STROBE Statement—checklist of items that should be included in reports of observational studies

Section/item	Item No	Recommendation	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 3, lines 33 and 42	Title section (#2)
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3, lines 35-52	Title section (#2) Paragraphs 1-3
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 4-6, lines 55-102	Introduction section (#2) Paragraphs 4-12
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, lines 97-101	Introduction section (#2) Paragraph 9
Methods				
Study design	4	Present key elements of study design early in the paper	Page 6, line 104	Methods section (#2) Paragraph 13
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6, lines 112-116 Page 7, lines 125-129	Methods section (#2) Paragraphs 14, 16
Participants	6	(a) ***Cohort study***—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up ***Case-control study***—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls ***Cross-sectional study***—Give the eligibility criteria, and the sources and methods of selection of participants	Pages 6-7 , lines 112-123	Methods section (#2) Paragraphs 14, 15
		(b) ***Cohort study***—For matched studies, give matching criteria and number of exposed and unexposed ***Case-control study***—For matched studies, give matching criteria and the number of controls per case	n/a This is a secondary study of a RCT already published. The dataset was selected from one of the four groups studied in the randomized clinical trial.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 7-8, lines 137-145	Methods section (#2) Paragraphs 18-20
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 7-8, lines 137-145	Methods section (#2) Paragraphs 18-20
Bias	9	Describe any efforts to address potential sources of bias	Page 6, lines 112-113	Methods section (#2) Paragraph 14
Study size	10	Explain how the study size was arrived at	n/a It was not necessary to do it because this was a secondary study derived from a RCT.	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 8, lines 148-153	Methods section (#2) Paragraph 22

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pages 8, lines 147-153	Methods section (#2) Paragraphs 20-21
		(b) Describe any methods used to examine subgroups and interactions	Pages 8, lines 147-153	Methods section (#2) Paragraph 22
		(c) Explain how missing data were addressed	n/a It was analyzed the entire dataset of one of the groups of the RCT. No missing data.	
		(d) ***Cohort study***—If applicable, explain how loss to follow-up was addressed ***Case-control study***—If applicable, explain how matching of cases and controls was addressed ***Cross-sectional study***—If applicable, describe analytical methods taking account of sampling strategy	n/a It was not necessary to do it because this was a secondary study derived from a RCT.	
		(e) Describe any sensitivity analyses	n/a This is a secondary analysis of a RCT.	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 8, lines 155-160, Results section (#2), paragraph 23.	
		(b) Give reasons for non-participation at each stage		
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	n/a De-identified data was used.	
		(b) Indicate number of participants with missing data for each variable of interest	n/a It was analyzed the entire dataset of one of the groups of the RCT. No missing data.	
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	n/a This was a cross-sectional study.	
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time		
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures	Page 8-9, lines 161-168	Results section (#2) Paragraphs 24,25
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Pages 9 lines 166-168	Results section (#2) Paragraph 25
		(b) Report category boundaries when continuous variables were categorized	n/a This is a secondary analysis of a RCT.	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a This is a secondary analysis of a RCT.	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Pages 8-9, lines 165-168	Results section (#2) Paragraph 25
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 9, lines 179-181; 226-230	Discussion section (#2) Paragraphs 27, 35

Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 11, lines 226-227	Discussion section (#2) Paragraph 35
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 9-11, lines 172-230	Discussion section (#2) Paragraphs 27-35
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11, lines 228-230	Discussion section (#2) Paragraph 35
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 12, lines 239-240	Acknowledgements section (#2) Paragraph 37

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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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.