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 1/Line 1-2	Title/Paragraph 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2/Line 36-61	Abstract/Paragraph 1-4
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3/Line 69-90	Introduction/ Paragraph 1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 3/Line 76-8	Introduction/ Paragraph 3
Methods				
Study design	4	Present key elements of study design early in the paper	Page 3/Line 88-90	Methods /Paragraph 1-2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4/Line 106-15	Methods /Paragraph 1-2
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	Page 4/Line 106-13	Methods /Paragraph 1-4
		(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	NA	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 4-5/Line 134-47	Methods /Paragraph 5
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	Page 5-6/Line 152-81	Methods /Paragraph 6-7
Bias	9	Describe any efforts to address potential sources of bias	Page 6 /Line 171-3	Methods /Paragraph 7
Study size	10	Explain how the study size was arrived at	Page 4/Line 106-34	Methods /Paragraph 1-5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5/Line 143-47	Methods /Paragraph 5

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 6/Line 185-9	Statistical analysis/Paragraph 1
		(b) Describe any methods used to examine subgroups and interactions	Page 6/Line 186-9	Statistical analysis/Paragraph 1
		(c) Explain how missing data were addressed	NA	NA
		(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	NA	NA
		(e) Describe any sensitivity analyses	NA	NA
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	Page7/Line 206-9	Efficacy/Paragraph 1
		(b) Give reasons for non-participation at each stage	Page7/Line 232-6	Efficacy/Paragraph 3
		(c) Consider use of a flow diagram	NA	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 4-5/Line 134-42	Methods /Paragraph 5
		(b) Indicate number of participants with missing data for each variable of interest	NA	NA
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	Page7/Line 207-14	Efficacy/Paragraph 1
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Page7/Line 206-14	Efficacy/Paragraph 1
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	NA	NA
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	Page7/Line 206-31	Results/Paragraph 1-2
		(b) Report category boundaries when continuous variables were categorized	Page7/Line 229-31	Results/Paragraph 2
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Page7/Line 229-31	Results/Paragraph 2
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page7/Line 215-31	Results/Paragraph 1-2
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page9/Line 272-7	Discussion/Paragraph 1
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	Page11/Line 350-6	Discussion/Paragraph 6

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page11/Line 350-6	Discussion/Paragraph 6
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page9-10/Line 327-41	Discussion/Paragraph 4
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	NA	NA

*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.