## **TREND Statement Checklist**

Paper Section/ Topic	Item	Descriptor	Reported?	
	No		$\checkmark$	Pg#
Title and Abst	ract			
Title and	1	Information on how unit were allocated to interventions	Yes	Abstract
Abstract		Structured abstract recommended	Yes	Abstract
		Information on target population or study sample	Yes	Abstract
Introduction				
Background	2	Scientific background and explanation of rationale	Yes	Intro
		Theories used in designing behavioral interventions	Yes	Intro
Methods				
Participants	3	Eligibility criteria for participants, including criteria at different levels in	Vaa	Mathada
		recruitment/sampling plan (e.g., cities, clinics, subjects)	Yes	Methods
		Method of recruitment (e.g., referral, self-selection), including the	Yes	Methods
		sampling method if a systematic sampling plan was implemented		
		Recruitment setting	Yes	Methods
		Settings and locations where the data were collected	Yes	Methods
Interventions	4	Details of the interventions intended for each study condition and how		
		and when they were actually administered, specifically including:		
		Content: what was given?	Yes	Methods
		Delivery method: how was the content given?	Yes	Methods
		O Unit of delivery: how were the subjects grouped during delivery?	Yes	Methods
		Deliverer: who delivered the intervention?	Yes	Methods
		Setting: where was the intervention delivered?	Yes	Methods
		<ul> <li>Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?</li> </ul>	N/A	
		<ul> <li>Time span: how long was it intended to take to deliver the intervention to each unit?</li> </ul>	Yes	Methods
		<ul> <li>Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	N/A	
Objectives	5	Specific objectives and hypotheses	Yes	Methods
Outcomes	6	Clearly defined primary and secondary outcome measures	Yes	Methods
		<ul> <li>Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	Yes	Methods
		<ul> <li>Information on validated instruments such as psychometric and biometric properties</li> </ul>	Yes	Methods
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Yes	Methods
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	N/A	
		<ul> <li>Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)</li> </ul>	N/A	
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	N/A	

## **TREND Statement Checklist**

Blinding	9	Whether or not participants, those administering the interventions, and		
(masking)		those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.	Yes	Methods
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Yes	Methods
		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)	N/A	
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Yes	Methods
		<ul> <li>Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis</li> </ul>	Yes	Methods
		Methods for imputing missing data, if used	Yes	Methods
		Statistical software or programs used	Yes	Methods
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)		
		<ul> <li>Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study</li> </ul>	Yes	Results
		<ul> <li>Assignment: the numbers of participants assigned to a study condition</li> </ul>	Yes	Results
		<ul> <li>Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention</li> </ul>	Yes	Results
		<ul> <li>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</li> </ul>	Yes	Results
		<ul> <li>Analysis: the number of participants included in or excluded from the main analysis, by study condition</li> </ul>	Yes	Results
		<ul> <li>Description of protocol deviations from study as planned, along with reasons</li> </ul>	N/A	
Recruitment	13	Dates defining the periods of recruitment and follow-up	Yes	Results
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	Yes	Results
		Baseline characteristics for each study condition relevant to specific disease prevention research	Yes	Results
		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	<ul> <li>Data on study group equivalence at baseline and statistical methods used to control for baseline differences</li> </ul>	N/A	

## **TREND Statement Checklist**

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	Yes	Results
		<ul> <li>Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses</li> </ul>	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	Yes	Results
		Inclusion of null and negative findings	Yes	Results
		<ul> <li>Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any</li> </ul>	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)	Yes	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	Yes	Discuss
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Yes	Discuss
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Yes	Discuss
		Discussion of research, programmatic, or policy implications	Yes	Discuss
Generalizability	21	<ul> <li>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</li> </ul>	Yes	Discuss
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	Yes	Discuss

*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: <a href="http://www.cdc.gov/trendstatement/">http://www.cdc.gov/trendstatement/</a>