**TREND Statement Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Paper**  **Section/**  **Topic** | **Item**  **No** | **Descriptor** | **Reported?** | |
| image37.jpegimage38.jpeg | **Pg #** |
| **Title and Abstract** | | | | |
| Title and  Abstract | 1 | image1.jpegimage2.jpeg In Information on how unit were allocated to interventions  Information on how unit were allocated to interventions |  |  |
| image3.jpegimage4.jpegimage5.jpegimage6.jpegStructured abstract recommended  Information on target population or study sample |
|
| **Introduction** | | | | |
| Background | 2 | image7.jpegimage8.jpegimage9.jpegimage10.jpegScientific background and explanation of rationale  Theories used in designing behavioral interventions |  |  |
|
| **Methods** | | | | |
| Participants | 3 | image11.jpegimage12.jpegimage13.jpegimage14.jpegimage15.jpegimage16.jpegimage17.jpegimage18.jpegEligibility 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 implemented  Recruitment setting  Settings and locations where the data were collected |  |  |
|
|
|
| Interventions | 4 | image19.jpegimage20.jpegDetails of the interventions intended for each study condition and how  and when they were actually administered, specifically including:  oContent: what was given?  oDelivery method: how was the content given?  oUnit of delivery: how were the subjects grouped during delivery?  oDeliverer: who delivered the intervention?  oSetting: where was the intervention delivered?  oExposure quantity and duration: how many sessions or episodes or  events were intended to be delivered? How long were they  intended to last?  oTime span: how long was it intended to take to deliver the  intervention to each unit?  oActivities to increase compliance or adherence (e.g., incentives) |  |  |
|
|
|
|
|
|
|
|
| Objectives | 5 | image21.jpegimage22.jpeg Specific objectives and hypotheses  Specific objectives and hypotheses |  |  |
| Outcomes | 6 | image23.jpegimage24.jpegimage25.jpegimage26.jpegimage27.jpegimage28.jpegClearly 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 | 7 | image29.jpegimage30.jpegHow sample size was determined and, when applicable, explanation of any  interim analyses and stopping rules |  |  |
| Assignment  Method | 8 | image31.jpegimage32.jpegimage33.jpegimage34.jpegimage35.jpegimage36.jpegUnit 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) |  |  |
|
|

**TREND Statement Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Blinding  (masking) | 9 | image39.jpegimage40.jpegWhether 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 | 10 | image41.jpegimage42.jpegDescription of the smallest unit that is being analyzed to assess  intervention effects (e.g., individual, group, or community) |  |  |
| image43.jpegimage44.jpegIf 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 | 11 | image45.jpegimage46.jpegimage47.jpegimage48.jpegimage49.jpegimage50.jpegimage51.jpegimage52.jpegStatistical 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** | | | | |
| Participant flow | 12 | image53.jpegimage54.jpegimage55.jpegimage56.jpegFlow of participants through each stage of the study: enrollment,  assignment, allocation, and intervention exposure, follow-up, analysis (a  diagram is strongly recommended)  oEnrollment: the numbers of participants screened for eligibility,  found to be eligible or not eligible, declined to be enrolled, and  enrolled in the study  oAssignment: the numbers of participants assigned to a study  condition  oAllocation and intervention exposure: the number of participants  assigned to each study condition and the number of participants  who received each intervention  oFollow-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  oAnalysis: 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 | 13 | image57.jpegimage58.jpeg Dates defining the periods of recruitment and follow-up  Dates defining the periods of recruitment and follow-up  Dates defining the periods of recruitment and follow-up  Dates defining the periods of recruitment and follow-up  Dates defining the periods of recruitment and follow-up |  |  |
| Baseline Data | 14 | image59.jpegimage60.jpegimage61.jpegimage62.jpegimage63.jpegimage64.jpegimage65.jpegimage66.jpegBaseline 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 |  |  |
|
|
|
| Baseline  equivalence | 15 | image67.jpegimage68.jpegData on study group equivalence at baseline and statistical methods used  to control for baseline differences |  |  |

**TREND Statement Checklist**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Numbers  analyzed | 16 | image69.jpegimage70.jpegNumber 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 |  |  |
| image71.jpegimage72.jpegIndication of whether the analysis strategy was “intention to treat” or, if  not, description of how non-compliers were treated in the analyses |
| Outcomes and  estimation | 17 | image73.jpegimage74.jpegimage75.jpegimage76.jpegimage77.jpegimage78.jpegFor 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  Inclusion of null and negative findings  Inclusion of results from testing pre-specified causal pathways through  which the intervention was intended to operate, if any |  |  |
|
|
| Ancillary  analyses | 18 | image79.jpegimage80.jpegSummary of other analyses performed, including subgroup or restricted  analyses, indicating which are pre-specified or exploratory |  |  |
| Adverse events | 19 | image81.jpegimage82.jpegSummary of all important adverse events or unintended effects in each  study condition (including summary measures, effect size estimates, and  confidence intervals) |  |  |
| **DISCUSSION** | | | | |
| Interpretation | 20 | image83.jpegimage84.jpegimage85.jpegimage86.jpegimage87.jpegimage88.jpegimage89.jpegimage90.jpegInterpretation 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  Discussion of results taking into account the mechanism by which the  intervention was intended to work (causal pathways) or alternative  mechanisms or explanations  Discussion of the success of and barriers to implementing the intervention,  fidelity of implementation  Discussion of research, programmatic, or policy implications |  |  |
|
|
|
| Generalizability | 21 | image91.jpegimage92.jpegGeneralizability (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 |  |  |
| Overall  Evidence | 22 | image93.jpegimage94.jpegGeneral interpretation of the results in the context of current evidence  and current theory |  |  |

*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/