

## 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	Page1-2/Line31-54	Abstract/Paragraph1-4
		• Structured abstract recommended	Page1-2/Line31-54	Abstract/Paragraph1-4
		• Information on target population or study sample	Page1-2/Line31-54	Abstract/Paragraph1-4
<b>Introduction</b>				
Background	2	• Scientific background and explanation of rationale	Page2-3/Line62-82	Introduction/Paragraph1-4
		• Theories used in designing behavioral interventions	Page2-3/Line62-82	Introduction/Paragraph1-4
<b>Methods</b>				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page3-4/Line88-111	Methods/Paragraph1-2
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page3-4/Line88-111	Methods/Paragraph1-2
		• Recruitment setting	Page3-4/Line88-111	Methods/Paragraph1-2
		• Settings and locations where the data were collected	Page3-4/Line88-111	Methods/Paragraph1-2
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page4-5/Line115-162	Methods/Paragraph3-5
		o Content: what was given?	Page4-5/Line115-162	Methods/Paragraph3-5
		o Delivery method: how was the content given?	Page4-5/Line115-162	Methods/Paragraph3-5
		o Unit of delivery: how were the subjects grouped during delivery?	Page4-5/Line115-162	Methods/Paragraph3-5
		o Deliverer: who delivered the intervention?	Page4-5/Line115-162	Methods/Paragraph3-5
		o Setting: where was the intervention delivered?	Page4-5/Line115-162	Methods/Paragraph3-5
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Page4-5/Line115-162	Methods/Paragraph3-5

		<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>	Page4-5/Line115-162	Methods/Paragraph3-5
		<ul style="list-style-type: none"> <li>o Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	Page4-5/Line115-162	Methods/Paragraph3-5
Objectives	5	<ul style="list-style-type: none"> <li>• Specific objectives and hypotheses</li> </ul>	Page4-5/Line115-162	Methods/Paragraph3-5
Outcomes	6	<ul style="list-style-type: none"> <li>• Clearly defined primary and secondary outcome measures</li> </ul>	Page5-6/Line166-200	Methods/Paragraph6-10
		<ul style="list-style-type: none"> <li>• Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	Page5-6/Line166-200	Methods/Paragraph6-10
		<ul style="list-style-type: none"> <li>• Information on validated instruments such as psychometric and biometric properties</li> </ul>	Page5-6/Line166-200	Methods/Paragraph6-10
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>	Page3-4/Line88-111	Methods/Paragraph1-2
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>	Page4-5/Line115-162	Methods/Paragraph3-5
		<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>	Page4-5/Line115-162	Methods/Paragraph3-5
		<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>	Page4-5/Line115-162	Methods/Paragraph3-5
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>	Page4-5/Line115-162	Methods/Paragraph3-5
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>	Page4-5/Line115-162	Methods/Paragraph3-5
		<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>	Page4-5/Line115-162	Methods/Paragraph3-5
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>	Page7/Line204-208	Methods/Paragraph11
		<ul style="list-style-type: none"> <li>• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis</li> </ul>	Page7/Line204-208	Methods/Paragraph11
		<ul style="list-style-type: none"> <li>• Methods for imputing missing data, if used</li> </ul>	Page7/Line204-208	Methods/Paragraph11
		<ul style="list-style-type: none"> <li>• Statistical software or programs used</li> </ul>	Page7/Line204-208	Methods/Paragraph11
<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>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5

		<ul style="list-style-type: none"> <li>o Assignment: the numbers of participants assigned to a study condition</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
		<ul style="list-style-type: none"> <li>• Description of protocol deviations from study as planned, along with reasons</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
Recruitment	13	<ul style="list-style-type: none"> <li>• Dates defining the periods of recruitment and follow-up</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
Baseline Data	14	<ul style="list-style-type: none"> <li>• Baseline demographic and clinical characteristics of participants in each study condition</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
		<ul style="list-style-type: none"> <li>• Baseline characteristics for each study condition relevant to specific disease prevention research</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
		<ul style="list-style-type: none"> <li>• Comparison between study population at baseline and target population of interest</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
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>	Page7-8/Line212-250	Results/Paragraph1-5
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>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
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>	Page7-8/Line212-250	Results/Paragraph1-5
		<ul style="list-style-type: none"> <li>• Inclusion of null and negative findings</li> </ul>	Page7-8/Line212-250	Results/Paragraph1-5
		<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>	Page7-8/Line212-250	Results/Paragraph1-5
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>	Page7-8/Line212-250	Results/Paragraph1-5
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>	Page7-8/Line212-250	Results/Paragraph1-5

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>	Page8-10/Line254-320	Results/Paragraph1-7
		<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>	Page8-10/Line254-320	Results/Paragraph1-7
		<ul style="list-style-type: none"> <li>• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation</li> </ul>	Page8-10/Line254-320	Results/Paragraph1-7
		<ul style="list-style-type: none"> <li>• Discussion of research, programmatic, or policy implications</li> </ul>	Page8-10/Line254-320	Results/Paragraph1-7
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>	Page8-10/Line254-320	Results/Paragraph1-7
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>	Page8-10/Line254-320	Results/Paragraph1-7

**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.