Supplementary table 2 CONSORT checklist and its extensions for pragmatic, cluster-randomized and non-inferiority trials

Section and Topic	Standard CONSORT 2010 Checklist item & addressed page number	Extension for pragmatic trial & addressed page number	Extension for cluster-randomized trial & addressed page number	Extension for non-inferiority trial & addressed page number
TITLE & ABSTRACT	Identification as a randomized trial in the title, p.1 Structured summary of trial design, methods, results, and conclusions in the Abstract, p.2		Identification as a cluster-randomized trial in the title, p.1	Identification as a non-inferiority randomized trial in the title, p.1
INTRODUCTION Background and objectives	Scientific background and explanation of rationale, p.4 Specific objectives or hypotheses, p.7	Description of the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem, p. 4	Rationale for using a cluster design. Whether objectives pertain to the cluster level, the individual participant level or both, p.16	Rationale for using a non-inferiority design, p.17 Hypotheses concerning non-inferiority, specifying the non-inferiority margin with the rationale for its choice, p.7 & 12
METHODS Trial design	Description of trial design, p.7		Definition of cluster and description of how the design features apply to the clusters, p.16	
Participants	Eligibility criteria for participants. Settings and locations where the data were collected, p.9	Eligibility criteria explicitly framed to show the degree to which they include typical participants, p.9	Eligibility criteria for clusters, p.8	Whether participants in the non-inferiority trial are similar to those in any trial(s) that established efficacy of the reference treatment, p.17
Interventions	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered, p.10	Description of extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate whether efforts were made to standardize the intervention or whether the intervention and its delivery were allowed to vary between participants,	Whether interventions pertain to the cluster level, the individual participant level or both, p.8	Whether the reference treatment in the non-inferiority trial is identical (or very similar) to that in any trial(s) that established efficacy, p.17

		practitioners, or study sites. Describe the comparator in similar detail to the intervention, p. 10		
Outcomes	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed, p.13, Table 1	Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial, p.7	Whether outcome measures pertain to the cluster level, the individual participant level or both, p.8	Specify the non-inferiority outcome(s) and whether hypotheses for main and secondary outcome(s) are non-inferiority or superiority. Whether the outcomes in the non-inferiority trial are identical (or very similar) to those in any trial(s) that established efficacy of the reference treatment, p.17
Sample size	How sample size was determined. When applicable, explanation of any interim analyses and stopping guideline, p.12	If calculated using the smallest difference considered important by the target decision maker audience, then report where this difference was obtained, p.12	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intra-cluster correlation (ICC or *k*), and an indication of its uncertainty, p.12	Whether the sample size was calculated using a non-inferiority criterion and, if so, what the non-inferiority margin was. To which outcome(s) they apply and whether related to a non-inferiority hypothesis, p.12
Randomization -- Sequence generation	Method used to generate the random allocation sequence. Type of randomization; details of any restriction, p.8	N/A	Details of stratification or matching if used, p.8	
Randomization -- Allocation concealment	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned, p.8	N/A	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, p.8	

Randomization -- Implementation	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups, p.8	N/A	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions. 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, or individual cluster members, or both), and whether consent was sought before or after randomization, p.7	
Blinding	If done, who was blinded after assignment to interventions and how. If relevant, description of the similarity of interventions, p.8	If blinding was not done, or was not possible, explain why, p.8		
Statistical methods	Statistical methods used to compare groups for primary and secondary outcomes. Methods for additional analyses, such as subgroup analyses and adjusted analyses, p.15		How clustering was taken into account, p.16	Whether a 1- or 2-sided confidence interval approach was used, N/A
RESULTS Participant flow	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome. For each group, losses and exclusions after randomization, together with reasons, N/A	The number of participants or units approached to take part in the trial, the number that were eligible, and reasons for non-participation should be reported, p.9, Figure 2	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analyzed for the primary outcome. For each group, losses and exclusions for both clusters and individual cluster members, p.2	
Recruitment	Dates defining the periods of recruitment and follow-up. Why the trial ended or was stopped, N/A	-		

Baseline data	A table showing baseline demographic and clinical characteristics for each group, N/A	N/A	N/A	
Numbers analyzed	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups, N/A	-	For each group, number of clusters included in each analysis, p.8	
Outcomes and estimation	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval), N/A	-	Results at the individual or cluster level as applicable and a coefficient of intra-cluster correlation (ICC or k) for each primary outcome, p.12	For the outcome(s) for which non-inferiority was hypothesized, a figure showing confidence intervals and the non-inferiority margin may be useful, N/A
Ancillary analyses	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory, p.15	-		
Harms	All important harms or unintended effects in each group, N/A	-		
DISCUSSION Limitation	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses, p.3	-		
Generalizability	Generalizability (external validity, applicability) of the trial findings, p.16	Describe key aspects of the setting that determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organization, staffing, or resources may vary from those	Generalizability to clusters and/or individual participants (as relevant), p.16	

		of the trial, p.16		
Interpretation	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence. N/A	-		Interpret results in relation to the non-inferiority hypothesis. If a superiority conclusion is drawn for outcome(s) for which non-inferiority was hypothesized, provide justification for switching, p.12
OTHER INFORMATION Registration	Registration number and name of trial registry, p.1			
Protocol	Where the full trial protocol can be accessed, if available, p.1			
Funding	Sources of funding and other support (such as supply of drugs), role of funders, p.1			

CONSORT: Consolidated Standards of Reporting Trials; N/A = Not applicable