Supplementary Table 1 CONSORT checklist and its extensions for pragmatic and cluster-randomized trial

Section	Standard CONSORT description	Extension for pragmatic trials	Extension for cluster designs
Title and abstract	How participants were allocated to interventions (eg, “random allocation,” “randomised,” or “randomly assigned”) (Page 1) Structured abstract (Page 3-4).	Stated in the Title as in Page 1 Structured abstract (Page 3-4)	Identification as a cluster randomised trial in the title (Page 1) Structured abstract (Page 3-4)
Introduction			
Background	Scientific background and explanation of rationale (Page 3-4).	Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem (Page 23).	Rationale for using a cluster design (Page 22).
Objectives	Specific objectives and hypotheses (Page 8)		Whether objectives pertain to the cluster level, the individual participant level or both (Page 22).
Methods			
Trial designs	Description of trial design (such as parallel, factorial)	Not applicable	Definition of cluster and description of how the design

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	including allocation ratio Important changes to methods after trial commencement (such as eligibility criteria), with reasons (Page 9).		features apply to the clusters (Page 22).
Participants	Eligibility criteria for participants; settings and locations where the data were collected (Page 12).	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable - settings of care (Page 23)	Eligibility criteria for clusters (Page 22).
Interventions	Precise details of the interventions intended for each group and how and when they were actually administered (Page 14)	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites (Page 14).	Whether interventions pertain to the cluster level, the individual participant level or both (Page 14)
		Describe the comparator in similar detail to the intervention (Page 14).	

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Outcomes	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors) (Page 11, 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 (Page 11, Table 1).	Whether outcome measures pertain to the cluster level, the individual participant level or both (Page 11, Table 1).
Sample size	How sample size was determined; explanation of any interim analyses and stopping rules when applicable (Page 16)	If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained (Page 16).	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 (Page 16).
Randomisation—sequence generation	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification) (Page 13).	Not applicable	Details of stratification or matching if used (Page 13).
Randomisation—allocation	Method used to implement the random allocation	Not applicable	Specification that allocation was based on clusters rather

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concealment	sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned (Page 13).		than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both (Page 13).
Randomisation—implementation	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions (Page 13).
Blinding (masking)	Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment (Page 9).	If blinding was not done, or was not possible, explain why	
Statistical methods	Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses (Page 21).		How clustering was taken into account (Page 22).
Results			
Participant flow	Flow of participants through	The number of participants or	For each group, the numbers of

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	each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study protocol, together with reasons (Not available).	units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported (Not available).	clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome (Not available).
Recruitment	Dates defining the periods of recruitment and follow-up (Not available).	Not available	Not available
Baseline data	Baseline demographic and clinical characteristics of each group (Not available).	Not available	Baseline characteristics for the individual and cluster levels as applicable for each group
Numbers analysed	Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (eg, 10/20, not 50%) (Not available).	Not available	For each group, number of clusters included in each analysis (Not available).

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Outcomes and estimation	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (eg, 95% CI) (Not available).		Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome (Not available).
Ancillary analyses	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory (Not available).		
Adverse events	All important adverse events or side effects in each intervention group (Not available).		
Discussion			
Interpretation	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes (Not		

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	available).		
Generalisability	Generalisability (external validity) of the trial findings (Page 23)	Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial (Not available).	Generalisability to clusters and/or individual participants (as relevant) (Not available).
Overall evidence	General interpretation of the results in the context of current evidence (Not available).		

CONSORT: Consolidated Standards of Reporting Trials