

Criteria/ Study	Albini et al [41]
1- Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?	x ^b
2. Was the method of randomization adequate (i.e., use of randomly generated assignment)?	x
3. Was the treatment allocation concealed (so that assignments could not be predicted)?	x
4. Were study participants and providers blinded to treatment group assignment?	x
5. Were the people assessing the outcomes blinded to the participants' group assignments?	x
6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?	CD ^e
7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?	√ ^a
8. Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?	NR
9. Was there high adherence to the intervention protocols for each treatment group?	NA ^d
10. Were other interventions avoided or similar in the groups (e.g., similar background treatments)?	NA
11. Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?	√
12. 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?	NR ^c
13. Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?	√

14. Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?	x
Quality rating & additional comment	Poor quality due to lack of randomization and blinding procedures (selection bias) that affect validity

^a√: Yes; ^bx: No; ^cNR, not reported; ^dNA, not applicable; ^eCD, cannot determine