

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 16-21	section 1/paragraph 2
		• Structured abstract recommended	page 1/line 10-39	section1/paragraph1-3
		• Information on target population or study sample	page 1/line 23,24	section1/paragraph 3
Introduction				
Background	2	• Scientific background and explanation of rationale	page 2/line 44-54	section2/paragraph 1
		• Theories used in designing behavioral interventions	page2,3/line 56-82	section2/pagragrph2,3
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	page 3/line 86-107	section3/paragraph 1-3
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	page 3/line 86-107	section3/paragraph 1-3
		• Recruitment setting	page3/line 86-107	section3/paragraph 1-3
		• Settings and locations where the data were collected	page 3/line 86-107	section 3/paragraph 1-3
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	page 4/line 110-129	section3/paragraph4,5
		o Content: what was given?	page4/line 110-129	section 3/paragraph4,5
		o Delivery method: how was the content given?	page4/line 110-129	section 3/paragraph4,5
		o Unit of delivery: how were the subjects grouped during delivery?	page4/line 110-129	section 3/paragraph4,5
		o Deliverer: who delivered the intervention?	page4/line110-114	section 3/paragraph4
		o Setting: where was the intervention delivered?	page4/line 110-129	section3/paragraph4
		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/line113-120	section3/paragraph4,5

		<ul style="list-style-type: none">o Time span: how long was it intended to take to deliver the intervention to each unit?	page4/line113-120	section3/paragraph4,5
		<ul style="list-style-type: none">o Activities to increase compliance or adherence (e.g., incentives)	page4/line 110-129	section3/paragraph4,5
Objectives	5	<ul style="list-style-type: none">• Specific objectives and hypotheses	page4,5/line130-139	section3/paragraph6
Outcomes	6	<ul style="list-style-type: none">• Clearly defined primary and secondary outcome measures	page4,5/line130-139	section3/paragraph6
		<ul style="list-style-type: none">• Methods used to collect data and any methods used to enhance the quality of measurements	page4,5/line130-139	section3/paragraph6
		<ul style="list-style-type: none">• Information on validated instruments such as psychometric and biometric properties	page4,5/line130-139	section3/paragraph6
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	page4/line110-129	section3/paragraph4,5
Assignment Method	8	<ul style="list-style-type: none">• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	page4/line110-129	section3/paragraph4,5
		<ul style="list-style-type: none">• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	page4/line110-129	section3/paragraph4,5
		<ul style="list-style-type: none">• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	page4/line110-129	section3/paragraph4,5
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.	page3/line 86-94	section3/paragraph1
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)	page5/line141-151	section3/paragraph7
		<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)	page5/line141-151	section3/paragraph7
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	page5/line141-151	section3/paragraph7
		<ul style="list-style-type: none">• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	page5/line141-151	section3/paragraph7
		<ul style="list-style-type: none">• Methods for imputing missing data, if used	page5/line141-151	section3/paragraph7
		<ul style="list-style-type: none">• Statistical software or programs used	page5/line141-151	section3/paragraph7
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)	page5,6/line154-170	section4/paragraph1,2
		<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	page5,6/line154-170	section4/paragraph1,2

		o Assignment: the numbers of participants assigned to a study condition	page5,6/line154-170	section4/paragraph1,2
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	page5,6/line154-170	section4/paragraph1,2
		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	page5,6/line154-170	section4/paragraph1,2
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	page5,6/line154-170	section4/paragraph1,2
		• Description of protocol deviations from study as planned, along with reasons	page5,6/line 154-170	section4/paragraph1,2
Recruitment	13	• Dates defining the periods of recruitment and follow-up	page5,6/line 154-170	section4/paragraph1,2
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	page5,6/line 154-170	section4/paragraph1,2
		• Baseline characteristics for each study condition relevant to specific disease prevention research	page5,6/line 154-170	section4/paragraph1,2
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	page5,6/line 154-170	section4/paragraph1,2
		• Comparison between study population at baseline and target population of interest	page5,6/line 154-170	section4/paragraph1,2
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	page5,6/line 154-170	section4/paragraph1,2
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	page5,6/line 154-170	section4/paragraph1,2
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	page5,6/line 154-170	section4/paragraph1,2
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	page5,6/line 154-170	section4/paragraph1,2
		• Inclusion of null and negative findings	page5,6/line 154-170	section4/paragraph1,2
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	page5,6/line 154-170	section4/paragraph1,2
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	page6/line171-177	section4/paragraph3
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)	page6/line171-177	section4/paragraph3

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 	page8/line238-244	section5/paragraph1-3
		<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 	page6,7/line180-227	section5/paragraph1-3
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	page6,7/line180-227	section5/paragraph1-3
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	page6,7/line 180-227	section5/paragraph1-3
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 	page8/line229-244	section5/paragraph4
Overall Evidence	22	<ul style="list-style-type: none"> • General interpretation of the results in the context of current evidence and current theory 	page8/line246-251	section6/paragraph1

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 copy editing and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.