Table 1 Information to Include When Reporting a Noninferiority or Equivalence Randomized Trial: Extension of CONSORT 2010 Checklist[a]

Section/Topic	Item No	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a noninferiority randomized trial in the title	Page1/Line4-5	Title/Paragraph1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see *Table 2*)	Page1/Line30-Page2/ Line25	Abstrct/Paragraph1-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale **(Rationale for using a noninferiority design)**	Page3/Line1-Page4/Line3	Introduction/Paragraph1-2
	2b	Specific objectives or hypotheses **(Hypotheses concerning noninferiority, specifying the noninferiority margin with the rationale for its choice)**	Page4/Line3-10	Introduction/Paragraph2
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page5/Line5	Methods/Paragraph2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page4/Line25-30	Methods/Paragraph1
Participants	4a	Eligibility criteria for participants **(Whether participants in the noninferiority trial are similar to those in any trial(s) that established efficacy of the reference treatment)**	Page4/Line19-25	Methods/Paragraph1
	4b	Settings and locations where the data were collected	Page4/Line16	Methods/Paragraph1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered **[Whether the reference treatment in the noninferiority trial is identical (or very similar) to that in any trial(s) that established efficacy]**	Page5/Line3-10	Methods/Paragraph2

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed **[Specify the noninferiority outcome(s) and whether hypotheses for main and secondary outcome(s) are noninferiority or superiority. Whether the outcomes in the noninferiority trial are identical (or very similar) to those in any trial(s) that established efficacy of the reference treatment]**	Page6/Line17-Page7/ Line30	Methods/Paragraph4-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Page6/Line8-10	Methods/Paragraph3
Sample size	7a	How sample size was determined **(Whether the sample size was calculated using a noninferiority criterion and, if so, what the noninferiority margin was)**	Page4/Line16-18	Methods/Paragraph1
	7b	When applicable, explanation of any interim analyses and stopping guidelines **(To which outcome(s) they apply and whether related to a noninferiority hypothesis)**	Page4/Line28-29	Methods/Paragraph1
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page4/Line18	Methods/Paragraph1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page4/Line17-18	Methods/Paragraph1
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	Page4/Line18-19	Methods/Paragraph1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page4/Line15-18	Methods/Paragraph1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page5/Line3-8	Methods/Paragraph2
	11b	If relevant, description of the similarity of interventions	Page5/Line11-22	Methods/Paragraph2
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes **(Whether a 1- or 2-sided confidence interval approach was used)**	Page7/Line1-5	Methods/Paragraph10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page7/Line3-5	Methods/Paragraph10
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	Page8/Line10-11	Results/Paragraph1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page8/Line10	Results/Paragraph1

Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page4/Line16	Methods/Paragraph1
	14b	Why the trial ended or was stopped	Page4/Line15-17	Methods/Paragraph1
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table1	Table1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page8/Line24-27	Results/Paragraph1
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) **[For the outcome(s) for which noninferiority was hypothesized, a figure showing confidence intervals and the noninferiority margin may be useful]**	Page8/Line29-Page10/ Line32	Results/Paragraph2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page9/Line32-Page10/	Results/Paragraph3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page10/Line11-22	Results/Paragraph4
Harms	19	All important harms or unintended effects in each group [for specific guidance see CONSORT for harms]	Page8/Line30-Page9/	Results/Paragraph2
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page12/Line29-Page13/	Discussion/Paragraph5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page12/Line4-7	Discussion/Paragraph3
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence **[Interpret results in relation to the noninferiority hypothesis. If a superiority conclusion is drawn for outcome(s) for which noninferiority was hypothesized, provide justification for switching]**	Page11/Line22-31	Discussion/Paragraph2
Other information				
Registration	23	Registration number and name of trial registry	Page4/Line10-11	Methods/Paragraph1
Protocol	24	Where the full trial protocol can be accessed, if available	Page3/Line5-10	Introduction/Paragraph1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page13/Line14	Funding

[a] This checklist relates to noninferiority trials, but the same issues apply to equivalence trials. The Consolidated Standards of ReportingTrials (CONSORT) Group “strongly recommends reading this checklist in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items.”5 This checklist may be republished without restriction.

Table 2 Information to Include in the Abstract of a Report of a Noninferiority or Equivalence Randomized Trial: Extension of CONSORT for Abstracts [a,b] Checklist

Item	Item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of study as a noninferiority trial	Page1/Line5	Title
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Page1/Line4-5	Title
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page2/Line3-5	Abstract/Paragraph2
Interventions	Interventions intended for each group	Page2/Line5-7	Abstract/Paragraph2
Objective	Specific objective or hypothesis **(Specific hypothesis concerning noninferiority, including noninferiority margin)**	Page2/Line4	Abstract/Paragraph2
Outcome	Clearly defined primary outcome for this report **(Clarify for all reported outcomes whether noninferiority or superiority)**	Page2/Line10-22	Abstract/Paragraph3
Randomization	How participants were allocated to interventions	Page2/Line3-4	Abstract/Paragraph2
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page2/Line3	Abstract/Paragraph2
Results			
Numbers randomized	Number of participants randomized to each group	Page2/Line3	Abstract/Paragraph2
Recruitment	Trial status	Page2/Line3-4	Abstract/Paragraph2
Numbers analysed	Number of participants analysed in each group	Page2/Line5	Abstract/Paragraph2
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision **(For the primary noninferiority outcome, results in relation to noninferiority margin)**	Page2/Line10-22	Abstract/Paragraph3
Harms	Important adverse events or side effects	Page2/Line10-12	Abstract/Paragraph3
Conclusions	General interpretation of the results **(Interpretation taking into account the noninferiority hypotheses and any superiority hypotheses)**	Page2/Line23-25	Abstract/Paragraph4

Trial registration	Registration number and name of trial register	Page4/Line10-11	Methods/Paragraph1
Funding	Source of funding	Page13/Line14	Funding

[a] This checklist relates to noninferiority trials, but the same issues apply to equivalence trials.

[b] This checklist may be republished without restriction.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.