CONSORT 2025 Checklist Checklist

Section / Topic	Item No	Checklist item	Reported on page No
TITLE AND ABSTRACT			
Title	**1a**	Identification as a randomised trial	标题页 / Title Page
Abstract	**1b**	Structured summary of trial design, methods, results, and conclusions	摘要 / Abstract
OPEN SCIENCE			
Trial registration	**2**	Name of trial registry, identifying number (with URL), and date of registration	方法部分 / Methods (注册信息)
Protocol and statistical analysis plan	**3**	Where the trial protocol and statistical analysis plan can be accessed	方法部分 / Methods (通讯作者提供)
Data sharing	**4**	Where and how the individual de-identified participant data (including data dictionary), statistical code, and any other materials can be accessed	方法部分 / Methods (数据声明)
Funding and conflicts of interest	**5a**	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis, and reporting of the trial	致谢 / Acknowledgements
—	**5b**	Financial and other conflicts of interest of the manuscript authors	利益冲突声明 / COI Statement
INTRODUCTION			
Background and rationale	**6**	Scientific background and rationale	引言 / Introduction (第1-4段)
Objectives	**7**	Specific objectives related to benefits and harms	引言末尾 / Introduction (末段)
METHODS			
Patient and public involvement	**8**	Details of patient or public involvement in the design, conduct, and reporting of the trial	不适用 / Not applicable
Trial design	**9**	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	方法 2.1 / Methods 2.1
Changes to trial protocol	**10**	Important changes to the trial after it commenced, including any outcomes or analyses that were not prespecified, with reason	无变更 / No changes
Trial setting	**11**	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	方法 2.2 / Methods 2.2

Eligibility criteria	**12a**	Eligibility criteria for participants	方法 2.2 / Methods 2.2
—	**12b**	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	方法 2.6 / Methods 2.6
Intervention and comparator	**13**	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	方法 2.7 / Methods 2.7
Outcomes	**14**	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	方法 2.8 / Methods 2.8
Harms	**15**	How harms were defined and assessed (e.g., systematically, non-systematically)	不适用 / Not applicable (无创研究)
Sample size	**16a**	How sample size was determined, including all assumptions supporting the sample size calculation	方法 2.3 / Methods 2.3
—	**16b**	Explanation of any interim analyses and stopping guidelines	不适用 / Not applicable
RANDOMISATION			
Sequence generation	**17a**	Who generated the random allocation sequence and the method used	方法 2.5 / Methods 2.5
—	**17b**	Type of randomisation and details of any restriction (e.g., stratification, blocking, and block size)	方法 2.5 / Methods 2.5
Allocation concealment mechanism	**18**	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	方法 2.5 / Methods 2.5
Implementation	**19**	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	方法 2.5 / Methods 2.5
Blinding	**20a**	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	方法 2.6 / Methods 2.6
—	**20b**	If blinded, how blinding was achieved and description of the similarity of interventions	方法 2.6 / Methods 2.6

STATISTICAL METHODS			
Statistical	**21a**	Statistical methods used to compare groups for primary	方法 2.10 / Methods

methods		and secondary outcomes, including harms	2.10
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	方法 2.10 / Methods 2.10
	21c	How missing data were handled in the analysis	方法 2.10 / Methods 2.10
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	方法 2.10 / Methods 2.10
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	结果 3.1 / Results 3.1
—	**22b**	For each group, losses and exclusions after randomisation, together with reasons	结果 3.1 / Results 3.1
Recruitment	**23a**	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	结果部分 / Results (招募时间)
—	**23b**	If relevant, why the trial ended or was stopped	不适用 / Not applicable
Intervention and comparator delivery	**24a**	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	结果部分 / Results
—	**24b**	Concomitant care received during the trial for each group	不适用 / Not applicable
Baseline data	**25**	A table showing baseline demographic and clinical characteristics for each group	结果 3.1 / 表1 / 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	结果 3.2-3.4 / 表2-3 / Tables 2-3
Harms	**27**	All harms or unintended events in each group	不适用 / Not applicable (无不良事件)
Ancillary analyses	**28**	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	结果部分 / Results
DISCUSSION			
Interpretation	**29**	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	讨论 / Discussion (全文)
Limitations	**30**	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	讨论 / Discussion (局限性部分)