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	Not applicable	This is an implementation trial, all patients received
		• Structured abstract recommended	P2, line 39-67	Abstract
		• Information on target population or study sample	P2, line 44-60	Abstract
Introduction				
Background	2	• Scientific background and explanation of rationale	P3, line 75-95	Introduction, background
		• Theories used in designing behavioral interventions	P3, line 96-706	Introduction, objective
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	P5, line 158-164	Methods, participants
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	P5, line 158-164	Methods, participants
		• Recruitment setting	P4, line 106	Methods, Study design
		• Settings and locations where the data were collected	P4, line 106 P5, line 165-179	Methods, Study design Methods, Data Collection
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	P4-6	Methods
		• Content: what was given?	P4, line 108-136	Methods, ePROM intervention
		• Delivery method: how was the content given?	P4, line 108-136	Methods, ePROM intervention
		• Unit of delivery: how were the subjects grouped during delivery?	Not applicable	This is an implementation trial, all patients received
		• Deliverer: who delivered the intervention?	P4, line 108-136	The intervention was delivered automatically to
		• Setting: where was the intervention delivered?	P4, line 108-136	Methods, ePROM intervention
		• Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	P4, line 108-136	Methods, ePROM intervention

		• Time span: how long was it intended to take to deliver the intervention to each unit?	P4, line 108-136	Methods, ePROM intervention
		• Activities to increase compliance or adherence (e.g., incentives)	P4, line 108-136	Methods, ePROM intervention
Objectives	5	• Specific objectives and hypotheses	P4, line 137-142	Methods, Implementation plan
Outcomes	6	• Clearly defined primary and secondary outcome measures	P4, line 137-142	Methods, Implementation plan
		• Methods used to collect data and any methods used to enhance the quality of measurements	P4, line 137-142 P5, line 165- 179	Methods, Data collecton
		• Information on validated instruments such as psychometric and biometric properties	P4, line 108-136	Methods, ePROM intervention
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	Not applicable	Feasibility trial with fixed recruitment period
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	Not applicable	Feasibility trial in one center
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	Not applicable	Feasibility trial
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	Not applicable	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.	Not applicable	NA
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	Not applicable	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	Not applicable	NA
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	Not applicable	NA
		• Methods for imputing missing data, if used	Not applicable	NA
		• Statistical software or programs used	P6, line 183	Methods, Analyses
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)	P7-10	Results
		• Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	P7, line 195	Results, Reach

		• Assignment: the numbers of participants assigned to a study condition	Not applicable	NA
		• Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	Not applicable	NA
		• 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	Not applicable	NA
		• Analysis: the number of participants included in or excluded from the main analysis, by study condition	Not applicable	NA
		• Description of protocol deviations from study as planned, along with reasons	Not applicable	NA
Recruitment	13	• Dates defining the periods of recruitment and follow-up	Not applicable	Discussed in Methods line 157-159
Baseline Data	14	• Baseline demographic and clinical characteristics of participants in each study condition	Not applicable	Some data available in Table 3/Table 4
		• Baseline characteristics for each study condition relevant to specific disease prevention research	Not applicable	NA
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	Not applicable	NA
		• Comparison between study population at baseline and target population of interest	Not applicable	NA
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	Not applicable	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	Not applicable	NA
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	Not applicable	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	Not applicable	Discussed in results under each part of the implementation model, not statistically analyzed
		• Inclusion of null and negative findings	Not applicable	Discussed in results under each part of the
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	Not applicable	NA
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	Not applicable	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)	Not applicable	NA

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	P12, line 380-451	Discussed in Discussion under each part of the implementation model
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	P12, line 380-451	Discussed in Discussion under each part of the
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	P14, line 452 onward	Focus on limitation in these lines, however discussed under parts of the implementation model
		• Discussion of research, programmatic, or policy implications	P12, line 452-462	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	P14, line 452-455	Discussion
Overall Evidence	22	• General interpretation of the results in the context of current evidence and current theory	P15, 463 onward	Conclusions

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/paragraph may be used as an alternative reference.