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Adapted* CONSORT Checklist for Clinical Trials

Section/Topic	Checklist Item	Response
Title	Identified as a randomized trial in the title.	Yes
Background	Specific objectives or hypotheses clearly stated.	Yes
Trial Design	Trial design *(such as parallel, factorial)* including allocation ratio.	Yes
	Important changes to methods after trial commencement *(such as eligibility criteria)*, with reasons.	Yes
Participants	Eligibility criteria for participants.	Yes
	Settings and locations where the data were collected.	Yes
Interventions	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.	Yes
Outcomes	Completely defined per-specified primary and secondary outcome measures, including how and when they were assessed.	Yes
	Any changes to trial outcomes after the trial commenced, with reasons.	Yes
Sample Size	How sample size was determined.	Yes
	Explanation of any interim analyses and stopping guidelines.	NA
Randomization		
• ***Sequence generation***	Method used to generate the random allocation sequence.	Yes
	Type of randomization; details of any restriction *(such as blocking and block size)*.	Yes
• ***Allocation concealment mechanism***	Mechanism used to implement the random allocation sequence *(such as sequentially numbered containers)*, describing any steps taken to conceal the sequence until interventions were assigned.	Yes
• ***Implementation***	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions.	Yes
Blinding	If done, who was blinded after assignment to interventions *(for example, participants, care providers, those assessing outcomes)*.	NA
	If relevant, description of the similarity of interventions.	Yes
Statistical Methods	Statistical methods used to compare groups for primary and secondary outcomes.	Yes
	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	Yes
Participant Flow *(a diagram is strongly recommended)*	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome .	Yes
	For each group, losses and exclusions after randomization, together with reasons.	Yes
Recruitment	Dates defining the periods of recruitment and follow-up.	Yes
	Why the trial ended or was stopped.	Yes
Baseline Data	A table showing baseline demographic and clinical characteristics for each group.	Yes
Numbers Analyzed	For each group, number of participants *(denominator)* included in each analysis and whether the analysis was by original assigned groups.	Yes
Outcomes and Estimation	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision *(such as 95% confidence interval)*.	Yes
	For binary outcomes, presentation of both absolute and relative effect sizes.	Yes
Ancillary Analyses	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory.	Yes
Harms	All important harms or unintended effects in each group.	Yes
Data Sharing	A data sharing statement is included.	Yes

Additional Details:

*This checklist has been adapted by the ASN journals for author and editor use.