CONSORT-SPI 2018 Checklist with Cluster Extension Items

SECTION	ITEM #	CONSORT 2010	CONSORT-SPI 2018	Cluster Extension Items	REPORTED ON PAGE #
TITLE AND ABSTRACT					
	1a	Identification as a randomised trial in the title		Identification as a cluster 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	Refer to CONSORT extension for social and psychological intervention trial abstracts with cluster extension items	Click here to enter text.
INTRODUCTION					
Background and Objectives	2a	Scientific background and explanation of rationale		Rationale for using a cluster design	Click here to enter text.
	2b	Specific objectives or hypotheses	If pre-specified, how the intervention was hypothesised to work	Whether objectives pertain to the cluster level, the individual participant level, or both	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	Definition of cluster and description of how the design features apply to the clusters	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	Eligibility criteria for clusters	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		Whether interventions pertain to the cluster level, the individual participant level, or both	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		Whether outcome measures pertain to the cluster level, the individual participant level, or both	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		Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or ***k***), and an indication of its uncertainty	Click here to enter text.

	7b	When applicable, explanation of any interim analyses and stopping guidelines			Click here to enter text.
RANDOMISATION					
Sequence generation	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)		Details of stratification or matching if used	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		Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level, or both	Click here to enter text.
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Click here to enter text.
				Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	
				From whom consent was sought (representatives of the cluster, individual cluster members, or both) and whether consent was sought before or after randomisation	
Awareness of assignment	11a	Who was aware of intervention assignment after allocation (for example, participants, providers, those assessing			Click here to enter text.

		outcomes), and how any masking was done			
	11b	If relevant, description of the similarity of interventions			Click here to enter text.
Analytical methods	12a	Statistical methods used to compare group outcomes	How missing data were handled, with details of any imputation method	How clustering was taken into account	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	For each group, the numbers of clusters that were randomly assigned, received the intended treatment, and were analysed for the primary outcome	Click here to enter text.
	13b	For each group, losses and exclusions after randomisation, together with reasons		For each group, losses and exclusions for both clusters and individual cluster members	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	Baseline characteristics for the individual and cluster levels as applicable for each group	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		For each group, the number of clusters included in each analysis	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	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or ***k***) for each primary outcome	Click here to enter text.
	17b	For binary outcomes, the presentation of both absolute and relative effect sizes is recommended			Click here to enter text.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses, adjusted analyses, and process evaluations, distinguishing pre-specified from exploratory			Click here to enter text.
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for Harms)			Click here to enter text.
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	Generalisability to clusters or individual participants (as relevant)	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

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.

- Campbell, M. K., Piaggio, G., Elbourne, D. R., & Altman, D. G. (2012). Consort 2010 statement: extension to cluster randomised trials. *BMJ*, *345*, e5661.

- Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ, 340, c332.