Additional material

A comparison of the effects of using the Crowe Critical Appraisal Tool versus informal appraisal in assessing health research: A randomised trial

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Instructions and notes [CCAT group]

Summary of main points
• Read each paper thoroughly.
• Each research design should be appraised on its own merits, not to a ‘gold standard’.
• All categories must be scored – it does not matter what research design is used.
  • Category scores are whole numbers only (0, 1, 2, 3, 4, 5)
  • The lowest score possible for a category is 0
  • The highest score possible for a category is 5.
• Items may be marked ☐ present, ☐ absent, or ■ not applicable.
  • Tick marks are not a checklist to be totalled – they are a guide to scoring a category.
• If in doubt use your best judgement, there is no right or wrong answer.
• Please indicate your current level of knowledge for the:
  • Topic discussed in each paper
  • Research design used in each paper.
• When you have finished reading all the papers rank order them from 1 (the best paper) to 5 (the least impressive paper).

Introduction
The critical appraisal tool assumes an awful lot. It assumes that the individual using the tool is familiar with research designs, sampling techniques, ethics, data collection methods, and statistical and non-statistical data analysis techniques.

It may be helpful to have a general research methods text available to refer to when appraising papers.

The papers being appraised are unlikely to have the information sought in the sequence outlined in the critical appraisal form. Therefore, it is suggested to read each paper quickly from start to finish, getting an overall sense of what is being discussed. Then re-read the paper and fill in the scores.

Paper ID and Research design
Each paper and each critical appraisal form has two pieces of information at the top:

1. Paper ID – This is to identify each paper and cross-reference it with the critical appraisal form so that scores from each appraiser can be compared. The Paper ID is made up of the first or main author’s surname and the year the paper was published. Please ensure that the Paper ID on the paper you are reading corresponds with the Paper ID on the critical appraisal form where you enter the scores.

2. Research design – To make appraising each paper a little easier, the research design used is written on the paper and on the form. This means that you do not need to decide which research design was used and can concentrate on appraising the paper based on the research design indicated. Two of the research designs have alternative names that you may be more familiar with: Single system designs include n-of-1, time-series, single-subject, and within subject designs; Descriptive, explanatory, observational designs are also know as quantitative non-experimental designs.

Scoring method
The appraisal form is divided into eight categories and 22 items. An item has multiple item descriptors and make it easier to appraise and score a category. Each category receives its own score on a 6 point scale from 0–5. A score of 0 is the lowest score a category can achieve, while a score of 5 is the highest.

Categories can only be scored as a whole number or integer, i.e. 0, 1, 2, 3, 4, or 5. Half marks are not allowed.
In the appraisal form, there are tick boxes (☐) beside descriptions of items. The tick box is useful to indicate if the descriptor for the item is:

- **Present (☐)** – For an item descriptors to be marked as present, there should be evidence of it being present rather than an assumption of presence.
- **Absent (☒)** – For an item descriptors to be marked as absent, it is implied that it should be present in the first place.
- **Not applicable (■)** – For an item descriptors to be marked as not applicable, the descriptor must not be relevant given the characteristics of the paper being appraised and is, therefore, not considered when assigning a score to a category.

Whether an item descriptors is present, absent, or not applicable is further explored in the *Categories and Items* section.

All categories must be scored. Although items may be marked ‘not applicable’, all categories are applicable in all research designs.

While it may be tempting to add up all the present marks (☐) and all the absent marks (☒) in each category and to use the proportion of one to the other to calculate the score for the category, this is strongly discouraged. It is strongly discouraged because not all descriptors of items in any category are of equal importance. For example, in the *Introduction* category there are two items (*Background* and *Objective*) and a total of five tick boxes. If a paper being appraised has all boxes marked as present (☐) except for *Primary objective(s), hypothesis(es), or aim(s)*, should the paper be scored 4/5 for that category? It could be argued that a research paper without a primary objective, hypothesis, or aim is fundamentally flawed and, as a result, should be scored 0/5 even though the other four tick boxes were marked as present.

