



CONSORT Statement 2001 Checklist

Items to include when reporting a randomized trial

PAPER SECTION And topic	Item	Descriptor	Reported on Page #
TITLE & ABSTRACT	1	<u>How participants were allocated to interventions</u> : "randomized", or "randomly assigned").	1 – 2
INTRODUCTION Background	2	<u>Scientific background and explanation of rationale.</u>	4 – 5
METHODS Participants	3	<u>Eligibility criteria for participants</u> and the <u>settings and locations where the data were collected.</u>	6
Interventions	4	<u>Precise details of the interventions intended for each group and how and when they were actually administered.</u> <ul style="list-style-type: none"> - Precise details of both the experimental treatment and comparator - Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants - Details of how the interventions were standardized - Details of how adherence of care providers with the protocol was assessed or enhanced 	7 – 9
Objectives	5	<u>Specific objectives and hypotheses.</u>	5
Outcomes	6	<u>Clearly defined primary and secondary outcome measures</u> and, when applicable, any <u>methods used to enhance the quality of measurements</u> (e.g., multiple observations, training of assessors).	10
Sample size	7	<u>How sample size was determined</u> and, when applicable, <u>explanation of any interim analyses and stopping rules.</u>	10 – 11
Randomization -- Sequence generation	8	<u>Method used to generate the random allocation sequence, including details of any restrictions</u> (e.g., blocking, stratification)	7
Randomization -- Allocation concealment	9	<u>Method used to implement the random allocation sequence</u> (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	7
Randomization -- Implementation	10	<u>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</u>	7
Blinding (masking)	11	<u>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.</u> If done, <u>how the success of blinding was evaluated.</u> If blinded, method of blinding and description of the similarity of interventions	7
Statistical methods	12	<u>Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses</u> , such as subgroup analyses and adjusted analyses.	11 – 12
RESULTS Participant flow	13	<u>Flow of participants through each stage</u> (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. <u>Describe protocol deviations from study as planned, together with reasons.</u>	Figure 1
Recruitment	14	<u>Dates defining the periods of recruitment and follow-up.</u>	13
Baseline data	15	<u>Baseline demographic and clinical characteristics of each group.</u>	13
Numbers analyzed	16	<u>Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat".</u> State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	13
Outcomes and estimation	17	<u>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision</u> (e.g., 95% confidence interval).	13 – 14
Ancillary analyses	18	<u>Address multiplicity by reporting any other analyses performed</u> , including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	13 – 14
Adverse events	19	<u>All important adverse events or side effects in each intervention group.</u>	–
DISCUSSION Interpretation	20	<u>Interpretation of the results</u> , taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	15 – 18
Generalizability	21	<u>Generalizability (external validity) of the trial findings.</u>	18
Overall evidence	22	<u>General interpretation of the results in the context of current evidence.</u>	18