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 1/line19-24	Abstract
		• Structured abstract recommended	Page 1/line15-32	Abstract
		• Information on target population or study sample	Page 1/line25-30	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 2/line35-46	Introduction
		• Theories used in designing behavioral interventions	Page 2/line47-62	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 3/line73-79	Patients selection
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 3/line73-79	Patients selection
		• Recruitment setting	Page 3/line73-79	Patients selection
		• Settings and locations where the data were collected	Page 3/line73-79	Patients selection
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 3/line64-146	Materials and Methods
		o Content: what was given?	Page 4/line109-137	Materials and Methods
		o Delivery method: how was the content given?	Page 4/line117-125	Materials and Methods
		o Unit of delivery: how were the subjects grouped during delivery?	Page 4/line110-116	Materials and Methods
		o Deliverer: who delivered the intervention?	Page 4/line110-116	Materials and Methods
		o Setting: where was the intervention delivered?	Page 4/line110-116	Materials and Methods
		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 4/line117-137	Materials and Methods

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 4/line109-137	Materials and Methods
		o Activities to increase compliance or adherence (e.g., incentives)	-	-
Objectives	5	• Specific objectives and hypotheses	Page 1/line15-18	Abstract
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 5/line147-216	Results
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 3/line64-146	Materials and Methods
		• Information on validated instruments such as psychometric and biometric properties	-	-
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 6/line162-164	Results
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 1/line4-7	Title and abstract
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 5/line138-146	Statistical analysis
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page 5/line138-146	Statistical analysis
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.	Page 3/line76-78	Patients selection
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page 6/line164-169	Results
		• 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)	Page 5/line137-145	Statistical analysis
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page 5/line138-146	Statistical analysis
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page 5/line138-146	Statistical analysis
		• Methods for imputing missing data, if used	-	-
		• Statistical software or programs used	Page 5/line144-146	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 5/line147-216	Results
		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	Page 5/line148-153	Results

		o Assignment: the numbers of participants assigned to a study condition	Page 5/line148-153	Results
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page 6/line162-164	Results
		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	Page 6/line178-184	Results
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page 6/line178-184	Results
		• Description of protocol deviations from study as planned, along with reasons	-	-
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 5/line149-176	Results
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page 7/line184-185	Results
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page 6/line177-185	Results
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page 6/line177-185	Results
		• Comparison between study population at baseline and target population of interest	Page 6/line177-185	Results
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page 5/line138-146	Statistical analysis
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 6/line177-185	Results
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Page 5/line138-146	Statistical analysis
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 7/line199-216	Results
		• Inclusion of null and negative findings	-	-
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Page 7/line186-198	Results
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page 7/line186-198	Results
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)	-	-

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 8/line218-233	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 9/line234-246	Discussion
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page 9/line247-260	Discussion
		• Discussion of research, programmatic, or policy implications	Page 10/line261-264	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 9/line217-264	Discussion
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page 10/line261-264	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.