TREND Statement Checklist

Paper Section/ Topic	Item	Descriptor	Reported?	
	No		\checkmark	section
Title and Abst	ract			
Title and	1	Information on how unit were allocated to interventions	×	Abstract
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	×	Method
·		in recruitment/sampling plan (e.g., cities, clinics, subjects)		
		Method of recruitment (e.g., referral, self-selection), including the	×	Method
		sampling method if a systematic sampling plan was implemented		
		Recruitment setting	×	Method
		Settings and locations where the data were collected	×	Method
Interventions	4	Details of the interventions intended for each study condition and		
		how and when they were actually administered, specifically including:		
		o Content: what was given?	×	Method
		o Delivery method: how was the content given?	×	Method
		 Unit of delivery: how were the subjects grouped during delivery? 	N/A	
		o Deliverer: who delivered the intervention?	×	Method
		o Setting: where was the intervention delivered?	×	Method
		o Exposure quantity and duration: how many sessions or	×	Method
		episodes or events were intended to be delivered? How long were they intended to last?		
		o Time span: how long was it intended to take to deliver the intervention to each unit?	×	Method
		 Activities to increase compliance or adherence (e.g., incentives) 	N/A	
Objectives	5	Specific objectives and hypotheses	×	Method
Outcomes	6	Clearly defined primary and secondary outcome measures	×	Introduction
		 Methods used to collect data and any methods used to enhance the quality of measurements 	×	Method
		 Information on validated instruments such as psychometric and biometric properties 	×	Method
Sample Size	7	 How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules 	×	Method
Assignment Method	8	 Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) 	N/A	
		 Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) 	N/A	
		 Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) 	N/A	

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

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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 	N/A	
		 Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the 	N/A	
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 	×	Table
		Inclusion of null and negative findings	N/A	
		 Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	N/A	
Ancillary analyses	18	 Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	N/A	
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
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 	N/A	
		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

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <u>http://www.cdc.gov/trendstatement/</u>