

Appendix 2.3 - NHLBI checklists in tabular form

Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Groups

Criteria	Yes	No	Notes
Was the study question or objective clearly stated?			
Were eligibility/selection criteria for the study population prespecified and clearly described?			
Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?			
Were all eligible participants that met the prespecified entry criteria enrolled?			
Was the sample size sufficiently large to provide confidence in the findings?			
Was the test/service/intervention clearly described and delivered consistently across the study population?			
Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?			
Were the people assessing the outcomes blinded to the participants' exposures/interventions?			
Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?			
Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?			
Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?			
If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?			

Quality Assessment Tool for Controlled Intervention Studies

Criteria	Yes	No	Notes
Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?			

Was the method of randomization adequate (i.e., use of randomly generated assignment)?

Was the treatment allocation concealed (so that assignments could not be predicted)?

~~Were study participants and providers blinded to treatment group assignment?~~

Were the people assessing the outcomes blinded to the participants' group assignments?

Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?

Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?

Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?

Was there high adherence to the intervention protocols for each treatment group?

Were other interventions avoided or similar in the groups (e.g., similar background treatments)?

Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?

Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?

Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?

Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?

Note: details of each question, as well as guidelines for determining overall study quality, can be found at <https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools>

