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, Line 1-3
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 1-2, Line 18-48
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Page 2, Line 52 Line 79-80
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Page 2, Line 52 Line 79-80
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Page 2, Line 52 Line 79-80
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	Page 7, Line 302-305
	5b	Financial and other conflicts of interest of the manuscript authors	Page 7, Line 306-307
Introduction			
Background and rationale	6	Scientific background and rationale	Page 2, Line 52 Line 54-73
Objectives	7	Specific objectives related to benefits and harms	Page 2, Line 76-78
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Page 2-3, Line 85-92
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)	Page 2-3, Line 85-92
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	Page 2-3, Line 85-92
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	Page 2-3, Line 85-92
Eligibility criteria	12a	Eligibility criteria for participants	
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	Page 3, Line 93-103
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	Page 3, Line 110-129
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	Page 3-4, Line129-144
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	Page 4, Line137-144
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Page 4, Line145-152
	16b	Explanation of any interim analyses and stopping guidelines	None
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Page 2-3, Line 85-92
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	Page 2-3, Line 85-92

			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	Page 2-3, Line 85-92
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Page 2-3, Line 85-92
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	Page 2-3, Line 85-92
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Page 2-3, Line 85-92
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Page 4, Line 153-171
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Page 4, Line 153-171
	21c	How missing data were handled in the analysis	none
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	Page 4, Line 153-171
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	Page 3, Line 93-128
	22b	For each group, losses and exclusions after randomisation, together with reasons	Page 3, Line 93-128
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 4-5, Line 172-208
	23b	If relevant, why the trial ended or was stopped	none
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))	Page 3, Line 93-128
	24b	Concomitant care received during the trial for each group	Page 4-5, Line 172-177
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Page 5, Line 172-208
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	Page 5, Line 199-208
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Page 5, Line 199-208
Discussion			Page 5-7, Line 209-275
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 7, Line 276-284
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	

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.