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LAMPIRAN

LAMPIRAN 1. TOOLS PENILAIAN KUALITAS ARTIKEL 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 personnel 'blind' to treatment? ☐Yes ☐Can't tell ☐No

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. PRISMA Cheklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	7
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.	1-7
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	9
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	8
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.	47
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.	47
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.	49
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	49
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).	53
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.	54
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	47
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.	54
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	55
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.	55

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).	54
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.	58
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.	57
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).	72
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.	64
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	63
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	73
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	67
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).	74
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).	74
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	76
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.	

KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN
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REKOMENDASI PERSETUJUAN ETIK

Nomor : 833/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 30 Desember 2020

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH20120717	No Sponsor Protokol	
Peneliti Utama	**Rini Angraini, S.Kep,Ns**	Sponsor	
Judul Peneliti	Efektivitas Hydrotherapy untuk Menurunkan Tekanan Darah pada Pasien Hipertensi A Systematic Review		
No Versi Protokol	**1**	Tanggal Versi	23 Desember 2020
No Versi PSP		Tanggal Versi	
Tempat Penelitian	**Fakultas Keperawatan Universitas Hasanuddin Makassar**		
Jenis Review	[X] Exempted [ ] Expedited [ ] Fullboard Tanggal	Masa Berlaku **30 Desember 2020** sampai **30 Desember 2021**	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FKUH	Nama **Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)**	Tanda tangan	
Sekretaris Komisi Etik Penelitian Kesehatan FKUH	Nama **dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)**	Tanda tangan	

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Lapor SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan