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	Page2/Line6-8	Abstract/Paragraph2
		• Structured abstract recommended	Page1-2/Line31-34,1-24	Abstract/Paragraph1-4
		• Information on target population or study sample	Page2/Line3-6	Abstract/Paragraph2
Introduction				
Background	2	• Scientific background and explanation of rationale	Page3/Line4-8	Introduction/Paragraph1
		• Theories used in designing behavioral interventions	Page3/Line20-24	Introduction/Paragraph2
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page4/Line13-24	Patients/Paragraph1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page4/Line13-27	Patients/Paragraph1-2
		• Recruitment setting	Page4/Line19-24	Patients/Paragraph1
		• Settings and locations where the data were collected	Page4/Line13-19	Patients/Paragraph1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page5/Line2-9	Study design/Paragrap1
		o Content: what was given?	Page5/Line2-9	Study design/Paragrap1
		o Delivery method: how was the content given?	Page5/Line2-9	Study design/Paragrap1
		o Unit of delivery: how were the subjects grouped during delivery?	Page5/Line2-9	Study design/Paragrap1
		o Deliverer: who delivered the intervention?	Page5/Line2-9	Study design/Paragrap1
		o Setting: where was the intervention delivered?	Page5/Line2-9	Study design/Paragrap1
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page5/Line2-9	Study design/Paragrap1

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page5/Line10-12	Study design/Paragrap2
		o Activities to increase compliance or adherence (e.g., incentives)	NA	NA
Objectives	5	• Specific objectives and hypotheses	NA	NA
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page5/Line7-31	Studydesign/Paragraph2-5
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page5/Line10-12,22-23	Studydesign/Paragraph3-4
		• Information on validated instruments such as psychometric and biometric properties	Page5/Line28-29	Studydesign/Paragraph4-5
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page4/Line18-24	Patients/Paragraph1
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page4/Line13-15	Patients/Paragraph1
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page5/Line2-6	Study design/Paragraph1
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page5/Line2-6	Study design/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.	NA	NA
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page6/Line1-2	Statistical analysis/ 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)	NA	NA
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page6/Line6-8	Statistical analysis/ Paragraph1
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page6/Line1-9	Statistical/Paragraph1
		• Methods for imputing missing data, if used	NA	NA
		• Statistical software or programs used	Page6/Line8-9	Statistical/Paragraph1
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/Line27-31	Results/Paragraph2
		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/Line14-16	Results/Paragraph1

		o Assignment: the numbers of participants assigned to a study condition	Page6/Line18-26	Results/Paragraph1
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page6/Line27-29	Results/Paragraph2
		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/Line29-31	Results/Paragraph2
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page6/Line23-26	Results/Paragraph1
		• Description of protocol deviations from study as planned, along with reasons	NA	NA
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page4/Line18	Methods/Paragraph1
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page6/Line14-16	Results/Paragraph1
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page7/Line8-11	Safety/Paragraph1
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	NA	NA
		• Comparison between study population at baseline and target population of interest	NA	NA
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	NA	NA
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	Page7/Line1-4	Tumor response and survival/Paragraph1
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Page7/Line1-4	Tumor response and survival/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/Line20-30	HRQOL/Paragraph1
		• Inclusion of null and negative findings	Page7/Line20-30	HRQOL/Paragraph1
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Page7/Line20-30	HRQOL/Paragraph1
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page7/Line12-16	Safety/Paragraph2
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/Line8-16	Safety/Paragraph1-2

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	Page8/Line17-21	Discussion/Paragraph3
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page8/Line32-34	Discussion/Paragraph4
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page9/Line21-23	Discussion/Paragraph5
		• Discussion of research, programmatic, or policy implications	Page8/Line12-16	Discussion/Paragraph2
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/Line3-10	Discussion/Paragraph7
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page10/Line11-17	Discussion/Paragraph8

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copy editing and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.