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	2/40	Methods
		• Structured abstract recommended	2/34	NA
		• Information on target population or study sample	2/43	Results
Introduction				
Background	2	• Scientific background and explanation of rationale	3/58	Introduction
		• Theories used in designing behavioral interventions	3/71	Introduction
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	5/84	Participants
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	5/84	Participants
		• Recruitment setting	5/84	Participants
		• Settings and locations where the data were collected	5/85	Participants
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	6/113	Trial design
		o Content: what was given?	6/115	Trial design
		o Delivery method: how was the content given?	6/116	Trial design
		o Unit of delivery: how were the subjects grouped during delivery?	6/116	Trial design
		o Deliverer: who delivered the intervention?	6/116	Trial design
		o Setting: where was the intervention delivered?	6/116	Trial design
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	6/119	Trial design

		o Time span: how long was it intended to take to deliver the intervention to each unit?	22/451	Table 1
		o Activities to increase compliance or adherence (e.g., incentives)	5/100	Telerobotic system
Objectives	5	• Specific objectives and hypotheses	8/170	Objectives
Outcomes	6	• Clearly defined primary and secondary outcome measures	9/181	Outcomes
		• Methods used to collect data and any methods used to enhance the quality of measurements	7/143	Trial design
		• Information on validated instruments such as psychometric and biometric properties	6/127	Trial design
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	NA	NA
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	11/203	Results
		• 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)	6/121	Trial design
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.	6/121	Trial design
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	6/127	Trial design
		• 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	9/190	Statistical methods
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	9/190	Statistical methods
		• Methods for imputing missing data, if used	NA	NA
		• Statistical software or programs used	9/189	Statistical 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)	11/203	Clinical Features/Figure 3
		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	11/204	Clinical Features/Figure 3

		o Assignment: the numbers of participants assigned to a study condition	11/203	Clinical Features/Figure 3
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	11/203	Clinical Features/Figure 3
		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	11/203	Clinical Features/Figure 3
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	11/203	Clinical Features/Figure 3
		• Description of protocol deviations from study as planned, along with reasons	11/203	Clinical Features/Figure 3
Recruitment	13	• Dates defining the periods of recruitment and follow-up	5/88	Participants
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	11/206	Clinical Features
		• 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	11/203	Clinical Features
		• 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	23/451	Table1/table2
		• Inclusion of null and negative findings	23/51	Table1/Table2
		• 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	NA	NA
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)	12/235	Patient assessment

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	13/253	Discussion
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	13/253	Discussion
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	16/323	Discussion
		• Discussion of research, programmatic, or policy implications	15/306	Discussion
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	NA	NA
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	16/334	Discussion

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 may be used as an alternative reference.