**CONSORT-SPI 2018 Checklist**

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| **SECTION** | **ITEM #** | **CONSORT 2010** | **CONSORT-SPI****2018** | **REPORTED ON PAGE #** |
| **TITLE AND ABSTRACT** |
|  | 1a | Identification as a randomised trial in the title§ |  | Click here to enter text. |
|  | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for Abstracts)§  | Refer to CONSORT extension for social and psychological intervention trial abstracts | Click here to enter text. |
| **INTRODUCTION** |
| Background and Objectives | 2a | Scientific background and explanation of rationale § |  | Click here to enter text. |
| 2b | Specific objectives or hypotheses § | If pre-specified, how the intervention was hypothesied to work | Click here to enter text. |
| **METHODS** |
| Trial Design | 3a | Describe of trial design (such as parallel, factorial), including allocation ratio § | If the unit of random assignment is not the individual, please refer to CONSORT for Cluster Randomized Trials | Click here to enter text. |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  | Click here to enter text. |
| Participants | 4a | Eligibility criteria for participants§ | When applicable, eligibility criteria for settings and those delivering the interventions | Click here to enter text. |
| 4b | Settings and locations where the data were collected |  | Click here to enter text. |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they are actually administered § |  | Click here to enter text. |
| 5a |  | Extent to which interventions were actually delivered by providers and taken up by participants as planned | Click here to enter text. |
| 5b |  | Where other informational materials about delivering the intervention can be accessed | Click here to enter text. |
| 5c |  | When applicable, how intervention providers were assigned to each group | Click here to enter text. |
| Outcomes | 6a | Completely defined pre-specified outcomes, including how and when they were assessed§ |  | Click here to enter text. |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  | Click here to enter text. |
| Sample Size | 7a | How sample size was determined§ |  | Click here to enter text. |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  | Click here to enter text. |
| **RANDOMISATION** |
| Sequencegeneration | 8a | Method used to generate the random allocation sequence |  | Click here to enter text. |
| 8b | Type of randomisation; detail of any restriction (such as blocking and block size)§ |  | Click here to enter text. |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned§ |  | Click here to enter text. |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions§ |  | Click here to enter text. |
| Awareness of assignment | 11a | Who was aware of intervention assignment after allocation (for example, participants, providers, those assessing outcomes), and how any masking was done |  | Click here to enter text. |
| 11b | If relevant, description of the similarity of interventions |  | Click here to enter text. |
| Analyticalmethods | 12a | Statistical methods used to compare group outcomes§ | How missing data were handled, with details of any imputation method | Click here to enter text. |
| 12b | Methods for additional analyses, such as subgroup analyses, adjusted analyses, and process evaluations |  | Click here to enter text. |
| **RESULTS** |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers randomly assigned, receiving the intended intervention, and analysed for the outcomes§ | Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment | Click here to enter text. |
| 13b | For each group, losses and exclusions after randomisation, together with reasons§ |  | Click here to enter text. |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  | Click here to enter text. |
| 14b | Why the trial ended or was stopped |  | Click here to enter text. |
| Baseline data | 15 | A table showing baseline characteristics for each group§ | Include socioeconomic variables where applicable | Click here to enter text. |
| Numbers analysed | 16 | For each group, number included in each analysis and whether the analysis was by original assigned groups§ |  | Click here to enter text. |
| Outcomes and estimation | 17a | For each outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)§ | Indicate availability of trial data |  |
| 17b | For binary outcomes, the presentation of both absolute and relative effect sizes is recommended |  |  |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses, adjusted analyses, and process evaluations, distinguishing pre-specified from exploratory |  |  |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for Harms) |  |  |
| **DISCUSSION** |
| Limitations | 20 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Click here to enter text. |
| Generalisability | 21 | Discuss the limitations of the scoping review process. | Generalisability (external validity, applicability) of the trial findings§ | Click here to enter text. |
| Interpretation | 22 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Click here to enter text. |
| **IMPORTANT INFORMATION** |
| Registration | 23 | Registration number and name of trial registry |  | Click here to enter text. |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  | Click here to enter text. |
| Declaration of Interests | 25 | Sources of funding and other support; role of funders | Declaration of any other potential interests | Click here to enter text. |
| Stakeholder investments | 26a |  | Any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial | Click here to enter text. |
| 26b |  | Other stakeholder involvement in trial design, conduct, or analyses | Click here to enter text. |
| 26c |  | Incentives offered as part of the trial | Click here to enter text. |

This table lists items from the CONSORT 2010 checklist (with some modifications for social and psychological intervention trials) and additional items in the CONSORT-SPI 2018 extension. Empty rows in the ‘CONSORT-SPI 2018’ column indicate that there is no extension to the CONSORT 2010 item

\*We strongly recommended that the CONSORT-SPI 2018 Explanation and Elaboration (E&E) document be reviewed when using the CONSORT-SPI 2018 checklist for important clarifications on each item

§An extension item for cluster trials exists for this CONSORT 2010 item

This checklist is derived from:

* Montgomery, P., Grant, S., Mayo-Wilson, E., Macdonald, G., Michie, S., Hopewell, S., & Moher, D. (2018). Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension. *Trials*, *19*(1), 407.
* Grant, S., Mayo-Wilson, E., Montgomery, P., Macdonald, G., Michie, S., Hopewell, S., & Moher, D. (2018). CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials. *Trials*, *19*(1), 406.
* Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ*, *340*, c332.

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