Critical Appraisal of Randomised Controlled Trials

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Introduction

A randomized clinical trial is a type of study designed to evaluate therapeutic interventions and is often used to test the efficacy of a treatment approach in a population of patients or to gather information about potential adverse events of a particular procedure. Furthermore, patients are randomly allocated to receive one of various clinical interventions (Figure 1).

In order to practice with the most up-to-date knowledge of evidence-based medicine, we should take into account as well as implement the results of clinical research well designed and adequately conducted in specific settings and individuals, which represent part of the decision making process. Table 1 shows the checklists needed to make a critical analysis of randomised controlled trials [1-12].

![Figure 1: Methodology of the randomized clinical trial.](image)

<table>
<thead>
<tr>
<th>Appraisal questions</th>
<th>Outcome event</th>
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<tbody>
<tr>
<td>Did the trial address a clearly focused issue?</td>
<td>Yes</td>
</tr>
<tr>
<td>The study addresses an appropriate and clearly focused question. The assignment of subjects to treatment groups is randomized. An adequate concealment method is used.</td>
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<td>The treatment and control groups are similar at the start of the trial. The only difference between groups is the treatment under investigation. Was allocation adequately concealed by a rigorous method (e.g. random numbers)?</td>
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<td>Were all subjects who entered the trial accounted for and were they analysed in the groups to which they were randomised, i.e. intention-to-treat analysis?</td>
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<td>Were appropriate measures of baseline characteristics taken in all groups before the intervention, and were study groups shown to be comparable in all characteristics likely to influence outcome? Was there a baseline measure of performance and patient outcomes, and were study groups comparable in these at baseline?</td>
<td></td>
</tr>
<tr>
<td>Was the assignment of patients to treatments randomised? How was this carried out, some methods may produce broken allocation concealment • Was the allocation concealed from researchers?</td>
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Relative risk reduction (RRR) = (CER-EER)/CER or 1-RR

| Experimental event rate=Risk of outcome event in experimental group=EER=a/ (a+b) Control event rate=Risk of outcome event in control group=CER=c/ (c+d) Relative risk reduction (RRR) = (CER-EER)/CER or 1-RR
<table>
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<td>a</td>
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Absolute risk reduction (ARR) = CER - EER
Number needed to treat (NNT) = 1/ARR = 1/ (CER - EER)

How great was the treatment effect? How the results were expressed (RRR, NNT, etc.).

Are the results of this study directly applicable to the patient group targeted by this guideline or clinical statement?

How great would the benefit of therapy be for my particular patient?

Can the results be applied to your organization? (Do you have any reason to believe that your population of interest is different to that in the trial? If so, in what way?)

Were all clinically important outcomes considered? (Is there any additional information you would like to have observed? Was the need for this trial clearly described?)

Was the primary outcome measure valid (i.e., do two independent raters agree that this was a sensible and reasonable measure of performance or outcome)? Was the primary outcome measure reliable (i.e., do two independent raters agree on the nature and extent of change)?

Is it unlikely that the control unit of allocation (professional, practice, institution, community) received the intervention through contamination? Were outcomes measured by ‘blinded’ observers or were they objectively verified (e.g., quantitative measures recorded prospectively and independently)?

Was there complete follow-up of patient groups (ideally >95%)? Was follow-up continued for long enough for the primary outcome measure to show an impact and for sustainability to be demonstrated?

Are the benefits worth the harms and costs? (Even if this is not addressed by the trial, what do you think?)

Should policy or practice change as a result of the evidence contained within this trial?

Conflicts of interest are declared.

Rate the overall methodological quality of the study, using the following as a guide:

High quality (++): Majority of criteria met. Little or no risk of bias.
Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias.
Low quality (-): Either most criteria not met, or significant flaws relating to key aspects of study design.

Reject (0): Poor quality study with significant flaws. Wrong study type. Not relevant to guideline.

Table 1: Critical appraisal of randomised controlled trials.

Use of this checklist can improve the evaluation of randomised controlled trials.

References