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

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| --- | --- | --- | --- | --- |
| 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](https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2733-1#ref-CR33)] |  | 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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