Supplementary table S2: STROBE and CONSORT checklists

STROBE checklist

Section/Topic	Item #	Recommendation	Stephenson [20]	Miravitlles [16]	O'Hagan [19]	Roche [17]	Kim [18]	Kessler [22]	Partridge [21]
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract		X			X	X	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	X	X			X	X	X
Introduction									
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	X	X	X	X	X	X	X
Objectives	3	State specific objectives, including any pre-specified hypotheses							
Methods									
Study design	4	Present key elements of study design early in the paper	X	X	X	X	X	X	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	X	X	X	X	X		X
Participants	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	X	X	X	X		X	X
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	X	X	X				X
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement).	X	X	X	X	X	X	X
Bias	9	Describe any efforts to address potential sources of bias		X	X			X	
Study size	10	Explain how the study size was arrived at		X					

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	X	X	X	X	X	X	X
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding				X	X	X	X
		(b) Describe any methods used to examine subgroups and interactions				X		X	X
		(c) Explain how missing data were addressed		X					
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy				Not rel.			X
		(e) Describe any sensitivity analyses						X	
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	X				X	X	
		(b) Give reasons for non-participation at each stage						X	
		(c) Consider use of a flow diagram	X				X	X	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	X	X	X	X	X	X	X
		(b) Indicate number of participants with missing data for each variable of interest		X		X		X	
Outcome data	15*	Cross-sectional study—Report numbers of outcome events or summary measures	X	X	X	X	X	X	X
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	X	X	X	X		X	X
		(b) Report category boundaries when continuous variables were categorized	X	X	X	X		Not rel.	X
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		X		X		Not rel.	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and	X		X	X	X		X

		sensitivity analyses							
Discussion									
Key results	18	Summarise key results with reference to study objectives	X	X	X	X	X	X	X
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	X	X	X	X	X	X	X
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, etc	X	X		X	X	X	X
Generalisability	21	Discuss the generalizability (external validity) of the study results	X	X		X			X
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	X	X	X	X	X	X	X
Total			**18**	**18**	**15**	**16**	**14**	**16**	**17**

*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.
STROBE: STrengthening the Reporting of OBservational studies in Epidemiology

CONSORT checklist

Section/Topic	**Item #**	**Recommendation**	**Bateman [15]**
Title and abstract	1	(a) Identification as a randomised trial in the title	X
		(b) Structured summary of trial design, methods, results, and conclusions	X
Introduction			
Background and objectives	2	(a) Scientific background and explanation of rationale	X
		(b) Specific objectives or hypotheses	X
Methods			

Trial design	3	(a) Description of trial design (such as parallel, factorial) including allocation ratio	X
		(b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4	(a) Eligibility criteria for participants	X
		(b) Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	X
Outcoumes	6	(a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	X
		(b) Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7	(a) How sample size was determined	
		(b) When applicable, explanation of any interim analyses and stopping guidelines	
Sequence generation	8	(a) Method used to generate the random allocation sequence	
		(b) Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11	(a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	X
		(b) If relevant, description of the similarity of interventions	
Statistical methods	12	(a) Statistical methods used to compare groups for primary and secondary outcomes	X
		(b) Methods for additional analyses, such as subgroup analyses and adjusted analyses	X
Results			
Participant flow	13	(a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were	X

		analysed for the primary outcome	
		(b) For each group, losses and exclusions after randomisation, together with reasons	X
Recruitment	14	(a) Dates defining the periods of recruitment and follow-up	
		(b) Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	X
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	X
Outcomes and estimation	17	(a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)	X
		(b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended	X
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	X
Harms	19	All important harms or unintended effects in each group	X
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	X
Other information			
Registration	23	Registration number and name of trial registry	X
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	X
Total			**17**

CONSORT: Consolidated Standards of Reporting Trials