

## TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported on Page Number/Line Number	Reported on Section/Paragraph
<b>Title and Abstract</b>				
Title and Abstract	1	• Information on how unit were allocated to interventions	Page 1 Line 1-3	Abstract/paragraph 2
		• Structured abstract recommended	Page 2 Line 2-34	Abstract/paragraph 1-4
		• Information on target population or study sample	Page2 Line 17	Abstract/paragraph 2
<b>Introduction</b>				
Background	2	• Scientific background and explanation of rationale	Page 3 line 2-13	Introduction/paragraph 1-2
		• Theories used in designing behavioral interventions	Page 3 Line 7-10	Introduction/paragraph 3
<b>Methods</b>				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	P6 Line 2 - P6 Line 8	Methods/paragraph 1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	P6 Line 2 - P6 Line 8	Methods/paragraph 1-2
		• Recruitment setting	P6 Line 2 - P6 Line 8	Methods/paragraph 1
		• Settings and locations where the data were collected	P6 Line 2 - P6 Line 8	Methods/paragraph 1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	P7 Line 15-22	Methods/paragraph 3-5
		o Content: what was given?	P7 Line 15-22	Methods/paragraph 3-5
		o Delivery method: how was the content given?	P7 Line 15-22	Methods/paragraph 3-5
		o Unit of delivery: how were the subjects grouped during delivery?	P7 Line 15-22	Methods/paragraph 3-5
		o Deliverer: who delivered the intervention?	P7 Line 15-22	Methods/paragraph 3-5
		o Setting: where was the intervention delivered?	P7 Line 15-22	Methods/paragraph 3-5
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	P7 Line 15-22	Methods/paragraph 3-5

		<ul style="list-style-type: none"> <li>o Time span: how long was it intended to take to deliver the intervention to each unit?</li> </ul>	P7 Line 15-22	Methods/paragraph 3-5
		<ul style="list-style-type: none"> <li>o Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	P7 Line 15-22	Methods/paragraph 3-5
Objectives	5	<ul style="list-style-type: none"> <li>• Specific objectives and hypotheses</li> </ul>	P6 Line 11-14	Methods/paragraph 3-5
Outcomes	6	<ul style="list-style-type: none"> <li>• Clearly defined primary and secondary outcome measures</li> </ul>	P8 Line 8-24	Methods/paragraph 6-8
		<ul style="list-style-type: none"> <li>• Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	P8 Line 8-24	Methods/paragraph 6-8
		<ul style="list-style-type: none"> <li>• Information on validated instruments such as psychometric and biometric properties</li> </ul>	P8 Line 8-24	Methods/paragraph 6-8
Sample Size	7	<ul style="list-style-type: none"> <li>• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules</li> </ul>	P9 Line 9	Methods/paragraph 9
Assignment Method	8	<ul style="list-style-type: none"> <li>• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)</li> </ul>	Page4 Line33-34	Methods/paragraph 1
		<ul style="list-style-type: none"> <li>• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)</li> </ul>	Page4 Line33-34	Methods/paragraph 1
		<ul style="list-style-type: none"> <li>• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)</li> </ul>	Page4 Line33-34	Methods/paragraph 1
Blinding (masking)	9	<ul style="list-style-type: none"> <li>• 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.</li> </ul>	Page4 Line33-34	Methods/paragraph 1
Unit of Analysis	10	<ul style="list-style-type: none"> <li>• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)</li> </ul>	P7 Line 1-8	Methods/paragraph 9
		<ul style="list-style-type: none"> <li>• 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)</li> </ul>	P7 Line 1-8	Methods/paragraph 9
Statistical Methods	11	<ul style="list-style-type: none"> <li>• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data</li> </ul>	P7 Line 1-8	Methods/paragraph 9
		<ul style="list-style-type: none"> <li>• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis</li> </ul>	P7 Line 1-8	Methods/paragraph 9
		<ul style="list-style-type: none"> <li>• Methods for imputing missing data, if used</li> </ul>	P7 Line 1-8	Methods/paragraph 9
		<ul style="list-style-type: none"> <li>• Statistical software or programs used</li> </ul>	P7 Line 1-8	Methods/paragraph 9
<b>Results</b>				
Participant flow	12	<ul style="list-style-type: none"> <li>• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)</li> </ul>	P7 Line16	Results/paragraph 1
		<ul style="list-style-type: none"> <li>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</li> </ul>	P7Line16	Results/paragraph 1

