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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 considered?

❒ Yes

❒ Can't tell ❒ No

HINT: Consider

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

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11. Are the benefits worth the harms and costs? ❒ Yes ❒ Can't tell

HINT: Consider

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

LAMPIRAN 2.

JBI Critical Appraisal tools (Checklist for Quasi experimental tools)

JBI Critical Appraisal Checklist for Quasi-Experimental Studies (non-randomized experimental studies)

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

		Yes	No	Unclear	Not applicable
1.	Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?	☐	☐	☐	☐
2.	Were the participants included in any comparisons similar?	☐	☐	☐	☐
3.	Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	☐	☐	☐	☐
4.	Was there a control group?	☐	☐	☐	☐
5.	Were there multiple measurements of the outcome both pre and post the intervention/exposure?	☐	☐	☐	☐
6.	Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	☐	☐	☐	☐
7.	Were the outcomes of participants included in any comparisons measured in the same way?	☐	☐	☐	☐

8. Were outcomes measured in a reliable way? ☐ ☐ ☐ ☐

9. Was appropriate statistical analysis used? ☐ ☐ ☐ ☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

_____

_____

_____

LAMPIRAN 3.

(*Critical Appraisal of a Cross- S ectional Study (Survey) Appraisal questions*, 2014)

CEBMa center for Evidence-Based Management

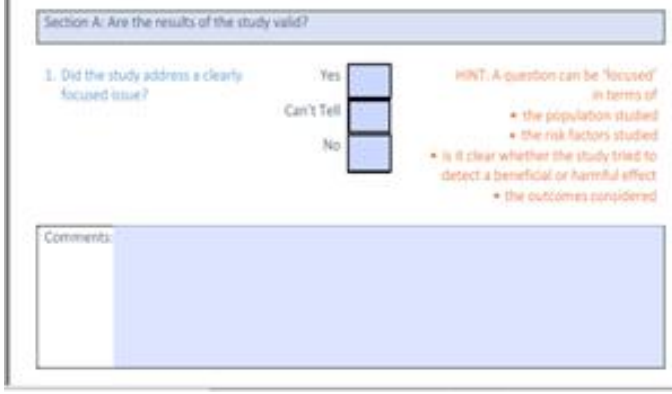
Critical Appraisal of a Cross-Sectional Study (Survey)

Appraisal questions	Yes	Can't tell	No
1. *Did the study address a clearly focused question / issue?*			
2. *Is the research method (study design) appropriate for answering the research question?*			
3. *Is the method of selection of the subjects (employees, teams, divisions, organizations) clearly described?*			
4. *Could the way the sample was obtained introduce (selection)bias?*			
5. *Was the sample of subjects representative with regard to the population to which the findings will be referred?*			
6. *Was the sample size based on pre-study considerations of statistical power?*			
7. *Was a satisfactory response rate achieved?*			
8. *Are the measurements (questionnaires) likely to be valid and reliable?*			
9. *Was the statistical significance assessed?*			
10. *Are confidence intervals given for the main results?*			
11. *Could there be confounding factors that haven't been accounted for?*			
12. *Can the results be applied to your organization?*			

Adapted from Crombie, *The Pocket Guide to Critical Appraisal*; the critical appraisal approach used by the Oxford Centre for Evidence Medicine, checklists of the Dutch Cochrane Centre, BMJ editor's checklists and the checklists of the EPPI Centre.

