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	Title Page	Title Page			
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1-2	Abstract/ Pg 1-2			
Introduction	Introduction						
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3/ Line 27-45	Background/ Para 1-2			
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4/ Line 46-49	Background/ Para 3			
Methods							
Study design	4	Present key elements of study design early in the paper	Page 4/ Line 53	Methods/ Para 1			
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4/ Line 52-57	Methods/ Para 1			
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 4-5/ Line 59-70 Para 6/ Line 86-90	Methods/ Para 2 Methods/ Para 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	Not applicable (this is a single-arm study)	Not applicable (this is a single-arm study)			
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6-9/ Line 93-152	Methods/ Para 5-8			
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 73-90	Methods/ Para 3			
Bias	9	Describe any efforts to address potential sources of bias	Not applicable	This is a single-arm study.			
Study size	10	Explain how the study size was arrived at	Not applicable	This is a single-arm study.			
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8-9/ Line 128-154	Methods/ Para 7-9			

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 8-9/ Line 128-154	Methods/ Para 7-9
		(b) Describe any methods used to examine subgroups and interactions	Page 8-9/ Line 128-154	Methods/ Para 8
		(c) Explain how missing data were addressed	Pafe 8/ Line 136-139	Methods/ Para 8
		(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	Pafe 8/ Line 136-139	Methods/ Para 8
		(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	Page 9-10/ Line 158-162	Results/ Para 1
		(b) Give reasons for non-participation at each stage	Page 9-10/ Line 158-162	Results/
		(c) Consider use of a flow diagram	Figure 1	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 10/ Line 162-169	Results/ Para 1
		(b) Indicate number of participants with missing data for each variable of interest	Page 10/ Line 172-176	Results/ Para 2
		(c) Cohort study - Summarise follow-up time (eg, average and total amount)	Page 12/ Line 202-205	Results/ Para 6
Outcome data	15*	Cohort study — Report numbers of outcome events or summary measures over time	Page 11-12/ Line 177-206	Results/ Para 3-6
		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	Not applicable	Not applicable
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 11-12/ Line 184-201	Results/
		(b) Report category boundaries when continuous variables were categorized	Page 11-12/ Line 189-201	Results/ Para 4-5
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not performed	Not performed
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11-12/ Line 189-201	Results/ Para 4-5
Discussion				
Key results	18	Summarise key results with reference to study objectives	Page 13-17/ Line 224-299	Discussion/ Para 1-9
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 18-19/ Line 319-338	Discussion/ Para 11

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 17-18/ Line 300- 318	Discussion/ Para 10				
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 15-16/ Line 271-279	Discussion/ Para 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 20/ Line 352-353	Footnote				

^{*}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.