

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	Lines 31-38	abstract
		• Structured abstract recommended	Lines 18-51	abstract
		• Information on target population or study sample	Lines 31-38	abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	Lines 70- 120	introduction
		• Theories used in designing behavioral interventions	Lines 121- 127	introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Lines 129- 138	methods
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Lines 139- 150	methods
		• Recruitment setting	Lines 129- 150	methods
		• Settings and locations where the data were collected	Lines 129- 150	methods
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Lines 152- 171	methods
		o Content: what was given?	Lines 161- 171	methods
		o Delivery method: how was the content given?	Lines 161- 171	methods
		o Unit of delivery: how were the subjects grouped during delivery?	Lines 161- 171	methods
		o Deliverer: who delivered the intervention?	Lines 161- 171	methods
		o Setting: where was the intervention delivered?	Lines 161- 171	methods
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	Lines 140- 141	methods

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Lines 153- 154	methods
		o Activities to increase compliance or adherence (e.g., incentives)	Lines 164- 171	methods
Objectives	5	• Specific objectives and hypotheses	Lines 141- 143	methods
Outcomes	6	• Clearly defined primary and secondary outcome measures	Lines 174- 178	methods
		• Methods used to collect data and any methods used to enhance the quality of measurements	Lines 136- 138	methods
		• 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	Lines 140- 141	methods
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	N/A	N/a
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Lines 140- 150	methods
		• 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)	Lines 140- 150	methods
		• 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)	N/A	N/a
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Lines 179- 184	methods
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Lines 179- 184	methods
		• Methods for imputing missing data, if used	N/A	N/a
		• Statistical software or programs used	Lines 179- 184	methods
Results				
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)	Table 1	results
		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	Table 1	results

		<ul style="list-style-type: none"> o Assignment: the numbers of participants assigned to a study condition 	Table 1	results
		<ul style="list-style-type: none"> o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 	Table 2	results
		<ul style="list-style-type: none"> 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 	N/A	N/a
		<ul style="list-style-type: none"> o Analysis: the number of participants included in or excluded from the main analysis, by study condition 	Lines 205-212	results
		<ul style="list-style-type: none"> • Description of protocol deviations from study as planned, along with reasons 	Lines 219-227	results
Recruitment	13	<ul style="list-style-type: none"> • Dates defining the periods of recruitment and follow-up 	Table 1	results
Baseline Data	14	<ul style="list-style-type: none"> • Baseline demographic and clinical characteristics of participants in each study condition 	Table 1	results
		<ul style="list-style-type: none"> • Baseline characteristics for each study condition relevant to specific disease prevention research 	Table 1	results
		<ul style="list-style-type: none"> • Baseline comparisons of those lost to follow-up and those retained, overall and by study condition 	N/A	N/a
		<ul style="list-style-type: none"> • Comparison between study population at baseline and target population of interest 	Table 1	results
Baseline equivalence	15	<ul style="list-style-type: none"> • Data on study group equivalence at baseline and statistical methods used to control for baseline differences 	Table 2	results
Numbers analyzed	16	<ul style="list-style-type: none"> • 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 	Table 1, 2	results
		<ul style="list-style-type: none"> • Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses 	N/A	N/a
Outcomes and estimation	17	<ul style="list-style-type: none"> • 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 	Lines 200-203 Lines 233-243	results
		<ul style="list-style-type: none"> • Inclusion of null and negative findings 	N/A	N/a
		<ul style="list-style-type: none"> • Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	N/A	N/a
Ancillary analyses	18	<ul style="list-style-type: none"> • Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	Figure 1, 2	results
Adverse events	19	<ul style="list-style-type: none"> • Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	N/A	N/a

DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> • 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 	Lines 270-278	discussion
		<ul style="list-style-type: none"> • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 	Lines 254-269	discussion
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	Lines 279-300	discussion
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	Lines 312-322	discussion
Generalizability	21	<ul style="list-style-type: none"> • 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 	Lines 254-300	discussion
Overall Evidence	22	<ul style="list-style-type: none"> • General interpretation of the results in the context of current evidence and current theory 	Lines 302-310	discussion

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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.