

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 2, Line 4-7	Abstract
		• Structured abstract recommended	Page 2, Line 2-19	Abstract
		• Information on target population or study sample	Page 2, Line 4-7	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 3, Line 24-38	Introduction
		• Theories used in designing behavioral interventions	Page 3, Line 39-50	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 3, Line 60-72	Subjects
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 3, Line 68-72	Subjects
		• Recruitment setting	Page 3, Line 68-72	Subjects
		• Settings and locations where the data were collected	Page 3, Line 60-72	Subjects
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 4, Line 96-119	Surgical Technique
		o Content: what was given?	Page 4, Line 96-119	Surgical Technique
		o Delivery method: how was the content given?	Page 4, Line 96-119	Surgical Technique
		o Unit of delivery: how were the subjects grouped during delivery?	Page 4, Line 96-119	Surgical Technique
		o Deliverer: who delivered the intervention?	Page 4, Line 96-119	Surgical Technique
		o Setting: where was the intervention delivered?	Page 3, Line 60-72	Subjects
		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 4, Line 96-119	Surgical Technique

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 4, Line 96-119	Surgical Technique
		o Activities to increase compliance or adherence (e.g., incentives)	Page 4, Line 96-119	Surgical Technique
Objectives	5	• Specific objectives and hypotheses	Page 3, Line 60-72	Subjects
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 4, Line 87-94	Outcome Measurements
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 4, Line 87-94	Outcome Measurements
		• Information on validated instruments such as psychometric and biometric properties	Page 4, Line 87-94	Outcome Measurements
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 3, Line 60-72	Subjects
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 3, Line 60-72	Subjects
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 4, Line 74-85	Preoperative Examination
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page 3, Line 60-72	Subjects
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 due to the study design (nonrandomized comparative cohort study)	
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Page 4, Line 87-94	Outcome Measurements
		• 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	Page 4-5, Line 121-129	Statistical analysis
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page 4-5, Line 121-129	Statistical analysis
		• Methods for imputing missing data, if used	Page 4-5, Line 121-129	Statistical analysis
		• Statistical software or programs used	Page 4-5, Line 121-129	Statistical analysis
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)	Page 3, Line 60-72 / Page 4, Line 96-119	Subjects / Surgical Technique
		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	Page 3, Line 60-72	Subjects

		<ul style="list-style-type: none"> o Assignment: the numbers of participants assigned to a study condition 	Page 3, Line 60-72	Subjects
		<ul style="list-style-type: none"> o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 	Page 4, Line 96-119	Surgical Technique
		<ul style="list-style-type: none"> 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 	Page 5, Line 133-136	Results
		<ul style="list-style-type: none"> o Analysis: the number of participants included in or excluded from the main analysis, by study condition 	Page 5, Line 133-136	Results
		<ul style="list-style-type: none"> • Description of protocol deviations from study as planned, along with reasons 	Page 5, Line 133-136	Results
Recruitment	13	<ul style="list-style-type: none"> • Dates defining the periods of recruitment and follow-up 	Page 4, Line 87-94	Outcome Measurements
Baseline Data	14	<ul style="list-style-type: none"> • Baseline demographic and clinical characteristics of participants in each study condition 	Page 5, Line 133-136	Results
		<ul style="list-style-type: none"> • Baseline characteristics for each study condition relevant to specific disease prevention research 	Page 5, Line 133-136	Results
		<ul style="list-style-type: none"> • Baseline comparisons of those lost to follow-up and those retained, overall and by study condition 	Page 5, Line 133-136	Results
		<ul style="list-style-type: none"> • Comparison between study population at baseline and target population of interest 	Page 5, Line 133-136	Results
Baseline equivalence	15	<ul style="list-style-type: none"> • Data on study group equivalence at baseline and statistical methods used to control for baseline differences 	Page 5, Line 133-136	Results
Numbers analyzed	16	<ul style="list-style-type: none"> • 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 3, Line 60-72	Subjects
		<ul style="list-style-type: none"> • Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses 	Page 4, Line 96-119	Surgical Technique
Outcomes and estimation	17	<ul style="list-style-type: none"> • 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 	Page 5, Line 137-154	Results
		<ul style="list-style-type: none"> • Inclusion of null and negative findings 	Page 5, Line 137-154	Results
		<ul style="list-style-type: none"> • Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	Page 5, Line 137-154	Results
Ancillary analyses	18	<ul style="list-style-type: none"> • Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	Page 5, Line 137-154	Results
Adverse events	19	<ul style="list-style-type: none"> • Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	Page 5, Line 133-136	Results

DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> • 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 5, Line 158-163	Discussion
		<ul style="list-style-type: none"> • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 	Page 5-6, Line 164-185	Discussion
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	Page 6, Line 186-191	Discussion
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	Page 5-6, Line 164-185	Discussion
Generalizability	21	<ul style="list-style-type: none"> • 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 6, Line 192-199	Discussion
Overall Evidence	22	<ul style="list-style-type: none"> • General interpretation of the results in the context of current evidence and current theory 	Page 6, Line 200-203	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: <http://www.cdc.gov/trendstatement/>

Article information: <https://dx.doi.org/10.21037/atm-22-1279>

*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.