Supplementary file 4



CONSORT 2010 checklist of information to include when reporting a randomised trial*

SectionTopic No Checklist item on page No Title and abstract 1 Identification as a randomised trial in the title		Item		Reported
Title and abstract 1 Identification as a randomised trial in the title	Section/Topic	No	Checklist item	on page No
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STROBE Statement—checklist of items that should be included in reports of observational studies

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	Item		Page
	No	Recommendation	No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
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	
		(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	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment	
measurement		methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(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	
		(c) Describe any sensitivity analyses	
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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
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time
		Case-control study-Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study-Report numbers of outcome events or summary measures
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
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other
		relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other informatio	on	
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