

RAPID CRITICAL APPRAISAL OF A RANDOMIZED CONTROLLED TRIAL (RCT) OR CONTROLLED CLINICAL TRIAL (CCT)

PROJECT DESCRIPTION/LEVEL OF STUDY

Project title:

Date:

Reviewer(s) name(s):

Article citation (APA):

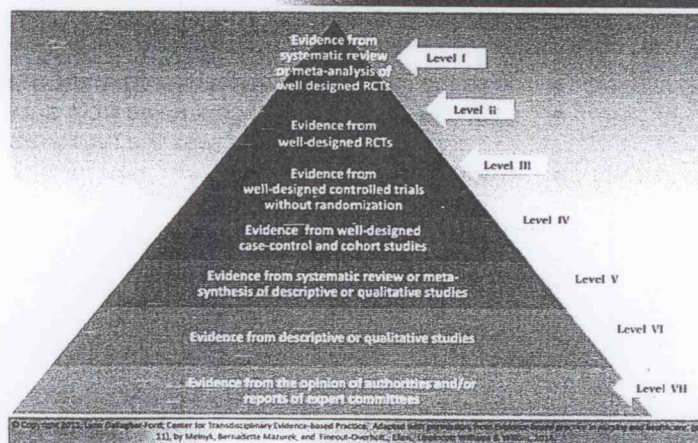
PICOT Question:

Indicate the level of the study you are appraising:

What is your recommendation for article use in body of evidence?



Levels of Evidence



GENERAL DESCRIPTION OF STUDY

OVERVIEW

1. Purpose of study, including research question(s) or hypotheses
2. Design/Method
3. Sample/Setting



QUALITY OF STUDY

VALIDITY: Are the results of this study valid?

1. Were patients randomly assigned to treatment and control groups?

☐ Yes ☐ No ☐ Unknown

- Note: If the study was not randomized, it should be assigned the level for a CCT
- Comments:

2. Was that randomization conducted appropriately?

☐ Yes ☐ No ☐ Unknown

- Was the intervention concealed from providers (were they blinded)?
- Was the randomization concealed from subjects (were they blinded)?
 - When applicable, was the randomization concealed from families (were they blinded)?
- Comments:

3. Were the groups similar at the start of the trial, with respect to known demographic and clinical variables?

☐ Yes ☐ No ☐ Unknown

- Comments:

4. Aside from the intervention, were the groups treated equally?

☐ Yes ☐ No ☐ Unknown

- Comments:

5. Were all patients who entered the trial accounted for at its conclusion?

☐ Yes ☐ No ☐ Unknown

(Note: If greater than 20% were lost to follow-up, bias may be of greater concern)

- What was the rate of attrition?
- Were reasons given to explain why subjects did not complete the study?
- Comments:

6. Were patients analyzed in the groups to which they were randomized?

☐ Yes ☐ No ☐ Unknown

- Comments:

7. Was the study process described and complete?

☐ Yes ☐ No ☐ Unknown

- Was the study process long enough to fully study the effects of the intervention?
- Comments:

8. Were instruments used to measure the outcomes valid and reliable?

☐ Yes ☐ No ☐ Unknown

- Were the instruments tested to be valid and reliable?
- What statistic was reported?
 - Cronbach's alpha? _____
 - Other? _____
- Comments:

9. Was there freedom from conflict of interest?

☐ Yes ☐ No ☐ Unknown

- Sponsor/funding agency: _____
- Investigators: _____
- Comments:

10. Is the date range of the cited literature current?

☐ Yes ☐ No ☐ Unknown

- What date ranges were included? _____ to _____
 - If older literature was included, why was it included?
- Comments:

RELIABILITY: Are these valid study results important?

11. Did the study have a sufficiently large sample size?

☐ Yes ☐ No ☐ Unknown

- Was there a power analysis?
- Did the sample size achieve or exceed the power analysis requirement?
- Did each subgroup also have sufficient sample size?
- Comments:

12. What were the main results of the RCT or CCT?

- What was the effect size? _____
- Was the precision of the intervention reported? ☐ Yes ☐ No
- How was the precision reported?
 - Confidence Intervals _____
 - Standard Deviations _____
- How precise was the intervention/treatment?
 - Narrow? _____ Wide? _____
- Comments:

13. Were the results clinically significant?

☐ Yes ☐ No ☐ Unknown

- Were the following reported: NNT _____, NNH _____, OR _____, RR _____?
- Comments:

14. Were the results statistically significant?

☐ Yes ☐ No ☐ Unknown

- P value? _____
- Comments:

15. If potential confounders were identified, were they discussed in relationship to the results?

☐ Yes ☐ No ☐ Unknown

- Comments:

16. Were adverse events identified?

☐ Yes ☐ No ☐ Unknown

- Comments:

17. Were safety concerns including risk/benefits described?

☐ Yes ☐ No ☐ Unknown

- Comments:

APPLICABILITY/TRANSFERABILITY: Can I apply these valid, important study results?

18. Can the results be applied to my population of interest?

☐ Yes ☐ No ☐ Unknown

- Is the treatment feasible in my care setting?
- Do the outcomes apply to my population of interest?
- Are the likely benefits worth the potential harm and costs?
- Were the subjects/participants in this study similar to my population of interest?
- Were all clinically important outcomes considered?
- Comments:

19. Would you include the article/study in your practice decision to make a difference in outcomes?

☐ Yes ☐ No ☐ Unknown

- If yes, why would you do this?
- If yes, how would you do this?
- If no, why would you not include the results to make a difference?
- Comments:

STRENGTH OF STUDY

Level of study: I, II, III, IV, V, VI, VII (Circle one)

Quality of study: High | Medium | Low (Circle one)

STRENGTH = LEVEL + QUALITY

What is the strength of the study?

What is your recommendation for article use in the body of evidence to answer your question?

Additional Comments: