

A CHECKLIST FOR APPRAISING RANDOMIZED CONTROLLED TRIALS

1. Was the objective of the trial sufficiently described?
2. Was a satisfactory statement given of the diagnostic criteria for entry to the trial?
3. Were concurrent controls used (as opposed to historical controls)?
4. Were the treatments well defined?
5. Was random allocation to treatments used?
6. Was the potential degree of blindness used?
7. Was there a satisfactory statement of criteria for outcome measures? Was a primary outcome measure identified?
8. Were the outcome measures appropriate?
9. Was a pre-study calculation of required sample size reported?
10. Was the duration of post-treatment follow-up stated?
11. Were the treatment and control groups comparable in relevant measures?
12. Were a high proportion of the subjects followed up?
13. Were the drop-outs described by treatment and control groups?
14. Were the side-effects of treatment reported?
15. How were the ethical issues dealt with?
16. Was there a statement adequately describing or referencing all statistical procedures used?
17. What tests were used to compare the outcome in test and control patients?
18. Were 95% confidence intervals given for the main results?
19. Were any additional analyses done to see whether baseline characteristics (prognostic factors) influenced the outcomes observed?
20. Were the conclusions drawn from the statistical analyses justified?