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LAMPIRAN :

1. *Critical Appraisal Skills Programme (CASP) Random Control Trial*

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.

(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 randomise

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, were the groups treated equally? Yes, Can't tell, No

(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?

11. Are the benefits worth the harms and costs? Yes, Can't tell, No

HINT: Consider

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

2. Oxford, Centre for Evidence-based Medicine – Levels of Evidence (CEMB)

Level	Therapy / Prevention, Aetiology / Harm	Prognosis	Diagnosis	Differential diagnosis / symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR” validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR” with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval”);	Individual inception cohort study with > 80% follow-up; CDR” validated in a single population	Validating** cohort study with good” ” ” reference standards; or CDR” tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts” “	All or none case-series	Absolute better-value or worse-value analyses ” ” ” “
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies

2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR” or validated on split-sample§§§ only	Exploratory* * cohort study with good” ” ” reference standards; CDR” after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	“Outcomes” Research; Ecological studies	“Outcomes” Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis

5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on economic theory or “first principles”
---	--	--	--	--	---

Grades of Recommendation :

A	consistent level 1 studies
B	consistent level 2 or 3 studies <i>or</i> extrapolations from level 1 studies
C	level 4 studies <i>or</i> extrapolations from level 2 or 3 studies
D	level 5 evidence <i>or</i> troublingly inconsistent or inconclusive studies of any level

“Extrapolations” are where data is used in a situation that has potentially clinically important differences than the original study situation.


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	State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere
	Prespecified		

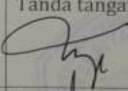
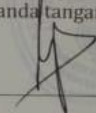
*Assessments should be made for each main outcome or class of outcomes\

4. Lembar Rekomendasi Persetujuan Etik


 KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
 UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
 KOMITE ETIK PENELITIAN KESEHATAN
 RSPTN UNIVERSITAS HASANUDDIN
 RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
 Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
 JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.
 Contact Person: dr. Agussalim Bukhari, MMed,PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK
 Nomor : 596/UN4.6.4.5.31/ PP36/ 2020
 Tanggal: 28 September 2020

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

No Protokol	UH20090523	No Sponsor	
Peneliti Utama	Maria Kurni Menga, S.Kep.,Ns	Sponsor	
Judul Peneliti	Efektivitas Terapi Akupresur terhadap Penurunan Fatigue Pada Pasien Kanker Yang Menjalani Kemoterapi : A Systematic Review		
No Versi Protokol	1	Tanggal Versi	25 September 2020
No Versi PSP		Tanggal Versi	
Tempat Penelitian	Fakultas Keperawatan Universitas Hasanuddin Makassar		
Jenis Review	<input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 28 September 2020 sampai 28 September 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 Laporan 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

5. Lampiran PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Halaman i
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.	Halaman x
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Halaman 5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Halaman 6
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.	Halaman 40
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.	Halaman 40
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.	Halaman 41
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Halaman 41
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).	Halaman 44
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.	Halaman 47

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Halaman 48
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.	Halaman 46-47
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Halaman 48
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.	Halaman 48

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).	Halaman 47
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Halaman 48
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.	Halaman 50
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.	Halaman 50
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).	Halaman 62 & 64
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.	Halaman 54-56
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Halaman 57
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Hal 60-61 dan 63
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Halaman 58 & 60
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).	Halaman 65-73

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).	Halaman 74
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Halaman 75-76
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.	Halaman 76

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(7): e1000097. doi:10.1371/journal.pmed1000097

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