Therefore, the tick marks for present, absent, or not applicable are to be used as a guide to scoring a category rather than as a simple check list. It is up to the appraiser to take into consideration all aspects of each category and, based on both the tick marks and judgement, assign a score to the category.

Similarly, the research design used in each paper should be appraised on its own merits and not relative to some preconceived notion of a hierarchy of research designs. What is most important is that the paper used an appropriate research design based on the research question it was addressing, rather than what research design in itself was used.

Finally, it is not the purpose of this tool to present a single score upon which an overall assessment of a paper can be made. Just like not all descriptors of items are of equal importance, neither are all categories the same. Categories and as an extension all scores are dissimilar, not equivalent, and can not be added.

**Level of knowledge**

At the end of each form there is a space to indicate your current level of knowledge regarding the topic discussed and the research design used in each paper you have read. Please circle the appropriate number which corresponds to your current level of knowledge in each case.
Scoring Categories and Items

1. Preliminary

Title
1. Includes study aims and design
   • Traditionally only required for reporting research.
   • It has been assumed that this does not affect the overall quality of the research but there is little evidence one way or the other.

Abstract
1. Contains key information
   • Traditionally only required for reporting research.
   • It has been assumed that this does not affect the overall quality of the research but there is little evidence one way or the other.
2. Balanced and informative
   • Traditionally only required for reporting research.
   • It has been assumed that this does not affect the overall quality of the research but there is little evidence one way or the other.

Text
Note This item can only be assessed when the article has been read in full.
1. Sufficient detail others could reproduce
   • This is an over-arching concept and should be present throughout the study.
2. Clear, concise writing/table(s)/diagram(s)/figure(s)
   • This is an over-arching concept and should be present throughout the study.

2. Introduction

Background
1. Summary of current knowledge
   • Current and applicable knowledge provides a context for the study.
2. Specific problem(s) addressed and reason(s) for addressing
   • Description of why the study was undertaken.
   • Links current knowledge and stated objective(s), hypothesis(es), or aim(s).

Objective
1. Primary objective(s), hypothesis(es), aim(s)
   • The study must have at least one stated objective, hypothesis, or aim.
2. Secondary question(s)
   • Secondary question(s) may sometimes arise based on the primary objective(s), hypothesis(es), or aim(s).
   • Since this is not always the case, a study without secondary questions should not be penalised.

3. Design

Research design
1. Research design(s) chosen and why
   • Description of the research design chosen and why it was chosen.
2. Suitability of research design(s)
   • The research design should be congruent with Background, Objective, Intervention(s)/treatment(s)/exposure(s), and Outcome(s)/output(s)/predictor(s).
Instructions and notes [CCAT group]

**Intervention, Treatment, Exposure**

1. Intervention(s)/treatment(s)/exposure(s) chosen and why
   - Where a study does not normally have an intervention/treatment/exposure, it should not be penalised when none is present.
   - Statement for every intervention/treatment/exposure chosen and why it was chosen.
   - Each intervention/treatment/exposure must be congruent with Background, Objective, and Research design.

2. Precise details of the intervention(s)/treatment(s)/exposure(s) for each group
   - Full details are presented for every intervention/treatment/exposure for every participant/case/group so that other studies could duplicate.

3. Intervention(s)/treatment(s)/exposure(s) valid and reliable
   - A statement of reliability/validation or why there is no validation/reliability for each intervention/treatment/exposure.

**Outcome, Output, Predictor, Measure**

1. Outcome(s)/output(s)/predictor(s)/measure(s) chosen and why
   - All research has at least one expected outcome/output/predictor/measure.
   - Statement for each outcome/output/predictor/measure chosen and why it was chosen.
   - Each outcome/output/predictor/measure must be congruent with Background, Objective, Research design, and Intervention/treatment/ exposure.

2. Clearly define outcome(s)/output(s)/predictor(s)/measure(s)
   - Full details are presented of every expected outcome/output/predictor/ measure for every participant/case/group so that other studies could duplicate.

3. Outcome(s)/output(s)/predictor(s)/measure(s) valid and reliable
   - A statement of reliability/validation or why there is no validation/reliability for each outcome/output/predictor/measure.

