TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported on page No	JPP Reviewer Comments	Author Responses
Title and Abstract					
	1a	Information on how units were allocated to interventions	2		
	1b	Structured abstract recommended	2		
	1c	Information on target population or study sample	2		
Introduction Background and objectives	2a	Scientific background and explanation of rationale	3-7		
	2b	Theories used in designing behavioral interventions	4-6		
Methods Participants	3a	Eligibility criteria for participants, including criteria at different levels in recruitment/ sampling plan (e.g., cities, clinics, subjects)	8		
	3b	Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	8		
	3c	Recruitment setting	8		
	3d	Settings and locations where the data were collected	8		
Interventions	4a	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: • Content: what was given?	Fig 1 ; Pg 9		
	4b	• Delivery method: how was the content given?	Fig 1 ; Pgs 9-10		
	4c	• Unit of delivery: how were the subjects grouped during delivery?	Fig 1 ; Pgs 9-10		
	4d	• Deliverer: who delivered the intervention?	9		
	4e	• Setting: where was the intervention delivered?	9		
	4f	• Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Fig 1 ; Pg 9		

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	4g	• Time span: how long was it intended to take to deliver the intervention to each unit?	9		
	4h	• Activities to increase compliance or adherence (e.g., incentives)	9		
Objectives	5	Specific objectives and hypotheses	7		
Outcomes	6a	Clearly defined primary and secondary outcome measures	7-8		
	6b	Methods used to collect data and any methods used to enhance the quality of measurements	9-10		
	6c	Information on validated instruments such as psychometric and biometric properties	11-13		
Sample size	7a	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	9-10 ; 13		
Assignment method	8a	Unit of assignment (the unit being assigned to study condition – e.g., individual, group, community)	9		
	8b	Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Fig 1 ; Pgs. 9-10		
	8c	Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	12		
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	12		
Unit of analysis	10a	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	13		
	10b	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)	13		

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Statistical methods	11a	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	13-14		
	11b	Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	13-14		
	11c	Methods for imputing missing data, if used	16		
	11d	Statistical software or programs used	14		
Results Participant flow	12a	Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended) • Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	Fig 2; Pg 14		
	12b	• Assignment: the numbers of participants assigned to a study condition	Fig 2; Pgs 15-16		
	12c	• Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Fig 2; Pgs 15-16		
	12d	• 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	Fig 2; Pg 16		
	12e	• Analysis: the number of participants included in or excluded from the main analysis, by study condition	Fig 2; Pgs 15-16		
	12f	Description of protocol deviations from study as planned, along with reasons	Fig 2 (footnote)		
Recruitment	13	Dates defining the periods of recruitment and follow-up	14		

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Baseline data	14a	Baseline demographic and clinical characteristics of participants in each study condition	14 ; Table 1		
	14b	Baseline characteristics for each study condition relevant to specific disease prevention research	14 ; Table 1		
	14c	Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Table 1		
	14d	Comparison between study population at baseline and target population of interest	14 ; Table 2		
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	14-15		
Numbers analyzed	16a	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	Fig 2 ; 15-16		
	16b	Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	Fig 2 ; 15-16		
Outcomes and estimation	17a	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	Figs 3&4 Pgs 14-20		
	17b	Inclusion of null and negative findings	19		
	17c	Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Fig 3 ; Pg 19		
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	16		
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)	9		

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Discussion					
Interpretation	20a	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	20-22		
	20b	Discussion of the results taking into account the mechanisms by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	20-22		
	20c	Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	22-23		
	20d	Discussion of research, programmatic, or policy implications	24-25		
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	23-24		
Overall evidence	22	General interpretation of the results in the context of current evidence and current theory	24-25		