TREND Statement Checklist

Paper Section/ Topic	ltem 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/Line4-5	Abstract/Paragraph1
		Structured abstract recommended	Page2/Line2-19	Abstract/Paragraph1-4
		Information on target population or study sample	Page2/Line6-7	Abstract/Paragraph2
Introduction				
Background	2	Scientific background and explanation of rationale	Page3/Line22-27	4
		Theories used in designing behavioral interventions	Page3/Line27-30	4
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page4/Line7-9	Methods/Paragraph2
		Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page4/Line1-3	Methods/Paragraph1
		Recruitment setting	Page4/Line4-5	Methods/Paragraph1
		Settings and locations where the data were collected	Page4/Line1-2	Methods/Paragraph1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page5/Line6-23	Methods/Paragraph6-8
		o Content: what was given?	Page4/Line17-21	Methods/Paragraph3
		o Delivery method: how was the content given?	Page5/Line1-4	Methods/Paragraph4
		o Unit of delivery: how were the subjects grouped during delivery?	Page4/Line6-8	Methods/Paragraph5
		o Deliverer: who delivered the intervention?	Page4/Line16-17	Methods/Paragraph6
		o Setting: where was the intervention delivered?	Page4/Line17-21	Methods/Paragraph3
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page4/Line17-21	Methods/Paragraph3

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page4/Line1-2	Methods/Paragraph1
		o Activities to increase compliance or adherence (e.g., incentives)	Page4/Line29-Page5/Lin	Methods/Paragraph5
Objectives	5	Specific objectives and hypotheses	Page6/Line3-6	Methods/Paragraph11
Outcomes	6	Clearly defined primary and secondary outcome measures	Page5/Line14-16	Methods/Paragraph7
		Methods used to collect data and any methods used to enhance the quality of measurements	Page6/Line9-11	Methods/Paragraph12
		Information on validated instruments such as psychometric and biometric properties	Page4/Line3-5	Methods/Paragraph1
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page4/Line1	Methods/Paragraph1
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page5/Line6-9	Methods/Paragraph6
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page5/Line20-23	Methods/Paragraph6
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page5/Line16-17	Methods/Paragraph7
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.	Page5/Line1-4	Methods/Paragraph5
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page5/Line26-Page6/Lin e2	Methods/Paragraph10
		• 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)	Page5/Line9-11	Methods/Paragraph6
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page6/Line9	Statistical analysis/Paragraph1
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page6/Line9	analysis/Paragraph1
		Methods for imputing missing data, if used	Page6/Line10	analysis/Paragraph1
		Statistical software or programs used	Page6/Line8	analysis/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/Line19-23	Results/Paragraph1
		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/Line19-23	Results/Paragraph1

		o Assignment: the numbers of participants assigned to a study condition	Page6/Line19-23	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/Line19-23	Results/Paragraph1
		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/Line19-23	Results/Paragraph1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page6/Line19-23	Results/Paragraph1
		Description of protocol deviations from study as planned, along with reasons	Page6/Line25-26	Results/Paragraph2
Recruitment	13	Dates defining the periods of recruitment and follow-up	Page6/Line25	Results/Paragraph2
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	Page6/Line21-23	Results/Paragraph2
		Baseline characteristics for each study condition relevant to specific disease prevention research	Page6/Line14-16	Results/Paragraph1
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page7/Line4-7	Results/Paragraph3
		Comparison between study population at baseline and target population of interest	Page6/Line24-27	Results/Paragraph2
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page6/Line16-18	Results/Paragraph1
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/Line2-4	Results/Paragraph3
		Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	Page7/Line4-6	Results/Paragraph3
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	Table1-5	Table1-5
		Inclusion of null and negative findings	Page6/Line23-26	Results/Paragraph2
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Page6/Line22-23	Results/Paragraph2
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre- specified or exploratory	Page7/Line13-15	Results/Paragraph4
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/Line13-15	Results/Paragraph4
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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	Page9/Line33-Page10/Li ne3	Discussion/Paragraph9	
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page9/Line14-16	Discussion/Paragraph5	
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page8/Line4-8	Discussion/Paragraph9	
		Discussion of research, programmatic, or policy implications	Page10/Line2-3	Discussion/Paragraph8	
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	Page8/Line11-14	Discussion/Paragraph5	
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	Page10/Line14-15	Conclusions/Paragraph1	

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: http://www.cdc.gov/trendstatement/

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