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| **Paper Section/ Topic** | **Item****No** | **Descriptor** | **Reported?** |
|  |  | **Pg #** |
| **Title and Abstract** |
| Title andAbstract | 1 | Information on how unit were allocated to interventionsStructured abstract recommendedInformation on target population or study sample | X | Pg 1-2 |
| **Introduction** |
| Background | 2 | Scientific background and explanation of rationaleTheories used in designing behavioral interventions | X | Pg 3-4 |
| **Methods** |
| Participants | 3 | Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implementedRecruitment settingSettings and locations where the data were collected | X | Pg 4,10  |
| 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?o Delivery method: how was the content given?o Unit of delivery: how were the subjects grouped during delivery?o Deliverer: who delivered the intervention?o Setting: where was the intervention delivered?o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were theyintended to last?o Time span: how long was it intended to take to deliver the intervention to each unit?o Activities to increase compliance or adherence (e.g., incentives) | X | Pg 4 |
| Objectives | 5 | Specific objectives and hypotheses | X | Pg 4 |
| Outcomes | 6 | Clearly defined primary and secondary outcome measuresMethods used to collect data and any methods used to enhance the quality of measurementsInformation on validated instruments such as psychometric and biometric properties | X | Pg 4-6,Protocol S1 |
| Sample Size | 7 | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | X | Pg 6 |
| AssignmentMethod | 8 | Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | NA |  |





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| 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 |  |
| Unit of Analysis | 10 | Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)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 |  |
| StatisticalMethods | 11 | Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated dataStatistical methods used for additional analyses, such as a subgroup analyses and adjusted analysisMethods for imputing missing data, if usedStatistical software or programs used | X | Pg 6 |
| **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)o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, andenrolled in the studyo Assignment: the numbers of participants assigned to a study conditiono Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participantswho received each interventiono 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 conditiono Analysis: the number of participants included in or excluded from the main analysis, by study conditionDescription of protocol deviations from study as planned, along with reasons | X | Pg 15 |
| Recruitment | 13 | Dates defining the periods of recruitment and follow-up | X | Pg 7 |
| Baseline Data | 14 | Baseline demographic and clinical characteristics of participants in each study conditionBaseline characteristics for each study condition relevant to specific disease prevention researchBaseline comparisons of those lost to follow-up and those retained, overall and by study conditionComparison between study population at baseline and target population of interest | NA |  |
| Baseline equivalence | 15 | Data on study group equivalence at baseline and statistical methods used to control for baseline differences | NA |  |

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| Numbersanalyzed | 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 feasibleIndication of whether the analysis strategy was “intention to treat” or, ifnot, description of how non-compliers were treated in the analyses | X | Pg 7 |
| Outcomes andestimation | 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 precisionInclusion of null and negative findingsInclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | NA |  |
| Ancillaryanalyses | 18 | Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | 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) | 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 studyDiscussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanationsDiscussion of the success of and barriers to implementing the intervention, fidelity of implementationDiscussion of research, programmatic, or policy implications | X | Pg 8-10 |
| 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 | X | Pg 8-10 |
| OverallEvidence | 22 | General interpretation of the results in the context of current evidence and current theory | X | Pg 8-10 |

*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/>

