eAppendix1: CONSORT Checklist

Based on the CONSORT guidelines.

		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	3
Introduction			
Background and objectives	#2a	Scientific background and explanation of rationale	4
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
Trial design	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4
Participants	#4a	Eligibility criteria for participants	5
Participants	#4b	Settings and locations where the data were collected	5
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

Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	5-6
Sample size	#7a	How sample size was determined.	eAppendix
Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization - Sequence generation	#8a	Method used to generate the random allocation. sequence. 4	
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.	n/a
Blinding	#11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	6
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6

Supplemental material

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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	6
Participant flow	[#13b]	For each group, losses and exclusions after randomization, together with reason	6
Recruitment	[#14a]	Dates defining the periods of recruitment and follow-up	4
Recruitment	[#14b]	Why the trial ended or was stopped	4
Baseline data	[#15]	A table showing baseline demographic and clinical characteristics for each group	13, eAppendix
Numbers analysed	[#16]	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6, 13
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)	6, 7
Outcomes and estimation	[#17b]	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	6, 7
Ancillary analyses	[#18]	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	7, 13
Harms	[#19]	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	7, 14

Discussion

Limitations	[#20]	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8

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Generalisability	[#21](#21)	Generalisability (external validity, applicability) of the trial findings	8
Interpretation	[#22](#22)	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9
Registration	[#23](#23)	Registration number and name of trial registry	n/a

Other information

Interpretation	[#22](#22)	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8, 9
Registration	[#23](#23)	Registration number and name of trial registry	n/a
Protocol	[#24](#24)	Where the full trial protocol can be accessed, if available	n/a
Funding	[#25](#25)	Sources of funding and other support (such as supply of drugs), role of funders	10