TREND Statement Checklist

Paper Section/ Topic	Item 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	Page 1/Line 8-14	Title/Para 2 (Affiliation)
		• Structured abstract recommended	Page 2/Line 32-51	Abstract/Para 1-4
		• Information on target population or study sample	Page 2 /Line 36-40	Abstract/Para 3
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 4,5/ Line 81-113	Introduction/Para 1
		• Theories used in designing behavioral interventions	Page 5,6/Line 115-128	Introduction/Para 1
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 6/ Line 139-147	Methods/Para 1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 6/Line 134-141	Methods/Para 1
		• Recruitment setting	Page 6 /Line 134-141	Methods/Para 1
		• Settings and locations where the data were collected	Page 6/ Line 134-137	Methods/Para 1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 6-9	Methods/Para1-5
		o Content: what was given?	Page 8/ Line 183-200	Methods/Para 3
		o Delivery method: how was the content given?	Page 7/ Line 149-155	Methods/ Para 1
		o Unit of delivery: how were the subjects grouped during delivery?	Page 6 /Line 134-141	Methods/ Para 1
		o Deliverer: who delivered the intervention?	Page 8/Line 198-200	Methods/Para 1
		o Setting: where was the intervention delivered?	Page 6/ Line 134-137	Methods/Para 1
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page 7/ Line:149-155	Methods/Para 1

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 7/ Line 150-155	Methods/Para 1 and
		o Activities to increase compliance or adherence (e.g., incentives)	NA	NA
Objectives	5	• Specific objectives and hypotheses	Page 6/ Line 125-128	Introduction/Para 1
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 9/ Line 201-218	Methods/Para 4
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 7/ Line 157-167	Methods/Para 1
		• Information on validated instruments such as psychometric and biometric properties	Page 9/ Line 210-213	Methods/Para 4
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 17/ Line 380-382	Discussion/Para 1
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 6 / Line 134	Methods/Para 1
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 6 / Line 134	Methods/Para 1
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page 6/ Line 221-235	Methods/Para 5
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.	Page 5 / Line 125	Introduction/Para 1
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page 9,10/ Line 221-235	Methods/Para 5
		• 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)	Page 10/Line 240-248	Results/Para 1
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page 6/ Line 221-235	Methods//Para 5
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page 6/ Line 221-235	Methods/Para 5
		• Methods for imputing missing data, if used	NA	NA
		• Statistical software or programs used	Page 10/Line 234-235	Methods/Para 5
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)	Page10/Line240-248	Results/Para 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	Page10/Line240-248	Results/Para 1

		o Assignment: the numbers of participants assigned to a study condition	Page10/Line240-248	Results/Para 1
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page10/Line240-248	Results/Para 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	Page10/Line240-248	Results/Para 1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page10/Line240-248	Results/Para 1
		• Description of protocol deviations from study as planned, along with reasons	Page10/line 243	Results/Para 1
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 6/ Line 139-141	Methods/Para 1
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page 11/ Line 249-254	Results/Para 1
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page 12/ Line 256-269	Results/Para 2
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page 13/ Line 272-298	Results/Para 3
		• Comparison between study population at baseline and target population of interest	Page14 /Line 301-311	Results/Para 4
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page 6/ Line 221-235	Methods/Para 5
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	Page 10/ Line 240-248	Results/Para 1
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Page 10/ Line 240-248	Results/Para 1
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	Page12-14/ Line 272-311	Results/Para 3
		• Inclusion of null and negative findings	NA	NA
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	NA
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page12-13/ Line 301-311	Results/Para 4
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)	Page 12,13/ Line 272-298	Results/Para 3

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	Page 14-17/ Line 314-388	Discussion/Para 1-2
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page 15/ Line 334-348	Discussion/Para 1
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page 17/Line 380-388	Discussion/Para 1
		• Discussion of research, programmatic, or policy implications	Page 15/ Line 350-361	Discussion/Para 1
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	Page 16/ Line 363-377	Discussion/Para 1
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page 17/392-395	Conclusion/Para 1

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/

Article Information: http://dx.doi.org/10.21037/tcr-22-1203
*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.