Reporting checklist for a randomized trial of a social or psychological intervention.

Based on the CONSORT-SPI guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORT-SPI reporting guidelines, and cite them as:

Montgomery P, Grant S, Mayo-Wilson E, Macdonald G, Michie S, Hopewell S, Moher D; on behalf of the CONSORT-SPI Group. Reporting randomized trials of social and psychological interventions: the CONSORT-SPI ٢٠١٨ Extension. Trials. ٢٠١٨; ١٩:٤٠٧.

CONSORT-SPI	N	Reporting Item	Page Number
Title and Abstract			
Title	#١a	Identification as a randomized trial in the title.	
Abstract	#١b	Structured summary of trial design, methods, results, and conclusions. Refer to CONSORT extension for social and psychological intervention trial abstracts (https://trialsjournal.biomedcentral.com/articles/١٠,١١٨٦/s١٣٠٦٣-٠١٨-٢٧٣٥-z/tables/٣)	
Introduction			
Background and objectives	#٢a	Scientific background and explanation of rationale	
Background and objectives	#٢b	Specific objectives or hypothesis, If pre-specified, how the intervention was hypothesized to work.	
Methods			
Trial design	#٣a	Description 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 Randomised Trials (https://www.equator-network.org/reporting-guidelines/consort-cluster/)	
Trial design	#٣b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	#٤a	Eligibility criteria for participants. When applicable, eligibility criteria for settings and those delivering the interventions	
Participants	#٤b	Settings and locations of intervention delivery and where the data were collected	
Interventions	#٥	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Interventions	#٥a	Extent to which interventions were actually delivered by providers and taken up by participants as planned	
Interventions	#٥b	Where other informational materials about delivering the interventions can be accessed	
Interventions	#٥c	When applicable, how intervention providers were assigned to each group	

Outcomes	#٦a	Completely defined pre-specified outcomes, including how and when they were assessed	
Outcomes	#٦b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	#٧a	How sample size was determined.	
Sample size	#٧b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization - Sequence generation	#٨a	Method used to generate the random allocation sequence.	
Randomization - Sequence generation	#٨b	Type of randomization; details of any restriction (such as blocking and block size)	
Randomization - Allocation concealment mechanism	#٩	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned	
Randomization - Implementation	#١٠	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	
Awareness of assignment	#١١a	Who was aware after assignment to interventions (for example, participants, providers, those assessing outcomes), and how any masking was done	
Awareness of assignment	#١١b	If relevant, description of the similarity of interventions	
Analytical methods	#١٢a	Statistical methods used to compare group outcomes. How missing data were handled, with details of any imputation method	
Analytical methods	#١٢b	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and process evaluations	
Results			
Participant flow diagram (strongly recommended)	#١٣a	For each group, the numbers randomly assigned, receiving intended treatment, and analysed for the outcomes. Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment	
Participant flow	#١٣b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	#١٤a	Dates defining the periods of recruitment and follow-up	
Recruitment	#١٤b	Why the trial ended or was stopped	
Baseline data	#١٥	A table showing baseline characteristics for each group. Include socioeconomic variables where applicable	
Numbers analyzed	#١٦	For each group, number included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	#١٧a	For each outcome, results for each group, and the estimated effect size and its precision (such as ٩٥٪ confidence interval). Indicate availability of trial data	
Outcomes and estimation	#١٧b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	#١٨	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	

Harms	#١٩	All-important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	
Discussion			
Limitations	#٢٠	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalizability	#٢١	Generalisability (external validity, applicability) of the trial findings	
Interpretation	#٢٢	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Important information			
Registration	#٢٣	Registration number and name of trial registry	
Protocol	#٢٤	Where the full trial protocol can be accessed, if available	
Declaration of interests	#٢٥	Sources of funding and other support, role of funders. Declaration of any other potential interests	
Stakeholder involvement	#٢٦a	Any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial	
Stakeholder involvement	#٢٦b	Other stakeholder involvement in trial design, conduct, or analyses	
Stakeholder involvement	#٢٦c	Incentives offered as part of the trial	