

Checklist of Items to Include When Submitting Reports of Randomized Controlled Trials to the *Archives of Internal Medicine*^a

Section and Topic	Item	Descriptor	Was It Reported? Yes or No?	If Yes, What Page No.?
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned").	___	___
Introduction				
Background	2	Scientific background and explanation of rationale.	___	___
Methods				
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	___	___
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	___	___
Objectives	5	Specific objectives and hypotheses.	___	___
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	___	___
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	___	___
Randomization				
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	___	___
Allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	___	___
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	___	___
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	___	___
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	___	___
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	___	___
Recruitment	14	Dates defining the periods of recruitment and follow-up.	___	___
Baseline data	15	Baseline demographic and clinical characteristics of each group.	___	___
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).	___	___
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% confidence interval).	___	___
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	___	___
Adverse events	19	All important adverse events or side effects in each intervention group.	___	___
Comment				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.	___	___
Generalizability	21	Generalizability (external validity) of the trial findings.	___	___
Overall evidence	22	General interpretation of the results in the context of current evidence.	___	___

^aThis checklist of 22 items is intended to assist authors, editors, and reviewers by ensuring that information pertinent to the trial is included in the study report. Adapted from Moher D, Schulz KF, Altman D, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*. 2001;285(15):1987-1991.