Supplementary Table 3. CONSORT-Outcomes checklist (combined CONSORT 2010 and CONSORT-Outcomes 2022 items)

Section	Item no.	CONSORT 2010 item	CONSORT-Outcomes 2022 item	Location reported[a]
Title and abstract				
	1a	Identification as a randomized trial in the title		1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		3
Introduction				
Background and objectives	2a	Scientific background and explanation of the rationale		5–6
	2b	Specific objectives or hypothesis		6
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio		6–7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		NA
Participants	4a	Eligibility criteria for participants		8
	4b	Settings and locations where the data were collected		8–9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered (for specific guidance see TIDieR checklist and guide)		8–9
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed		9–10, Supplementary Table 2
	6a.1		Provide a rationale for the selection of the domain for the trial's primary outcome	Supplementary Table 2
	6a.2		Describe the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), methods of aggregation (e.g., mean proportion), and the time point for each outcome	9–10, Supplementary Table 2
	6a.3		If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	NA
	6a.4		If the outcome data were continuous but were analyzed as categorical (method of aggregation), specify the cutoff values used	NA
	6a.5		If outcome assessments were performed at several time points after randomization, state the time points used for the analysis	9

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Supplementary Table 3. Continued

Section	Item no.	CONSORT 2010 item	CONSORT-Outcomes 2022 item	Location reported[a]
	6a.6		If a composite outcome was used, define all individual components of the composite outcome	NA
	6a.7		Identify any outcomes that were not prespecified in a trial registry of trial protocol	NA
	6a.8		Provide a description of the study instruments used to access the outcome (e.g., questionnaires, laboratory tests) along with reliability, validity, and responsiveness in a population similar to the study sample	Supplementary Table 2
	6a.9		Describe who assessed the outcome (e.g., nurse, patient) and any qualifications of trial-specific training necessary to administer the study instruments to access the outcome	8–9
	6a.10		Describe any processes used to promote outcome data quality during data collection (e.g., duplicate measurements) and after data collection (e.g., range checks of outcome data values), or state where these details can be found	8–9
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined		10
	7a.1		Define and justify the target difference between treatment groups (e.g., the minimal important difference)	NA
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomization				
Sequence generation	8a	The method used to generate the random allocation sequence		Not reported
	8b	Type of randomization; details of any restriction (such as blocking and block size)		Not reported
Allocation concealment mechanism	9	The 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		Not reported
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions?		8–9

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Supplementary Table 3. Continued

Section	Item no.	CONSORT 2010 item	CONSORT-Outcomes 2022 item	Location reported[a]
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		NA
	11b	If relevant, a description of the similarity of interventions		NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes		10–11
	12a.1		Describe any methods used to account for multiplicity in the analysis of interpretation of the primary and secondary outcomes (e.g., coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	10–11
	12a.2		State and justify any criteria for excluding any outcome data from the analysis and reporting, or report that no outcome data were excluded	Fig. 1
	12a.3		Describe the methods used to assess patterns of missingness (e.g., missing not at random), and describe the methods used to handle missing outcome items or entire assessments	NA
	12a.4		Provide a definition of the outcome analysis population relating to nonadherence to the trial protocol (e.g., as a randomized analysis)	Fig. 1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		10–11
Results				
Participants flow (a diagram is strongly recommended)	13a	For each group, the number of participants who were randomly assigned received the intended treatment and were analyzed for the primary outcome		11–12, Fig. 1
	13b	For each group, losses and exclusions after randomization, together with reasons		11–12, Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		NA
	14b	Why the trial ended or was stopped		11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group		11–12, Table 1
Number analyzed	16	For each group, the number of participants (denominator) included in each analysis and whether the analysis was by the originally assigned group		11

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Supplementary Table 3. Continued

Section	Item no.	CONSORT 2010 item	CONSORT-Outcomes 2022 item	Location reported[a]
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)		12–14, Table 2, Figs. 2, 3, Supplementary Tables 5, 6, Supplementary Fig. 2
	17a.1		Include the results for all prespecified outcome analyses or state where the results can be found if not in this report	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory		Table 2, Figs. 2, 3, Supplementary Tables 5, 6, Supplementary Fig. 2
	18.1		If there were any analyses that were not prespecified, explain why they were performed	NA
	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		14
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		17
Generalizability	21	Generalizability (external validity, applicability) of the trial findings		14–18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		14–18
Other information				
Registration	23	Registration number and name of trial registry		11
Protocol	24	Where the full trial protocol can be accessed, if available		11
Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders		18

CONSORT, Consolidated Standards of Reporting Trials; NA, not applicable.
[a]Indicates page numbers.