



CONSORT
include

**checklist of information to
when reporting a randomized trial***

Section/Topic	Item No	Checklist item	Reported on page No
Consolidated Standards of Reporting Trials			
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of the rationale	3-5
	2b	Specific objectives or hypotheses	1
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
		Participants	
	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-8

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6	_____
8	6b	Any changes to trial outcomes after the trial commenced, with reasons : No changes		_____
Sample size	7a	How sample size was determined	9	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines: Not applicable		_____
Randomization: Sequence generation Allocation concealment mechanism	8a	The method used to generate the random allocation sequence: pages 5-8		_____
	8b	Type of randomization; details of any restriction (such as blocking and block size) : Random allocation		_____
	9	The 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 : software randomization		_____
Implementation	10	Who generated the random allocation sequence : An independent person , who enrolled participants: The investigator and who assigned participants to interventions: An independent person		_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those		_____
		assessing outcomes) and how : those assessing outcomes		_____
	11b	If relevant, description of the similarity of interventions: not relevant		_____
Statistical Methods	12a	Statistical methods used to compare groups for primary and secondary outcomes : page 10		_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses : page10		_____
Results				
Participant flow (a diagram is strongly	13a	For each group, the number of participants who were randomly assigned received the intended treatment and were analyzed for the primary outcome: 30 per group		_____

recommended)	13b	For each group, losses and exclusions after randomization, together with reasons : No losses	_____

Recruitment	14a	Dates defining the periods of recruitment and follow-up : 3-4 and explained in the flow chart	_____

	14b	Why the trial ended or was stopped : Completion of the required sample size and required follow up	
	Baseline data 15	A table showing baseline demographic and clinical characteristics for each group: Table 1	
	Numbers analyzed 16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups : yes	

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) : Page 7 and 8	_____
	17b	For binary outcomes, the presentation of both absolute and relative effect sizes is recommended : NA	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory : done	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) : Not applicable	_____
Discussion			_____

Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses : Not applicable	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings : A study is externally valid	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence yes	
Other information			
Registration	23	Registration number and name of trial registry : https://clinicaltrials.gov/study/NCT06555705 : Effect of Omega 3 Supplementation on the Heart Rate Variability in Obese Children	

Protocol	24	Where the full trial protocol can be accessed, if available: on ClinicalTrial.gov	
Funding	25	Sources of funding and other support (such as the supply of drugs), role of funders : Self-Funded	

