# S1 CONSORT checklist of information to include when reporting a randomised trial

| Section/Topic       | Item No | Checklist item                                                                 | Reported on page No |
|---------------------|---------|---------------------------------------------------------------------------------|---------------------|
| **Title and abstract** |         |                                                                                 |                     |
| 1a                  | Info on how units were allocated to interventions                               | N.A.                |
| 1b                  | Structured abstract recommended                                                 | 2                   |
| 1c                  | Info on target population or study sample                                       | 2                   |
| **Introduction**    |         |                                                                                 |                     |
| 2a                  | Scientific background and explanation of rationale                              | 3-4                 |
| 2b                  | Theories used in designing behavioural interventions                            | N.A.                |
| **Methods**         |         |                                                                                 |                     |
| 3a                  | Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | 5                   |
| 3b                  | Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | 5                   |
| 3c                  | Recruitment setting                                                             | 5                   |
| 3d                  | Settings and locations where the data were collected                            | 5                   |
| **Interventions**   |         |                                                                                 |                     |
| 4a                  | Details of the interventions intended for each study condition and how and when they were actually administered, specifically including | 5-6                 |
|                     | - Content: what was given?                                                      | 5                   |
|                     | - Delivery method: how was the content given?                                   | 5                   |
|                     | - Unit of delivery: how were the subjects grouped during delivery?              | N.A.                |
|                     | - Deliverer: who delivered the intervention?                                    | 6                   |
|                     | - Setting: where was the intervention delivered?                                 | 6                   |
|                     | - Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last? | 5                   |
|                     | - Time span: how long was it intended to take to deliver the intervention to each unit? | N.A.                |
| Section                      | Code | Description                                                                                                                                                                                                 | Notes |
|------------------------------|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Objectives                   | 5    | Specific objectives and hypotheses                                                                                                                                                                        | 4     |
| Outcomes                     | 6a   | Clearly defined primary and secondary outcome measures                                                                                                                                                     | 6-9   |
|                              | 6b   | 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 | 6-7   |
| Sample size                  | 7a   | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules                                                                                               | 5     |
| Assignment Method            | 8a   | Unit of assignment                                                                                                                                                                                          | N.A.  |
|                              | 8b   | Methods used to assign units to study conditions, including details of any restriction                                                                                                                     | N.A.  |
|                              | 8c   | Inclusion of aspects employed to help minimize potential bias induced due to non-randomization                                                                                                                | N.A.  |
| Blinding                     | 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. | 9-10  |
| Unit of Analysis             | 10a  | Description of the smallest unit that is being analysed to assess intervention effects                                                                                                                      | 5     |
|                              | 10b  | If the unit of analysis differs from the unit of assignment, the analytical method used to account for this                                                                                                  | N.A.  |
| Statistical methods          | 11a  | Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data                                                                               | 9     |
|                              | 11b  | Statistical methods used for additional analyses, such as a subgroup analysis and adjusted analysis.                                                                                                                                                                   | N.A.  |
|                              | 11c  | Methods for imputing missing data, if used                                                                                                                                                                  | N.A.  |
|                              | 11d  | Statistical software or programs used                                                                                                                                                                       | 9     |
## Results

| Section                        | Code | Description                                                                                   | Reference |
|--------------------------------|------|-----------------------------------------------------------------------------------------------|-----------|
| Participant flow               | 12   | Flow of participants through each stage of the study: enrolment, assignment, allocation, and intervention exposure, follow-up, analysis | Fig. 1    |
|                                | 12b  | Description of protocol deviations from study as planned, along with reasons                  | Fig. 1    |
| Recruitment                    | 13   | Dates defining the periods of recruitment and follow-up                                        | 6         |
| Baseline data                  | 14a  | Baseline demographic and clinical characteristics of participants in each study condition       | N.A.      |
| Numbers analysed               | 14b  | Baseline characteristics for each study condition relevant to specific disease prevention research | N.A.      |
|                                | 14c  | Baseline comparison of those lost to follow-up and those retained, overall and by study condition | N.A.      |
|                                | 14d  | Comparison between study population at baseline and target population of interest               | 9-20      |
| Baseline equivalence           | 15   | Data on study group equivalence at baseline and statistical methods used to control for baseline differences | 9-20      |
| Numbers analyzed               | 16a  | Number of participants 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 | 5         |
|                                | 16b  | Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses. | N.A.      |
| Outcomes and estimation        | 17a  | 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 | N.A.      |
|                                | 17b  | Inclusion of null and negative findings                                                        | N.A.      |
|                                | 17c  | Inclusion of results from treating pre-specified causal pathways through which the intervention was intended to operate, if any | 9-20      |
| Ancillary analyses | 18 | Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | N.A. |
|-------------------|----|---------------------------------------------------------------------------------------------------------------------------------|------|
| Adverse events    | 19 | Summary of all important adverse events or unintended effects in each study condition                                           | 6    |
| **Discussion**    |    |                                                                                                                                |      |
| **Interpretation**|    |                                                                                                                                |      |
| 20a               |    | 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 | 21-24|
| 20b               |    | Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | 21-24|
| 20c               |    | Discussion of the success of and barriers to implementing the intervention, fidelity of implementation                           | 21-24|
| 20d               |    | Discussion of research, programmatic, or policy implications                                                                    | 24   |
| **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 | 24   |