547 Appendix 3, CONSORT checklist

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549 CONSORT checklist of information to include when reporting randomised crossover trials

Section/topic	Item No	Description	Page No*
Title†	1a	Identification as a randomised crossover trial in the title	Page 1
Abstract†	1b	Specify a crossover design and report all information outlined in table 2	Page 2
Introduction:			
Background‡	2a	Scientific background and explanation of rationale	Page 4
Objectives‡	2b	Specific objectives or hypotheses	Page 4
Methods:			
Trial design†	3a	Rationale for a crossover design. Description of the design features including allocation ratio, especially the number and duration of periods, duration of washout period, and consideration of carry over effect	Rationale now provided. Carry over effect not applicable since each randomization sequence included also a new series of abstracts to be judged
Change from protocol‡	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 11, No protocol was published. No changes to the initial plan have been made.
Participants‡	4a	Eligibility criteria for participants	Page 6
Settings and location‡	4b	Settings and locations where the data were collected	Page 6
Interventions†	5	The interventions with sufficient details to allow replication, including how and when they were actually administered	Page 6-7
Outcomes‡	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Page 8-10
Changes to outcomes‡	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a

Section/topic	Item No	Description	Page No*
Sample size†	7a	How sample size was determined, accounting for within participant variability	Page 8
Interim analyses and stopping guidelines‡	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation‡	8a	Method used to generate the random allocation sequence	Page 6
Sequence generation‡	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 6
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	Page 6
Implementation†	10	Who generated the random allocation sequence,§ who enrolled participants, and who assigned participants to the sequence of interventions	Page 6
Blinding‡	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	n/a
Similarity of interventions‡	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 which are appropriate for crossover design (that is, based on within participant comparison)	Page 8
Additional analyses‡	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 8
Results			
Participant flow (a diagram is strongly recommended)†	13a	The numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary	Figure 4

Section/topic	Item No	Description	Page No*
		outcome, separately for each sequence and period	
Losses and exclusions†	13b	No of participants excluded at each stage, with reasons, separately for each sequence and period	Page 8
Recruitment‡	14a	Dates defining the periods of recruitment and follow-up	Page 7-8
Trial end‡	14b	Why the trial ended or was stopped	Page 8
Baseline data†	15	A table showing baseline demographic and clinical characteristics by sequence and period	n/a
Numbers analysed†	16	Number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page 8
Outcomes and estimation†	17a	For each primary and secondary outcome, results including estimated effect size and its precision (such as 95% confidence interval) should be based on within participant comparisons.¶ In addition, results for each intervention in each period are recommended	Page 9
Binary outcomes‡	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses‡	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	See point 12b
Harms†	19	Describe all important harms or untended effects in a way that accounts for the design (for specific guidance, see CONSORT for harms[32])	n/a
Discussion:			
Limitations†	20	Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses. Consider potential carry over effects	Page 11

Section/topic	Item No	Description	Page No*
Generalisability‡	21	Generalisability (external validity, applicability) of the trial findings	Page 11
Interpretation‡	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 12
Other information:			
Registration‡	23	Registration number and name of trial registry	Page 11
Protocol‡	24	Where the full trial protocol can be accessed, if available	Page 11
Funding‡	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 13

CONSORT=Consolidated Standards of Reporting Trials.

- * Note: page numbers are optional depending on journal requirements.
- † Modified original CONSORT item.
- ‡ Unmodified CONSORT item.
- § Random sequence here refers to a list of random orders, typically generated through a computer program. This should not be confused with the sequence of interventions in a randomised crossover trial, for example receiving intervention A before B for an individual trial participant.
- ¶ A within participant comparison takes into account the correlation between measurements for each participant because they act as their own control, therefore measurements are not independent.