		Reporting Item	Page Number	Specific Location
Title and Abstract				
Title	#1a	Identification as a randomized trial in the title.	1	Title Page
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	2	Abstract Page
Introduction				
Background and objectives	#2a	Scientific background and explanation of rationale	7 to 8	Background Section
	#2b	Specific objectives or hypothesis	8	Background, Final paragraph, final sentence.
Methods				
Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	8	Methods, paragraph 1, first sentence.
	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	13	Methods, Changes to study design and outcomes
Participants	#4a	Eligibility criteria for participants	9 & Supp Appendix 1	Methods, paragraph 1, 4th sentence and Supplementary appendix 1
	#4b	Settings and locations where the data were collected	9	Methods, paragraph 1, 2nd sentence.
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10 to 11 and Suppl Appendix 2	Methods, Interventions. Supplementary Appendix 2
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	12	Methods, Statistical Methods, paragraph 2, first sentence.
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	13	Methods, Changes to study design and outcomes
Sample size	#7a	How sample size was determined.	12	Methods, Statistical Methods, paragraph 1, sentences 1 - 3
	#7b	When applicable, explanation of any interim analyses and stopping guidelines	12	Methods, Statistical Methods, paragraph 1, 4th sentence
Randomization - Sequence generation	#8a	Method used to generate the random allocation sequence.	9 to 10	Methods, randomisation and blinding, 1st paragraph, 3rd sentence
	#8b	Type of randomization; details of any restriction (such as blocking and block size)	9 to 10	Methods, randomisation and blinding, 1st paragraph, 3rd sentence
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	9	Methods, randomisation and blinding, 1st paragraph, 1st+2nd sentence.
Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	9	Methods, randomisation and blinding, 1st paragraph, 1st sentence.
Blinding	#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	10	Methods, randomisation and blinding, 1st paragraph, 4th+5th sentences
Blinding	#11b	If relevant, description of the similarity of interventions	Not relevant	Not relevant
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	12	Methods, Statistical Methods, paragraph 2, 3rd sentence
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12	Methods, Statistical Methods, paragraph 3, sentences 1 - 5
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	25	Figure 1
Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	25	Figure 1
Recruitment	#14a	Dates defining the periods of recruitment and follow-up	13	Results, 1st paragraph, 1st sentence
	#14b	Why the trial ended or was stopped	13	Methods, changes to study design and outcomes, 1st paragraph, 1st sentence.
Baseline data	#15	A table showing baseline demographic and clinical characteristics for each group	27 and Suppl Appendix 3	Table 1
Numbers analysed	#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	25, 30, 14-15	Figure 1, Table 2 and Results, Outcomes, paragraphs 2, 3, 4.
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)	30, 14-15	Table 2, Results, Outcomes, paragraphs 2, 3, 4.
	#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	30, 14-15	Table 2, Results, Outcomes, paragraphs 2, 3, 4. Absolute Difference provided, along with raw data. Relative effects not provided as not part of Statistical Analysis Plan.
Ancillary analyses	#18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16	Results, Updated Meta-Analysis

		Reporting Item	Page Number	Specific Location
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	16 to 17	Results, Harms. Also, Results, Costs.
Discussion				
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16 and 17	Discussion, paragraphs 3 and 4
Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	16 and 17	Discussion, paragraph 4
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20	Conclusion, paragraphs 1 and 2.
Registration	#23	Registration number and name of trial registry	Page 3, 8, 21	Abstract, final sentence, Methods, first paragraph, first sentence. Trial Registration detail
Other information				
Protocol	#24	Where the full trial protocol can be accessed, if available	9	Methods, second paragraph, 2nd sentence.
Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	Page 5	Declarations