TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	Page 5-6/114-125	Abstract/Methods
		• Structured abstract recommended	Page 5-7/97-166	Abstract
		• Information on target population or study sample	Page 5-6/114-125	Abstract/Methods
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 10-11/192-220	Introduction
		• Theories used in designing behavioral interventions	Page 10-11/192-220	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 12-14/241-296	Methods/study subject
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 12-14/241-296	Methods/study subject
		• Recruitment setting	Page 12-14/241-296	Methods/study subject
		• Settings and locations where the data were collected	Page 12-14/241-296	Methods/study subject
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Content: what was given?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Delivery method: how was the content given?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Unit of delivery: how were the subjects grouped during delivery?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Deliverer: who delivered the intervention?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Setting: where was the intervention delivered?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc

		• Time span: how long was it intended to take to deliver the intervention to each unit?	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
		• Activities to increase compliance or adherence (e.g., incentives)	Page 14-18/298-385	Methods/Preoperative preparation/Surgical procedure/ etc
Objectives	5	• Specific objectives and hypotheses	Page 11/216-220	Introduction
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 12-14/241-296	Methods/study subject
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 12-14/241-296	Methods/study subject
		• Information on validated instruments such as psychometric and biometric properties	Page 12-14/241-296	Methods/study subject
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 12-14/241-296	Methods/study subject
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 12-14/241-296	Methods/study subject
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 12-14/241-296	Methods/study subject
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Not applicable	Not applicable
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.	N/A	N/A
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Not applicable	Not applicable
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	Not applicable	Not applicable
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page 18-19/398-427	Methods/Statistical analysis
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page 18-19/398-427	Methods/Statistical analysis
		• Methods for imputing missing data, if used	Not applicable	Not applicable
		• Statistical software or programs used	Page 18/399-402	Methods/Statistical analysis
Results				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	Page 20-22/432-487	Results
		• Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	Page 20-22/432-487	Results

		• Assignment: the numbers of participants assigned to a study condition	Page 20-22/432-487	Results
		• Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page 20-22/432-487	Results
		• Follow-up: the number of participants who completed the follow- up or did not complete the follow-up (i.e., lost to follow-up), by study condition	Page 20-22/432-487	Results
		• Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page 20-22/432-487	Results
		• Description of protocol deviations from study as planned, along with reasons	Page 20-22/432-487	Results
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 20-22/432-487	Results
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page 20-22/432-487	Results/Table 1
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page 20-22/432-487	Results/Table 1
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page 20-22/432-487	Results/Table 1
		• Comparison between study population at baseline and target population of interest	Page 20-22/432-487	Results/Table 1
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page 20-22/432-487	Results/Table 1
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	Page 20-22/432-487	Results/Table 1
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Page 20-22/432-487	Results/Table 1
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	Page 20-22/432-487	Results/Table 1
		• Inclusion of null and negative findings	Page 20-22/432-487	Results/Table 1
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Page 20-22/432-487	Results/Table 1
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page 20-22/432-487	Results/Table 1
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	Page 20-22/432-487	Results/Table 1

DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	Page 23-29/504-655	Discussion
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page 23-29/504-655	Discussion
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page 23-29/504-655	Discussion
		• Discussion of research, programmatic, or policy implications	Page 23-29/504-655	Discussion
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	Page 23-29/504-655	Discussion
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page 23-29/504-655	Discussion

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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.