

Critical Appraisal Worksheet: Therapy Study (RCT) With Continuous Outcomes

SCREENING	
<ul style="list-style-type: none"> • Does the study question match your question? • Was the study design appropriate? 	
VALIDITY	
<p>F: Patient Follow-Up</p> <ul style="list-style-type: none"> • Were all patients who entered the trial properly accounted for at its conclusion? Losses to follow-up should be less than 20% and reasons for drop-out given. • Was follow-up long enough? 	
<p>R: Randomization</p> <ul style="list-style-type: none"> • Were the recruited patients representative of the target population? • Was the allocation (assignment) of patients to treatment randomized and concealed? 	
<p>I: Intention to Treat Analysis</p> <ul style="list-style-type: none"> • Were patients analyzed in the groups to which they were randomized? • Were all randomized patient data analyzed? If not, was a sensitivity or “worst case scenario” analysis done? 	
<p>S: Similar Baseline Characteristics of Patients</p> <ul style="list-style-type: none"> • Were groups similar at the start of the trial? 	
<p>B: Blinding</p> <ul style="list-style-type: none"> • Were patients, health workers, and study personnel “blind” to treatment? • If blinding was impossible, were blinded raters and/or objective outcome measures used? 	
<p>E: Equal Treatment</p> <ul style="list-style-type: none"> • Aside from the experimental intervention, were the groups treated equally? 	
<p>Conflict of Interest</p> <ul style="list-style-type: none"> • Are the sources of support and other potential conflicts of interest acknowledged and addressed? 	
<p>Summary of Article’s Validity</p> <ul style="list-style-type: none"> • Notable study strengths or weaknesses or concerns? • How serious are the threats to validity and in what direction could they bias the study outcomes? 	

CLINICAL IMPORTANCE	
How large was the treatment effect? (see below)	
How precise was the treatment effect? (confidence interval; in its absence p-value tells statistical significance)	

Effect size is a measure of the degree of overlap between experimental and control groups when there is a continuous outcome measure (e.g., body weight, rating scale scores) [from the Concise Guide to Evidence-Based Psychiatry by Gregory E. Gray, American Psychiatric Publishing Inc., 2004].

	n	Mean	SD	Mean diff	Pooled SD	Effect Size
Treated/exposed						
Control/not exposed						

Effect Size = Mean diff / Pooled SD

$$\text{Mean diff} = M_e - M_c$$

[Pooled SD Shortcut: If Ns are equivalent (or close to equivalent), take the average of the 2 SDs. If they're not equivalent, just use the the SD of the control group.]

Abbreviations: SD=standard deviation; M=mean; the subscript "e" refers to value for the exposed group and the subscript "c" refers to value for the control group.

Rule of thumb for effect size: Small 0.2 Medium 0.5 Large 0.8

Adapted from "Expanded Critical Appraisal Worksheet with Key Learning Points" Duke Program on Teaching Evidence Based Practice and Oxford Centre for Evidence-Based Medicine "Critical Appraisal Form for Single Therapy Studies". Rule of thumb for effect size from Cohen, J. (1969). Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ: Lawrence Erlbaum Associates.