

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 | Title page. | Title |
| | | • Structured abstract recommended | Page 3 | Abstract |
| | | • Information on target population or study sample | Page 3/Line 5-7 | Abstract |
| Introduction | | | | |
| Background | 2 | • Scientific background and explanation of rationale | Page 4/Line 2-29; Page 5, Line 1-12 | Introduction/Paragraph 1-3 |
| | | • Theories used in designing behavioral interventions | Page 4/Line 24-29; Page 5/Line 1-11 | Introduction/Paragraph 3 |
| Methods | | | | |
| Participants | 3 | • Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | Page 5/Line 28-29; Page 6/Line 1-23; | Materials and Methods /Participants/Paragraph 1 |
| | | • Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | Page 5/Line 28-29; Page 6/Line 1 | Materials and Methods /Participants/Paragraph 1 |
| | | • Recruitment setting | Page 5/Line 28-29 | Materials and Methods /Participants/Paragraph 1 |
| | | • Settings and locations where the data were collected | Page 5/Line 28-29; Page 6/Line 1; | Materials and Methods /Participants/Paragraph 1 |
| Interventions | 4 | • Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | Page 6/Line 28-30; Page 7/Line 1-9 | Materials and Methods /Study design/Paragraph 2 |
| | | o Content: what was given? | Page 6/Line 26-27 | Materials and Methods /Study design/Paragraph 1 |
| | | o Delivery method: how was the content given? | Page 6/Line 26-27 | Materials and Methods /Study design/Paragraph 1 |
| | | o Unit of delivery: how were the subjects grouped during delivery? | Page 6/Line 28-30; Page 7/Line 1-3 | Materials and Methods /Study design/Paragraph 2 |
| | | o Deliverer: who delivered the intervention? | Page 6/Line 29-30 | Materials and Methods /Study design/Paragraph 2 |
| | | o Setting: where was the intervention delivered? | 4-1 Page 7/Line 1 | Materials and Methods /Study design/Paragraph 2 |
| | | 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 6/Line 28-30; Page 7/Line 1-9 | Materials and Methods /Study design/Paragraph 2 |

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| | | o Time span: how long was it intended to take to deliver the intervention to each unit? | Page 6/Line 28-30; Page 7/Line 1-9 | Materials and Methods /Study design/Paragraph 2 |
| | | o Activities to increase compliance or adherence (e.g., incentives) | Page 7/Line 6-7 | Materials and Methods /Study design/Paragraph 2 |
| Objectives | 5 | • Specific objectives and hypotheses | Page 5/Line 8-12 | Introduction/Paragraph 3 |
| Outcomes | 6 | • Clearly defined primary and secondary outcome measures | Page 7/Line 11-23 | Materials and Methods /Measurements/Paragraph 1-2 |
| | | • Methods used to collect data and any methods used to enhance the quality of measurements | Page 7/Line 26-28; | Materials and Methods /Data management and analysis/Paragraph 1 |
| | | • Information on validated instruments such as psychometric and biometric properties | Page 7/Line 11-23 | Materials and Methods /Measurements/Paragraph 1-2 |
| Sample Size | 7 | • How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | Not applicable | Not applicable |
| Assignment Method | 8 | • Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | Not applicable | Not applicable |
| | | • Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | Not applicable | Not applicable |
| | | • Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | Not applicable | Not applicable |
| 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 | Not applicable |
| Unit of Analysis | 10 | • Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) | Page 8/Line 5 | Materials and Methods /Data management and analysis/Paragraph 2 |
| | | • 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) | Not applicable | Not applicable |
| Statistical Methods | 11 | • Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data | Page 7/Line 28; Page 8/Line 1-2 | Materials and Methods /Data management and analysis/Paragraph 1-2 |
| | | • Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis | Page 8/Line 3-6 | Materials and Methods /Data management and analysis/Paragraph 2 |
| | | • Methods for imputing missing data, if used | Page 7/Line 27-28 | Materials and Methods /Data management and analysis/Paragraph 1 |
| | | • Statistical software or programs used | Page 7/Line 26-27 | Materials and Methods /Data management and analysis/Paragraph 1 |
| 4-2 | | | | |
| Results | | | | |

