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 37-44 | Abstract/Paragraph 2 |
|  |  | - Structured abstract recommended | Page 2/Line 35-53 | Abstract/Paragraph 1-4 |
|  |  | - Information on target population or study sample | Page 2/Line 37-44 | Abstract/Paragraph 2 |
| Introduction |  |  |  |  |
| Background | 2 | - Scientific background and explanation of rationale | Page 2/Line 63-Page | Introduction/Paragraph |
|  |  | - Theories used in designing behavioral interventions | Page 2/Line 63-Page | Introduction/Paragraph |
| Methods |  |  |  |  |
| Participants | 3 | - Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | Page 4/Line 113-118 | Methods/Paragraph 3 |
|  |  | - Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | Page 4/Line 110-113 | Methods/Paragraph 3 |
|  |  | - Recruitment setting | Page 4/Line 110-112 | Methods/Paragraph 3 |
|  |  | - Settings and locations where the data were collected | Page 4/Line 110-112 | Methods/Paragraph 3 |
| Interventions | 4 | - Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | Page 4/Line 127-Page 5/Line 133 | Methods/Paragraph 4 |
|  |  | - Content: what was given? | Page 4/Line 127-Page | Methods/Paragraph 4 |
|  |  | o Delivery method: how was the content given? | Page 4/Line 127-Page | Methods/Paragraph 4 |
|  |  | o Unit of delivery: how were the subjects grouped during delivery? | N/A (This study involved | N/A (This study involved |
|  |  | - Deliverer: who delivered the intervention? | Page 4/Line 127-Page | Methods/Paragraph 4 |
|  |  | - Setting: where was the intervention delivered? | Page 4/Line 127-Page | Methods/Paragraph 4 |
|  |  | 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 127-Page 5/Line 133 | Methods/Paragraph 4 |


|  |  | - Time span: how long was it intended to take to deliver the intervention to each unit? | Page 4/Line 127-Page | Methods/Paragraph 4 |
| :---: | :---: | :---: | :---: | :---: |
|  |  | - Activities to increase compliance or adherence (e.g., incentives) | N/A (This term was not | N/A (Thia term was not |
| Objectives | 5 | - Specific objectives and hypotheses | Page 3/Line 94-95 | Methods/Paragraph 1 |
| Outcomes | 6 | - Clearly defined primary and secondary outcome measures | Page 5/line 137-Page | Methods/Paragraph 5-10 |
|  |  | - Methods used to collect data and any methods used to enhance the quality of measurements | Page 5/line 137-Page | Methods/Paragraph 5-10 |
|  |  | - Information on validated instruments such as psychometric and biometric properties | Page 5/line 137-Page | Methods/Paragraph 5-10 |
| Sample Size | 7 | - How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | Page 4/Line 102-106 | Methods/Paragraph 2 |
| Assignment Method | 8 | - Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | Page 4/Line 112-113 | Methods/Paragraph 3 |
|  |  | - Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | N/A (This study involved one group) | N/A (This study involved one group) |
|  |  | - Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | Page 5/Line 137-138; | Methods/Paragraph 5-6 |
| 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. | Page 4/line 122-123; <br> Page 5/Line 147-148 | Methods/Paragraph 3;Paragraph 6 |
| Unit of Analysis | 10 | - Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) | Page 7/Line 199-200 | Methods/Paragraph 11 |
|  |  | - 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 (The unit of analysis was line with the unit of accimnmant in thic cturis | $\mathrm{N} / \mathrm{A}$ (The unit of analysis was line with the unit of accirnmont in thic ctuin) |
| Statistical Methods | 11 | - Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data | Page 7/Line 200-204 | Methods/Paragraph 11 |
|  |  | - Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis | Page 7/Line 205 | Methods/Paragraph 11 |
|  |  | - Methods for imputing missing data, if used | N/A (There was no | N/A (There was no |
|  |  | - Statistical software or programs used | Page 7/Line 202-203 | Methods/Paragraph 11 |
| 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 7/Line 212 | Results/Paragraph 1 |
|  |  | 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 7/Line 212-217 | Results/Paragraph 1 |


|  |  | - Assignment: the numbers of participants assigned to a study condition | N/A (This study involved | N/A (This study involved |
| :---: | :---: | :---: | :---: | :---: |
|  |  | - Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention | N/A (This study involved one group) | N/A (This study involved one group) |
|  |  | - 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 7/Line 212-217 | Results/Paragraph 1 |
|  |  | - Analysis: the number of participants included in or excluded from the main analysis, by study condition | Page 7/Line 212-217 | Results/Paragraph 1 |
|  |  | - Description of protocol deviations from study as planned, along with reasons | N/A (This term was not | N/A (This term was not |
| Recruitment | 13 | - Dates defining the periods of recruitment and follow-up | Page 7/Line 222;Line | Results/Paragraph 2-4 |
| Baseline Data | 14 | - Baseline demographic and clinical characteristics of participants in each study condition | Table 1 | Table 1 |
|  |  | - Baseline characteristics for each study condition relevant to specific disease prevention research | N/A (This study involved | N/A (This study involved |
|  |  | - Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | N/A (There was no | N/A (There was no |
|  |  | - Comparison between study population at baseline and target population of interest | N/A (This study involved | N/A (This study involved |
| Baseline equivalence | 15 | - Data on study group equivalence at baseline and statistical methods used to control for baseline differences | N/A (This study involved one group) | N/A (This study involved one group) |
| 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 7/Line 212-217 | 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 | Page 4/Line 120-122 | Methods/Paragraph 3 |
| 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 | Table 2-4 | Table 2-4 |
|  |  | - Inclusion of null and negative findings | Table 2-4 | Table 2-4 |
|  |  | - Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | N/A (This term was not involved in this study) | N/A (This term was not involved in this study) |
| Ancillary analyses | 18 | - Summary of other analyses performed, including subgroup or restricted analyses, indicating which are prespecified or exploratory | N/A (This study involved one group) | N/A (This study involved one group) |
| 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) | N/A (This study involved one group) | N/A (This study involved one group) |


| 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 | Page 8/Line 250-Page 9/Line 277 | Discussion/Paragraph 2-4 |
|  |  | - 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 241-249 | Discussion/Paragraph 1 |
|  |  | - Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | Page 8/Line 241-249 | Discussion/Paragraph 1 |
|  |  | - Discussion of research, programmatic, or policy implications | Page 9/Line 278-281 | Discussion/Paragraph 5 |
| 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 | Page 9/Line 278-281 | Discussion/Paragraph 5 |
| Overall Evidence | 22 | - General interpretation of the results in the context of current evidence and current theory | Page 8/Line 250-Page | Discussion/Paragraph |

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.

