STROBE Statement—checklist of items that should be included in reports of observational studies

Section/item	Item No	Recommendation	Reported on Page Number/Line	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 29	Abstract – Background section
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2 / Lines 33 – 46	Abstract – Methods/Results
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4 / Lines 57 -90	Introduction section / Paragraphs 1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4 / Lines	Introduction/Paragraph
Methods				
Study design	4	Present key elements of study design early in the paper	Page 6 / Lines 115-127	Methods – Study Population/ paragraph
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5 / Lines 103 – 112	Methods – Data Source
Participants	6	(a) <i>Cohort study</i> —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	Page 6-7/Lines 138 -151	Methods – Study Population / Paragraph 3
		ascertainment and control selection. Give the rationale for the choice of cases and		
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed	Page 6 / Lines 128-137	Methods – Study Population / Paragraph
		Case-control study—For matched studies, give matching criteria and the number of		_

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 7-8 / Lines 153 - 187	Methods – Treatment Exposure, Survival Outcomes, Covariates
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	Page 7-8 / Lines 153 - 187	Methods – Treatment Exposure, Survival Outcomes, Covariates
Bias	9	Describe any efforts to address potential sources of bias	Page 6 / Line 128, Page 7 / line 160-167, Page 9 / lines 201 - 218	Methods – Study population / paragraph 2, Methods – Treatment exposure / Paragraph 1, Methods – Statistical analysis / paragraph 2
Study size	10	Explain how the study size was arrived at	Page 6 – 7 / Lines 138 - 151	Methods / Paragraph 3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7-8/ Lines 158-168	Methods – Treatment Exposure
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 8-9 / Lines 190-200	Methods – statistical Analysis
		(b) Describe any methods used to examine subgroups and interactions	Page 9 / Lines 213-220	Methods – statistical analysis
		(c) Explain how missing data were addressed	Page 6 /Lines 117- 118	Methods – Study population/ paragraph 1
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	Page 6 /lines 171 - 173	Methods – survival outcome
		(e) Describe any sensitivity analyses	Page 9/ Lines 201 – 213	Methods – Statistical Analysis

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,	223-226	Results / Paragraph 1 and figure 1
		(b) Give reasons for non-participation at each stage	Figure 1	Figure 1
		(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/ Lines 227 – 234	Results Paragraph 2 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest		Figure 1
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Page 10/ Lines 235 – 236	Results /Paragraph 3
Outcome data	15	* Cohort study—Report numbers of outcome events or summary measures over time	Page 10 / Lines 236 – 246	Results / Paragraph 3
		Case-control study—Report numbers in each exposure category, or summary measures of	NA	
		Cross-sectional study—Report numbers of outcome events or summary measures	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	Page 10 / Lines 236 – 246	Results / Paragraph 3
		(b) Report category boundaries when continuous variables were categorized	NA	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	NA	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 10-11 / Lines 241 – 265	Results / Paragraph 3 - 5
Discussion	· ·		l	1
Key results	18	Summarise key results with reference to study objectives	Page 11 / Lines 268 – 272	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 13/ Lines 308 – 334	Discussion – Paragraph 5
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Interpretation		Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 14 / Lines 327-340	Conclusions

Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13/ Lines 308 – 334 Discussion – Paragraph 5			
Other informat	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 4 / Lines 349 - Acknowledgements 351			

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.