CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Study name noted in the title, p1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract, p5
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	P9 and 10
	2b	Specific objectives or hypotheses	P10 and 11
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P12
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	P12
	4b	Settings and locations where the data were collected	P12 and 14 and in the main paper for this study (cited in the text)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P12 and in the main paper for this study (cited in the text)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P12 and p13 and in the main paper for this study (cited in the

			text)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	Sample size was determined based on the full escalation and expansion phase of this study. This is explained in the published main paper for this study (cited in our manuscript).
	7b	When applicable, explanation of any interim analyses and stopping guidelines	P13
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Noted in the published main paper for this study (cited in our manuscript).
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Noted in the published main paper for this study cited in our manuscript).
Allocation concealment	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	-

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Those who enrolled patients noted in authors' contributions, p4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	P13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
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	P14
	13b	For each group, losses and exclusions after randomisation, together with reasons	Noted in the published main paper for this study, (cited in our manuscript)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P5 and p18
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and suppl 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	P14
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)	Table 2 and 3, Suppl table 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Figures 1-4 and suppl fig

			2-4. Table 4 and suppl table 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 3 and suppl table 4. Pages 16-17
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	P21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	P18-21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P18-20
Other information			
Registration	23	Registration number and name of trial registry	Abstract (p5)
Protocol	24	Where the full trial protocol can be accessed, if available	Protocol supplied to journal
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	P3 and 22

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.