Expanded Critical Appraisal Worksheet: Therapy Study

Validity (FRISBE)	Questions to ask	Key Learning points
F: Patient Follow-Up Were all patients who entered the trial properly accounted for and attributed at its conclusion? Was follow-up complete?	• Is there outcome data for all patients show entered the trial? • If so, was the percentage of patients without outcome data similar between groups? • Were reasons why patients dropped out or were missing outcome data well-described?	How do dropouts threaten validity? Dropouts or those lost to follow-up create missing data that might disrupt the balance in groups created by randomization, especially since those who discontinue a study often have a different prognosis than do those who continue. A large number of dropouts may introduce systematic differences between groups in those lost to follow-up
R: Randomization Was the allocation (assignment) of patients to treatment randomized? Was the allocation concealed?	• Were patients selected at random from the target population? • Was the assignment randomized? • Was the method to generate randomization appropriate? • Was evidence of concealment provided?	Why is randomization important? Randomization guarantees that each subject has the same chance of entering any group and aims to balance groups for known and unknown prognostic factors so that group differences can be attributed to the effect of treatment. Allocation concealment assures that those assessing eligibility and assigning patients 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?	• Were all patients analyzed in the groups to which they were randomized? • What percentage of patients was excluded from the analyses? • How were missing outcomes handled (e.g., were missing data imputed using statistical modeling techniques)? • If missing data were imputed was a sensitivity analysis or "worst case scenario" analysis done? If so, what did that analysis show?	Why intention-to-treat analysis is 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, non-adherents, dropouts and those lost to follow-up
S: Similar Baseline Characteristics of Patients Were groups similar at the start of the trial?	• Was sufficient information provided about important demographic and clinical characteristics known to affect prognosis? • If important differences existed between the groups, did the imbalance favor the control or treatment group?	Why should the 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?	• Potential groups needing blinding: patients, providers, raters or assessors, data analysts, adjudicators. • While patients and providers are necessarily unblinded in psychotherapy trials, objectivity is enhanced by the use of blinded raters and objective outcome measures. • If appropriate, was the integrity of the blinding tested and found to have been preserved?	Why is blinding important? Blinding equalizes the effect of patient and therapist 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, such as co-interventions (unintended additional care to either group) or contamination (provision of the intervention to the control group).
E: Equal Treatment Aside from the experimental intervention, were the groups treated equally?	• Were patients in the different groups treated differently in any way (other than the intervention)?	Why should groups be treated equally? Equal treatment helps guarantee that the groups remain prognostically balanced by avoiding systematic differences in the care provided other that the intervention.
Summary of article's validity	Notable strengths: Weaknesses or concerns: How serious are the threats to validity and in what direction could they bias the study outcomes?	

Adapted from "Expanded Critical Appraisal Worksheet with Key Learning Points" Duke Program on Teaching Evidence Based Practice