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	✓	Abstract
		Structured abstract recommended	✓	Abstract
		Information on target population or study sample	✓	Abstract
Introduction				
Background	2	Scientific background and explanation of rationale	✓	Introduction
		Theories used in designing behavioral interventions	✓	Introduction
Methods				
Participants	3	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	Methods-Patient selection criteria
		Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	Methods-Patient selection criteria
		Recruitment setting	✓	Methods-Patient selection criteria
		Settings and locations where the data were collected	✓	Methods-Patient selection criteria
Interventions	4	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	Methods-Study design
		o Content: what was given?	✓	Methods-Study design
		o Delivery method: how was the content given?	✓	Methods-Study design
		o Unit of delivery: how were the subjects grouped during delivery?	✓	Methods-Study design
		o Deliverer: who delivered the intervention?	✓	Methods-Study design
		o Setting: where was the intervention delivered?	✓	Methods-Study design
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	Methods-Study design
		o Time span: how long was it intended to take to deliver the intervention to each unit?	✓	Methods-Study design
		o Activities to increase compliance or adherence (e.g., incentives)	✓	Methods-Study design
Objectives	5	Specific objectives and hypotheses	✓	Methods-Outcome
Outcomes	6	Clearly defined primary and secondary outcome measures	✓	Methods-Outcome
		Methods used to collect data and any methods used to enhance the quality of measurements	✓	Methods-Outcome
		Information on validated instruments such as psychometric and biometric properties	✓	Methods-Outcome
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	✓	Methods-Statistical Analysis
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✓	Methods-Study design
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	✓	Methods-Study design
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	✓	Methods-Study design

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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.	✓	Methods-Study design
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✓	Methods-Pharmacokinetic Analysis
		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)	✓	Methods-Pharmacokinetic Analysis
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	✓	Methods-Statistical Analysis
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	✓	Methods-Statistical Analysis
		Methods for imputing missing data, if used	✓	Methods-Statistical Analysis
		Statistical software or programs used	✓	Methods-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)	✓	Results + Fig. 1
		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	✓	Results + Fig. 1
		o Assignment: the numbers of participants assigned to a study condition	✓	Results + Fig. 1
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	✓	Results + Fig. 1
		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	✓	Results + Fig. 1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	✓	Results + Fig. 1
		Description of protocol deviations from study as planned, along with reasons	✓	Results + Fig. 1
Recruitment	13	Dates defining the periods of recruitment and follow-up	✓	Results-Patient population
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	✓	Results-Patient population + Table 1
		Baseline characteristics for each study condition relevant to specific disease prevention research	✓	Results-Patient population + Table 1
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	✓	Results-Patient population + Table 1
		Comparison between study population at baseline and target population of interest	✓	Results-Patient population + Table 1
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	✓	Results-Patient population + Table 1

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

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