*Note* In some cases the Outcome(s)/output(s)/predictor(s)/measure(s) may be similar to or the same as the Objective(s), hypothesis(es), aim(s). However, in most cases to achieve the Objective(s), hypothesis(es), aim(s) a series of Outcome(s)/output(s)/predictor(s)/measure(s) are required.

**Bias, etc**

1. Potential sources of bias, confounding variables, effect modifiers, interactions
   - Identification of potential sources of:
     - Bias – e.g. attrition, detection, experimental, information, interview, observation, performance, rater, recall, selection.
     - Confounding variables or factors – A variable which interferes between the intervention/treatment/exposure and the outcome/output/ predictor/measure.
     - Effect modification – A variable which modifies the association between the intervention/treatment/exposure and the outcome/output/ predictor/ measure.
     - Interaction effects – When various combinations of intervention(s)/treatment(s)/ exposure(s) cause different outcome(s)/output(s)/ predictor(s)/ measure(s).
   - Should be identified, as far as possible, within the Research design before data collection begins in order to minimise their effect.
   - See also Sampling and Data collection.

2. Sequence generation, group allocation, group balance, and by whom
   - In studies where participants/cases are allocated to groups, the methods used should be stated and procedures established before recruitment or data collection begins (e.g. blinding, method used to randomise, allocate to or balance groups).
3. Equivalent treatment of participants/cases/groups
   • Each participant/case/group must be treated equivalently apart from any intervention/treatment/exposure.
   • If participants/cases/groups are not treated equivalently a statement regarding why this was not possible, how this may affect results, and procedures in place for managing participants/cases/groups.
   • See also Sampling protocol, Collection protocol, and Participant ethics.

4. Sampling
   Sampling method
   1. Sampling method(s) chosen and why
      • Description of the sampling method chosen and why it was chosen.
      • Sampling methods are normally probability or non-probability based.
      • Examples include: Simple random, systematic, stratified, cluster, convenience, representative, purposive, snowball, and theoretical.
      • Also included here is the search strategy used for a systematic review (e.g. databases searched, search terms).
   2. Suitability of sampling method
      • The sampling method should be decided and in place before recruitment or data collection begins.
      • The sampling method should be congruent with Objective, Research design, Intervention/treatment/exposure, Outcome/output/predictor/measure, and Bias etc.

Sample size
   1. Sample size, how chosen, and why
      • Description of the sample size, the method of sample size calculation, and why that method was chosen.
      • Sample size calculations are normally probability or non-probability based.
      • Examples of how calculations can be made include: Accuracy [e.g. confidence interval (α), population or sample variance ($s^2$, $\sigma^2$), effect size or index (ES, d), power (1-β)], analysis, population, redundancy, saturation, and budget.
   2. Suitability of sample size
      • The sample size or estimate of sample size, with contingencies, should be described and calculated before recruitment/data collection begins.
      • The sample size should be congruent with Objective, Research design, Intervention/treatment/exposure, Outcome/output/predictor/measure, and Bias etc.

   Note  Sample size calculations are not required for systematic reviews, as it is not possible to know the number of papers that will meet the selection criteria, or for some single system designs.

Sampling protocol
   1. Description and suitability of target/actual/sample population(s)
      • The target/actual/sample population(s) should be described.
      • The target/actual/sample population(s) should be congruent with Objective, Research design, Intervention/treatment/exposure, Outcome/output/predictor/measure, and Bias etc.
   2. Inclusion and exclusion criteria for participants/cases/groups
      • Inclusion and exclusion criteria should be explicitly stated and established before recruitment/data collection begins.
      • The use of inclusion and exclusion criteria (especially exclusion criteria) should not be used in such a way as to bias the sample.
3. Recruitment of participants/cases/groups
   • Description of procedures for recruitment and contingencies put in place.
   • Recruitment should be congruent with **Objective**, **Research design**, **Intervention/treatment/exposure**, **Bias etc.**, and other aspects of **Sampling**.
   • See also **Participant ethics**, **Researcher ethics**, and **Collection protocol**.

Note  For systematic reviews inclusion and exclusion criteria *only* need to be appraised, as this refers to the parameters used to select papers.

