

Critical Appraisal Skills Programme (CASP)

Making sense of evidence

Critical Appraisal Checklist for a Randomised Controlled Trial

How to use this appraisal tool

Three broad questions need to be considered when appraising the report of a randomised controlled trial:

- Is the study valid?
- What are the results?
- Will the results help locally?

The 10 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.

You are asked to record a 'yes', 'no' or 'can't tell' to most of the questions. A number of prompts are given after each question.

These are designed to remind you why the question is important.

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Screening Questions

<p>1. Did the study ask a clearly focused question?</p> <p>Consider if the question is focused in terms of:</p> <ul style="list-style-type: none"> - The population studied - The intervention given or exposure - The outcomes considered 	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">Yes</td> <td style="width: 33%;">No</td> <td style="width: 33%;">Can't tell</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Yes	No	Can't tell	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Yes	No	Can't tell					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
<p>2. Was this a randomised controlled trial (RCT) and was it appropriately so?</p> <p>Consider:</p> <ul style="list-style-type: none"> - Why this study was carried out as an RCT - If this was the right research approach for the question being asked 	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">Yes</td> <td style="width: 33%;">No</td> <td style="width: 33%;">Can't tell</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Yes	No	Can't tell	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Yes	No	Can't tell					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					

Detailed Questions

<p>3. Were participants appropriately allocated to intervention and control groups?</p> <p>Consider:</p> <ul style="list-style-type: none"> - How participants were allocated to intervention and control groups. Was the process truly random? - Whether the method of allocation was described - How the randomisation schedule was generated and how a participant was allocated to a study group. - If the groups were balanced. Are any differences between the groups at entry to the trial reported? - If there were differences reported that might have explained any outcome(s). 	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">Yes</td> <td style="width: 33%;">No</td> <td style="width: 33%;">Can't tell</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Yes	No	Can't tell	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Yes	No	Can't tell					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					

<p>4. Were participants, staff and study personnel 'blind' to participants' study group?</p> <p>Consider:</p> <ul style="list-style-type: none"> - The fact that blinding is not always possible. - If every effort was made to achieve blinding - If you think it matters in this study. - The fact that we are looking for 'observer bias'. 	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>	<p>Can't tell <input type="checkbox"/></p>
<p>5. Were all of the participants who entered the trial accounted for at its conclusion?</p> <p>Consider:</p> <ul style="list-style-type: none"> - If any intervention group participants got a control group option or vice versa. - If all participants were followed up in each study group (was there loss to follow up?) - If all participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis). - What additional information would you like to have seen. 	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>	<p>Can't tell <input type="checkbox"/></p>
<p>6. Were the participants in all groups followed up and data collected in the same way?</p> <p>Consider:</p> <ul style="list-style-type: none"> - If, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias. 	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>	<p>Can't tell <input type="checkbox"/></p>
<p>7. Did the study have enough participants to minimise the play of chance?</p> <p>Consider:</p> <ul style="list-style-type: none"> - If there is a power calculation. This will estimate how many participants are needed to be reasonably sure of finding something important. 	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>	<p>Can't tell <input type="checkbox"/></p>

<p>8. How are the results presented and what is the main result?</p> <p>Consider:</p> <ul style="list-style-type: none"> - If, for example, the results are presented as a proportion of people experiencing an outcome, or as risks or measurements. - How large this size of result is and how meaningful it is. - How would you sum up the bottom-line result of the trial. 	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p>
<p>9. How precise are the results?</p> <p>Consider:</p> <ul style="list-style-type: none"> - If the result is precise enough to make a decision. - If a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit? - If a p-value is reported where confidence intervals are unavailable. 	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p>
<p>10. Should policy or practice change as a result of the evidence obtained in this trial?</p> <p>Consider whether:</p> <ul style="list-style-type: none"> - The people included in the trial could be different from your population in ways that would produce different results. - Your local setting differs much from that of the trial. - You can provide the same treatment in your setting - Whether any benefit reported outweighs any harm and/or cost. 	<p>Yes <input type="checkbox"/></p> <p>No <input type="checkbox"/></p> <p>Can't tell <input type="checkbox"/></p>