

CONSORT CHECKLIST

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

The paragraph number indicates the paragraph number in each section (bold) or subsection (standard type) where the relevant checklist item can be found.

	Reporting Item	Section of manuscript	Paragraph Number or Table/Figure
#1a	Identification as a randomized trial in the title.	Title	
#1b	Structured summary of trial design, methods, results, and conclusions	Abstract	
#2a	Scientific background and explanation of rationale	Introduction	1, 2, 3.
#2b	Specific objectives or hypothesis	Aims and objectives	1.
		Methods	
#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	Study design	1.
#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Mitigations for COVID-19 pandemic disruptions	1.
#4a	Eligibility criteria for participants	Study population	1, table 1.
#4b	Settings and locations where the data were collected	Study population	1.
#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Study procedures	1.

#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Outcomes	Para 1 and bullet list
#6b	Any changes to trial outcomes after the trial commenced, with reasons	Study progress	5
#7a	How sample size was determined.	Statistical analysis	1.
#7b	When applicable, explanation of any interim analyses and stopping guidelines	No planned interim analyses or stopping guidelines	n/a
#8a	Method used to generate the random allocation sequence.	Study procedures	1.
#8b	Type of randomization; details of any restriction (such as blocking and block size) 7	Study procedures	1.
#9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Study procedures	1.
#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	Study procedures	1.
#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	Study procedures	1.
#11b	If relevant, description of the similarity of interventions	Study procedures	1.
#12a	Statistical methods used to compare groups for primary and secondary outcomes	Statistical analysis	2, 3.
#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Statistical analysis	3.

Results

#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Study progress	1, figure 4.
#13b	For each group, losses and exclusions after randomization, together with reason	Study progress	1, figure 4.
#14a	Dates defining the periods of recruitment and follow-up	Study progress	1.
#14b	Why the trial ended or was stopped	Study progress	1.
#15	A table showing baseline demographic and clinical characteristics for each group	Study progress	Table 2.
#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Study progress	5, table 3.
#17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Primary outcome Secondary outcomes <ul style="list-style-type: none"> • Corrected SBWC and delta SBW • Corrected colonic volumes • Gastric half-emptying times • GI symptoms Exploratory outcomes <ul style="list-style-type: none"> • MRI analysis • Stool markers 	1, table 3. 1, table 3. 1, table 3. 1, table 3. 1, table 3, figure 9. 1, table 3. 1, table 3.

#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	No binary outcomes	n/a
#18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Corrected SBWC and delta SBW	2, table 3.
#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	Study progress	5.
Discussion			
#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Strengths and weaknesses	1, 2, 3, 4.
#21	Generalisability (external validity, applicability) of the trial findings	Discussion	1.
#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion	1.
#23	Registration number and name of trial registry	At conclusion of Abstract	
		Study Design	1.
Other information			
#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Conclusions	1.
#23	Registration number and name of trial registry	At conclusion of Abstract	
		Study Design	1.
#24	Where the full trial protocol can be accessed, if available	In the trial registry	
#25	Sources of funding and other support (such as supply of drugs), role of funders	Grant information	

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