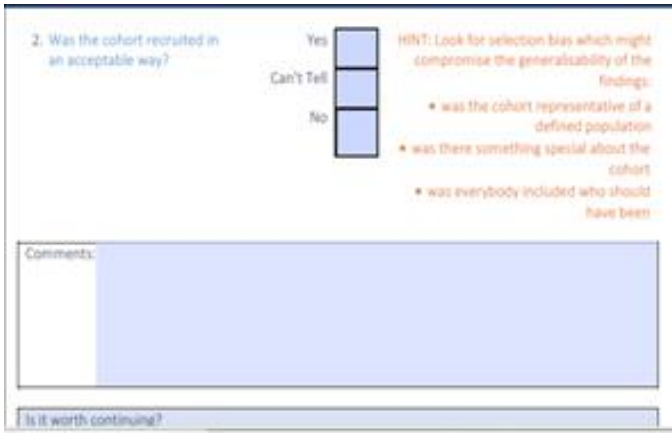
Cite as: Center for Evidence Based Management (July, 2014), Critical Appraisal Checklist for Cross-Sectional Study. Retrieved (month, day, year) from https://www.cebma.org

A. Validitas Penelitian



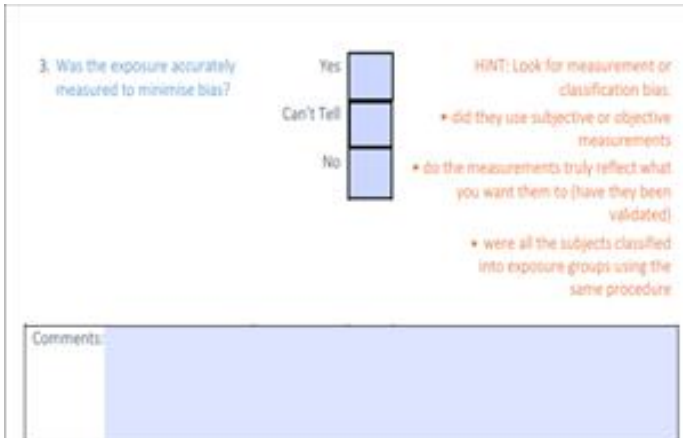
Apakah penelitian ditujukan pada masalah yang jelas?

Perhatikan
- Populasi yang diteliti
- Faktor resiko yang diteliti
- Efek menguntungkan dan efek yang merugikan
- Pertimbangan outcome



Apakah proses cohort dapat diterima

Perhatikan potensi bias dalam pemilihan:
- Populasi yang diteliti jelas.
- Apakah ada hal yang special terkait cohort
- Apakah setiap orang yg dinklusi sesuai



Apakah 'exposure" diukur dengan akurat sehingga meminimalkan bias

Perhatikan bagaimana proses pengukuran atau klasifikasi bias
- Apakah pengukuran obyektif atau subyektif?
- Apakah pengukuran valid?
- Apakah setiap subject pada kelompok eksposure mengunakan prosedur yang sama?

4. Was the outcome accurately measured to minimize bias?

Yes ☐
Can't Tell ☐
No ☐

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:

Apakah 'exposure" diukur dengan akurat sehingga meminimalkan bias

Perhatikan bagaiman proses pengukuran atau klasifikasi bias
- Apakah pengukuran obyektif atau subyektif?
- Apakah pengukuran valid?
- Apakah setiap subject pada kelompok eksposure mengunakan prosedur yang sama?

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

Yes ☐
Can't Tell ☐
No ☐

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

Comments:

Apakah penulis mengidentifikasi factor perancu yang penting?

Perhatikan factor yang anda anggap penting dan yang penulis abaikan

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

Yes ☐
Can't Tell ☐
No ☐

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:

Apakah factor perancu dipertimbangkan dalam desain atau analisa

Perhatikan keterbatasan desain, tekhnik (model, stratifikasi, regresi) atau sensitifitas Analisa dalam mengoreksi, mengontrol atau mengatasi factor perancu

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

Yes ☐
Can't Tell ☐
No ☐

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

Apakah follow up terhadap subject tuntas?
Perhatikan
- Efek yg diobservasi harus cukup waktu untuk membuktikannya
- Subject yang drop out dari observasi mungkin memiliki outcome yang berbeda.
- Dalam "open atau dynamic cohort" apakah ada outcome tersendiri bagi subject yang drop out, atau yang terpapar dengan "exposure"

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

Yes ☐
Can't Tell ☐
No ☐

Apakah periode follow up mencukupi?

