Items to report in the abstract for cluster randomised social and psychological intervention trials

Section	CONSORT Abstract item	Relevant CONSORT-SPI item	Relevant CONSORT Cluster extension item	Reported on Page #		
Title	Identification of the study as randomised		Identification of study as cluster randomized	Click here to enter text.		
Authors	Contact details for the corresponding author			Click here to enter text.		
Trial Design	Description of the trial design (e.g. parallel, cluster, noninferiority)	If the unit of random assignment is not the individual, refer to CONSORT for Cluster Randomised Trials and report the items included in its extension for abstracts [33]		Click here to enter text.		
Methods						
Participants	Eligibility criteria for participants and the settings where the data were collected	When applicable, the eligibility criteria for the setting of the intervention delivery and the eligibility criteria for the persons who delivered the interventions	Eligibility criteria for clusters	Click here to enter text.		
Interventions	Interventions intended for each group			Click here to enter text.		
Objective	Specific objective or hypothesis	If pre-specified, how the intervention was hypothesised to work	Whether objective or hypothesis pertains to the cluster level, the individual participant level, or both	Click here to enter text.		
Outcomes	Clearly defined primary outcome for this report		Whether the primary outcome pertains to the cluster level, the individual participant level, or both	Click here to enter text.		
Randomisation	How participants were allocated to interventions		How clusters were allocated to interventions	Click here to enter text.		

Awareness of assignment	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.
Results				
Number randomly assigned	Number randomised to each group		Number of clusters randomised to each group	Click here to enter text.
Recruitment	Trial status			Click here to enter text.
Interventions		Extent to which interventions were actually delivered by providers and taken up by participants as planned		Click here to enter text.
Number Analysed	Number analysed in each group		Number of clusters analysed in each group	Click here to enter text.
Outcomes	For the primary outcome, a result for each group and the estimated effect size and its precision		Results at the cluster or individual level as applicable for each primary outcome	Click here to enter text.
Harms	Important adverse events or side effects			Click here to enter text.
Conclusions	General interpretation of the results			Click here to enter text.
Trial registration	Registration number and name of trial register			Click here to enter text.
Funding	Source of funding			Click here to enter text.

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.
- Hopewell, S., Clarke, M., Moher, D., Wager, E., Middleton, P., Altman, D. G., Schulz, K. F., .& the CONSORT Group. (2008). CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Medicine*, *5*(1), e20.
- Campbell, M. K., Piaggio, G., Elbourne, D. R., & Altman, D. G. (2012). Consort 2010 statement: extension to cluster randomised trials. *BMJ*, 345, e5661.

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