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 3/line 57	Abstract/Paragraph 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	pages 3-4/lines 57-74	Abstract/Paragraphs 1-4
Introduction				
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	pages 5-6/lines 97-127	Intrduction/paragraphs 1-4
Objectives	3	State specific objectives, including any prespecified hypotheses	pages 6/ line 122-127	Introduction/paragraph 4
Methods				
Study design	4	Present key elements of study design early in the paper	page 6 /line 131	Methods/paragraph 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	pages 6-7/lines 132-181	subjects, materials, and methods/paragraphs 1-3
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	pages 6-7/lines 132-155	subjects, materials, and methods/paragraph1
		(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 (not a matched study)	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	pages 6-9/lines 132-201	subjects, materials, and methods/paragraphs 1-4
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	pages 8-9/lines 183-201	subjects, materials, and methods/paragraph 4
Bias	9	Describe any efforts to address potential sources of bias	n/a small cohort	of only 20 volunteers
Study size	10	Explain how the study size was arrived at	n/a small cohort	of only 20 volunteers
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	page 9/ lines 203-206	subjects, materials, and methods/paragraphs 5

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	page 9/ lines 203-206	methods/paragraphs 5
		(b) Describe any methods used to examine subgroups and interactions	page 9/ lines 203-206	methods/paragraphs 5
		(c) Explain how missing data were addressed	n/a, no missing data	n/a
		(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	n/a, no loss to follow up	n/a
		(e) Describe any sensitivity analyses	n/a, not in scope of study	n/a
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	n/a, small cohort of 20 volunters	all participants completed study
		(b) Give reasons for non-participation at each stage	n/a (as above)	n/a
		(c) Consider use of a flow diagram	n/a (as above)	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	page 9, lines 209-213	results/paragraph 1 table 1
		(b) Indicate number of participants with missing data for each variable of interest	n/a, no missing data	n/a
		(c) ***Cohort study***—Summarise follow-up time (eg, average and total amount)	n/a, not in scope	n/a
Outcome data	15*	***Cohort study***—Report numbers of outcome events or summary measures over time	pages25-27;lines 644-65	tables 2, 3, and 4
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	n/a, cohort study	n/a
		Cross-sectional study—Report numbers of outcome events or summary measures	n/a, cohort study	n/a
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	pages25-27; lines644-65	tables 2, 3, and 4
		(b) Report category boundaries when continuous variables were categorized	n/a	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	pages26-27; lines651-65	tables 3 and 4
Discussion				
Key results	18	Summarise key results with reference to study objectives	pages11-12; lines 261-70	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 17; lines 412-421	Discussion, paragraph 11

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	pages 12-17; lines 272-410	Discussion; paragraphs 2-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	page 17; lines 412-421	Discussion, paragraph 11
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 19; lines 479-481	Acknowledgemtns/paragraph 1

*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.