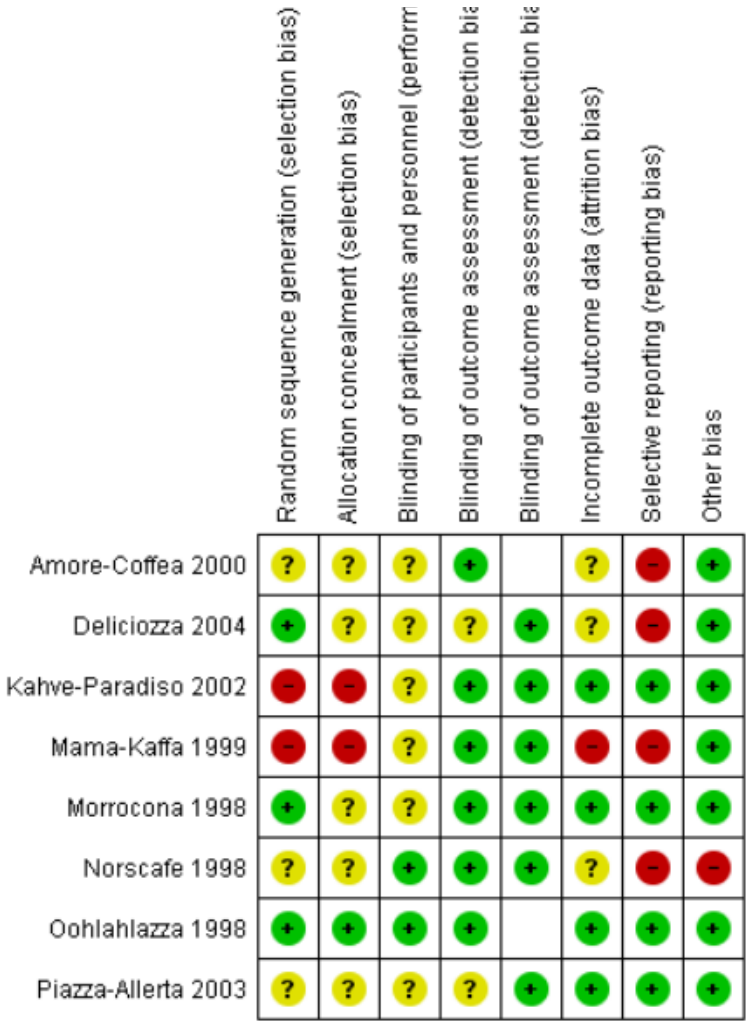
RoB

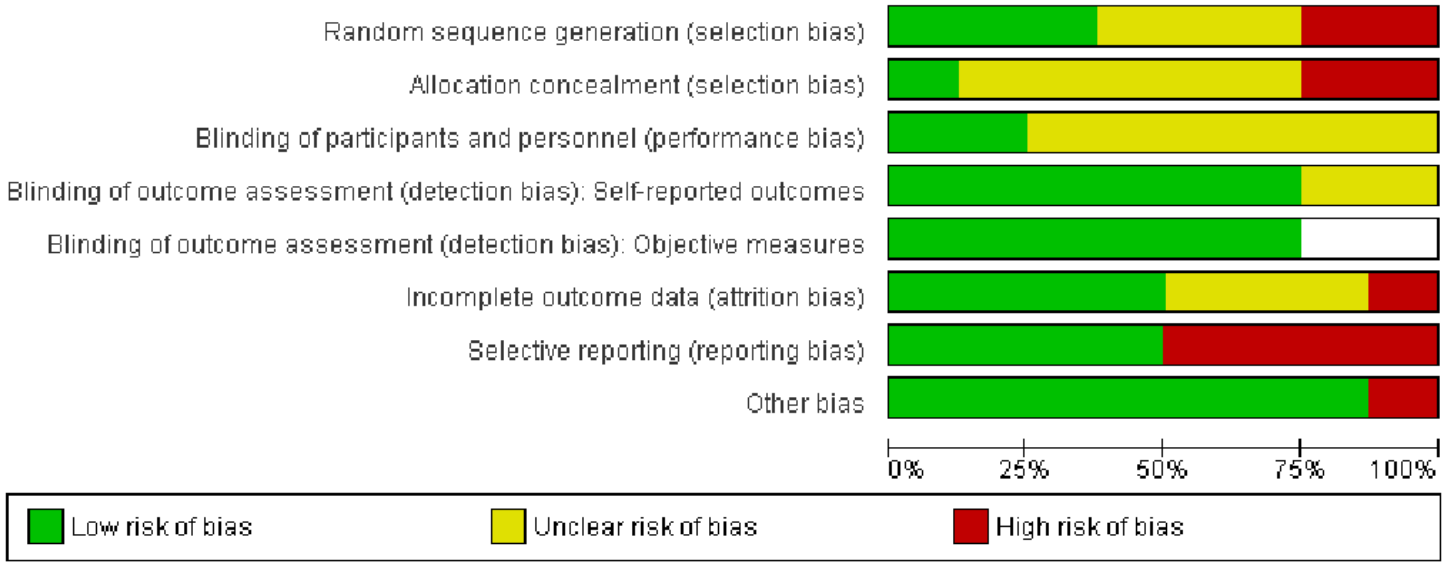
Signalling questions	Elaboration	Response options
4.1 Was the method of measuring the outcome inappropriate?	This question aims to identify methods of outcome measurement (data collection) that are unsuitable for the outcome they are intended to evaluate. The question *does not* aim to assess whether the choice of outcome being evaluated was sensible (e.g. because it is a surrogate or proxy for the main outcome of interest). In most circumstances, for pre-specified outcomes, the answer to this question will be 'No' or 'Probably no'. Answer 'Yes' or 'Probably yes' if the method of measuring the outcome is inappropriate, for example because: (1) it is unlikely to be sensitive to plausible intervention effects (e.g. important ranges of outcome values fall outside levels that are detectable using the measurement method); or (2) the measurement instrument has been demonstrated to have poor validity.	Y/PY/PN/N/NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Comparable methods of outcome measurement (data collection) involve the same measurement methods and thresholds, used at comparable time points. Differences between intervention groups may arise because of 'diagnostic detection bias' in the context of passive collection of outcome data, or if an intervention involves additional visits to a healthcare provider, leading to additional opportunities for outcome events to be identified.	Y/PY/PN/N/NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Answer 'No' if outcome assessors were blinded to intervention status. For participant-reported outcomes, the outcome assessor is the study participant.	NA/Y/PY/PN/N/NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Knowledge of the assigned intervention could influence participant-reported outcomes (such as level of pain), observer-reported outcomes involving some judgement, and intervention provider decision outcomes. They are unlikely to influence observer-reported outcomes that do not involve judgement, for example all-cause mortality.	NA/Y/PY/PN/N/NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	This question distinguishes between situations in which (i) knowledge of intervention status could have influenced outcome assessment but there is no reason to believe that it did (assessed as 'Some concerns') from those in which (ii) knowledge of intervention status was likely to influence outcome assessment (assessed as 'High'). When there are strong levels of belief in either beneficial or harmful effects of the intervention, it is more likely that the outcome was influenced by knowledge of the intervention received. Examples may include patient-reported symptoms in trials of homeopathy, or assessments of recovery of function by a physiotherapist who delivered the intervention.	NA/Y/PY/PN/N/NI
Risk-of-bias judgement	See Table 11, Table 12 and Figure 5.	Low / High / Some concerns

