

## Critical Appraisal Worksheet: Therapy Study with Continuous Outcome Calculations

<b>Citation:</b>	
<b>SCREENING</b>	
<ul style="list-style-type: none"> <li>Why was the study done (what was the research question)?</li> <li>Was the study design appropriate?</li> <li>Does the study PICO match your question PICO?</li> <li>Are there potential conflict of interest issues?</li> </ul>	
<b>VALIDITY</b>	
<b>F: Patient Follow-Up</b> <ul style="list-style-type: none"> <li>Were all patients who entered the trial properly accounted for and attributed at its conclusion (losses to follow-up should be less than 20%)?</li> <li>Was follow-up complete?</li> </ul>	
<b>R: Randomization</b> <ul style="list-style-type: none"> <li>Were the recruited patients representative of the target population?</li> <li>Was the allocation (assignment) of patients to treatment randomized?</li> <li>Was the allocation concealed?</li> </ul>	
<b>I: Intention to treat analysis</b> <ul style="list-style-type: none"> <li>Were patients analyzed in the groups to which they were randomized?</li> <li>Were all randomized patient data analyzed? If not, was a sensitivity or "worst case scenario" analysis done?</li> </ul>	
<b>S: Similar Baseline Characteristics of Patients</b> <ul style="list-style-type: none"> <li>Were groups similar at the start of the trial?</li> </ul>	
<b>B: Blinding</b> <ul style="list-style-type: none"> <li>Were patients, health workers, and study personnel "blind" to treatment?</li> <li>If blinding was impossible, were blinded raters and/or objective outcome measures used?</li> </ul>	
<b>E: Equal Treatment</b> <ul style="list-style-type: none"> <li>Aside from the experimental intervention, were the groups treated equally?</li> </ul>	
<b>Summary of article's validity</b> <ul style="list-style-type: none"> <li>Notable study strengths or weaknesses or concerns?</li> <li>How serious are the threats to validity and in what direction could they bias the study outcomes?</li> </ul>	

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)	

### A. Dichotomous Outcome (rates, proportions)

	Outcome Present	Outcome Absent	
Treated/exposed	a=	b=	EER (Experimental Event Rate) $\frac{a}{a+b}$
Control/not exposed	c=	d=	CER (Control Event Rate) $\frac{c}{c+d}$

		RRR [RRI] Relative Risk Reduction/Increase	ARR [ARI] Absolute Risk Reduction/Increase	NNT [NNH] Numbers Needed to Treat/Harm
CER	EER	$\frac{CER-EER}{CER}$	CER-EER	$\frac{1}{ARR}$

### B. Continuous Outcome (means)

**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 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.*