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Adapted* CONSORT Checklist for Clinical Trials

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

Additional Details:

*This checklist has been adapted by CJASN and JASN for author and editor usage.