TREND Statement Checklist

Paper Section/ Topic	ltem 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	Page2/ Line 37-42	Abstract/Paragraph 1-4
		Structured abstract recommended	Page2/ Line 31-53	Abstract/Paragraph 1-4
		Information on target population or study sample	Page Line 37	Abstract/Paragraph 1-4
Introduction				
Background	2	Scientific background and explanation of rationale	Page4/ Line 74-101	Introduction/Paragraph1-2
		Theories used in designing behavioral interventions	Page 4/Line 97-101	Introduction/Paragraph2
Methods			-	
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 5/Line 107-112	Methods/Paragraph1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page5/ Line 107-112	Methods/Paragraph1-2
		Recruitment setting	Page5/ Line 107-127	Methods/Paragraph1-2
		Settings and locations where the data were collected	Page5/ Line 107-127	Methods/Paragraph1-2
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page5-6/ Line 128-137	Intervention/Paragraph1
		o Content: what was given?	Page5/ Line 129	Intervention/Paragraph1
		o Delivery method: how was the content given?	Page6/ Line 130-135	Intervention/Paragraph1
		o Unit of delivery: how were the subjects grouped during delivery?	Page5-6/ Line 129-130	Intervention/Paragraph1
		o Deliverer: who delivered the intervention?	Page5-6/ Line 129-137	Intervention/Paragraph1
		o Setting: where was the intervention delivered?	Page5-6/ Line 129-137	Intervention/Paragraph1
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page 5-6Line 129-137	Intervention/Paragraph1

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page5-6/ Line 128-137	Intervention/Paragraph1
		o Activities to increase compliance or adherence (e.g., incentives)	Page5-6/ Line 128-137	Intervention/Paragraph1
Objectives	5	Specific objectives and hypotheses	Page Line5/ 102-104	Objective/Paragraph1
Outcomes	6	Clearly defined primary and secondary outcome measures	Page6/ Line 138-149	Outcomes/Paragraph1
		Methods used to collect data and any methods used to enhance the quality of measurements	Page6/ Line 138-149	Outcomes/Paragraph1
		Information on validated instruments such as psychometric and biometric properties	Page6/ Line 138-149	Outcomes/Paragraph1
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	NA	NA
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page5/ Line 107	Methods/Paragraph1
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page5/ Line 107-112	Methods/Paragraph1
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page5/ Line 107-112	Methods/Paragraph1
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.	Page5/ Line 107	Methods/Paragraph1
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page6/ Line 139-149	Outcomes/Paragraph1
		• 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)	Page6/ Line 139-149	Outcomes/Paragraph1
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page6/ Line 150-157	Methods/ Paragraph 2.4
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page6/ Line 150-157	Methods/ Paragraph 2.4
		Methods for imputing missing data, if used	Page6/ Line 150-157	Methods/ Paragraph 2.4
		Statistical software or programs used	Page6/ Line 150-157	Methods/ Paragraph 2.4
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)	Page6-7/Line 158-161	Results/ Figure 1. Flowchart
		o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	Page6-7/ Line 159-165	Results/Paragraph1

		o Assignment: the numbers of participants assigned to a study condition	Page6-7 Line 158-165	Results/Paragraph1
		 Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 	Page6-7/ Line 158-165	Results/Paragraph1
		o 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	Page6-7/ Line 158-165	Results/Paragraph1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page6-7/ Line 158-165	Results/Paragraph1
		Description of protocol deviations from study as planned, along with reasons	Page6-7/ Line 158-165	Results/Paragraph1
Recruitment	13	Dates defining the periods of recruitment and follow-up	Page6-7/ Line 158-165	Results/Paragraph1
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	Page6-7/ Line 158-165	Results/Table.1-2
		Baseline characteristics for each study condition relevant to specific disease prevention research	Page6-7/ Line 158-165	Results/Table.1-2
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page6-7/ Line 158-165	Results/Table.1-2
		Comparison between study population at baseline and target population of interest	Page6-7/ Line 158-165	Results/Table.1-2
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page6-7/ Line 158-165	Results/Paragraph1
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	Page6-7/ Line 158-165	Results/Paragraph1
		Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	Page6-7/ Line 158-165	Results/Paragraph1
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	Page7/ Line 166-181	Results/Figure.2-3 Table.3
		Inclusion of null and negative findings	Page7/ Line 166-181	Results/Paragraph2-4
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	NA
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre- specified or exploratory	NA	NA
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)	Page7/ Line 182-184	Results/Paragraph5
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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 	Page7-8/ Line 186-208	Discussion/ Paragraph 4.1
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page9/ Line 209-217	Discussion/ Paragraph 4.2
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page9-10/ Line 228-274	Discussion/ Paragraph4.4
		Discussion of research, programmatic, or policy implications	Page7-8/ Line 186-208	Discussion/ Paragraph4.1
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	Page10-11/ Line 275-280	Discussion/ Paragraph4.5
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	Page11 Line 281-287	Conclusions/ Paragraph1

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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.