RoB

Signalling questions	Elaboration	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	If the researchers' pre-specified intentions are available in sufficient detail, then planned outcome measurements and analyses can be compared with those presented in the published report(s). To avoid the possibility of selection of the reported result, finalization of the analysis intentions must precede availability of unblinded outcome data to the trial investigators. Changes to analysis plans that were made before unblinded outcome data were available, or that were clearly unrelated to the results (e.g. due to a broken machine making data collection impossible) do not raise concerns about bias in selection of the reported result.	Y/PY/PN/N/NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from…		
5.2. … multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	A particular outcome domain (i.e. a true state or endpoint of interest) may be **measured** in multiple ways. For example, the domain pain may be measured using multiple scales (e.g. a visual analogue scale and the McGill Pain Questionnaire), each at multiple time points (e.g. 3, 6 and 12 weeks post-treatment). If multiple measurements were made, but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result. Attention should be restricted to outcome measurements that are eligible for consideration by the RoB 2 tool user. For example, if only a result using a specific measurement scale is eligible for inclusion in a meta-analysis (e.g. Hamilton Depression Rating Scale), and this is reported by the trial, then there would not be an issue of selection even if this result was reported (on the basis of the results) in preference to the result from a different measurement scale (e.g. Beck Depression Inventory). Answer 'Yes' or 'Probably yes' if: There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a domain was measured in multiple eligible ways, but data for only one or a subset of measures is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results can arise from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception, or vested interest in showing, that an experimental intervention is beneficial may be inclined to report outcome measurements selectively that are favourable to the experimental intervention. Answer 'No' or 'Probably no' if: There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all eligible reported results for the outcome domain correspond to all intended outcome measurements.	Y/PY/PN/N/NI

RoB – Apresentação dos resultados





Equator

equator network

Enhancing the QUAlity and Transparency Of health Research

Website translation help

Home | About us | Library | Toolkits | Courses & events | News | Blog | Contact

Your one-stop-shop for writing and publishing high-impact health research

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines

Library for health research reporting

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

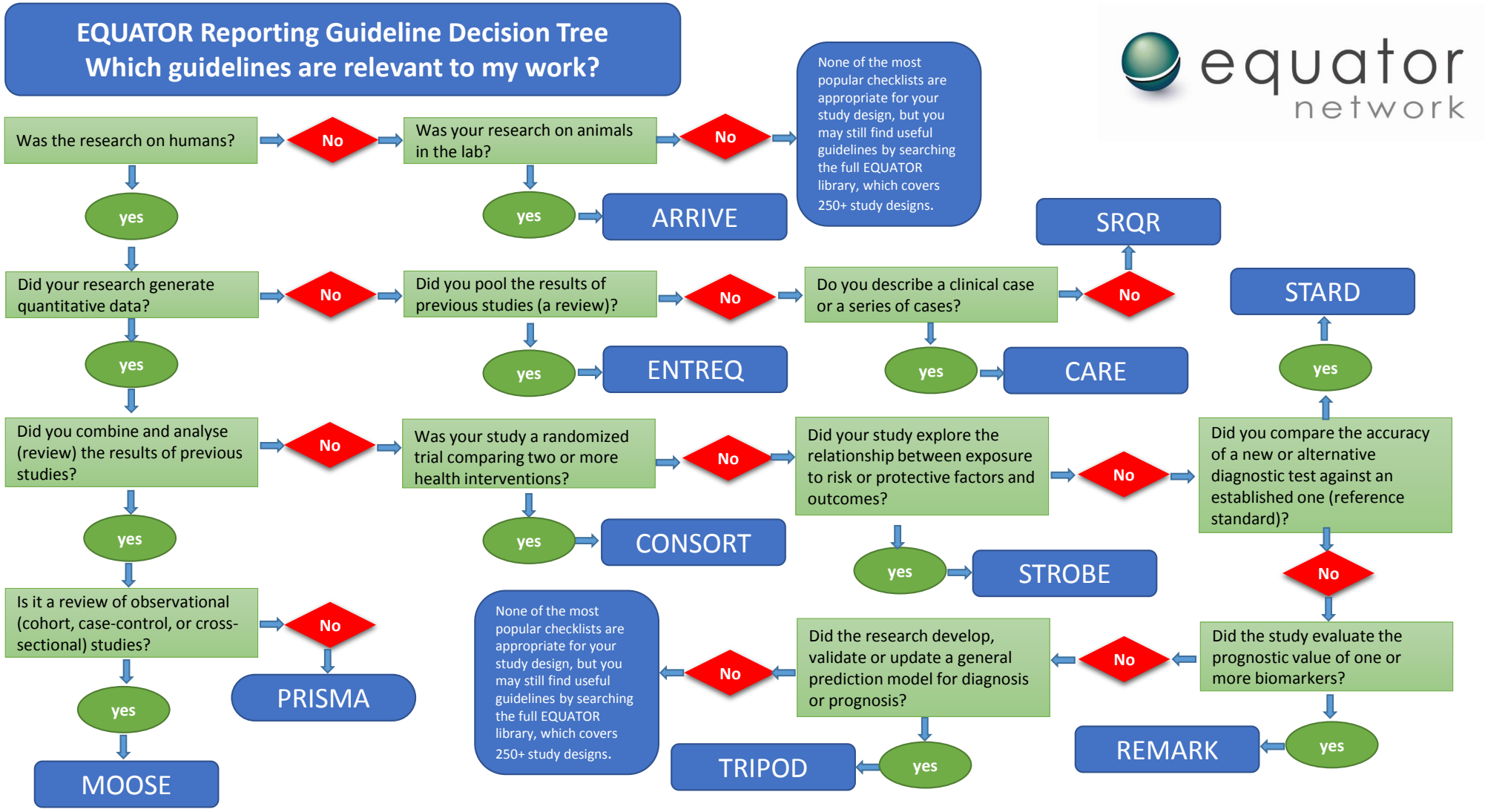
- Search for reporting guidelines
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	Extensions
Economic evaluations	CHEERS	Extensions

