Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	Page 1
	1b	Structured summary of the trial design, methods, results, and conclusions	Lines 1 to 23 on Page 2
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Line 108 on Page 5
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed9/23/2025	Lines 7 to 68 on Pages 2 to 4
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Lines 268 to 297 on Pages 9 to 10
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Lines 647 to 649 on Page 21
	5b	Financial and other conflicts of interest of the manuscript authors	Lines 644 to 645 on Page 21
Introduction			
Background and rationale	6	Scientific background and rationale	Lines 29 to 68 on Pages 2 to 4
Objectives	7	Specific objectives related to benefits and harms	Lines 70 to 77 on Page 4
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Lines 90 to 126 on Pages 4 to 5
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	Lines 111 to 166 on Pages 5 to 6
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	None
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	Lines 102 to 106 on Page 5
Eligibility criteria	12a	Eligibility criteria for participants	Lines 90 to 98 on Page 4
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	Line 170 on Page 6

Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	Lines 168 to 214 on Pages 6 to 8
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	Lines 216 to 279 on Pages 8 to 10
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	Lines 207 to 208 on Page 8
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Lines 80 to 88 on Page 4
	16b	Explanation of any interim analyses and stopping guidelines	Lines 123 to 125 on Page 5
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Lines 113 to 114 on Page 5
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	Lines 111 to 126 on Pages 5 to 6
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Lines 112 to 114 on Page 5
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	NO
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	Lines 112 to 114 on Page 5
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Lines 168 to 273 on Pages 6 to 8
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Lines 280 to 296 on Page 10
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Lines 111 to 126 on Page 5
	21c	How missing data were handled in the analysis	Lines 266 to 278 on Page 9 to 10
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	Lines 280 to 296 on Page 10
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Lines 168 to 185 on Pages 5 to 6

	22b	For each group, losses and exclusions after randomisation, together with reasons	Lines 123 to 125 on Pages 5 to 6
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Lines 118 to 121 on Page 5
	23b	If relevant, why the trial ended or was stopped	Lines 123 to 125 on Page 5
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	Lines 168 to 185 on Pages 6 to 8
	24b	Concomitant care received during the trial for each group	Lines 168 to 185 on Pages 6 to 8
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Lines 299 to 307 on Page 11
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	None
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Lines 308 to 382 on Pages 11 to 14
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Lines 384 to 437 on Pages 15 to 16
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Lines 439 to 448 on Page 16

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.