Checklist S1: Checklist of information to include when reporting a stepped wedge cluster randomised trial (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and abstract			
	1a	Identification as a SW-CRT in the title.	Title
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	Abstract
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	Introduction, Paragraphs 1-4
	2b	Specific objectives or hypotheses.	Introduction, Para 4
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	Methods - Study design, Randomization, Study Intervention, and Study Participants sections; Figure 2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	N/A
Participants	4a	Eligibility criteria for clusters and participants.	Methods - Study Participants, Para 2
	4b	Settings and locations where the data were collected.	Methods - Study Setting; Figure 1
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	Methods - Study Intervention; Figure S1
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	Methods - Outcomes
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	Methods - Outcomes, Para 2
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	Methods - Power Calculation and Sample Size
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	Methods – Randomization, Para 2
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	Methods – Randomization, Para 2; Table S1
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after recruitment.	Methods - Study Design and Randomization
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	Methods - Study Design and Randomization
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	Methods - Study Intervention and Study Participants
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	Methods - Study Participants
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	N/A
	11b	If relevant, description of the similarity of treatments.	N/A
Statistical methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	Methods – Statistical Methods; Supplemental Methods file
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	Methods – Statistical Methods, Para 2

(*Continued*)

Supplementary materials 3 (*Continued*)

Topic	Item no	Checklist item	Page no
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analysed for the primary outcome (see separate SW-CRT flow chart).	Results – Study Population; Figure 2; Figure S2; Figure 3
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	Figure 3
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	Results – Study Population, Para 1; Figure 2 and S2
	14b	Why the trial ended or was stopped.	N/A
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	Table 1; Results - Study Population, Para 1
Numbers analysed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule.	Results – Study Population; Tables 1-4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	Table 3; Figure 4; Tables S3 and S4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	Table 3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	Results - Clinical Failure and Adverse Events; Figure 4; Table S4
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	Figure 4; Table S4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	Discussion -Para 7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	Discussion - Para 7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	Discussion - Para 1-5
Other information			Methods – Research ethics review and trial registration
Registration	23	Registration number and name of trial registry.	
Protocol	24	Where the full trial protocol can be accessed, if available.	Supplemental Regulatory Material File
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	Funding Statement
Research ethics review	26	Whether the study was approved by a research ethics committee, with identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	Methods – Research ethics review and trial registration

This checklist has been taken from table 3 in *BMJ* 2018;363:k1614, as a standalone document for readers to print out or fill in electronically.