See all 665 reporting guidelines

Equator



CASP

HOME CASP TRAINING CHECKLISTS RESOURCES ARTICLES

The CASP checklists are easy to understand but in case you need any further guidance on how they are structured, take a look at our guide on how to use our CASP checklists.

- Systematic Reviews with Meta-Analysis of Observational Studies
- Systematic Reviews with Meta-Analysis of Randomised Controlled Trials (RCTs)
- Randomised Controlled Trial (RCT) Checklist
- Systematic Review Checklist
- Qualitative Studies Checklist
- Cohort Study Checklist
- Diagnostic Study Checklist
- Case Control Study Checklist
- Economic Evaluation Checklist
- Clinical Prediction Rule Checklist
- Cross-Sectional Studies Checklist
- Checklist Archive

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

Section A: Are the results valid?	
1. Did the study address a clearly focused issue?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *A question can be 'focused' in terms of* • *the population studied* • *the risk factors studied* • *is it clear whether the study tried to detect a beneficial or harmful effect* • *the outcomes considered*	
2. Was the cohort recruited in an acceptable way?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *Look for selection bias which might compromise the generalisability of the findings:* • *was the cohort representative of a defined population* • *was there something special about the cohort* • *was everybody included who should have been*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

3. Was the exposure accurately measured to minimise bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *Look for measurement or classification bias:* • *did they use subjective or objective measurements* • *do the measurements truly reflect what you want them to (have they been validated)* • *were all the subjects classified into exposure groups using the same procedure*	
4. Was the outcome accurately measured to minimise bias?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: *Look for measurement or classification bias:* • *did they use subjective or objective measurements* • *do the measurements truly reflect what you want them to (have they been validated)* • *has a reliable system been established for detecting all the cases (for measuring disease occurrence)* • *were the measurement methods similar in the different groups* • *were the subjects and/or the outcome assessor blinded to exposure (does this matter)*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

5. (a) Have the authors identified all important confounding factors?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *list the ones you think might be important, and ones the author missed*	
b) Have they taken account of the confounding factors in the design and/or analysis?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

