Treatment Group	N	Baseline	Week 24	Week 48	Week 72	Week 96
Placebo	Observed	119 (97%)	119 (99%)	111 (98%)	106 (99%)	106 (97%)
	Expected	123	120	113	107	109
Ibudilast	Observed	116 (96%)	114 (97%)	106 (96%)	95 (91%)	94 (94%)
	Expected	121	117	111	104	100

Supplemental Table 1: Completeness of data contributing to the primary OCT outcome

Treatment Group	N	Contribute to Analysis*	Baseline [†]	Week 24 ⁱ	Week 48 ⁱ	Week 72 ¹	Week 96 ¹	Event Driven (Early Termination)
Placebo	123	122 (99%)	119 (97%)	119 (97%)	111 (90%)	106 (86%)	106 (86%)	3
Ibudilast	121	120 (99%)	116 (96%)	114 (94%)	106 (88%)	95 (79%)	94 (78%)	5

*have at least one oct measurement during the study.

⁴Count having either the left or right side (or both).

- Subject 157-1104 (ibudilast group) had no scans collected and sent by the clinical site
- Subject 116-1143 (placebo group) had an ungradable baseline scan, with no scans collected thereafter

Supplemental Table 2: Data availability by instrument (Cirrus or Spectralis, expressed as number of patients):

Visit	Cirrus Machine			Spectralis Machine			
	Placebo	Ibudilast	Total	Placebo	Ibudilast	Total	
Baseline	93	90	183	30	31	61	
Week 24	90	86	176	30	31	61	
Week 48	83	82	165	30	29	59	
Week 72	78	76	154	29	28	57	
Week 96	80	72	152	29	28	57	



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

Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1 (3 if no title update)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	3
objectives	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4*
Participants	4a	Eligibility criteria for participants	4*
	4b	Settings and locations where the data were collected	4*
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3, 4*
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3, 4*
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	4*, 7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	4*
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4*
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	4*
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4*

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4*
	11b	If relevant, description of the similarity of interventions	4*
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
ecommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4*
	14b	Why the trial ended or was stopped	4*
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7
lumbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Dutcomes 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)	7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	7
ncillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	7
larms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
imitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8
Seneralisability	21	Generalisability (external validity, applicability) of the trial findings	8 8
nterpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
unding	25	Sources of funding and other support (such as supply of drugs), role of funders	10

This was a secondary outcome for the NN102/SPRINT-MS ClinicalTrials.gov number, NCT01982942. Complete trial design and primary outcome were reported and previously published. This is cited on page 4

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**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 <u>www.consort-statement.org</u>.