CONSORT 2025 checklist of information to include when reporting a randomised trial*

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	Not reported; the article only presents online baseline trial data. A more detailed trial description is cited on p. 10 (ref. 58).
	1b	Structured summary of the trial design, methods, results, and conclusions	Summary of microbiome data methods, results and conclusions reported on p. 2
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	10
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	10
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	15
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	15 and 20 (competing interests)
	5b	Financial and other conflicts of interest of the manuscript authors	20 (competing interests)
Introduction			
Background and rationale	6	Scientific background and rationale	2-4
Objectives	7	Specific objectives related to benefits and harms	4
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	10
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)	10 (trial design + reference to article with details),

Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	No changes
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	10 and 11
Eligibility criteria	12a	Eligibility criteria for participants	11
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	NA
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	10 (reference to article with details)
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	10 (+ on page 10 reference to article with details of secondary outcomes)
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	10 (reference to article with details)
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	10 (reference to article with details)
	16b	Explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	10 (reference to article with details)
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	10 (reference to article with details)
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	10 (reference to article with details)
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	10 (reference to article with details)
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	10 (reference to article with details)
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	10 (reference to article with details)

Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	13-15 (Bioinformatics and statistics)
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	4 + Table 1 (p. 25 and 26) and Supplementary Fig S1
	21c	How missing data were handled in the analysis	15
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	15
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	Supplementary Fig S1 + p. 10 with reference to article with details
	22b	For each group, losses and exclusions after randomisation, together with reasons	Supplementary Fig S1 + p. 10 with reference to article with details
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	11
	23b	If relevant, why the trial ended or was stopped	NA
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])	10 (reference to article with details)
	24b	Concomitant care received during the trial for each group	NA
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	26 (Table 1) + for the entire trial population (reference stated on page 10)
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	4-7 and 26 (Table 1, description in table note) + figures on p. 21-24
Harms	27	All harms or unintended events in each group	10 (reference to article with details)

Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	7 (clinical variables influences on microbiota) + figure on page 25
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8 and 9
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	9 and 10

*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.

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.