

## Critical Appraisal Worksheet: Therapy Study (Randomized Controlled Trial)

<b>SCREENING</b>	
<ul style="list-style-type: none"> <li>• Does the study question match your question?</li> <li>• Was the study design appropriate?</li> </ul>	
<b>VALIDITY</b>	
<p><b>F: Patient Follow-Up</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Was follow-up long enough?</li> </ul>	
<p><b>R: Randomization</b></p> <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 and concealed?</li> </ul>	
<p><b>I: Intention to Treat Analysis</b></p> <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>	
<p><b>S: Similar Baseline Characteristics of Patients</b></p> <ul style="list-style-type: none"> <li>• Were groups similar at the start of the trial?</li> </ul>	
<p><b>B: Blinding</b></p> <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>	
<p><b>E: Equal Treatment</b></p> <ul style="list-style-type: none"> <li>• Aside from the experimental intervention, were the groups treated equally?</li> </ul>	
<p><b>Conflict of Interest</b></p> <ul style="list-style-type: none"> <li>• Are the sources of support and other potential conflicts of interest acknowledged and addressed?</li> </ul>	
<p><b>Summary of Article's Validity</b></p> <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)	

	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	$\frac{1}{ARR}$

**EER** (experimental event rate). The proportion of patients in the experimental treatment group who are observed to experience the outcome of interest.

**CER** (control event rate). The proportion of patients in the control group who are observed to experience the outcome of interest.

**ARR** (absolute risk reduction). The absolute arithmetic difference in rates of bad outcomes between experimental and control participants in a trial. (This is sometimes called the risk difference.)

**RRR** (relative risk reduction). The proportional reduction in rates of bad outcomes between experimental and control participants in a trial.

**NNT** (number needed to treat). The number of patients who need to be treated with the specified intervention to prevent one bad outcome or produce one good outcome over the period of time specified in the study.

*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". Definitions adapted from <http://www.cebm.utoronto.ca/glossary/> (Centre for Evidence-based Medicine).*