

APPENDIX 3: DOWNS AND BLACK CHECKLIST FOR CLINICAL TRIAL QUALITY ASSESSMENT

REPORTING	Yes/No/Partially	Score
1. Is the objective of the study clear?	Yes = 1, No = 0	
2. Are the main outcomes clearly described in the Introduction or Methods?	Yes = 1, No = 0	
3. Are characteristics of the patients included in the study clearly described?	Yes = 1, No = 0	
4. Are the interventions clearly described?	Yes = 1, No = 0	
5. Are the distributions of principal confounders in each group of subjects clearly described?	Yes = 2, Partially = 1, No = 0	
6. Are the main findings of the study clearly described?	Yes = 1, No = 0	
7. Does the study estimate random variability in data for main outcomes?	Yes = 1, No = 0	
8. Have all the important adverse events consequential to the intervention been reported?	Yes = 1, No = 0	
9. Have characteristics of patients lost to follow-up been described?	Yes = 1, No = 0	
10. Have actual probability values been reported for the main outcomes except probability < 0.001?	Yes = 1, No = 0	
11. Is the source of funding clearly stated? ^a	Yes = 1, No = 0	
EXTERNAL VALIDITY	Yes/No/Unclear	Score
12. Were subjects who were asked to participate in the study representative of the entire population recruited?	Yes = 1, No = 0, Unclear = 0	
13. Were those subjects who were prepared to participate representative of the recruited population?	Yes = 1, No = 0, Unclear = 0	
14. Were staff, places, and facilities where patients were treated representative of treatment most received?	Yes = 1, No = 0, Unclear = 0	
INTERNAL VALIDITY	Yes/No/Unclear	Score
15. Was an attempt made to blind study subjects to the intervention?	Yes = 1, No = 0, Unclear = 0	
16. Was an attempt made to blind those measuring the main outcomes?	Yes = 1, No = 0, Unclear = 0	
17. If any of the results of the study were based on data dredging was this made clear?	Yes = 1, No = 0, Unclear = 0	
18. Was the time period between intervention and outcome the same for intervention and control groups or adjusted for?	Yes = 1, No = 0, Unclear = 0	
19. Were the statistical tests used to assess main outcomes appropriate?	Yes = 1, No = 0, Unclear = 0	
20. Was compliance with the interventions reliable?	Yes = 1, No = 0, Unclear = 0	
INTERNAL VALIDITY (continued)	Yes/No/Unclear	Score

21. Were main outcome measures used accurate? (valid and reliable)	Yes = 1, No = 0, Unclear = 0	
INTERNAL VALIDITY-CONFOUNDING (SELECTION BIAS)	Yes/No/Unclear	Score
22. Were patients in different intervention groups recruited from the same population?	Yes = 1, No = 0, Unclear = 0	
23. Were study subjects in different intervention groups recruited over the same period of time?	Yes = 1, No = 0, Unclear = 0	
24. Were study subjects randomized to intervention groups?	Yes = 1, No = 0, Unclear = 0	
25. Was the randomized intervention assignment concealed from patients and staff until recruitment was complete?	Yes = 1, No = 0, Unclear = 0	
26. Was there adequate adjustment for confounding in the analyses from which main findings were drawn?	Yes = 1, No = 0, Unclear = 0	
27. Were losses of patients to follow-up taken into account?	Yes = 1, No = 0, Unclear = 0	
POWER	Size of Smallest Intervention Group Score of 0 to 5	Score
28. Was the study sufficiently powered to detect clinically important effects where probability value for a difference due to chance is < 5%?		

^aCriteria was added for the current systematic review.