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LAMPIRAN-LAMPIRAN

LAMPIRAN 1. TOOLS PENILAIAN KUALITAS ARTIKEL CASP RCT

11 questions to help you make sense of a trial

How to use this appraisal tool

Three broad issues need to be considered when appraising a randomised controlled trial study: Are the results of the study valid? (Section A)
What are the results? (Section B)
Will the results help locally? (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

For each new checklist a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.:
Critical Appraisal Skills Programme (2017). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: *URL*. Accessed: *Date Accessed*.

(A) Are the results of the trial valid?

Screening Questions

- 1. Did the trial address a clearly focused issue?** Yes
 Can't tell No

HINT: An issue can be 'focused' In terms of

- The population studied
- The intervention given
- The comparator given
- The outcomes considered

-
- 2. Was the assignment of patients to treatments** Yes Can't tell
 No randomised?

HINT: Consider

- How was this carried out?
- Was the allocation sequence concealed from researchers and patients?

-
- 3. Were all of the patients who entered** Yes Can't tell
 No the trial properly accounted for at its conclusion?

HINT: Consider

- Was the trial stopped early?

- Were patients analysed in the groups to which they were randomised?

Is it worth continuing?



Detailed questions

4. Were patients, health workers and study Yes Can't tell
 No personnel 'blind' to treatment?

HINT: Think about

- Patients?
- Health workers?
- Study personnel?

5. Were the groups similar at the start of the trial? Yes Can't tell No

HINT: Look at

- Other factors that might affect the outcome such as age, sex, social class

6. Aside from the experimental intervention, Yes
 Can't tell No were
the groups treated equally?

(B) What are the results?

7. How large was the treatment effect?

HINT: Consider

- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?

8. How precise was the estimate of the treatment effect?

HINT: Consider

- What are the confidence limits?

(C) Will the results help locally?

•

9. Can the results be applied in your context?

Yes

Can't tell

No (or to

the local population?)

HINT: Consider whether

- Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?

10. Were all clinically important outcomes

Yes

Can't tell

No

considered?

HINT: Consider

- a. Is there other information you would like to have seen?
- b. If not, does this affect the decision?

11. Are the benefits worth the harms and costs?

Yes

Can't tell

No

HINT: Consider

- c. Even if this is not addressed by the trial, what do you think?

LAMPIRAN 2 .TOOLS PENILAIAN KUALITAS ARTIKEL CASP KOHOR STUDY



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CASP Checklist: 12 questions to help you make sense of a Cohort Study

How to use this appraisal tool: Three broad issues need to be considered when appraising a cohort study:

- ▶ Are the results of the study valid? (Section A)
- ▶ What are the results? (Section B)
- ▶ Will the results help locally? (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL, and Cook DJ), and piloted with health care practitioners.

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Paper for appraisal and reference:

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: 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

Comments:

2. Was the cohort recruited in an acceptable way?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: 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

Comments:

Is it worth continuing?

3. Was the exposure accurately measured to minimise bias?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: 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

Comments:

4. Was the outcome accurately measured to minimise bias?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: 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)

Comments:

5. (a) Have the authors identified all important confounding factors?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT:
+ list the ones you think might be important, and ones the author missed

Comments:

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT:
+ look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments:

6. (a) Was the follow up of subjects complete enough?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
+ the good or bad effects should have had long enough to reveal themselves
+ 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

6. (b) Was the follow up of subjects long enough?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

Section B: What are the results?

7. What are the results of this study?

HINT: 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)

Comments:

8. How precise are the results?

HINT:

- look for the range of the confidence intervals, if given

Comments:

9. Do you believe the results?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: 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)

Comments:

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider whether
- a cohort study was the appropriate method to answer this question
 - the subjects covered in this study could be sufficiently different from your population to cause concern
 - your local setting is likely to differ much from that of the study
 - you can quantify the local benefits and harms

Comments:

11. Do the results of this study fit with other available evidence?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

12. What are the implications of this study for practice?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: 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

Comments:

LAMPIRAN 3. PENILAIAN RISIKO BIAS
Cochrane Collaboration's tool for assessing risk of bias (adapted from Higgins and Altman13)

Bias domain	Source of bias	Support for judgment	Review authors' judgment (assess as low, unclear or high risk of bias)
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	Blinding of participants and personnel*	Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study
Detection bias	Blinding of outcome assessment*	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Detection bias due to knowledge of the allocated interventions by outcome assessment
Attrition bias	Incomplete outcome data*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any reinclusions in analyses for the review	Attrition bias due to amount, nature, or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found	Reporting bias due to selective outcome reporting
Other bias	Anything else, ideally Prespecified	State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere

Section/topic	#	Checklist item	√	Report ed on page #
TITLE				
Title	1	Identify the report as a systematic review, meta-analysis, or both.	√	Page 1 line 2
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.	√	Page 1 Line 4-24
INTRODUCTION				
Rationale	3	Describe the rationale for the review in the context of what is already known.	√	Page 2 Line 62-72
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	√	Page 2 Line 75-78
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.	√	Page 3 Line 81-84
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 Line 93-101 Line 109-113
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 Line 104-105 Line 114-116
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	√	Page 3 Line 105-113
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).	√	Page 3 Line 118-132 Page 15
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 3 Line 133-138
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	√	Page 14

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.	√	Page 3-4 Line 140-157
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.		-
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.	√	Page 3 Line 118-132
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.	√	Page 4 Line 165-165
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).	√	Page 4 Line 158-162 Page 16-17
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.	√	Page 4-6 Line 174-252
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).	√	Page 6-8 Line 255-331
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).	√	Page 8 Line 346-352

Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	√	Page 8 Line 334- 344
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.	√	Page 8 Line 361-362

LAMPIRAN 4. PRISMA 2009 CHECKLIST

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