Supplementary Material 3a. CONSORT 2010 checklist of information for the Activate cluster-randomised controlled trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs
Title and abstract			
	1a	Identification as a randomised trial in the title: YES	Identification as a cluster randomised trial in the title: YES
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts):[1,2] MOSTLY	See Appendix 3b below
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale: YES	Rationale for using a cluster design: YES
	2b	Specific objectives or hypotheses: YES	Whether objectives pertain to the cluster level, the individual participant level or both: YES
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio: YES	Definition of cluster and description of how the design features apply to the clusters: YES
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons: Not applicable	
Participants	4a	Eligibility criteria for participants: YES	Eligibility criteria for clusters: YES
	4b	Settings and locations where the data were collected: YES	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered: YES	Whether interventions pertain to the cluster level, the individual participant level or both: YES (also in published protocol)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed: YES	Whether outcome measures pertain to the cluster level, the individual participant level or both: YES
	6b	Any changes to trial outcomes after the trial commenced, with reasons: not applicable	
Sample size	7a	How sample size was determined: YES	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: YES
	7b	When applicable, explanation of any interim analyses and stopping guidelines: not applicable	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence: YES	
	8b	Type of randomisation; details	Details of stratification or matching if

		of any restriction (such as blocking and block size): YES	used: YES
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned: YES	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: YES
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions: YES
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling): YES
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation: YES
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how: YES	
	11b	If relevant, description of the similarity of interventions: not applicable	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes: YES	How clustering was taken into account: YES
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses: YES	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome: YES	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome: YES (CONSORT diagram)
	13b	For each group, losses and exclusions after randomisation, together with reasons: YES	For each group, losses and exclusions for both clusters and individual cluster members: YES (CONSORT diagram)
Recruitment	14a	Dates defining the periods of recruitment and follow-up: YES	
	14b	Why the trial ended or was stopped: not applicable	
Baseline data	15	A table showing baseline	Baseline characteristics for the

		demographic and clinical characteristics for each group: YES	individual and cluster levels as applicable for each group: YES (for individuals for each group)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups: YES (CONSORT diagram)	For each group, number of clusters included in each analysis: NO (but not necessary, as individual analyses, taking account of clustering in analyses)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval): YES	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome: YES (results at individual level)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended: not applicable	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory: YES	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3]): Not applicable	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses: YES	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings: YES	Generalisability to clusters and/or individual participants (as relevant): YES (to individual participants)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence: YES	
Other information			
Registration	23	Registration number and name of trial registry: YES	
Protocol	24	Where the full trial protocol can be accessed, if available: YES	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders: YES	

Supplementary Material 3b. Extension of CONSORT for abstracts[1,2,3] to reports of cluster-randomised trials

Item	**Standard Checklist item**	**Extension for cluster trials**
Title		
Trial design	Identification of study as	Identification of study as cluster

	randomised: YES Description of the trial design (e.g. parallel, cluster, non-inferiority): YES	randomised: YES
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected: Partly	Eligibility criteria for clusters: NO
Interventions	Interventions intended for each group: YES	
Objective	Specific objective or hypothesis: YES	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both: YES (individual)
Outcome	Clearly defined primary outcome for this report: YES	Whether the primary outcome pertains to the cluster level, the individual participant level or both: YES (individual)
Randomization	How participants were allocated to interventions: YES	How clusters were allocated to interventions: YES
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment: NO	
Results		
Numbers randomized	Number of participants randomized to each group: YES	Number of clusters randomized to each group: YES
Recruitment	Trial status	Not applicable
Numbers analysed	Number of participants analysed in each group: YES	Number of clusters analysed in each group: NO, not applicable, as analysis at individual level controlling for clustering.
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision: Yes	Results at the cluster or individual participant level as applicable for each primary outcome: At individual level
Harms	Important adverse events or side effects: Not applicable	
Conclusions		
	General interpretation of the results: YES	
Trial registration	Registration number and name of trial register: YES	
Funding	Source of funding: YES	

References

1. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.