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

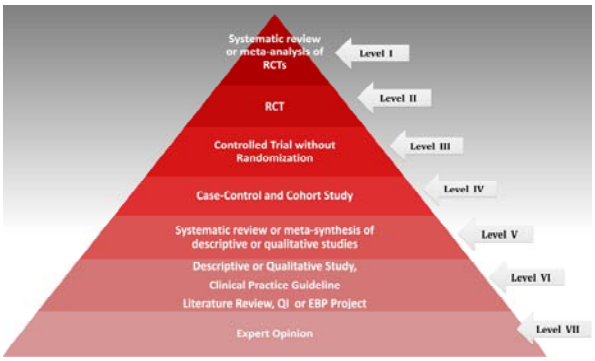
PROJECT DESCRIPTION/LEVEL OF STUDY

Project title:

Date:

Reviewer(s) name(s):

PICOT Question:



Article citation (APA):

Indicate the level of the study you are appraising:

Recommendation for article inclusion in the body of evidence to answer your question:

GENERAL DESCRIPTION OF STUDY

OVERVIEW

1. **Purpose of study, including research question(s) or hypotheses:**
2. **Design/Method:**
3. **Sample:**
4. **Setting:**
5. **Data Collection:**

THE OHIO STATE UNIVERSITY
COLLEGE OF NURSING
Updated 12052017

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)

2. **Was that randomization conducted appropriately?** ☐ Yes ☐ No ☐ Unknown
   - How was the randomization conducted? (ex: computer-generated, coin-toss, etc.)
   - Was the intervention concealed from providers (were they blinded)? ☐ Yes ☐ No
   - Was the randomization concealed from subjects (were they blinded)? ☐ Yes ☐ No
   - When applicable, was the randomization concealed from families (were they blinded)? ☐ Yes ☐ No

3. **Were the groups similar at the start of the trial, with respect to known demographic and clinical variables?** ☐ Yes ☐ No ☐ Unknown
   - Was the demographic data collected relevant to the intent of the study? ☐ Yes ☐ No
   - Were the clinical variables collected relevant to the intent of the study? ☐ Yes ☐ No
   - Was a statistic calculated to verify the similarities/differences between the groups? ☐ Yes ☐ No

4. **Aside from the intervention, were the groups treated equally?** ☐ Yes ☐ No ☐ Unknown
   - What did the control group receive? (check one)
     - o No intervention ☐
     - o Current Practice ☐
     - o Placebo ☐
     - o An Intervention matched for time and attention ☐

5. **Were all patients who entered the trial accounted for at its conclusion?** ☐ Yes ☐ No ☐ Unknown
   - What was the rate of attrition? _____
   - What reasons were given to explain why subjects did not complete the study?

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

6. **Were patients analyzed in the groups to which they were randomized?** ☐ Yes ☐ No ☐ Unknown

7. **Was the study process well described and complete?** ☐ Yes ☐ No ☐ Unknown

8. **Was the study timeframe long enough to capture the effects of the intervention?** ☐ Yes ☐ No ☐ Unknown

9. **Were instruments used to measure the outcomes valid and reliable?** ☐ Yes ☐ No ☐ Unknown
   - Were the instruments tested to be valid and reliable? ☐ Yes ☐ No
   - What statistic was reported and what was the finding? (Cronbach's alpha/Other?)

10. **Was there freedom from conflict of interest?** ☐ Yes ☐ No ☐ Unknown
    - Sponsor/funding agency
    - Investigators

11. Was the date range of the cited literature current? ☐ Yes ☐ No ☐ Unknown

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

RELIABILITY: Are these valid study results important?

12. Did the study have a sufficiently large sample size? ☐ Yes ☐ No ☐ Unknown

- Was a power analysis conducted? ☐ Yes ☐ No
- Did the sample size achieve or exceed the power analysis requirement? ☐ Yes ☐ No
- Did each subgroup also have sufficient sample size? ☐ Yes ☐ No

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

- Statistical Significance (*p* value) _____
- Confidence Interval and/or Standard Deviations _____
- How precise was the intervention/treatment?
  - o Narrow? Wide? _____
- Effect size _____

14. Were the results clinically significant? ☐ Yes ☐ No ☐ Unknown

- Were the following reported: NNT, NNH, OR, RR? ☐ Yes ☐ No

15. Were potential confounders identified? ☐ Yes ☐ No ☐ Unknown

- Were the potential confounders discussed in relationship to the results? ☐ Yes ☐ No

16. Were adverse events identified? ☐ Yes ☐ No ☐ Unknown

17. Were safety concerns including risk/benefits described? ☐ Yes ☐ No ☐ Unknown

APPLICABILITY/GENERALIZABILITY: 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? ☐ Yes ☐ No
- Do the outcomes apply to my population of interest? ☐ Yes ☐ No
- Are the likely benefits worth the potential harm and costs? ☐ Yes ☐ No
- Were the subjects/participants in this study similar to my population of interest? ☐ Yes ☐ No
- Were all clinically important outcomes considered? ☐ Yes ☐ No

19. Will 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 & how would you do this?
- If no, why would you not include the results to make a difference?

STRENGTH OF STUDY

Level of study: I *(Select One)*

Quality of study: Low *(Select one)*

STRENGTH = LEVEL + QUALITY

What is the strength of the study?

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

☐ Include this article in the body of evidence (place article on evaluation & synthesis tables)
☐ Do NOT include this article in the body of evidence

Additional Comments: