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 no. 3 / line no. 10-18	Abstract / Methods
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page no. 4 / line no. 1-13	Abstract / Results,
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page no. 5 / line no. 3-19; page no. 6 / line no. 1-19;	Introduction / Background
Objectives	3	State specific objectives, including any prespecified hypotheses	Page no. 7 / line no. 8-15	Introduction / Study
Methods				
Study design	4	Present key elements of study design early in the paper	Page no. 8 / line no. 3-16	Methods / Study design
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page no. 8 / line no. 3-16	Methods / Study design and patient selection
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 no. 8 / line no. 3-16	Methods / Study design and patient selection
		(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	Not applicable	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page no. 9 / line no. 10-18; page no. 10; page no. 11 /	Methods / Independent variables, Dependent
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 no. 8 / line no. 18-19; page no. 9 / line no. 1-6	Methods / Data collection
Bias	9	Describe any efforts to address potential sources of bias	Page no, 8 / line no. 6-7;	Methods / Study design
Study size	10	Explain how the study size was arrived at	Page no. 11 / line no.	Methods / Sample size
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page no. 9 / line no. 10-18; page no. 10; page no. 11 /	Methods / Independent variables, Dependent

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page no. 12 / line no. 8-19;	Methods / Statistical
		(b) Describe any methods used to examine subgroups and interactions	Page no. 12 / line no. 8-19;	Methods / Statistical
		(c) Explain how missing data were addressed	Page no. 8 / line no. 10	Methods / Study design
		(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 no. 12 / line no. 8-19; page no. 13 / line no. 1-8	Methods / Statistical analysis
		(e) Describe any sensitivity analyses	Not applicable	Not applicable
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	See Figure 1	See Figure 1
		(b) Give reasons for non-participation at each stage	See Figure 1	See Figure 1
		(c) Consider use of a flow diagram	See Figure 1	See Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	See Table 3; page no. 14 / line no. 3-19	See Table 3; Results / Patient characteristics
		(b) Indicate number of participants with missing data for each variable of interest	Not applicable (see page	Not applicable (see
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	Not applicable	Not applicable
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	Not applicable	Not applicable
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	Not applicable	Not applicable
		Cross-sectional study—Report numbers of outcome events or summary measures	See Table 4-7; page no.	See Table 4-7; Results /
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	See Table 4-7; page no. 15-16	See Table 4-7; Results / Clinical outcomes
		(b) Report category boundaries when continuous variables were categorized	See Table 4-7; page no.	See Table 4-6; Results /
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable	Not applicable
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page no. 17 / line no. 3-8	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	Page no. 20 / line no. 9-19; page no. 21 / line no. 1-5	Discussion / paragraph 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 no. 17-21	Discussion / paragraph 1-7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page no. 20 / line no. 9-10	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	Page no. 24	Acknowledgements

*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.