Reporting checklist for randomised trial.

		Reporting Item	Page Number
Title and Abstract			
Title	#1a	Identification as a randomized trial in the title.	1
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	2
Introduction			
Background and objectives	#2a	Scientific background and explanation of rationale	3
Background and objectives	#2b	Specific objectives or hypothesis	4
Methods			
Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	4-5
Trial design	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4
Participants	#4a	Eligibility criteria for participants	4
Participants	#4b	Settings and locations where the data were collected	6-7
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6-7

Sample size	#7a	How sample size was determined.	5
Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomization - Sequence generation	#8a	Method used to generate the random allocation sequence.	5
Randomization - Sequence generation	#8b	Type of randomization; details of any restriction (such as blocking and block size)	5
Randomization - 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	5
Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	4-8
Blinding	#11b	If relevant, description of the similarity of interventions	5-7
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	7
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	6-7
Results			
Participant flow diagram (strongly recommended)	#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	19

Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	19
Recruitment	#14a	Dates defining the periods of recruitment and follow-up	2
Recruitment	#14b	Why the trial ended or was stopped	13
Baseline data	#15	A table showing baseline demographic and clinical characteristics for each group	21
Numbers analysed	#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	21-27
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)	21-24, 26
Outcomes and estimation	#17b	For binary outcomes, 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	NA
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	22
Discussion			
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12-14
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Registration	#23	Registration number and name of trial registry	8
Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	14
Other information			

Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Registration	#23	Registration number and name of trial registry	8
Protocol	#24	Where the full trial protocol can be accessed, if available	8
Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	8