CONSORT (CONSOLIDATED STANDARDS OF REPORTING TRIALS) CHECKLIST

Questions	Yes	No
1. Title and Abstract • Identification as a randomized trial in the title. • Structured summary of trial design, methods, results, and conclusions.	☐	☐
2. Introduction • Scientific background and explanation of rationale. • Specific objectives or hypotheses.	☐	☐
3. Methods • Description of trial design including allocation ratio. • Eligibility criteria for participants. • Settings and locations where the data were collected. • Interventions for each group with sufficient details. • Completely defined prespecified primary and secondary outcome measures. • Sample size determination. • Method used to generate the random allocation sequence. • Statistical methods used for primary and secondary outcomes.	☐	☐
4. Results • Participant flow (a diagram is recommended). • Recruitment dates and follow-up periods. • Baseline demographic and clinical characteristics for each group. • Number of participants included in each analysis. • For each primary and secondary outcome, results for each group, and the estimated effect size.	☐	☐
5. Discussion • Trial limitations and potential bias. • Generalizability of the trial findings. • Interpretation consistent with results, balancing benefits, and harms.	☐	☐

Questions	Yes	No
6. Other Information • Trial registration number and name of registry. • Where the full trial protocol can be accessed. • Sources of funding and other support.	☐	☐