

## **Author's response to reviews**

**Title:** Improving calculation, interpretation and communication of familial colorectal cancer risk: a randomized controlled trial

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## CONSORT Checklist of items to include when reporting a cluster randomised trial

(Campbell MK, Elbourne DR, Altman DG: CONSORT statement: extension to cluster randomised trials. BMJ 2004, 328(7441):702-708.)

Paper section and topic	Item	Descriptor [section title] <sup>1</sup>	Page number
<b>Title and abstract</b> Design	1	How participants were allocated to interventions (eg random allocation, randomised, or randomly assigned), specifying that allocation was based on clusters <b>[Title; Abstract]</b> .	1,3
<b>Introduction</b> Background	2	Scientific background and explanation of rationale <b>[Background]</b> , including the rationale for using a cluster design <b>[Trial design]</b> .	5-8
<b>Methods</b> Participants	3	Eligibility criteria for participants and clusters <b>[Inclusion criteria; Exclusion criteria]</b> and the settings and locations where the data were collected <b>[Recruitment of general practices; Recruitment of patient participants]</b> .	8-10
Interventions	4	Precise details of the interventions intended for each group, whether they pertain to the individual level, the cluster level, or both, and how <b>[Control group; Intervention group]</b> and when they were actually administered <b>[Timing of recruitment, intervention delivery and follow-up]</b> .	10-11
Objectives	5	Specific objectives and hypotheses and whether they pertain to the individual level, the cluster level, or both <b>[Trial objectives]</b> .	8
Outcomes	6	Report clearly defined primary and secondary outcome measures, whether they pertain to the individual level, the cluster level, or both <b>[Primary outcome measures; Secondary outcome measures; Table 1]</b> , and, when applicable, any methods used to enhance the quality of measurements (eg multiple observations, training of assessors) <b>[Data quality assurance]</b> .	9, 13-15
Sample size	7	How total sample size was determined (including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty) and, when applicable, explanation of any interim analyses and stopping rules <b>[Sample size]</b> .	13
Randomization Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching) <b>[Randomisation and allocation concealment]</b> .	8
Allocation concealment	9	Method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned <b>[Randomisation and allocation concealment]</b> .	8
Implementation	10	Who generated the allocation sequence <b>[Randomisation and allocation concealment]</b> , who enrolled participants <b>[Recruitment of general practices; Recruitment of patient participants; Applying the eligibility criteria]</b> , and who assigned participants to their groups <b>[Randomisation and allocation concealment]</b> .	8
Blinding (masking)	11	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment <b>[Blinding]</b> . If done, how the success of blinding was evaluated.	NA
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses <b>[Analyses]</b> .	16-17

<sup>1</sup> The bold text in square brackets refers to the section title within the publication.