

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 4/Line 42	Abstract/Paragraph 2
		• Structured abstract recommended	Page 4-5/Line 40-57	Abstract/Paragraph 1-5
		• Information on target population or study sample	Page 4/Line 42-44	Abstract/Paragraph 2
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 5-7/Line 59-85	Introduction/Paragraph 1
		• Theories used in designing behavioral interventions	Page 7-8/Line 85-91	Introduction/Paragraph 1
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 8/Line 94-97	Methods/Paragraph 1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 8/Line 97-100	Methods/Paragraph 1
		• Recruitment setting	Page 9/Line 102-106	Methods/Paragraph 2-3
		• Settings and locations where the data were collected	Page 8/Line 97-100	Methods/Paragraph 1
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		
		o Content: what was given?	Page 10-12/Line 119-144	Methods/Paragraph 7-11
		o Delivery method: how was the content given?	Page 10-12/Line 119-144	Methods/Paragraph 7-11
		o Unit of delivery: how were the subjects grouped during delivery?	Page 10-12/Line 119-144	Methods/Paragraph 7-11
		o Deliverer: who delivered the intervention?	Page 11/Line132	Methods/Paragraph 9
		o Setting: where was the intervention delivered?	Page 8/Line 95-97	Methods/Paragraph 1
		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 13/Line 159-161	Methods/Paragraph 15

		<ul style="list-style-type: none">o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 13/Line 159-161	Methods/Paragraph 15
		<ul style="list-style-type: none">o Activities to increase compliance or adherence (e.g., incentives)	Page 13/Line 159-161	Methods/Paragraph 15
Objectives	5	<ul style="list-style-type: none">• Specific objectives and hypotheses	Page 8/Line 99-100	Methods/Paragraph 1
Outcomes	6	<ul style="list-style-type: none">• Clearly defined primary and secondary outcome measures	Page 12-13/Line 146-158	Methods/Paragraph 14
		<ul style="list-style-type: none">• Methods used to collect data and any methods used to enhance the quality of measurements	Page 12-13/Line 146-158	Methods/Paragraph 14
		<ul style="list-style-type: none">• Information on validated instruments such as psychometric and biometric properties	Page 12-13/Line 146-158	Methods/Paragraph 14
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	Page 8/Line 95-97	Methods/Paragraph 1
Assignment Method	8	<ul style="list-style-type: none">• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Page 8/Line 95-97	Methods/Paragraph 1
		<ul style="list-style-type: none">• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Page 8/Line 97-99	Methods/Paragraph 1
		<ul style="list-style-type: none">• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Page 8/Line 97-99	Methods/Paragraph 1
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.	Page 8/Line 97-98	Methods/Paragraph 1
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)	Page 8/Line 97-98	Methods/Paragraph 1
		<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)	Page 8/Line 98-99	Methods/Paragraph 1
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	Page 14/Line 166-170	Methods/Paragraph 16
		<ul style="list-style-type: none">• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Page 14/Line 166-170	Methods/Paragraph 16
		<ul style="list-style-type: none">• Methods for imputing missing data, if used	N/A	No missing data
		<ul style="list-style-type: none">• Statistical software or programs used	Page 14/Line 166-167	Methods/Paragraph 16
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)	Page 15/Line 179	Results/ Paragraph 1
		<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	Page 15/Line 179	Results/ Paragraph 1

		o Assignment: the numbers of participants assigned to a study condition	Page 15/Line 179	Results/ Paragraph 1
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Page 15/Line 179	Results/ Paragraph 1
		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	Page 15/Line 179	Results/ Paragraph 1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page 15/Line 179	Results/ Paragraph 1
		• Description of protocol deviations from study as planned, along with reasons	N/ A	No deviations
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 16/Line 181	Results/ Paragraph 2
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page 16/Line 181-188	Results/ Paragraph 2
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Page 16/Line 181-188	Results/ Paragraph 2
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Page 16/Line 181-188	Results/ Paragraph 2
		• Comparison between study population at baseline and target population of interest	Page 16/Line 181-188	Results/ Paragraph 2
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Page 16/Line 187-188	Results/ Paragraph 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	Page 16/Line 181-182	Results/ Paragraph 2
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Page 16/Line 181-182	Results/ Paragraph 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	Page 17-23/Line 190-240	Results/ Paragraph 3-10
		• Inclusion of null and negative findings	Page 17-23/Line 190-240	Results/ Paragraph 3-10
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	N/ A	No pre-specified results
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page 17-23/Line 190-240	Results/ Paragraph 3-10
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)	Page 17-23/Line 190-240	Results/ Paragraph 3-10

DISCUSSION				
Interpretation	20	• 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	Page 25/Line 264-267	Discussion/ Paragraph 2
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	Page 24-25/Line 242-267	Discussion/ Paragraph 1-2
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	Page 24-25/Line 242-267	Discussion/ Paragraph 1-2
		• Discussion of research, programmatic, or policy implications	Page 24-25/Line 242-267	Discussion/ Paragraph 1-2
Generalizability	21	• 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	Page 26/Line 270-272	Conclusions /Paragraph 1
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	Page 26/Line 270-272	Conclusions /Paragraph 1

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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.