5. **Data collection**

   **Collection method**
   1. Collection method(s) chosen and why
      • Description of the method(s) used to collect data and why each was chosen.
      • In systematic reviews, this refers to how information was extracted from papers, as this is the data collected.
   2. Suitability of collection method(s)
      • The data collection method(s) should be congruent with **Objective**, **Research design**, **Intervention/treatment/exposure**, **Outcome/output/predictor/measure**, **Bias etc.**, and **Sampling**.

   **Collection protocol**
   1. Include date(s), location(s), setting(s), personnel, materials, processes
      • Description of and details regarding exactly how data was collected, especially any factor(s) which may affect **Outcome/output/predictor/measure** or **Bias etc.**
   2. Method(s) to ensure/enhance quality of measurement/instrumentation
      • Description of any method(s) used to enhance or ensure the quality of data collected (e.g. pilot study, instrument calibration, standardised test(s), independent/multiple measurement, valid/reliable tools).
      • Also includes any method(s) which reduce or eliminate bias, confounding variables, effect modifiers, interactions which are not an integral part of the **Design** category (e.g. blinding of participants, intervention(s), outcome(s), analysis; protocols and procedures implemented).
      • In qualitative studies, this relates to concepts such as trustworthiness, authenticity, and credibility.
      • See also **Bias etc.**
   3. Manage non-participation, withdrawal, incomplete/lost data
      • Description of any method(s) used to manage or prevent non-participation, withdrawal, or incomplete/lost data.
      • These include but are not limited to: Intention to treat analysis (ITT); last observation carried forward (LOCF); follow up (FU), e.g. equal length, adequate, or complete; and, completer analysis, e.g. on-treatment, on-protocol.

6. **Ethical matters**

   Note  Some studies may have been conducted before **Ethical matters** were a major point of concern. The research ethics standards of the time may need to be taken into consideration rather than the prevailing standards.

   **Participant ethics**
   1. Informed consent, equity
      • All participants must have provided their informed consent.
      • Equity includes, but is not limited to, cultural respect, just and equitable actions, no harm to participants, debriefing, and consideration for vulnerable individuals or groups.
2. Privacy, confidentiality/anonymity
   • The privacy and confidentiality and/or anonymity of participants must be catered for.
   • If this is not possible, the informed and written consent of individuals affected must be obtained.

Researcher ethics
1. Ethical approval, funding, conflict(s) of interest
   • A statement of ethical approval from recognised Ethics Committee(s) or Board(s) suitable for
     the study being undertaken.
   • Any real, perceived, or potential conflict(s) of interest should be stated.
   • All sources of funding should be stated.

2. Subjectivities, relationship(s) with participants/cases
   • Description of how the researcher(s) could have potentially or did affect the outcomes of the
     study through their presence or behaviour.
   • Includes a description of procedures used to minimise this occurring.
   • See also Bias etc.

7. Results/Findings

Analysis, Integration, Interpretation method
1. A.I.I. (Analysis/Integration/Interpretation) method(s) for primary outcome(s)/output(s)/
   predictor(s) chosen and why
   • Description of statistical and non-statistical method(s) used to analyse/integrate/interpret
     Outcome(s)/output(s)/predictor(s)/measure(s) and why each was chosen.

2. Additional A.I.I. methods (e.g. subgroup analysis) chosen and why
   • Description of additional statistical and non-statistical method(s) used to analyse/integrate/
     interpret Outcome(s)/output(s)/predictor(s)/measure(s) and why each was chosen.

3. Suitability of analysis/integration/interpretation method(s)
   • The analysis/integration/interpretation method(s) should be congruent with Objective,
     Research design, Intervention/treatment/exposure, Outcome/output/predictor, Bias etc.,
     Sampling, and Data collection.

Essential analysis
1. Flow of participants/cases/groups through each stage of research
   • Description of how participants/cases/groups advanced through the study.
   • Explanation of course of intervention/treatment/exposure.

2. Demographic and other characteristics of participants/cases/groups
   • Description of baseline characteristics of participants/cases/groups so this can be integrated
     into the analysis.

