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 2/Line 56	Methods/Paragraph 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2/Lines 56-72	Methods/Results/Conclusi
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4/Lines 111-129	Introduction/Para 1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4/Lines 130-133	Introduction/Para 3
Methods				
Study design	4	Present key elements of study design early in the paper	Page 5/Lines 137-195	Full Materials & Methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5/Lines 136-141; Lines 152-154	Materials & Methods Patient Population &
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 5/Lines 136-141	Materials & Methods Patient Population Paragraph
		(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; No matching done.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6-7/Lines 156-195	Materials & Methods - Data Assessment and
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 6-7/Lines 156-195	Materials & Methods - Data Assessment and
Bias	9	Describe any efforts to address potential sources of bias	Page 7/Lines 179-195	Material & Methods -
Study size	10	Explain how the study size was arrived at	Page 5/Lines 136-141	Material & Methods -
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6-7/Lines 156-195	aterials & Methods - Data Assessment and Statistical

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 7/Lines 179-195	Material & Methods -
		(b) Describe any methods used to examine subgroups and interactions	Page 7/Lines 179-195	Material & Methods -
		(c) Explain how missing data were addressed	Page 11-12/Lines 291-293	Discussion
		(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	Page 7/Lines 179-195	Material & Methods - Statistical Considerations Paragraphs
		(e) Describe any sensitivity analyses	Page 7/Lines 179-195	Material & Methods -
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 7/Lines 197-202	Results Paragraph 1
		(b) Give reasons for non-participation at each stage	N/A	No non-participation,
		(c) Consider use of a flow diagram	N/A	Not needed
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 7/Lines 197-208	Results Paragraph 1
		(b) Indicate number of participants with missing data for each variable of interest	Page 17/Line 408 (Table)	Table 1
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	Page 8/Line 209-210	Results Paragraph 2
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Page 7-8/Lines 197-214	Results Paragraph 1-2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	Page 7-8/Lines 197-214	Results Paragraph 1-2
		Cross-sectional study—Report numbers of outcome events or summary measures	Page 7-8/Lines 197-214	Results Paragraph 1-2
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	Page 8-9/Lines 209-223	Results Paragraph 2 & 3
		(b) Report category boundaries when continuous variables were categorized	Page 8-9/Lines 209-223	Results Paragraph 2 & 3
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Page 8-9/Lines 209-223	Results Paragraph 2 & 3
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 9/Lines 224-230	Results Paragraph 4
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 9-11/Lines 231-280	Discussion Paragraphs 1-5
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 11-12/Lines 281-309	Discussion Paragraphs 6-7

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 12/Lines 310-313	Conclusion Paragraph 1
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11/Lines 281-284	Discussion Paragraph 6
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 13/Line 339	Acknowledgments

*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.