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	P1/L1-2, P2/L24-36	Title, Abstract (Objective,
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	P2/L37-46	Abstract (Results)
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	P4/L55-P5/L94	Introduction/paragraph 1-4
Objectives	3	State specific objectives, including any prespecified hypotheses	P5/L95-100	Introduction/paragraph 5
Methods				
Study design	4	Present key elements of study design early in the paper	P5/L102-P7/154	Methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P5/L110-116	Methods/paragraph 2 (Clinical Data)
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	P5/L103-109	Methods/paragraph 1 (Inclusion criteria)
		(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	P5/L103-P6/116	Methods/paragraph 1-2
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P6/L126-139	Methods/paragraph 4
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	P6/L126-139	Methods/paragraph 4
Bias	9	Describe any efforts to address potential sources of bias	P7/L146-154	Methods/paragraph 6
Study size	10	Explain how the study size was arrived at	NA	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA	NA

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	P7/L146-154	Methods/paragraph 6
		(b) Describe any methods used to examine subgroups and interactions	P8/L188-193	Results/paragraph 3
		(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	P7/L157-176	Results/paragraph 1
		(b) Give reasons for non-participation at each stage	P6/L141-146	Methods/paragraph 5
		(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	P7/L157-176	Results/paragraph 1
		(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)	**P6/L197-201**	**Methods/paragraph4**
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	P7/L157-P8/L184	Results/paragraph1-2
		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	P7/157-198	Results/paragraph 1-4
		(b) Report category boundaries when continuous variables were categorized	P7/L161-172	Results/paragraph 1
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	P8/L177-184	Results/paragraph 2
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	P8/188-193	Results/paragraph 3
Discussion				
Key results	18	Summarise key results with reference to study objectives	P8/L205-221	Discussion/paragraph 1-2
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	P9/L236-239,P9/L251-278	Discussion/paragraph 3, 5-7

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P9/L210-250	Discussion/paragraph 2-4
Generalisability	21	Discuss the generalisability (external validity) of the study results	P9/L275-278	Discussion/paragraph 7
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.