

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	Title page
		• Structured abstract recommended	Page 2-3	Abstract
		• Information on target population or study sample	Page 2, line 25-30	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 4	Introduction
		• Theories used in designing behavioral interventions	Page 4-5	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 6-8	Methods
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 6-8	Methods
		• Recruitment setting	Page 6-8	Methods
		• Settings and locations where the data were collected	Page 6-8	Methods
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 6-8	Methods
		o Content: what was given?	Page 6-8	Methods
		o Delivery method: how was the content given?	Page 6-8	Methods
		o Unit of delivery: how were the subjects grouped during delivery?	Page 6-8	Methods
		o Deliverer: who delivered the intervention?	Page 6-8	Methods
		o Setting: where was the intervention delivered?	Page 6-8	Methods
		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 6-8	Methods

		<ul style="list-style-type: none"> o Time span: how long was it intended to take to deliver the intervention to each unit? 	Page 6-8	Methods
		<ul style="list-style-type: none"> o Activities to increase compliance or adherence (e.g., incentives) 	Page 6-8	Methods
Objectives	5	<ul style="list-style-type: none"> • Specific objectives and hypotheses 	Page 2	Abstract
Outcomes	6	<ul style="list-style-type: none"> • Clearly defined primary and secondary outcome measures 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Methods used to collect data and any methods used to enhance the quality of measurements 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Information on validated instruments such as psychometric and biometric properties 	Page 6-8	Methods
Sample Size	7	<ul style="list-style-type: none"> • How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules 	Page 6	Methods
Assignment Method	8	<ul style="list-style-type: none"> • Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) 	Page 6-8	Methods
Blinding (masking)	9	<ul style="list-style-type: none"> • 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 6-8	Methods
Unit of Analysis	10	<ul style="list-style-type: none"> • Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) 	Page 6-8	Methods
		<ul style="list-style-type: none"> • 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 6-8	Methods
Statistical Methods	11	<ul style="list-style-type: none"> • Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Methods for imputing missing data, if used 	Page 6-8	Methods
		<ul style="list-style-type: none"> • Statistical software or programs used 	Page 6-8	Methods
Results				
Participant flow	12	<ul style="list-style-type: none"> • Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) 	Page 10-12	Results
		<ul style="list-style-type: none"> 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 10-12	Results

		<ul style="list-style-type: none"> o Assignment: the numbers of participants assigned to a study condition 	Page 10-12	Results
		<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 10-12	Results
		<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 10-12	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 10-12	Results
		<ul style="list-style-type: none"> • Description of protocol deviations from study as planned, along with reasons 	Page 10-12	Results
Recruitment	13	<ul style="list-style-type: none"> • Dates defining the periods of recruitment and follow-up 	Page 10-12	Results
Baseline Data	14	<ul style="list-style-type: none"> • Baseline demographic and clinical characteristics of participants in each study condition 	Page 10-12	Results
		<ul style="list-style-type: none"> • Baseline characteristics for each study condition relevant to specific disease prevention research 	Page 10-12	Results
		<ul style="list-style-type: none"> • Baseline comparisons of those lost to follow-up and those retained, overall and by study condition 	Page 10-12	Results
		<ul style="list-style-type: none"> • Comparison between study population at baseline and target population of interest 	Page 10-12	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 10-12	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 10-12	Results
		<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 10-12	Results
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 10-12	Results
		<ul style="list-style-type: none"> • Inclusion of null and negative findings 	Page 10-12	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 10-12	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 10-12	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 10-12	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 13-15	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 13-15	Discussion
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	Page 13-15	Discussion
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	Page 13-15	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 13-15	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 13-15	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/>

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*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.