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|-------------------------|----|---|------------------------------------|--|
| Participant flow | 12 | <ul style="list-style-type: none"> Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) | Page 8/Line 24-25; Figure 1 | Result/Baseline characteristics of the patients/Paragraph 1 |
| | | <ul style="list-style-type: none"> 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 8/Line 24-25; Figure 1 | Result/Baseline characteristics of the patients/Paragraph 1 |
| | | <ul style="list-style-type: none"> o Assignment: the numbers of participants assigned to a study condition | Figure 1 | Figure 1 |
| | | <ul style="list-style-type: none"> o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention | Figure 1 | Figure 1 |
| | | <ul style="list-style-type: none"> o 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 8/Line 25-26; Figure 1 | Result/Baseline characteristics of the patients/Paragraph 1 |
| | | <ul style="list-style-type: none"> o Analysis: the number of participants included in or excluded from the main analysis, by study condition | Figure 1 | Figure 1 |
| | | <ul style="list-style-type: none"> • Description of protocol deviations from study as planned, along with reasons | Not applicable | Not applicable |
| Recruitment | 13 | <ul style="list-style-type: none"> Dates defining the periods of recruitment and follow-up | Page 5/Line 28-29; Page 6/Line 1 | Materials and Methods /Participants/Paragraph 1 |
| Baseline Data | 14 | <ul style="list-style-type: none"> Baseline demographic and clinical characteristics of participants in each study condition | Page 8/Line 26-28; Table 1 | Result/Baseline characteristics of the patients/Paragraph 1 |
| | | <ul style="list-style-type: none"> Baseline characteristics for each study condition relevant to specific disease prevention research | Not applicable | Not applicable |
| | | <ul style="list-style-type: none"> Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | Not applicable | Not applicable |
| | | <ul style="list-style-type: none"> Comparison between study population at baseline and target population of interest | Not applicable | Not applicable |
| Baseline equivalence | 15 | <ul style="list-style-type: none"> Data on study group equivalence at baseline and statistical methods used to control for baseline differences | Not applicable | Not applicable |
| Numbers analyzed | 16 | <ul style="list-style-type: none"> 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 9/Line 4 | Result/Outcome measures/Primary outcome measures/Paragraph 1 |
| | | <ul style="list-style-type: none"> Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses | Page 9/Line 4 | Result/Outcome measures/Primary outcome measures/Paragraph 1 |
| Outcomes and estimation | 17 | <ul style="list-style-type: none"> 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 | Page 9/Line 4-11; Page 10/Line 2-5 | Result/Outcome measures/Primary outcome measures/Paragraph 1-2; Result/Outcome measures/Secondary outcome measures/Paragraph 1 |
| | | <ul style="list-style-type: none"> Inclusion of null and negative findings | Page 10/Line 2-5 | Secondary outcome measures/Paragraph 1 |
| | | <ul style="list-style-type: none"> Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | Page 9/Line 4-11; Page 10/Line 2-5 | Result/Outcome measures/Primary outcome measures/Paragraph 1-2; |

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|--------------------|----|---|-------------------|---|
| | | | | Result/Outcome measures/Secondary outcome measures/Paragraph 1 |
| Ancillary analyses | 18 | <ul style="list-style-type: none"> Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | Page 9/Line 7-26; | Result/Outcome measures/Primary outcome measures/Paragraph 2-5; |
| Adverse events | 19 | <ul style="list-style-type: none"> Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) | Page 9/Line 4-26 | Result/Outcome measures/Primary outcome measures/Paragraph 2-5; |

| DISCUSSION | | | | |
|-------------------|----|--|---|---------------------------|
| Interpretation | 20 | <ul style="list-style-type: none"> 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 10/Line 11-28; Page 11/Line 1-31; Page 12/Line 1-3 | Discussion/Paragraph 1-3 |
| | | <ul style="list-style-type: none"> Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | Page 10/Line 20-21; Page 11/Line 14-20; | Discussion/Paragraph 1, 3 |
| | | <ul style="list-style-type: none"> Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | Page 11/Line 19-31; | Discussion/Paragraph 3 |
| | | <ul style="list-style-type: none"> Discussion of research, programmatic, or policy implications | Page 11/Line 19-31; Page 12/Line 1-3 | Discussion/Paragraph 3 |
| Generalizability | 21 | <ul style="list-style-type: none"> 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 11/Line 9-31; Page 12/Line 1-3 | Discussion/Paragraph 3 |
| Overall Evidence | 22 | <ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory | Page 12/Line 6-9 | Conclusion/Paragraph 1 |

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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.

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