3. Analyse raw data, response rate, non-participation, withdrawal, incomplete/lost data
   • Unadjusted data should be analysed.
   • There may be differences between those that completed and those that did not complete the
     study.

Outcome, Output, Predictor analysis
1. Summary of results and precision for each outcome/output/predictor/measure
   • Results summarised with, where possible, an indicator of the precision and effect size of each
     result for each outcome/output/predictor/measure.
   • Where data is adjusted, make clear what was adjusted and why.
   • Where data is categorised, report of internal and external boundaries.
• Use of quotations to illustrate themes/findings, privileging of subject meaning, adequate
description of findings, evidence of reflexivity.
2. Consideration of benefits/harms, unexpected results, problems/failures
• Description of all outcomes, not just ones being looked for.
• Description of differences between planned and actual implementation, and the potential
affect on results.
3. Description of outlying data (e.g. diverse cases, adverse effects, minor themes)
• Exploration of outlier(s) as they may not be an anomaly.

8. Discussion

Interpretation
1. Interpretation of results in the context of current evidence and objectives
   • Summarises key results in relation to Background and Objective.
   • Compare and contrast other research findings.
2. Draw inferences consistent with the strength of the data
   • Does not over or under represent data.
   • Draws inferences based on the entirety of available evidence.
   • See also Sampling and Data collection.
3. Consideration of alternative explanations for observed results
   • Exploration of reasons for differences between observed and expected.
   • Determines if other factors may lead to similar results.
4. Account for bias, confounding, interactions, effect modifiers, imprecision
   • Discussion on magnitude and direction of Bias etc and how this may have affected the results.
   • See also Essential analysis.

Generalisation
1. Consideration of overall practical usefulness of the study
   • Discussion on practical vs theoretical usefulness.
2. Description of generalisability (external validity) of the study
   • Dependent on Design, Sampling, and Data collection.

Concluding remarks
1. Highlight study’s particular strengths
   • What did the study do well?
2. Suggest steps that may improve future results (e.g. limitations)
   • How could the study have been better?
3. Suggest further studies
   • Where should the next study begin?
# Critical appraisal form [CCAT group]

<table>
<thead>
<tr>
<th>Category Item</th>
<th>Item descriptor</th>
<th>Score (0–5)</th>
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<tbody>
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<td>Research design</td>
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**Topic** Please circle the appropriate number to indicate your level of knowledge for the topic discussed in this paper:

- No knowledge
- Extensive knowledge

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Instructions and notes [IA group]

1. Each paper has two pieces of information:
   a. Paper ID – This is to identify each paper so that scores from each appraiser can be compared. The Paper ID is made up of the first or main author’s surname and the year the paper was published. Please ensure that the Paper ID on the paper you have read corresponds with the Paper ID on the form where you write the paper’s rank order.
   b. Research design – To make appraising each paper a little easier, the research design used is written on the paper and in each section below. This means that you do not need to decide which research design was used and can concentrate on appraising the paper based on the research design indicated. Two of the research designs have alternative names that you may be more familiar with: Single system designs include n-of-1, time-series, single-subject, and within subject designs; Descriptive, explanatory, observational designs are also known as quantitative non-experimental designs.

2. Read each paper thoroughly.

3. Having read a paper:
   a. Write a score, from 0 (the lowest score) and 10 (the highest score), in the “Score” box based on how good you think the paper covered the topic discussed.
   b. Each research design should be appraised on its own merits, not to a ‘gold standard’
   c. Scores are whole numbers only (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10)
   d. If in doubt use your best judgement, there is no right or wrong answer.

4. Please indicate your current level of knowledge for the:
   a. Topic discussed in each paper.
   b. Research design used in each paper.
## Critical appraisal form [IA group]

<table>
<thead>
<tr>
<th>Paper ID</th>
<th>Research Design</th>
<th>Score [out of 10]</th>
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<tr>
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<td>True experimental</td>
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<td><strong>Topic</strong></td>
<td>Please circle the appropriate number to indicate your level of knowledge for the topic discussed in this paper:</td>
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<td>Systematic review</td>
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