Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question?

- Yes ☐  No ☐  Unknown ☐

- Study Aim/Purpose/Objectives:

- Inclusion Criteria:

- Exclusion Criteria:

Is a RCT or CCT congruent with the author’s study aim/purpose/objectives above?

- Yes ☐  No ☐  Unknown ☐

Comments:

When reading the bolded questions, consider the bulleted questions to help answer the main question.

If you are uncertain of your skills in evidence evaluation, please consult a local evidence expert for assistance:

CCHMC Evidence Experts: [http://groups/ce/NewEBC/EBDMHelp.htm](http://groups/ce/NewEBC/EBDMHelp.htm)

Unfamiliar terms can be found in the LEGEND Glossary: [http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf](http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf)

### VALIDITY: ARE THE RESULTS OF THE RCT OR CCT VALID OR CREDIBLE?

1. Were patients randomly assigned to experimental/exposure and control groups?

   - Yes ☐  No ☐  Unknown ☐

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

   Comments:

2. Was that randomization conducted appropriately?

   - Yes ☐  No ☐  Unknown ☐

   - Was the randomization concealed from those responsible for recruiting subjects?

   - Was the randomization concealed from patients, parents, clinicians, and analysts?

   Comments:

3. At the start of the study, were the participants similar (homogeneous) with respect to known factors of interest (e.g., demographic, exposure, risk, treatment, or etiology)?

   - Yes ☐  No ☐  Unknown ☐

   Comments:

4. Aside from the experiment/exposure, were the groups treated equally?

   - Yes ☐  No ☐  Unknown ☐

   Comments:
5. Were all patients who entered the study accounted for at its conclusion?
   • Were withdrawals from the study explained?
   • Was the rate of attrition acceptable?
   Comments:
   ☐ Yes ☐ No ☐ Unknown

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

7. Was the study process long enough to fully study effects of the experiment/exposure?
   Comments:
   ☐ Yes ☐ No ☐ Unknown

8. Were instruments used to measure the outcomes valid and reliable?
   Comments:
   ☐ Yes ☐ No ☐ Unknown

9. Was there freedom from conflict of interest?
   • Sponsor/Funding Agency or Investigators
   Comments:
   ☐ Yes ☐ No ☐ Unknown

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

10. Did the study have a sufficiently large sample size?
    • Was there a power analysis?
    • Did the sample size achieve or exceed that resulting from the power analysis?
    • Did each subgroup also have sufficient sample size (e.g., at least 6 to 12 participants)?
    Comments:
    ☐ Yes ☐ No ☐ Unknown

11. Were the statistical analysis methods appropriate?
    • Were the statistical analysis methods clearly described?
    • If subgroups were evaluated, was a statistical adjustment made for the differences?
    Comments:
    ☐ Yes ☐ No ☐ Unknown

12. What were the main results of the RCT or CCT? (e.g., Helpful data: Page #, Table #, Figures, Graphs)
• How strong is the association between experiment/exposure and outcome?  
  (What is the correlation or estimate of risk?)

• What were the measures of statistical uncertainty (e.g., precision)?  
  (Were the results presented with Confidence Intervals or Standard Deviations?)

• What was the effect size?  (How large was the effect of the experiment/exposure?)

13. Were the results statistically significant?  
   □ Yes □ No □ Unknown
   Comments:

14. Were the results clinically significant?  
   □ Yes □ No □ Unknown
   Comments:
   • If potential confounders were identified, were they discussed in relationship to the results?

15. Were adverse events assessed?  
   □ Yes □ No □ Unknown
   Comments:

**APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO MY POPULATION?**

16. Can the results be applied to my population of interest?  
   □ Yes □ No □ Unknown
   Comments:
   • Is the setting of the study applicable to my population of interest?
   • Do the patient outcomes apply to my population or question of interest?
   • Were the patients in this study similar to my population of interest?

17. Are my patient’s and family’s values and preferences satisfied by the knowledge gained from this study (such as outcomes considered)?  
   □ Yes □ No □ Unknown
   Comments:

18. Would you include this study/article in development of a care recommendation?  
   □ Yes □ No □ Unknown
   Comments:
ADDITIONAL COMMENTS OR CONCLUSIONS (“TAKE-HOME POINTS”):

QUALITY LEVEL / EVIDENCE LEVEL

- Consider each “No” answer and the degree to which this limitation is a threat to the validity of the results, then check the appropriate box to assign the level of quality for this study/article.
- Consider an “Unknown” answer to one or more questions as a similar limitation to answering “No,” if the information is not available in the article.

THE EVIDENCE LEVEL IS:  
☐ Good Quality RCT [2a]  
☐ Lesser Quality RCT [2b]  
☐ Good Quality CCT [3a]  
☐ Lesser Quality CCT [3b]  
☐ Not Valid, Reliable, or Applicable

Table of Evidence Levels

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*RCT = Randomized Controlled Trial; CCT = Controlled Clinical Trial

Development for this appraisal form is based on: