Expanded Critical Appraisal Worksheet with Key Learning Points

THERAPY STUDY	Article author/year: _____	Key Learning Points
A. ARE THE RESULTS VALID? ("FRISBE") **F = Patient Follow-Up** Were all patients who entered the trial properly accounted for and attributed at its conclusion? Was follow-up complete?		How do dropouts threaten validity? Study participants are lost to follow up (LTF) when their status/outcomes are not known at the end of the trial. Often the *reason* that they are lost to follow up relates to a systematic difference in their prognosis from those who continue with a study until the end (e.g. patients LTF do worse/are dead or may be greatly improved/ don't feel the need to continue in the study). Thus the loss of many participants may threaten validity. Furthermore, if loss to follow up is different between the two groups, dropouts or those lost to follow-up may create missing data that can disrupt the balance in groups created by randomization.
R = Randomization Was the allocation (assignment) of patients to treatment randomized? Was the allocation concealed?		Why is randomization important? Effective randomization guarantees that each subject has an independent and fixed chance of being allocated to each group. The chance is usually equal (e.g. in parallel group design where a participant is randomized to one of two or more interventions). Randomization aims to balance groups for known and unknown prognostic factors by allocating subjects to groups by chance alone. If randomization is correctly done, any group differences should be attributable to chance alone. The intent is to minimize chance differences so that any observed group differences can be attributed to the effect of treatment. Allocation concealment assures that those assessing eligibility and assigning subjects to groups don't have knowledge of the allocation sequence.

I = Intention-to-Treat Analysis Were patients analyzed in the groups to which they were randomized? Were all randomized patient data analyzed?		Why is intention-to-treat analysis important? ITT preserves the balance of prognostic factors in groups created by the original random group allocation. It provides the truest estimate of the effects of treatment allocation in real-world practice by including data from crossovers, nonadherents, dropouts and those lost to follow-up, plus estimates of missing data points. ITT thereby avoids overly optimistic estimates of treatment efficacy resulting from excluding non-compliers.
S = Similar Baseline Characteristics of Patients Were groups similar at the start of the trial?		Why should groups be similar at baseline? It is important to verify that those factors known to influence outcome are equally distributed. And to assess the potential effect on the study outcome of an imbalance that occurs by chance.
B = Blinding Were patients, health workers, and study personnel "blind" to treatment?	Blinded groups included (Y=yes, N=no, U=uncertain): ____ patients ____ providers ____ raters or assessors ____ data analysts ____ adjudicators	Why is blinding important? Blinding equalizes the effect of patient and provider expectations on outcome across groups. For raters, blinding minimizes subjectivity in outcome measurement. For providers, blinding eliminates the possibility of either conscious/unconscious differential administration of effective intervention to either group: i.e. co-interventions (unintended additional care to either group) or contamination (provision of intervention to control group).
E = Equal Treatment Aside from the experimental intervention, were the groups treated equally?		Why should groups be treated equally? Equal treatment helps guarantee that the groups will remain prognostically balanced by avoiding systematic differences in the care provided other than the intervention.
Summary of article's validity	Notable strengths / weaknesses: Overall, this trial methods are *(strong/adequate/weak)* Potential threats are *(minimal/modest/serious/fatal)* and would likely bias the results of the study towards *(overestimate/underestimate)* of treatment effect.	How serious are the threats to validity and in what direction could they bias the study outcomes? Include notable strengths /weaknesses as well as *direction* of the biases and how that may impact interpretation of results.

B. WHAT ARE THE RESULTS?

How large was the treatment effect?

How precise was the treatment effect?

1) Response rates on dichotomous outcome measure:

Outcome	EER_1 (n=)	CER or EER_2 (n=)	Risk Difference	NNT (95%CI)

Risk Ratio

Risk Difference

NNT or NNH

Calculate and state the plain English meaning of summary statistics for dichotomous outcomes:

Risk Ratio

Risk Difference

NNT or NNH

C. WILL THE RESULTS HELP ME IN CARING FOR MY PATIENTS?

Can the results be applied to my patient?

Were all clinically important outcomes considered?

Are the likely treatment benefits worth the potential harms and costs?