# HLT2IEP Assessment 2

# Critical Appraisal of a Randomised Controlled Trial

**Due date**

21/04/2024@11.59pm

**Weighting**

50% of the overall mark for the subject

**Rationale**

You can usually find a study to support or refute almost any theory or claim. As a health professional, you must determine which studies are trustworthy and which are not if you are to implement best practice for your patients and/or the community. To determine the trustworthiness or rigour of a scientific study, we need to evaluate its methodological quality.

In this assessment, we want you to **evaluate** (APPRAISE) the methodological quality of a randomised controlled trial related to your discipline.

Guided by your appraisal, you will make a **recommendation** for practice. This is an essential skill for all allied health and medical professionals.

Relevant SILOs

* Ask, and develop and refine, relevant and answerable practice-related questions using a structured approach.
* Acquire evidence relevant to practice by developing and implementing complex and comprehensive search strategies applicable to databases and other repositories of evidence.
* Appraise the strength of evidence generated by a range of methodologies/methods.
* Apply appraised evidence to practice-related problems, issues, or situations.
* Assess your own performance in developing capacity to be an evidence-based practitioner

**Task**

In this assessment you will select one study (a randomised controlled trial [RCT]) that has evaluated the effectiveness of an intervention (i.e., treatment) for a particular outcome. The RCT relates to the effectiveness of a health-related intervention that you explored in Assessment 1.

You will be required to evaluate the study quality, risk of bias, report the results, make recommendations for practice and reflect on your ability to complete this evidence-based practice process.

**Instructions**

This assignment is to be completed in 2,250 words (approximately) using the template included below.

The word count excludes all text that is part of the template and the reference list (of cited sources). All in-text citations are included in the word count. Any in-text citations (and the associated reference list) need to be in keeping with APA style ([click on this link to access how to use APA style](https://latrobe.libguides.com/apa7)). All words added to a table are included in the word count.

* You will be marked against an assessment rubric, which clearly outlines how you will be assessed for each section of the template. You should scrutinise the assessment rubric before commencing the task.
* **Depending on your discipline, you may or may not have to select one paper from a list of papers, as directed by your instructor. If this is the case, please select one paper/article from the list of papers/articles posted in the Assessment section of the LMS section of the LMS.** An appraisal of this paper/article is to be conducted and reported as per sections that follow (see below).

# Template

Please use this template to complete this assessment

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| Student number:Workshop facilitator's name:Word count:Date of submission:Article reference: provide the reference to your allocated RCT here using APA style ([click on this link to access how to use APA style](https://latrobe.libguides.com/apa7))* Write the reference here…
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**PLEASE NOTE:**

**Feel free to delete/remove the instructions from the template as you complete the different sections of your assessment (just leave the main headers). Do not change the formatting of the template (spacing, margins, font size, font type, etc).**

## Part 1: Methodological quality – internal validity (35 marks)

Approximately 900 words

Evaluate the internal validity of the study reported in the selected article. In your response, identify factors that affected the internal validity including bias (if bias was present, define the bias and then describe the likely impact of the bias; if bias was minimised, define the bias and describe how the study avoided it).

This evaluation may be aided by, **but not limited to**, the use of a quality appraisal tool/checklist (as specified by your discipline). Examples of appraisal tools can be found in the Assessment section of the LMS. [Click on this link to access the resources](https://lms.latrobe.edu.au/course/view.php?id=143037&section=3). In addition, refer to the green LMS e-book (Module 1, Week 2) for guidance. [Click on this link to access the resources.](https://lms.latrobe.edu.au/mod/book/view.php?id=6834321)

If you used an appraisal tool to complete this section, please mention the tool at the beginning of your response and then explain the items you appraised (in the same order as the tool). You are welcome to provide evidence of a completed tool (with your notes on it) as a separate appendix file.

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| Complete your response in this box. Included below is a suggestion for how you might like to complete this section. Please delete the text when completing your response.To appraise the internal validity of the RCT, I have chosen to use the (insert PEDro or CASP). This tool includes ‘x’ number of items related to the internal validity of the RCT. In the section below, I have provided a response to each criterion of the quality appraisal tool that relates to internal validity. In addition, I have identified if bias was present and described the likely impact of the bias; if bias was minimised, I have described how the study reduced the risk of bias.*PEDro scale – Item 2 (Subjects were randomly allocated to groups), or CASP – Item 2 (Was the assignment of participants to interventions randomised)?*1. Was the assignment of participants to interventions randomised? The student describes the process of randomisation performed in the trial.
2. The student describes how this process can reduce the risk of bias
3. If bias was present, the student should define the bias and then describe the likely impact of the bias.
4. If bias was minimised, the student should define the bias and describe how the study avoided it.

