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	p. 1 (Title)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	p. 2 (Abstract)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	pp.3-4 (Introduction)
	2b	Specific objectives or hypotheses	**For current analysis:** top of p. 4 (last sentence before "Materials and Methods") **For ORATORIO trial:** Montalban X, et al. New Engl. J Med 2017;376:209-220.
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p. 4 ("Study design and patient population") & Montalban X, et al. New Engl. J Med 2017;376:209-220
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), pp. 371-430
Participants	4a	Eligibility criteria for participants	Montalban X, et al. New Engl. J Med 2017;376:209-220
	4b	Settings and locations where the data were collected	Montalban X, et al. New Engl. J Med 2017;376:209-220, Supplementary Appendix

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p.4, “Study design and patient population”
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	**For current analysis:** pp.4-5 (“Nine-Hole Peg Test” and “Statistical Analysis”) **For ORATORIO trial:** Montalban X, et al. New Engl. J Med 2017;376:209-220
	6b	Any changes to trial outcomes after the trial commenced, with reasons	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), pp. 371-430
Sample size	7a	How sample size was determined	Montalban X, et al. New Engl. J Med 2017;376:209-220
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), p.43, section 3.1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), p.51, section 3.2
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	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), p.51, section 3.2

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	ORATORIO trial protocol (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf), p.51, section 3.2 Montalban X, et al. New Engl. J Med 2017;376:209-220
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not applicable
	11b	If relevant, description of the similarity of interventions	Not relevant
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	**For current analysis:** p.5 (“Statistical Analysis”) **For ORATORIO trial:** Montalban X, et al. New Engl. J Med 2017;376:209-220
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p.5 (“Statistical Analysis” and “Analysis populations”)
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	**For current analysis:** Table 1 **For ORATORIO trial:** Montalban X, et al. New Engl. J Med 2017;376:209-220 Suppl. Appendix
	13b	For each group, losses and exclusions after randomisation, together with reasons	Montalban X, et al. New Engl. J Med 2017;376:209-220 Suppl. Appendix
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Montalban X, et al. New Engl. J Med 2017;376:209-220, Suppl. Appendix.

	14b	Why the trial ended or was stopped	Montalban X, et al. New Engl. J Med 2017;376:209-220
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables S1 and S2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1, 2; Fig 1
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)	pp.6-7; Table 2; Fig 1, 2, 3, 4, and 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	pp.6-7; Table 2; Fig 1, 2, 3, 4, and 5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Fig S1
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Montalban X, et al. New Engl. J Med 2017;376:209-220, manuscript and suppl. appendix
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	pp.8-9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p. 8 (Discussion, 3rd paragraph, last sentence)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p. 8 (bottom) through p. 9
Other information			
Registration	23	Registration number and name of trial registry	p. 3 (“Introduction,” third para)

Protocol	24	Where the full trial protocol can be accessed, if available	http://www.nejm.org/doi/suppl/10.1056/NEJMoa1606468/suppl_file/nejmoa1606468_protocol.pdf
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p.10, “Funding”

*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.