



**Short Critical Appraisal Checklist: Interventions for Prevention, Screening & Therapy**

**General:** Note sponsorship, funding and affiliations, recognizing that any entity or person involved in research may have a bias.

<b>Study Design Assessment</b>	<input type="checkbox"/> <b>Is the design appropriate to the research question? Is the research question useful?</b> <input type="checkbox"/> For <b>efficacy</b> , use of <b>experimental study design</b> (meaning there was no choice made to determine intervention) <input type="checkbox"/> <b>Clinically significant area</b> for study (morbidity, mortality, symptom relief, functioning and health-related quality of life) and reasonable <b>definitions for clinical outcome such as response, treatment success or failure</b> <input type="checkbox"/> If <b>composite endpoints</b> used, reasonable combination used — and used for safety if used for efficacy
<b>Internal Validity Assessment</b>	<input type="checkbox"/> <b>Can bias, confounding or chance explain the study results?</b> <input type="checkbox"/> Ensure <b>prespecified</b> and <b>appropriate</b> 1) research questions, 2) populations to analyze, and 3) outcomes
<b>Selection Bias</b>	<input type="checkbox"/> Groups are <b>appropriate</b> for study, of appropriate size, <b>concurrent</b> and <b>similar in prognostic variables</b> <input type="checkbox"/> Methods for generating the group assignment sequence are truly <b>random</b> , sequencing avoids potential for anyone <b>affecting assignment</b> to a study arm and <b>randomization remains intact</b> <input type="checkbox"/> <b>Concealment of allocation</b> strategies are employed to prevent anyone affecting assignment to a study arm
<b>Performance Bias</b>	<input type="checkbox"/> <b>Double-blinding</b> methods employed (i.e., subject and all working with the subject or subject’s data) and achieved <input type="checkbox"/> Reasonable <b>intervention</b> and reasonable <b>comparator</b> used (e.g., placebo) <input type="checkbox"/> <b>No bias or difference, except for what is under study, between groups during course of study</b> (e.g., intervention design and execution, care experiences, co-interventions, concomitant medication use, adherence, inappropriate exposure or migration, cross-over threats, protocol deviations, measurement methods, study duration, changes due to time etc.)
<b>Attrition Bias</b>	<input type="checkbox"/> Zero or minimal <b>missing data points</b> or loss from randomization (e.g., approximately 5% with differential loss, or approximately 10% without differential loss) unless good ITT analysis (see ITT below)
<b>Assessment Bias</b>	<input type="checkbox"/> Assessors are <b>blinded</b> <input type="checkbox"/> Low likelihood of findings due to <b>chance, false positive and false negative outcomes</b> <input type="checkbox"/> <b>Non-significant findings</b> are reported, but the <b>confidence intervals include clinically meaningful differences</b> <input type="checkbox"/> <b>Intention-to-Treat Analysis (ITT)</b> performed (all people are analyzed as randomized + reasonable method for imputing missing values which puts the intervention through a challenging trial or reasonable sensitivity analysis) <input type="checkbox"/> <b>Analysis methods</b> are appropriate and use of <b>modeling</b> only with use of reasonable assumptions <input type="checkbox"/> No problems of <b>selective reporting</b>
<b>Usefulness</b>	<input type="checkbox"/> <b>Clinically significant area + sufficient benefit size</b> = meaningful clinical benefit (consider efficacy vs effectiveness)
<b>External Validity</b>	<p><b>How likely are research results to be realized in the real world considering population and circumstances for care?</b></p> <input type="checkbox"/> Review n, inclusions, exclusions, baseline characteristics and intervention methods — this is a <b>judgment call</b> .
<b>Patient Perspective</b>	<input type="checkbox"/> Consider benefits, harms, risks, costs, uncertainties, alternatives and satisfaction
<b>Provider Perspective</b>	<input type="checkbox"/> Satisfaction, acceptability (includes adherence issues, potential for abuse, dependency issues), likely appropriate application and actionability (e.g., FDA approval, affordability, external relevance, circumstances of care, able to apply, tools available)

- Non-Inferiority & Equivalence Supplement:** Absence of the following problems: lack of sufficient evidence confirming efficacy of referent treatment; study not sufficiently similar to referent study; inappropriate Deltas; or significant biases or analysis methods which would tend to diminish an effect size (e.g., conservative application of ITT analysis, insufficient power, etc.)
- Diagnostic Test Supplement:** New test requires better outcomes or value. Test is compared to gold standard or reasonable comparator and finds same abnormality and within time period that does not result in a change in diagnosis. Test is applied to all or random sample of subjects with and without disease. Assessors are blinded. There is minimal bias from indeterminate results. Measures of test function are useful.
- Screening Supplement:** Early diagnosis and treatments determined to be effective will improve outcomes more than later diagnosis and treatment. Beneficial outcomes are not explained by bias (e.g., lead time, length, overdiagnosis or volunteer bias).