*PEDro scale – Item 3 (Allocation was concealed) or CASP – Item 2 (Was the allocation sequence concealed from investigators and participants)?*1. Was the allocation sequence concealed from investigators and participants? The student describes the process of allocation concealment used in the trial.
2. The student describes how this process can reduce the risk of bias
3. If bias was present, the student should define the bias and then describe the likely impact of the bias.
4. If bias was minimised, the student should define the bias and describe how the study avoided it.

\*The student continues to use the format for other elements of the PEDro or CASP that relates to internal validity.\*Students are encouraged to attach a completed copy of their appraisal checklist as an Appendix (which does not count toward the word limit). |

## Part 2: External validity (15 marks)

Approximately 400 words

Evaluate the **external** validity of the study reported in the selected article. In your response, identify and explainfactors that affected the **external** validity and the potential impact on the generalisability of the results[. Click on this link to access resources related to external validity.](https://lms.latrobe.edu.au/mod/book/view.php?id=6834321)

*Please note: some of these factors will be used in your response to Part 4(b) when you provide a recommendation for practice.*

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| Complete your response in this box. Included below is a suggestion for how you might like to complete this section. Please delete the text when completing your response.There are several factors that can affect the external validity of an RCT. Included below are a list of those factors, although the list is not exhaustive. For each factor listed, I have provided an explanation of the factor and described how it might impact on the generalisability of the results to clinical practice and the general population. The factors that I have chosen to review are:1. the setting of the trial
2. the selection of patients
3. characteristics of randomised participants
4. differences between trial protocol and routine practice
5. outcome measures and follow up
6. adverse effects of treatment

\*Students are encouraged to provide an explanation for each point including the potential impact on the generalisability of the results.\*Students are encouraged to review the following article from the Reading List: Rothwell PM. Factors that can affect the external validity of randomised controlled trials. PLoS Clin Trials. 2006;1(1):e9. |

Part 3: Study results (10 marks)

Approximately 150 words

In this section you should outline the results for the **key (or primary) outcome(s)** of the study reported in the selected paper/article. When outlining the result for the key outcomes, provide the:

1. point estimates
2. between group difference (population effect size) (if it is provided) and the 95% confidence limits for this difference and/or identify the p value associated with it.
3. in the absence of 95% confidence limits, please provide any form of spread around the mean value for the effect size (e.g. Standard Error, Variance, etc). [Click on this link to access resources related to point estimates and 95%CIs.](https://lms.latrobe.edu.au/mod/book/view.php?id=6834330&chapterid=944468)

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| Complete your response in this box |

Part 4: Clinical/practical importance of the study findings (30 marks)

Approximately 650 words

1. With reference to one of the effects reported in the selected article (try to use the key outcome), specify what the minimum clinically important differences (or what value on the outcome measure would be classified as clinically worthwhile).

If one is not specified in the article, try to estimate what you think the minimum clinically important difference might be for the key outcome measure ([click on this link to access information related to the minimum clinically important difference](https://lms.latrobe.edu.au/mod/book/view.php?id=6834330&chapterid=944472))

For categorical or dichotomous data, you might consider the number needed to treat (NNT).

1. Using the result (i.e. the difference between groups) provide a recommendation regarding the intervention for clinical practice. When making the recommendation please consider:
* The internal validity of the RCT (i.e., the overall methodological quality of the study).
* If the result is statistically significant is the difference clinically important?
* Do the benefits of the intervention outweigh any costs, harms, inconveniences of the treatment?
* Patient preferences
* Availability and accessibility of the intervention
* Skill of the health professional

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| Complete your response in this box |

Part 5: Reflection on learning (10 marks)

Approximately 150 words

Reflect on your completion of the critical appraisal of your selected paper/article. Share your reflections on your learning and your development as an evidence-based practitioner.

1. Describe aspects of the critical appraisal that you found challenging or difficult
2. Describe aspects (if any) of the appraisal process that remain unclear to you or you think you would be unable to explain to another student?
3. Explain how you might improve your effectiveness and efficiency in executing Steps 1-4 of evidence-based practice next time
4. Imagine for a moment you have commenced work in your discipline/professional field. Describe the knowledge and skills that have your acquired in completing this assessment task that could translate to your professional environment.

Complete your response in this box