

Appendix 1. Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

	Reporting Item	Page Number
Title and Abstract		
Title	Identification as a randomized trial in the title.	1
Abstract	Structured summary of trial design, methods, results, and conclusions	1-2
Introduction		
Background and objectives	Scientific background and explanation of rationale	3-5
Background and objectives	Specific objectives or hypothesis	4-5
Methods		
Trial design	Description of trial design (such as parallel, factorial) including allocation ratio.	5
Trial design	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	Eligibility criteria for participants	5
Participants	Settings and locations where the data were collected	5
Interventions	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	6-8
Sample size	How sample size was determined.	6

Sample size	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization - Sequence generation	Method used to generate the random allocation sequence.	
5		
Randomization - Sequence generation	Type of randomization; details of any restriction (such as blocking and block size)	
5		
Randomization - Allocation concealment mechanism	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	6
Randomization - Implementation	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	6
Blinding	If relevant, description of the similarity of interventions	6-7
Statistical methods	Statistical methods used to compare groups for primary and secondary outcomes	8
Statistical methods	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Outcomes	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Results		
Participant flow diagram (strongly recommended)	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
Participant flow	For each group, losses and exclusions after randomization, together with reason	9
Recruitment	Dates defining the periods of recruitment and follow-up	9

Recruitment	Why the trial ended or was stopped	9
Baseline data	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-10
Outcomes and estimation	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10
Harms	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	n/a
Discussion		
Limitations	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Interpretation	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
Registration	Registration number and name of trial registry	5
Generalisability	Generalisability (external validity, applicability) of the trial findings	13
Other information		
Interpretation	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
Registration	Registration number and name of trial registry	5
Protocol	Where the full trial protocol can be accessed, if available	5

