### TREND Statement Checklist

| Paper Section/Topic | Item No | Descriptor | Reported? |
|---------------------|---------|------------|-----------|
| **Title and Abstract** | | | |
| Title and Abstract | 1 | - Information on how unit were allocated to interventions | yes p2 |
| | | - Structured abstract recommended | yes p2 |
| | | - Information on target population or study sample | yes p2 |
| **Introduction** | | | |
| Background | 2 | - Scientific background and explanation of rationale | yes p3-4 |
| | | - Theories used in designing behavioral interventions | Not relevant |
| **Methods** | | | |
| Participants | 3 | - Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | yes p8 |
| | | - Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | yes p8 |
| | | - Recruitment setting | yes p8 |
| | | - Settings and locations where the data were collected | yes p8 |
| Interventions | 4 | - Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | yes p9 |
| | | o Content: what was given? | yes p9 |
| | | o Delivery method: how was the content given? | yes p9 |
| | | o Unit of delivery: how were the subjects grouped during delivery? | yes p9 |
| | | o Deliverer: who delivered the intervention? | yes p10 |
| | | o Setting: where was the intervention delivered? | yes p9 |
| | | o Time span: how long was it intended to take to deliver the intervention to each unit? | yes p9 |
| | | o Activities to increase compliance or adherence (e.g., incentives) | yes p9 |
| Objectives | 5 | - Specific objectives and hypotheses | yes p2,4 |
| Outcomes | 6 | - Clearly defined primary and secondary outcome measures | yes p2,4 |
| | | - Methods used to collect data and any methods used to enhance the quality of measurements | yes p11 |
| | | - Information on validated instruments such as psychometric and biometric properties | Not relevant |
| Sample Size | 7 | - How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | yes p11 |
| Assignment Method | 8 | - Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | yes p9 |
| | | - Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | Not relevant |
| | | - Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | Not relevant |
### TREND Statement Checklist

| Topic                                      | Page(s) | Notes       |
|--------------------------------------------|---------|-------------|
| Blinding (masking)                         |         | Not relevant|
| Unit of Analysis                           | p9      |             |
| Statistical Methods                        | p9, p11 |             |
| Results                                    |         |             |
| Participant flow                           |         |             |
| Recruitment                                | p12     |             |
| Baseline Data                              | p9-10   |             |
| Baseline equivalence                       |         |             |

#### Blinding (masking)
- 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.

#### Unit of Analysis
- 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)

#### Statistical Methods
- Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data
- Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis
- Methods for imputing missing data, if used
- Statistical software or programs used

#### Results
- Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)
- Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study
- Assignment: the numbers of participants assigned to a study condition
- Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention
- 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
- Analysis: the number of participants included in or excluded from the main analysis, by study condition
- Description of protocol deviations from study as planned, along with reasons

#### Recruitment
- Dates defining the periods of recruitment and follow-up

#### Baseline Data
- Baseline demographic and clinical characteristics of participants in each study condition
- Baseline characteristics for each study condition relevant to specific disease prevention research
- Baseline comparisons of those lost to follow-up and those retained, overall and by study condition
- Comparison between study population at baseline and target population of interest
| TREND Statement Checklist | | |
|---|---|---|
| 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 | yes | All tables |
| | | • Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses | yes | p9 |
| 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 | yes | p14-21 |
| | | • Inclusion of null and negative findings | Not relevant |
| | | • Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | Not relevant |
| Ancillary analyses | 18 | • Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | yes | Tables 3-4 |
| 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) | yes | Table 1 |
| **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 | yes | p18-21 |
| | | • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | yes | p18-21 |
| | | • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | Not relevant |
| | | • Discussion of research, programmatic, or policy implications | Not relevant |
| 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 | Not relevant |
| Overall Evidence | 22 | • General interpretation of the results in the context of current evidence and current theory | yes | p21 |

*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/](http://www.cdc.gov/trendstatement/)*