

CONSORT 2025 checklist

Section/topic	No	Item description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
Title and structured abstract	1a	Identification as a randomised trial	Page 2/Line 22-27	Abstract
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 2/Line16-46	Abstract
Open science				
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Page2/Line22-23	Abstract
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Page 6/Line 158-170	Methods/Statistical analysis
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 15/Line 393-395	Data availability
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 15/Line 390-392	Funding
	5b	Financial and other conflicts of interest of the manuscript authors	Page 15/Line 407-408	Competing Interest
Introduction				
Background and rationale	6	Scientific background and rationale	Page 3/Line 49-82	Background
Objectives	7	Specific objectives related to benefits and harms	Page 4/Line 83-87	Background
Methods				
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Page 4/Line 90-107	Methods/Study design and participants
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 4-5/Line 108-123	Methods/Randomization and interventions
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	N/A	N/A
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	Page 4/Line 90-92	Methods/Study design and participants
Eligibility criteria	12a	Eligibility criteria for participants	Page 4/Line 96-102	Methods/Study design and participants

	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	Page 4/Line 90-94	Methods/Study design and participants
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 4-5/Line 108-123	Methods/Randomization and interventions
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 5-6/ Line 134-157	Methods/ Study endpoints
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	N/A	N/A
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Page 6/ Line 159-161	Methods/Statistical analysis
	16b	Explanation of any interim analyses and stopping guidelines	N/A	N/A
Randomisation:				
Sequence generation	17a	Who generated the random allocation sequence and the method used	Page 4/Line 109-111	Methods/Randomization and interventions
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	Page 4/Line 109-111	Methods/Randomization and interventions
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 4/Line 109-110	Methods/Randomization and interventions
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Page 4/Line 110-111	Methods/Randomization and interventions
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	N/A	N/A
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	N/A	N/A
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Page 6/Line 159-169	Methods/Statistical analysis
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Page 6/Line 161-166	Methods/Statistical analysis
	21c	How missing data were handled in the analysis	N/A	N/A
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	Page 5/Line 138-140 Page 6/Line 147-149	Methods/ Study endpoints
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 6/Line 173-176 Page 7-8/Line 196-198	Results/Patient characteristics
	22b	For each group, losses and exclusions after randomisation, together with reasons	Page 7-8/Line 196-198	Results/Primary endpoint
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 11/Line 269-277	Results/Follow-up: additional cycles

	23b	If relevant, why the trial ended or was stopped	N/A	N/A
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 4-5/Line 112-123	Methods/Randomization and interventions
	24b	Concomitant care received during the trial for each group	N/A	N/A
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Page 7/Line 192-194	Results/Patient characteristics Table 1
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	Page 7-9/Line 195-236	Results/Primary outcome, Secondary outcome
Harms	27	All harms or unintended events in each group	Page 10/Line 241-259	Results/Safety
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Page 11/Line 269-277	Results/Follow-up: additional cycles
Discussion				
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 11-14/Line 279-362	Discussion
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Page 14/Line 363-372	Discussion

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*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.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.