		<ul style="list-style-type: none"> <li>o Assignment: the numbers of participants assigned to a study condition</li> </ul>	P7Line16	Results/paragraph 1
		<ul style="list-style-type: none"> <li>o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention</li> </ul>	P7Line16	Results/paragraph 1
		<ul style="list-style-type: none"> <li>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</li> </ul>	P7Line16	Results/paragraph 1
		<ul style="list-style-type: none"> <li>o Analysis: the number of participants included in or excluded from the main analysis, by study condition</li> </ul>	P7Line16	Results/paragraph 1
		<ul style="list-style-type: none"> <li>• Description of protocol deviations from study as planned, along with reasons</li> </ul>	P7Line16	Results/paragraph 1
Recruitment	13	<ul style="list-style-type: none"> <li>• Dates defining the periods of recruitment and follow-up</li> </ul>	P7Line14	Results/paragraph 1
Baseline Data	14	<ul style="list-style-type: none"> <li>• Baseline demographic and clinical characteristics of participants in each study condition</li> </ul>	P7Line 25	Results/paragraph 1
		<ul style="list-style-type: none"> <li>• Baseline characteristics for each study condition relevant to specific disease prevention research</li> </ul>	P7Line 25	Results/paragraph 1
		<ul style="list-style-type: none"> <li>• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition</li> </ul>	P7Line 25	Results/paragraph 1
		<ul style="list-style-type: none"> <li>• Comparison between study population at baseline and target population of interest</li> </ul>	P7Line 25	Results/paragraph 1
Baseline equivalence	15	<ul style="list-style-type: none"> <li>• Data on study group equivalence at baseline and statistical methods used to control for baseline differences</li> </ul>	P7Line 25	Results/paragraph 1
Numbers analyzed	16	<ul style="list-style-type: none"> <li>• 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</li> </ul>	P7Line 14-25	Results/paragraph 1
		<ul style="list-style-type: none"> <li>• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses</li> </ul>	P7Line 14-25	Results/paragraph 1
Outcomes and estimation	17	<ul style="list-style-type: none"> <li>• 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</li> </ul>	P7Line 27-Page8Line33	Results/paragraph 2-4
		<ul style="list-style-type: none"> <li>• Inclusion of null and negative findings</li> </ul>	P7Line 27-Page8Line33	Results/paragraph 2-4
		<ul style="list-style-type: none"> <li>• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any</li> </ul>	P7Line 27-Page8Line33	Results/paragraph 2-4
Ancillary analyses	18	<ul style="list-style-type: none"> <li>• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory</li> </ul>	P7Line 27-Page8Line33	Results/paragraph 2-4
Adverse events	19	<ul style="list-style-type: none"> <li>• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)</li> </ul>	P7Line 27-Page8Line18	Results/paragraph 2-3

DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> <li>• 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</li> </ul>	P9 Line 3-5	Discussion/paragraph 1
		<ul style="list-style-type: none"> <li>• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations</li> </ul>	P10 Line 10-15	Discussion/paragraph 4
		<ul style="list-style-type: none"> <li>• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation</li> </ul>	P11 Line 4-13	Discussion/paragraph 5
		<ul style="list-style-type: none"> <li>• Discussion of research, programmatic, or policy implications</li> </ul>	P11 Line 4-13	Discussion/paragraph 5
Generalizability	21	<ul style="list-style-type: none"> <li>• 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</li> </ul>	P10Line15-P11 Line3	Discussion/paragraph 4
Overall Evidence	22	<ul style="list-style-type: none"> <li>• General interpretation of the results in the context of current evidence and current theory</li> </ul>	P11 Line 17-22	Conclusion/paragraph 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/>

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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.