

## 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 3/Line 36-45	Abstract/Paragraph 2
		• Structured abstract recommended	Page 3-4/Line 30-57	Abstract/Paragraph 1-4
		• Information on target population or study sample	Page 3/Line 36	Abstract/Paragraph 2
<b>Introduction</b>				
Background	2	• Scientific background and explanation of rationale	Page 5-6/Line 62-92	Introduction/Paragraph 1-3
		• Theories used in designing behavioral interventions	Page 5-6/Line 79-92	Introduction/Paragraph3
<b>Methods</b>				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 7/Line 119-124	Methods/Paragraph 2
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 6-7/Line 102-103	Methods/Paragraph 1
		• Recruitment setting	Page 6-7/Line 102-103	Methods/Paragraph 1
		• Settings and locations where the data were collected	Page 6-7/Line 102-103	Methods/Paragraph 1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 9-10/Line 150-170	Methods/Paragraph 6
		○ Content: what was given?	Page 9-10/Line 155-166	Methods/Paragraph 6
		○ Delivery method: how was the content given?	Page 10/Line 166-169	Methods/Paragraph 6

		<ul style="list-style-type: none"> <li>○ Unit of delivery: how were the subjects grouped during delivery?</li> </ul>	Page 9/Line 151-154	Methods/Paragraph 6
		<ul style="list-style-type: none"> <li>○ Deliverer: who delivered the intervention?</li> </ul>	Page 10/Line 166-169	Methods/Paragraph 6
		<ul style="list-style-type: none"> <li>○ Setting: where was the intervention delivered?</li> </ul>	Page 10/Line 166-168	Methods/Paragraph 6
		<ul style="list-style-type: none"> <li>○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?</li> </ul>	Page 9/Line 151-154	Methods/Paragraph 6
		<ul style="list-style-type: none"> <li>○ Time span: how long was it intended to take to deliver the intervention to each unit?</li> </ul>	Page 9/Line 151-154	Methods/Paragraph 6
		<ul style="list-style-type: none"> <li>○ Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	Page 10/Line 166-169	Methods/Paragraph 6
Objectives	5	<ul style="list-style-type: none"> <li>• Specific objectives and hypotheses</li> </ul>	Page 6/Line 93-97	Introduction/Paragraph 4
Outcomes	6	<ul style="list-style-type: none"> <li>• Clearly defined primary and secondary outcome measures</li> </ul>	Page 10/Line 184-185	Methods/Paragraph 9
		<ul style="list-style-type: none"> <li>• Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	Page 8-9/Line 133-148	Methods/Paragraph 4-5
		<ul style="list-style-type: none"> <li>• Information on validated instruments such as psychometric and biometric properties</li> </ul>	Page 8-9/Line 133-148	Methods/Paragraph 4-5
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>	Page 10/Line 183-185	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>	Page 7/Line 104-105	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>	Page 7/Line 104-105	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>	Page 7, 8, 10/Line 105-108, 139-140, 178-179	Methods/Paragraph 1, 4, 8
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>	Page 8, 10/Line 139-140, 178-179	Methods/Paragraph 4, 8
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>	Page 10-11/Line 183-195	Methods/Paragraph 9-10
		<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>	Page 10-11/Line 186-195	Methods/Paragraph 10
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>	Page 10-11/Line 186-195	Methods/Paragraph 10
		<ul style="list-style-type: none"> <li>Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis</li> </ul>	Page 11/Line 191-195	Methods/Paragraph 10
		<ul style="list-style-type: none"> <li>Methods for imputing missing data, if used</li> </ul>	N/A (no missing data)	N/A (no missing data)
		<ul style="list-style-type: none"> <li>Statistical software or programs used</li> </ul>	Page 10/Line 186	Methods/Paragraph 10
<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>	Page 6-10/Line 102-181	Methods/Paragraph 1-8

		<ul style="list-style-type: none"> <li>○ 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>	Page 6-7/Line 102-103	Methods/Paragraph 1
		<ul style="list-style-type: none"> <li>○ Assignment: the numbers of participants assigned to a study condition</li> </ul>	Page 6-7/Line 102-103	Methods/Paragraph 1
		<ul style="list-style-type: none"> <li>○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention</li> </ul>	Page 7/Line 104-105	Methods/Paragraph 1
		<ul style="list-style-type: none"> <li>○ 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>	Page 10/Line 177-178	Methods/Paragraph 8
		<ul style="list-style-type: none"> <li>○ Analysis: the number of participants included in or excluded from the main analysis, by study condition</li> </ul>	Page 11/Line 188-191	Methods/Paragraph 10
		<ul style="list-style-type: none"> <li>• Description of protocol deviations from study as planned, along with reasons</li> </ul>	Page 14/Line 259-264	Discussion/Paragraph 4
Recruitment	13	<ul style="list-style-type: none"> <li>• Dates defining the periods of recruitment and follow-up</li> </ul>	Page 6-7/Line 102-103	Methods/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>	Page 8/Line 133-140	Methods/Paragraph 4
		<ul style="list-style-type: none"> <li>• Baseline characteristics for each study condition relevant to specific disease prevention research</li> </ul>	Page 8/Line 133-140	Methods/Paragraph 4
		<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>	Page 7/Line 105-108	Methods/Paragraph 1
		<ul style="list-style-type: none"> <li>• Comparison between study population at baseline and target population of interest</li> </ul>	Page 10/Line 177-181	Methods/Paragraph 8

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>	Page 7/Line 105-108	Methods/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>	Page 11/Line 188-195	Methods/Paragraph 10
		<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>	Page 6-7, 11/Line 102-103, 188-195	Methods/Paragraph 1, 10
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>	Page 11/Line 199-204	Results/Paragraph 1
		<ul style="list-style-type: none"> <li>Inclusion of null and negative findings</li> </ul>	Page 11/Line 204	Results/Paragraph 1
		<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>	Page 11/Line 199-203	Results/Paragraph 1
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>	Page 11-12/Line 206-227	Results/Paragraph 2
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>	Page 14/Line 259-264	Discussion/Paragraph 4
<b>DISCUSSION</b>				
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,</li> </ul>	Page 13-14/Line 234-258	Discussion/Paragraph 2-3

		<p>multiplicative analyses, and other limitations or weaknesses of the study</p> <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> <li>• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation</li> <li>• Discussion of research, programmatic, or policy implications</li> </ul>		
			Page 13-14/Line 234-258	Discussion/Paragraph 2-3
			Page 13-14/Line 234-258	Discussion/Paragraph 2-3
			Page 13-14/Line 234-258	Discussion/Paragraph 2-3
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>	Page 13/Line 230-233	Discussion/Paragraph 1
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>	Page 13-14/Line 234-258	Discussion/Paragraph 2-3

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/>

Article information: <http://dx.doi.org/10.21037/apm-20-346>

\*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.

