## 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 | Line 3-4/Page 1 | Title |
|                      |         | • Structured abstract recommended                  | Line 3-4/Page 1 | Title |
|                      |         | • Information on target population or study sample  | Line 3-4/Page 1 | Title |
| **Introduction**     |         |            |                                     |                              |
| Background           | 2       | • Scientific background and explanation of rationale | Line 78-87/Page 3 | Introduction/Paragraph2 |
|                      |         | • Theories used in designing behavioral interventions | Line 70-77/Page 3 | Introduction/Paragraph2 |
| **Methods**          |         |            |                                     |                              |
| Participants         | 3       | • Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | Line 97-112/Page 4 | Methods/Paragraph1-3 |
|                      |         | • Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | Line 95-96/Page 4 | Methods/Paragraph1-3 |
|                      |         | • Recruitment setting                               | Line 95-96/Page 4 | Methods/Paragraph1-3 |
|                      |         | • Settings and locations where the data were collected | Line 95-96/Page 4 | Methods/Paragraph1-3 |
| Interventions        | 4       | • Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | Line 118-184/Page 4-6 | Methods/Paragraph5-12 |
|                      |         | o Content: what was given?                         | Line 120-128/Page 4 | Methods/Paragraph9 |
|                      |         | o Delivery method: how was the content given?      | Line 118-184/Page 4-6 | Methods/Paragraph5-12 |
|                      |         | o Unit of delivery: how were the subjects grouped during delivery? | Line 118-184/Page 4-6 | Methods/Paragraph5-12 |
|                      |         | o Deliverer: who delivered the intervention?        | Line 118-184/Page 4-6 | Methods/Paragraph5-12 |
|                      |         | o Setting: where was the intervention delivered?    | Line 118-184/Page 4-6 | Methods/Paragraph5-12 |
|                      |         | o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last? | N/A | N/A |
| Section | Line/Paragraph |
|---------|----------------|
| Objectives | Line 213-216 | Methods/Paragraph 19 |
| Outcomes | Line 205 | Methods/Paragraph 18 |
| Sample Size | Line 211-222 | Methods/Paragraph 19 |
| Assignment Method | Line 225-228 | Methods/Paragraph 19 |
| Blinding (masking) | Line 225-228 | Methods/Paragraph 19 |
| Unit of Analysis | Line 225-228 | Methods/Paragraph 19 |
| Statistical Methods | Line 230-238 | Methods/Paragraph 20 |
| Results | Line 242-247 | Results/Paragraph 1 |
| Participant flow | Line 242-247 | Results/Paragraph 1 |

### Objectives
- Specific objectives and hypotheses

### Outcomes
- Clearly defined primary and secondary outcome measures
- Methods used to collect data and any methods used to enhance the quality of measurements
- Information on validated instruments such as psychometric and biometric properties

### Sample Size
- How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules

### Assignment Method
- 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)

### 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
| Recruitment | 13 | Dates defining the periods of recruitment and follow-up | Line 95-96 /Page 3 | Methods/Paragraph 1 |
| Baseline Data | 14 | • Baseline demographic and clinical characteristics of participants in each study condition | Line 249-253/Page 8 | Results/Paragraph 2 |
| | | • Baseline characteristics for each study condition relevant to specific disease prevention research | Line 249-253/Page 8 | Results/Paragraph 2 |
| | | • Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | Line 249-253/Page 8 | Results/Paragraph 2 |
| | | • Comparison between study population at baseline and target population of interest | Line 249-253/Page 8 | Results/Paragraph 2 |
| Baseline equivalence | 15 | • Data on study group equivalence at baseline and statistical methods used to control for baseline differences | Line 249-253/Page 8 | Results/Paragraph 2 |
| 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 | Line 243-245/Page 8 | 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 | Line 245-247/Page 8 | Results/Paragraph 1 |
| 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 | Line 255-281/Page 8-9 | Results/Paragraph 2-5 |
| | | • Inclusion of null and negative findings | Line 255-281/Page 8-9 | Results/Paragraph 2-5 |
| | | • Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | Line 255-281/Page 8-9 | Results/Paragraph 2-5 |
| Ancillary analyses | 18 | • Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | Line 269-273/Page 9 | Results/Paragraph 5 |
| 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) | Line 272-275/Page 9 | Results/Paragraph 6 |
| DISCUSSION                                                                 | 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 | Line 284-287 /Page 9 Discussion/Paragraph 1 |
|---------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations |    |                                                                                                                                                                               | Line 313- 318 /Page 9 Discussion/Paragraph 4 |
| • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation |    |                                                                                                                                                                               | Line 319- 331 /Page9 Discussion/Paragraph 5 |
| • Discussion of research, programmatic, or policy implications            |    |                                                                                                                                                                               | Line 319- 331 /Page9 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 | Line 332-341 /Page 11 Discussion/Paragraph 6 |
| Overall Evidence                                                         | 22 | General interpretation of the results in the context of current evidence and current theory                                                                                    | Line 352- 356 /Page 11 Discussion/Paragraph 9 |

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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.*