



## CONSORT Statement 2001 Checklist

### Items to include when reporting a randomized trial

<i>PAPER SECTION And topic</i>	<b>Item</b>	<b>Descriptor</b>	<b>Reported on Page #</b>
<i>TITLE &amp; ABSTRACT</i>	1	<u>How participants were allocated to interventions</u> (e.g., "random allocation", "randomized", or "randomly assigned").	4
<i>INTRODUCTION</i> Background	2	<u>Scientific background and explanation of rationale.</u>	2,3
<i>METHODS</i> Participants	3	<u>Eligibility criteria for participants</u> and the <u>settings and locations where the data were collected.</u>	3,4,5,6,7
Interventions	4	<u>Precise details of the interventions intended for each group and how and when they were actually administered.</u>	4,5
Objectives	5	<u>Specific objectives and hypotheses.</u>	3
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).	3,6,7
Sample size	7	<u>How sample size was determined</u> and, when applicable, <u>explanation of any interim analyses and stopping rules.</u>	6
Randomization -- Sequence generation	8	<u>Method used to generate the random allocation sequence, including details of any restrictions</u> (e.g., blocking, stratification)	4, Table 1
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.	4
Randomization -- Implementation	10	<u>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</u>	4
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>	No blinding
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.	5,6,7
<i>RESULTS</i> 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>	8,9,10
Recruitment	14	<u>Dates defining the periods of recruitment and follow-up.</u>	4,8(Fig 1)
Baseline data	15	<u>Baseline demographic and clinical characteristics of each group.</u>	5 (Table 2)
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%).	8 (Table 5)
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).	8,9,10
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.	8,9,10
Adverse events	19	<u>All important adverse events or side effects in each intervention group.</u>	4, Flow chart
<i>DISCUSSION</i> 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.	10,11,12,13
Generalizability	21	<u>Generalizability (external validity) of the trial findings.</u>	13,14
Overall evidence	22	<u>General interpretation of the results in the context of current evidence.</u>	10,13,14

From Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001; 357(9263):1191-1194.

**The CONSORT Statement 2001 checklist is intended to be accompanied with the explanatory document that facilitates its use. For more information, visit [www.consort-statement.org](http://www.consort-statement.org).**