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	P2, L34-36	Abstract
		• Structured abstract recommended	P2-3, L23-50	Abstract
		• Information on target population or study sample	P2, L28-29	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	P4, L53-61	Introduction
		• Theories used in designing behavioral interventions	P4, L62-71	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	L5, L74-79	Methods-Patients
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	L5, L74-79	Methods-Patients
		• Recruitment setting	L5, L74-79	Methods-Patients
		• Settings and locations where the data were collected	L5, L74-79	Methods-Patients
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?	P5 L90-P6 L115	Surgical technique
		o Delivery method: how was the content given?	P5 L90-P6 L115	Surgical technique
		o Unit of delivery: how were the subjects grouped during delivery?	P8 L141-143	Statistical analyses
		o Deliverer: who delivered the intervention?	P5 L90-P6 L115	Surgical technique
		o Setting: where was the intervention delivered?	P5 L90-92	Surgical technique
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	P6 L116-P7 L134	Data collection and follow-up study

		o Time span: how long was it intended to take to deliver the intervention to each unit?	P6 L116-P7 L134	Data collection and
		o Activities to increase compliance or adherence (e.g., incentives)	N/A	N/A
Objectives	5	• Specific objectives and hypotheses	P4 L68-71	Introduction
Outcomes	6	• Clearly defined primary and secondary outcome measures	P6 L117-P7 L134	Data collection and
		• Methods used to collect data and any methods used to enhance the quality of measurements	P6 L117-P7 L134	Data collection and
		• Information on validated instruments such as psychometric and biometric properties	P6 L111-115	Surgical technique
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	P5 L74-77	Methods-Patients
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	P8, L141-143	Statistical analyses
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	P8, L141-143	Statistical analyses
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	P8 L143-145	Statistical analyses
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	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)	P5 L74-88	Methods-Patients
		• 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	N/A
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	P7, L138-P8, L149	Statistical analyses
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	P7, L138-P8, L149	Statistical analyses
		• Methods for imputing missing data, if used	N/A	N/A
		• Statistical software or programs used	P7, Line138-139	Statistical analyses
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)		
		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	P5,L74-79	Methods-Patients

		o Assignment: the numbers of participants assigned to a study condition	P5,L74-79	Methods-Patients
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	P8, L143	Statistical analyses
		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	P10, L185-187	Results
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	N/A	N/A
		• Description of protocol deviations from study as planned, along with reasons	P8, L143-145	Statistical analyses
Recruitment	13	• Dates defining the periods of recruitment and follow-up	P7,L128-134	Methods-Patients
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	P8, L151-158	Baseline characteristics
		• Baseline characteristics for each study condition relevant to specific disease prevention research	P8, L151-158	Baseline characteristics
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	P8, L151-158	Baseline characteristics
		• Comparison between study population at baseline and target population of interest	P8, L151-158	Baseline characteristics
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	P8, L151-158	Baseline characteristics
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	N/A
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	P9, L166-P10, L207	Results
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	P9, L166-P10, L207	Results
		• Inclusion of null and negative findings	P9, L166-P10, L207	Results
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	N/A	N/A
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	P10, L184-P11, L207	Results
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)	P9, L166-P11, L207	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	P14, L283-286	Limitations
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	L13, L253-270	Discussion
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	P11, L216-224	Discussion
		• Discussion of research, programmatic, or policy implications	P13, L271-P14, L282	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	P12 L236-249	Discussion
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	P14 L287-P15, L298	Conclusion

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/jtd-20-3479
*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.