TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported? ✓	Reported? Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	Yes	2
		• Structured abstract recommended	Yes	2
		• Information on target population or study sample	Yes	2
Introduction				
Background	2	• Scientific background and explanation of rationale	Yes	4-6
		• Theories used in designing behavioral interventions	N.A	
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	yes	10
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Yes	9
		• Recruitment setting	Yes	9-10
		• Settings and locations where the data were collected	Yes	13-18
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		
		○ Content: what was given?	Yes	10-13
		○ Delivery method: how was the content given?	Yes	10-13
		○ Unit of delivery: how were the subjects grouped during delivery?	Yes	10-13
		○ Deliverer: who delivered the intervention?	Yes	10-13
		○ Setting: where was the intervention delivered?	Yes	13
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Yes	13
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	Yes	13
		○ Activities to increase compliance or adherence (e.g., incentives)	N.A.	
Objectives	5	• Specific objectives and hypotheses	Yes	6
Outcomes	6	• Clearly defined primary and secondary outcome measures	Yes	13-14, 18-23
		• Methods used to collect data and any methods used to enhance the quality of measurements	yes	13-14, 18-23
		• Information on validated instruments such as psychometric and biometric properties	Yes	18-23
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Yes	9
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Yes	9
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Yes	9
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	NA	

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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.	Yes	16,18,23
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	NA	
		• 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)	NA	
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Yes	15-16
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Yes	23-24
		• Methods for imputing missing data, if used	Yes	24
		• Statistical software or programs used	Yes	23-24
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)	Yes	Figure 1
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	Yes	Figure 1
		○ Assignment: the numbers of participants assigned to a study condition	Yes	Figure 1
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Yes	Figure 1
		○ 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	Yes	Figure 1
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	Yes	Figure 1
		• Description of protocol deviations from study as planned, along with reasons	Yes	9,12,40
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Yes	9-10
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Yes	27-28
		• Baseline characteristics for each study condition relevant to specific disease prevention research	NA	
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	NA	
		• Comparison between study population at baseline and target population of interest	NA	
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Yes	24

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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	Yes	24
		• Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	Yes	24
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	Yes	39-42
		• Inclusion of null and negative findings	Yes	40-42
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Yes	40-42
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)	Yes	29
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	Yes	42-50
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Yes	42-50
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Yes	42-50
		• Discussion of research, programmatic, or policy implications	Yes	42-50
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	Yes	51
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Yes	42-50

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