6. a) Was the follow up of subjects complete enough?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *the persons that are lost to follow-up may have different outcomes than those available for assessment* • *in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort*	
b) Was the follow up of subjects long enough?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *the good or bad effects should have had long enough to reveal themselves*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

Section B: What are the results?	
7. What are the results of this study?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *what are the bottom line results* • *have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference* • *how strong is the association between exposure and outcome (RR)* • *what is the absolute risk reduction (ARR)*	
8. How precise are the results?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER:	
• *look for the range of the confidence intervals, if given*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

9. Do you believe the results?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *big effect is hard to ignore* • *can it be due to bias, chance or confounding* • *are the design and methods of this study sufficiently flawed to make the results unreliable* • *Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)*	

https://casp-uk.net/casp-tools-checklists/

CASP - Cohort

Section C: Will the results help locally?	
10. Can the results be applied to the local population?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *Is a cohort study the appropriate method to answer this question* • *If the subjects covered in this study could be sufficiently different from your population to cause concern* • *If your local setting is likely to differ much from that of the study* • *If you can quantify the local benefits and harms*	
11. Do the results of this study fit with other available evidence?	☐ Yes ☐ No ☐ Can't Tell
12. What are the implications of this study for practice?	☐ Yes ☐ No ☐ Can't Tell
CONSIDER: • *one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making* • *for certain questions, observational studies provide the only evidence* • *recommendations from observational studies are always stronger when supported by other evidence*	

CASP

Supplementary Table S1. Quality of Randomized Controlled Trials assessed through the Critical Appraisal Skills Programme (CASP) checklist.

Study	1	2	3	4	5	6	7	8	9	Quality
Strath, 2020 [19]										Good
Koh, 2019 [31]										Good
Lenguerrand, 2019 [44]										Good
Zheng, 2019 [84]										Good
Ahn, 2019a [18]										Good
Karp, 2019 [62]										Good
Gay, 2019 [95]										Medium
O'moore, 2018 [47]										Good
Ozkuk, 2018 [54]										Good
Uslu Güvendi, 2017 [52]										Good
Allen, 2017 [69]										Good
Mallen, 2017 [65]										Medium
Hsieh, 2016 [78]										Good
Yıldırum, 2015 [90]										Good
Kim, 2014 [103]										Good
Weiner, 2013 [110]										Good
French, 2013 [107]										Medium
Ulus, 2012 [114]										Good
Bearne, 2011 [122]										Medium
Akyol, 2010 [130]										Medium
Corsinovi, 2009 [137]										Medium
Wang, 2009 [22]										Good
Chen, 2008 [27]										Good
Buszewicz, 2006 [35]										Good

Arrive – Estudos animais

The ARRIVE Essential 10

These items are the basic minimum to include in a manuscript. Without this information, readers and reviewers cannot assess the reliability of the findings.

