Clear Form

Rady Faculty of Health Sciences | University of Manitoba

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Department of Family Medicine Residency Program

PEARLS Therapy (Randomized Controlled Trial) Critical Appraisal Worksheet

Modified from the "PEARLS for Residents Critical Appraisal Worksheet" from the College of Family Physicians of Canada.

Resident Name: _____
Faculty Supervisor: _____
Randomized Controlled Trial: _____
Date: _____

Links connect to JAMAevidence User's Guide to the medical literature. You will need to sign in to the University of Manitoba Library to access them. (Link to glossary) (Link to chapter on randomized trials)

Section A. Are the results valid?

1. How was this randomized controlled trial (RCT) funded? Do the researchers have a financial conflict of interest?

2. What was the PICO question addressed by the researchers in this trial?
(Population/Intervention/Control/Outcome)(how to pose a PICO question)

3. Was the assignment of patients to treatment groups truly randomized?
(As opposed to pseudo-randomized)

4. Was allocation of patients to control or treatment groups adequately concealed?
(For randomization to be successfully implemented, the randomization sequence must be adequately protected (concealed) so that investigators, health care providers, and subjects are not aware of the upcoming assignment. The absence of adequate allocation concealment can lead to selection bias, one of the few problems randomization is supposed to eliminate. A plan of allocation concealment can always be

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5. Were all those who entered the study appropriately accounted for?

(Is the number randomized at the start the same as in results? (Try a best case /worst case scenario.)

6. Were patients, physicians, and those doing assessments "blind" to treatment?

(Keeping knowledge of subjects' assignment after allocation from investigators/health care providers or those assessing outcomes is referred to as masking (aka blinding). The goal of masking is to prevent ascertainment bias. In contrast to allocation concealment, masking cannot always be incorporated into a RCT.)

7. Was similarity between groups documented?

(Is there a table of baseline characteristics?
Were differences controlled for in the analysis?
Could any differences between the groups rationally explain any of the results of the study?)

8. Aside from the intervention, were the groups treated in the same ways?

(Did one group get an additional treatment? Did one group have more or different monitoring?)

Section B. What were the results?

9. What is the answer to the PICO question addressed by the researchers in this trial?

(Population/Intervention/Control/Outcome)

10. How large was the treatment effect?

(Provided that the result is statistically significant, magnitude of treatment effect is usually measured by a number needed to treat using a specified outcome at a specified point in time.) (how to calculate, use, and interpret a number needed to treat)

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11. How precise was the estimate of the treatment effect?

(Precision is measured by confidence intervals.)(how to use and interpret confidence intervals)

Section C. Can the results be applied to your patients?

12. What is the clinical question you would like answered? How does this compare to the PICO in the study? Are they similar enough to be useful?

(How similar is the study population to your practice population? Is the intervention something you would consider using in your clinical setting? Assuming that a placebo is equivalent to "no intervention", is the study control similar to how you usually treat a patient in this clinical situation? Is the outcome something a patient would likely notice and value?)

13. Were all clinically important outcomes reported?

14. Estimate the likely treatment benefits of the intervention in your population based on the trial results and what you know about the disease and about your population. *(The absolute risk reduction ARR equals the relative risk reduction RRR multiplied by the risk of a bad outcome in each population. ARR = RRR x risk. If the risk of a bad outcome is higher in your population then the absolute risk reduction will also increase. Find the RRR from the trial and multiply it by your estimate of risk in your population based on what you know about the disease to calculate the ARR. Number needed to treat is the inverse of the absolute risk reduction. NNT = 1/ARR.)*

15. Are the likely treatment benefits greater than the potential harms and costs?

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16. Is this trial the best available evidence? How do you know?

(Your conclusions rest heavily on this question. If you do not have the best available evidence then you cannot answer your clinical question. Whether you identified this trial through a direct literature search or through a systematic review, it is important that your search did not exclude a better clinical trial that contradicts this one.)

17. Was this clinical trial identified via a guideline? If so did that guideline reasonably reflect the strength and applicability of the evidence from this clinical trial in its recommendation?

Further information on how to evaluate a therapy trial can be found in JAMAevidence Users' Guide to the Medical Literature: A Manual for Evidence Based Clinical Practice chapter 7 in the EBM tab of the University of Manitoba Medical Library. http://libguides.lib.umanitoba.ca/ebm