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	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	4–5
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	7
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	7
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	For 8a–10, please refer to page 3 of this document
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
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	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	N/A

		assessing outcomes) and how	
	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	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
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	8 and Fig1
	13b	For each group, losses and exclusions after randomisation, together with reasons	8 and Fig1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13 and Table3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13 and Table3
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)	13 and Table3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13 and Table3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19−20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19−20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19−20
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	Attached as S1 Protocol
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*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.

8a Method used to generate the random allocation sequence

Stratified permuted blocks were used to generate the allocation sequence. **Reference:** Zelen M. The Randomization and Stratification of Subjects to Clinical Trials. Journal of Chronic Diseases, 1974 Sept; 27 (7-8): 365-75.

8b Type of randomisation; details of any restriction (such as blocking and block size)

Permuted blocks were used for the randomization. The block size was set to 4.

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

The random allocation sequence was generated by the Subject Enrollment System (SES) that is located on the Data Management Center (DMC) of IMPAACT's website. The random assignment was conducted by the SES using stratified permuted blocks. The clinical site staff do not have access to the full permuted block, thus, the site clinical staff are not able to predict the random sequence.

10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

A candidate was randomized when a clinic staff person from an institution uses the enrollment screens developed by FSTRF, the Data Management Center (DMC) of IMPAACT. The enrollment screens are accessible via the Subject Enrollment System (SES), located on the DMC web site. In order to enroll candidates, the clinic staff member at the institution must have a DMC web site password and enrollment privileges. The candidate's eligibility is checked by answering questions in the Subject Enrollment System (SES). Once all eligibility questions have been answered and passed, the Patient Registration System (PRS) reads the record that was generated from the eligibility check in SES. For eligible candidates, PRS performs a stratified randomization of treatment (if applicable), registers the participant on the DMC's central computer, and gives the participant a SID (Study Identification Number). The SID is given to the site pharmacist who compares it to the SID list containing treatment information for the particular study and dispenses study drug.