Study design	1	For each experiment, provide brief details of study design including: a. The groups being compared, including control groups. If no control group has been used, the rationale should be stated. b. The experimental unit (e.g. a single animal, litter, or cage of animals).
Sample size	2	a. Specify the exact number of experimental units allocated to each group, and the total number in each experiment. Also indicate the total number of animals used. b. Explain how the sample size was decided. Provide details of any *a priori* sample size calculation, if done.
Inclusion and exclusion criteria	3	a. Describe any criteria used for including and excluding animals (or experimental units) during the experiment, and data points during the analysis. Specify if these criteria were established *a priori*. If no criteria were set, state this explicitly. b. For each experimental group, report any animals, experimental units or data points not included in the analysis and explain why. If there were no exclusions, state so. c. For each analysis, report the exact value of *n* in each experimental group.
Randomisation	4	a. State whether randomisation was used to allocate experimental units to control and treatment groups. If done, provide the method used to generate the randomisation sequence. b. Describe the strategy used to minimise potential confounders such as the order of treatments and measurements, or animal/cage location. If confounders were not controlled, state this explicitly.
Blinding	5	Describe who was aware of the group allocation at the different stages of the experiment (during the allocation, the conduct of the experiment, the outcome assessment, and the data analysis).
Outcome measures	6	a. Clearly define all outcome measures assessed (e.g. cell death, molecular markers, or behavioural changes). b. For hypothesis-testing studies, specify the primary outcome measure, i.e. the outcome measure that was used to determine the sample size.
Statistical methods	7	a. Provide details of the statistical methods used for each analysis, including software used. b. Describe any methods used to assess whether the data met the assumptions of the statistical approach, and what was done if the assumptions were not met.
Experimental animals	8	a. Provide species-appropriate details of the animals used, including species, strain and substrain, sex, age or developmental stage, and, if relevant, weight. b. Provide further relevant information on the provenance of animals, health/immune status, genetic modification status, genotype, and any previous procedures.
Experimental procedures	9	For each experimental group, including controls, describe the procedures in enough detail to allow others to replicate them, including: a. What was done, how it was done and what was used. b. When and how often. c. Where (including detail of any acclimatisation periods). d. Why (provide rationale for procedures).
Results	10	For each experiment conducted, including independent replications, report: a. Summary/descriptive statistics for each experimental group, with a measure of variability where applicable (e.g. mean and SD, or median and range). b. If applicable, the effect size with a confidence interval.

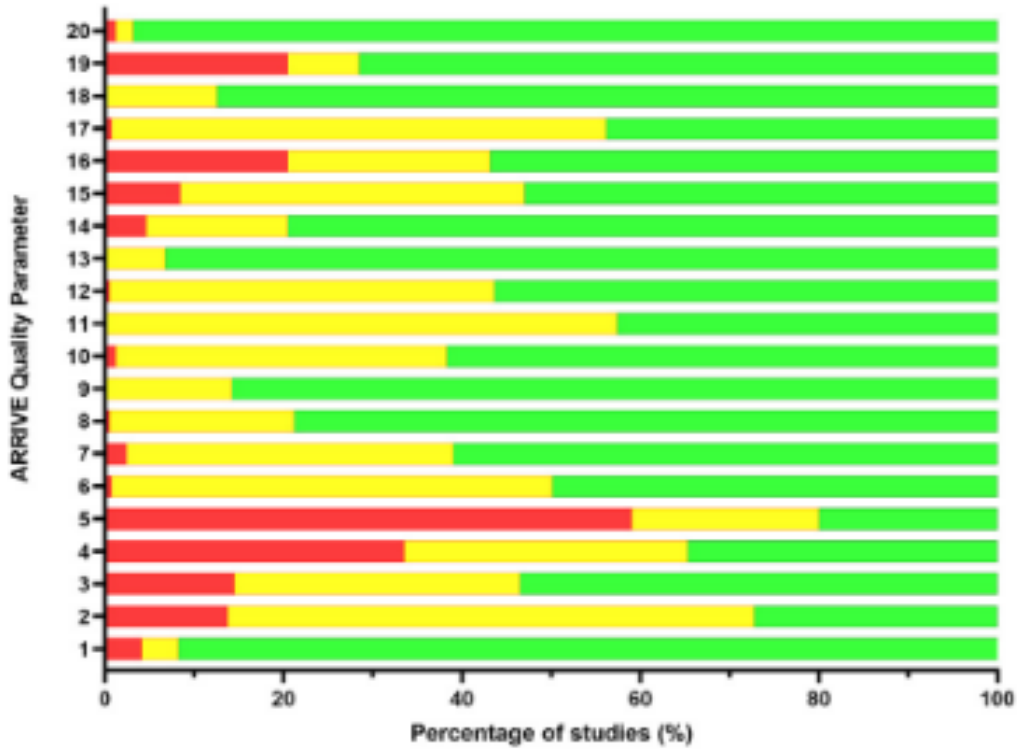
Arrive – Estudos animais

The Recommended Set

These items complement the Essential 10 and add important context to the study. Reporting the items in both sets represents best practice.

