

How to Review an Article on Therapy

GUIDE	COMMENTS
Are the results valid?	
1. Was the assignment of patients to treatments randomized? And was the randomization list concealed?	<ul style="list-style-type: none"> • Randomization is important in balancing prognostic factors (both known & unknown) between treatment & control groups. • This methodology is the gold standard for clinical trials. • It is important that physicians who enter patients into a Randomized Clinical Trials (RCT) cannot influence which group their patient enters (control or experimental). The randomization should be concealed in some fashion – sealed envelopes or calling to remote site for assignment are two examples.
2. Was follow-up of patients sufficiently long and complete?	<ul style="list-style-type: none"> • Was the follow-up of patients sufficiently long to see a clinically important effect? Example – several weeks is fine for streptococcal pharyngitis, while years may be appropriate for chronic diseases, ie cancer, cardiac disease • Was there an acceptable loss of follow-up of patients? Greater than 20% is usually considered unacceptable.
3. Were patients analyzed in the groups which they were randomized?	<ul style="list-style-type: none"> • To preserve the value of randomization “intention to treat analysis” should be performed. • The subject is analyzed in the group which they were randomized.
4. Were patients and clinicians kept “blind” to treatment?	<ul style="list-style-type: none"> • Blinding both the clinician and patient to the treatment (or lack thereof) is ideal. • Sometimes patients and clinicians can’t be blinded, such as in surgical trials. • The most important blinding is that of the assessment of the outcomes of the study.
5. Were the groups treated equally, apart from the experimental treatment?	<ul style="list-style-type: none"> • The experimental and control group should be treated equally apart from the experimental treatment. They should have the same testing, the same number of follow-up visits, the same educational interventions other than experimental treatment.
6. Were the groups similar at the start of the trial?	<ul style="list-style-type: none"> • While randomization should make the groups similar, they may not be exactly equal. • Groups should be similar in all prognostically important ways. • If they are not similar, there should be some adjustment for potentially important prognostic factors carried out in the analysis phase. This can include stratification or multiple regression analysis.
Are the valid results of this randomized study important?	
1. What is the magnitude of the treatment effect?	<p>CER – control event rate EER – experimental event rate Relative risk reduction (RRR) = (CER – EER)/CER Absolute risk reduction (ARR) = CER – EER Number Needed to Treat (NNT) = 1/ARR</p> <p>*Note – there are formulas to calculate confidence intervals for each of the above measures. They are not included as you are not expected to be able to calculate them.</p>
2. How precise is this estimate of the treatment effect?	<ul style="list-style-type: none"> • Look for 95% confidence intervals. Confidence intervals are the measure of precision • The wider the confidence intervals, the less precise the measurement. This is relative.
Are these valid, important results applicable to our patient?	
1. Is our patient so different from those in the study that its results cannot apply?	<ul style="list-style-type: none"> • Our patient does not have to fit all the inclusion criteria of this study. • Consider whether our patient’s sociodemographic features or pathobiology are so different from those in the study that its results are useless to us and our patient.
2. Is the treatment feasible in our setting?	<ul style="list-style-type: none"> • Is the treatment economically feasible and available in our geographic region?

3. What are our patient's potential benefits and harms from the therapy?	<ul style="list-style-type: none">• There is always constant weighing of the treatment's potential benefits and harms.
4. What are our patient's values and expectations for both the outcome we are trying to prevent and the treatment we are offering?	<ul style="list-style-type: none">• We must elicit our patient's preferences for both the outcome we are trying to prevent and the treatment we are offering.

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