

CONSORT 2010 Checklist

Section/Topic	Item No	Checklist Item	Reported on Page No
Title and abstract	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 1-2 (Abstract)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 2-5 (Introduction)
	2b	Specific objectives or hypotheses	Page 5 (last paragraph)
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 5 (Study Design)
	3b	Description of trial design (such as parallel, factorial) including allocation ratio	N/A
Participants	4a	Eligibility criteria for participants	Page 6
	4b	Settings and locations where the data were collected	Page 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 6-7 (3D-ITM Intervention & Control Group)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 7-8 (Data Collection)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Page 6 (n=54, based on cohort size)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 6 (Stratified randomization)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 6-7
Allocation concealment mechanism	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	Page 6-7 (implied by randomization method)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers,	Page 7-8 (Blinded researchers for proposal

		those assessing outcomes) and how	scoring)
	11b	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 7-8 (SPSS, Mann-Whitney U tests)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 6 (54 allocated; all analysed)
	13b	For each group, losses and exclusions after randomisation, with reasons	None reported
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 6 (2025 academic year)
	14b	Why the trial ended or was stopped	N/A (completed as planned)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A (groups comparable by stratification)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page 7 (all 27 per group)
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 8-11 (Results section; medians and p-values reported)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 11-13
Harms	19	All important harms or unintended effects in each group	None reported
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 13 (Limitations section)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 15-16
Other Information			
Registration	23	Registration number and name of trial registry	Abstract (pending,

			application submitted)
Protocol	24	Where the full trial protocol can be accessed, if available	Available from corresponding author on request
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 15 (Funding)