Abstract	11	Provide an accurate summary of the research objectives, animal species, strain and sex, key methods, principal findings, and study conclusions.
Background	12	a. Include sufficient scientific background to understand the rationale and context for the study, and explain the experimental approach. b. Explain how the animal species and model used address the scientific objectives and, where appropriate, the relevance to human biology.
Objectives	13	Clearly describe the research question, research objectives and, where appropriate, specific hypotheses being tested.
Ethical statement	14	Provide the name of the ethical review committee or equivalent that has approved the use of animals in this study, and any relevant licence or protocol numbers (if applicable). If ethical approval was not sought or granted, provide a justification.
Housing and husbandry	15	Provide details of housing and husbandry conditions, including any environmental enrichment.
Animal care and monitoring	16	a. Describe any interventions or steps taken in the experimental protocols to reduce pain, suffering and distress. b. Report any expected or unexpected adverse events. c. Describe the humane endpoints established for the study, the signs that were monitored and the frequency of monitoring. If the study did not have humane endpoints, state this.
Interpretation/ scientific implications	17	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including potential sources of bias, limitations of the animal model, and imprecision associated with the results.
Generalisability/ translation	18	Comment on whether, and how, the findings of this study are likely to generalise to other species or experimental conditions, including any relevance to human biology (where appropriate).
Protocol registration	19	Provide a statement indicating whether a protocol (including the research question, key design features, and analysis plan) was prepared before the study, and if and where this protocol was registered.
Data access	20	Provide a statement describing if and where study data are available.
Declaration of interests	21	a. Declare any potential conflicts of interest, including financial and non-financial. If none exist, this should be stated. b. List all funding sources (including grant identifier) and the role of the funder(s) in the design, analysis and reporting of the study.

Arrive – Resultados



Article/ Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	Global rating
[95]																							Strong
[71]																							Strong
[140]																							Strong
[78]																							Moderate
[87]																							Strong
[79]																							Strong
[141]																							Strong
[142]																							Moderate
[143]																							Weak
[70]																							Strong
[144]																							Strong
[104]																							Moderate
[108]																							Strong
[111]																							Moderate
[86]																							Strong
[145]																							Moderate
[73]																							Strong
[146]																							Strong
[147]																							Moderate
[103]																							Strong
[148]																							Strong
[64]																							Strong
[149]																							Moderate
[74]																							Strong
[65]																							Strong
[106]																							Strong
[150]																							Strong
[97]																							Moderate
[84]																							Strong
[75]																							Strong
[66]																							Strong
[151]																							Strong
[93]																							Moderate
[152]																							Strong
[153]																							Moderate
[154]																							Strong
[98]																							Strong
[69]																							Strong
[155]																							Strong
[82]																							Strong
[156]																							Moderate
[94]																							Strong
[99]																							Strong
[67]																							Weak
[68]																							Strong
[157]																							Moderate
[100]																							Moderate
[158]																							Moderate
[76]																							Strong
[77]																							Strong

PRISMA

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	

PRISMA

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	
Study characteristics	17	Cite each included study and present its characteristics.	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	
	23b	Discuss any limitations of the evidence included in the review.	
	23c	Discuss any limitations of the review processes used.	
	23d	Discuss implications of the results for practice, policy, and future research.	
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	

Life and Health Sciences Research Institute
Instituto de Investigação em Ciências da Vida e Saúde

ICVS/3B's
Associate Laboratory
University of Minho

Universidade do Minho
Escola de Ciências da Saúde

Sessão "Avaliação da Qualidade"

Questões

PhD4Moz
Fostering a sustainable platform to support PhD training in Health Sciences in Mozambique

Filipa Pinto Ribeiro

filiparibeiro@med.uminho.pt