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

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1	Randomised controlled trial
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3	Methods section in the abstract
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4	Paragraph 2 in the introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5	Paragraph 3 in the introduction
Methods				
Study design	4	Present key elements of study design early in the paper	6	First paragraph of the methods section
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6	First paragraph of the methods section
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	6	First paragraph of the methods section
		(*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.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7	Section 'study procedures' in the methods section
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	7	Section 'study procedures' in the methods section
Bias	9	Describe any efforts to address potential sources of bias	12-13	Section 'Strengths and limitations' in the discussion
Study size	10	Explain how the study size was arrived at	Protocol	

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8	Section 'statistical analyses' in the methods section
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8	Section 'statistical analyses' in the methods section
		(*b*) Describe any methods used to examine subgroups and interactions	8	Section 'statistical analyses' in the methods section
		(*c*) Explain how missing data were addressed	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.	
		(*e*) Describe any sensitivity analyses	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	9	Section 'patient population' in the results section
		(b) Give reasons for non-participation at each stage	N.A.	
		(c) Consider use of a flow diagram	N.A.	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9	Section 'patient population' in the results section
		(b) Indicate number of participants with missing data for each variable of interest	N.A.	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	9	Section 'patient population' in the results section
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	9-10	Across the results section; Table 2
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	N.A.	
		Cross-sectional study—Report numbers of outcome events or summary measures	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	9-10	Across the results section; Table 2
		(*b*) Report category boundaries when continuous variables were categorized	N.A.	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N.A.	

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10	Across the results section; Table 3; Table 4
Discussion				
Key results	18	Summarise key results with reference to study objectives	11	Section 'Summary of main findings' in the results section
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	12-13	Section 'Strengths and limitations' in the discussion
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12	Section 'Implications for clinical practice' in the discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	11-12	Section 'Comparison with previous research' in the discussion
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	14	Section 'Funding'

*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.