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

## SCREENING

- Does the study question match your question?
- Was the study design appropriate?

## VALIDITY

### F: Patient Follow-Up
- 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?

### R: Randomization
- Were the recruited patients representative of the target population?
- Was the allocation (assignment) of patients to treatment randomized and concealed?

### I: Intention to Treat Analysis
- 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?

### S: Similar Baseline Characteristics of Patients
- Were groups similar at the start of the trial?

### B: Blinding
- Were patients, health workers, and study personnel “blind” to treatment?
- If blinding was impossible, were blinded raters and/or objective outcome measures used?

### E: Equal Treatment
- Aside from the experimental intervention, were the groups treated equally?

### Conflict of Interest
- Are the sources of support and other potential conflicts of interest acknowledged and addressed?

## Summary of Article's Validity

- 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**

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<thead>
<tr>
<th></th>
<th>Treated/exposed</th>
<th>Control/not exposed</th>
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<tbody>
<tr>
<td>How large was the treatment effect? (see below)</td>
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<tr>
<td>How precise was the treatment effect? (confidence interval; in its absence p-value tells statistical significance)</td>
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**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].

<table>
<thead>
<tr>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Mean diff</th>
<th>Pooled SD</th>
<th>Effect Size</th>
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Effect Size = Mean diff / Pooled SD

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