

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 2, Line 36-39	Abstract, Paragraph 2
		• Structured abstract recommended	Page 1-2, Line 28-54	Abstract, Paragraph 1-6
		• Information on target population or study sample	Page 2, Line 43-44	Abstract, Paragraph 3
Introduction				
Background	2	• Scientific background and explanation of rationale	Page 2-3, Line 57-79	Introduction, Paragraph 2-3
		• Theories used in designing behavioral interventions	Page 3, Line 80-93	Introduction, Paragraph 3
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	Page 4, Line 103-111	Methods, Paragraph 1
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	Page 3, Line 101-102	Methods, Paragraph 1
		• Recruitment setting	Page 3, Line 101-102	Methods, Paragraph 1
		• Settings and locations where the data were collected	Page 3, Line 101-102	Methods, Paragraph 2
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	Page 4, Line 114-131	Methods, Paragraph 2
		o Content: what was given?	Page 4, Line 114-116	Methods, Paragraph 2
		o Delivery method: how was the content given?	Page 4, Line 114-116	Methods, Paragraph 2
		o Unit of delivery: how were the subjects grouped during delivery?	Page 4, Line 114-116	Methods, Paragraph 2
		o Deliverer: who delivered the intervention?	Page 3, Line 101-102	Methods, Paragraph 1
		o Setting: where was the intervention delivered?	Page 3, Line 101-102	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 4, Line 116-118, 129-131	Methods, Paragraph 2

		o Time span: how long was it intended to take to deliver the intervention to each unit?	Page 4, Line 116-118	Methods, Paragraph 2
		o Activities to increase compliance or adherence (e.g., incentives)	NA	NA
Objectives	5	• Specific objectives and hypotheses	Page 3, Line 89-95	Introduction, Paragraph 4
Outcomes	6	• Clearly defined primary and secondary outcome measures	Page 4-5, Line 134-143	Methods, Paragraph 3
		• Methods used to collect data and any methods used to enhance the quality of measurements	Page 4, Line 118-129	Methods, Paragraph 2
		• Information on validated instruments such as psychometric and biometric properties	Page 4, Line 124-127	Methods, Paragraph 2
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Page 5, Line 146-153	Methods, Paragraph 4
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	NA	NA
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	NA	NA
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	NA	NA
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.	NA	NA
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	NA	NA
		• 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)	NA	NA
Statistical Methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	Page 5, Line 156-159	Methods, Paragraph 5
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	NA	NA
		• Methods for imputing missing data, if used	NA	NA
		• Statistical software or programs used	Page 5, Line 160-162	Methods, Paragraph 5
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)	Page 5-7, Line 166-206	Results, Paragraph 1-4
		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 5, Line 166-168	Results, Paragraph 1

		o Assignment: the numbers of participants assigned to a study condition	Page 5, Line 166-168	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 5, Line 166-168	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 6, Line 166-168	Results, Paragraph 1
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	Page 6, Line 166-168	Results, Paragraph 1
		• Description of protocol deviations from study as planned, along with reasons	Page 6, Line 195-198	Results, Paragraph 2
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Page 6, Line 166-168	Results, Paragraph 1
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Page 6, Line 170-173	Results, Paragraph 1
		• Baseline characteristics for each study condition relevant to specific disease prevention research	NA	NA
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	NA	NA
		• Comparison between study population at baseline and target population of interest	NA	NA
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	NA	NA
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 5-6, Line 166-175	Results, Paragraph 1
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	NA	NA
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 6, Line 178-190	Results, Paragraph 2
		• Inclusion of null and negative findings	Page 6, Line 178-190	Results, Paragraph 2
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	NA
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Page 6, Line 191-198	Results, Paragraph 3
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 6-7, Line 201-206	Results, Paragraph 4

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 	Page 7-8, Line 227-244	Discussion, Paragraph 3-4
		<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 	Page 8, Line 242-244	Discussion, Paragraph 4
		<ul style="list-style-type: none"> • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	Page 8, Line 242-246	Discussion, Paragraph 4
		<ul style="list-style-type: none"> • Discussion of research, programmatic, or policy implications 	Page 8, Line 248-251	Discussion, Paragraph 5
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 	Page 8, Line 254-255	Conclusions, Paragraph 1
Overall Evidence	22	<ul style="list-style-type: none"> • General interpretation of the results in the context of current evidence and current theory 	Page 8, Line 255-256	Conclusions, Paragraph 1

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: <https://dx.doi.org/10.21037/tau-22-507>

*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.