

## 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	P2 L5	Abstract/P2
		• Structured abstract recommended	P1 L25	Abstract/P1
		• Information on target population or study sample	P2 L3	Abstract/P2
<b>Introduction</b>				
Background	2	• Scientific background and explanation of rationale	P3 L15	Introduction/P3
		• Theories used in designing behavioral interventions	P3 L28	Introduction/P5
<b>Methods</b>				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	P4 L28	Method/P3
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	P4 L15	Method/P1
		• Recruitment setting	N/A	N/A
		• Settings and locations where the data were collected	P4 L15	Method/P1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	P4 L24	Method/P2
		o Content: what was given?	P4 L24	Method/P2
		o Delivery method: how was the content given?	P4 L24	Method/P2
		o Unit of delivery: how were the subjects grouped during delivery?	N/A	N/A
		o Deliverer: who delivered the intervention?	P4 L34	Method/P4
		o Setting: where was the intervention delivered?	P4 L15	Method/P1
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	N/A	N/A

		o Time span: how long was it intended to take to deliver the intervention to each unit?	N/A	N/A
		o Activities to increase compliance or adherence (e.g., incentives)	N/A	N/A
Objectives	5	• Specific objectives and hypotheses	P4 L2	Introduction/P5
Outcomes	6	• Clearly defined primary and secondary outcome measures	P5 L4	Method/P5
		• Methods used to collect data and any methods used to enhance the quality of measurements	N/A	N/A
		• Information on validated instruments such as psychometric and biometric properties	N/A	N/A
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	P4 L12	Method/P1
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	P4 L17	Method/P1
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	P4 L17	Method/P1
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	N/A	N/A
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	N/A
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	N/A	N/A
		• 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)	P5 L15	Method/P6
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	P5 L13	Method/P6
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	N/A	N/A
		• Methods for imputing missing data, if used	N/A	N/A
		• Statistical software or programs used	P5 L11	Method/P6
<b>Results</b>				
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)	P6 L5	Result/P1
		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	P6 L5	Result/P1

		<ul style="list-style-type: none"> <li>o Assignment: the numbers of participants assigned to a study condition</li> </ul>	P6 L7	Result/P2
		<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>	P6 L7	Result/P2
		<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>	N/A	N/A
		<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>	N/A	N/A
		<ul style="list-style-type: none"> <li>• Description of protocol deviations from study as planned, along with reasons</li> </ul>	N/A	N/A
Recruitment	13	<ul style="list-style-type: none"> <li>• Dates defining the periods of recruitment and follow-up</li> </ul>	P4 L16	Method/P1
Baseline Data	14	<ul style="list-style-type: none"> <li>• Baseline demographic and clinical characteristics of participants in each study condition</li> </ul>	Table 1	Table 1
		<ul style="list-style-type: none"> <li>• Baseline characteristics for each study condition relevant to specific disease prevention research</li> </ul>	N/A	N/A
		<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>	N/A	N/A
		<ul style="list-style-type: none"> <li>• Comparison between study population at baseline and target population of interest</li> </ul>	N/A	N/A
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>	N/A	N/A
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>	N/A	N/A
		<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>	P5 L10	Method/P6
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>	P6 L9	Result/P2
		<ul style="list-style-type: none"> <li>• Inclusion of null and negative findings</li> </ul>	P6 L16	Result/P2
		<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>	N/A	N/A
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>	N/A	N/A
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>	N/A	N/A

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>	P7 L16	Discussion/P3
		<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>	P7 L16	Discussion/P3
		<ul style="list-style-type: none"> <li>• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation</li> </ul>	N/A	N/A
		<ul style="list-style-type: none"> <li>• Discussion of research, programmatic, or policy implications</li> </ul>	N/A	N/A
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>	N/A	N/A
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>	N/A	N/A

**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 refere