B. Apa hasil penelitiannya?

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:

Bagaimana hasil penelitian?

- Apa temuan mendasar
- Apakah penulis melaporkan rate atau proporsi antara kelompok terpapar/tidak terpapar, perbedaan rasio/rate?
- Seberapa kuat keterkaitan antara paparan dan outcome **(RR).**
- Bagaimana dengan absolute risk reduction **(ARR)?**

8. How precise are the results?

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

Comments:

Seberapa akurat hasil penelitian?

Perhatikan:
- Confidence Interval

9. Do you believe the results?

Yes ☐
Can't Tell ☐
No ☐

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:

Apakah anda percaya dengan hasil penelitian ini?

Perhatikan:
- Jangan abaikan "big effect"
- Dapat diakibatkan oleh bias, peluang, atau perancu.
- Apakah desain dan metode penelitian memiliki "kecacatan" yang menyebabkan hasil tidak dapat diterima?
- Pertimbangkan "Bradford Hills Criteria" (periode observasi, gradien dosis-respon, biological plausibility, dan konsistensi)

C. Apakah dapat membantu masalah lokal

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

Yes ☐
Can't Tell ☐
No ☐

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:

Apakah penelitian ini dapat diaplikasikan pada populasi lokal?

Perhatikan:
- Apakah metode tepat dalam menjawab pertanyaan
- Apakah subject yang terlibat berbeda dengan populasi anda?
- Kondisi lokal kemungkinan besar berbeda dengan desain penelitian anda
- Pertimbangkan keuntungan dan resiko lokal

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

Yes ☐
Can't Tell ☐
No ☐

Comments:

Apakah hasil penelitian ini sesuai dengan evidence yang sudah ada?

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

Yes ☐
Can't Tell ☐
No ☐

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:

Apa implikasi dari hasil penelitian ini ke dalam praktek?

Pertimbangkan:

- Satu penelitian observasional sangat jarangan memberikan evidence yang kuat dalam praktek atau untuk pengambilan kepeutusan
- Untuk beberapa pertanyaan, penelitian observasional dapat memberikan evidence.
- Evidence dari penelitian observasional biasanya lebih kuat bila ditunjang hasil penelitian lain

LAMPIRAN 4. 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

*Assessments should be made for each main outcome or class of outcomes

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Cover
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.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 5 Line 10 – 27
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 6 Line 29 – 31 Page 7 Line 1 – 2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 27 Line 4 – 7 Page 35 Line 19 – 20 Page 36 Line 1 – 20
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 27 Line 20 – 31 Page 28 Line 1 – 16 Page 29 Line 9 – 17
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 28 Line 19 – 29
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 29 Line 23 – 30 Page 30 Line 1 – 11
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 34 Line 17 – 31 Page 35 Line 1 – 6
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 37 Line 21 – 36

Section/topic	#	Checklist item	Reported on page #
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 8 Line 25 – 31 Page 9 Line 1 – 23
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 36 Line 29 – 31 Page 37 Line 1 – 19
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 38 Line 4 – 11
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.	Page 37 Point 38 – 32 Page 38 Line 1 – 2
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).	Page 36 Line 22 – 29
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	None
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 42 Line 7 – 24
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 41 Line 15 – 32 Page 42 Line 1 – 6
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 56 Line 8 – 22 Page 57 Line 4 – 23
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 43 – 46
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Page 47 – 55 (Table 4.1)
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Page 66 (Table 4.7) Page 67 Line 1 – 30
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	None

Section/topic	#	Checklist item	Reported on page #
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 68 Line 11 – 16 Page 69 Line 1 – 11 Page 70 Line 5 – 11 Line 21 – 31 Page 71 Line 11 – 18
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 72 Line 28 – 31 Page 73 Line 1 – 11
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 74 Line 4 – 14
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 74 Line 24