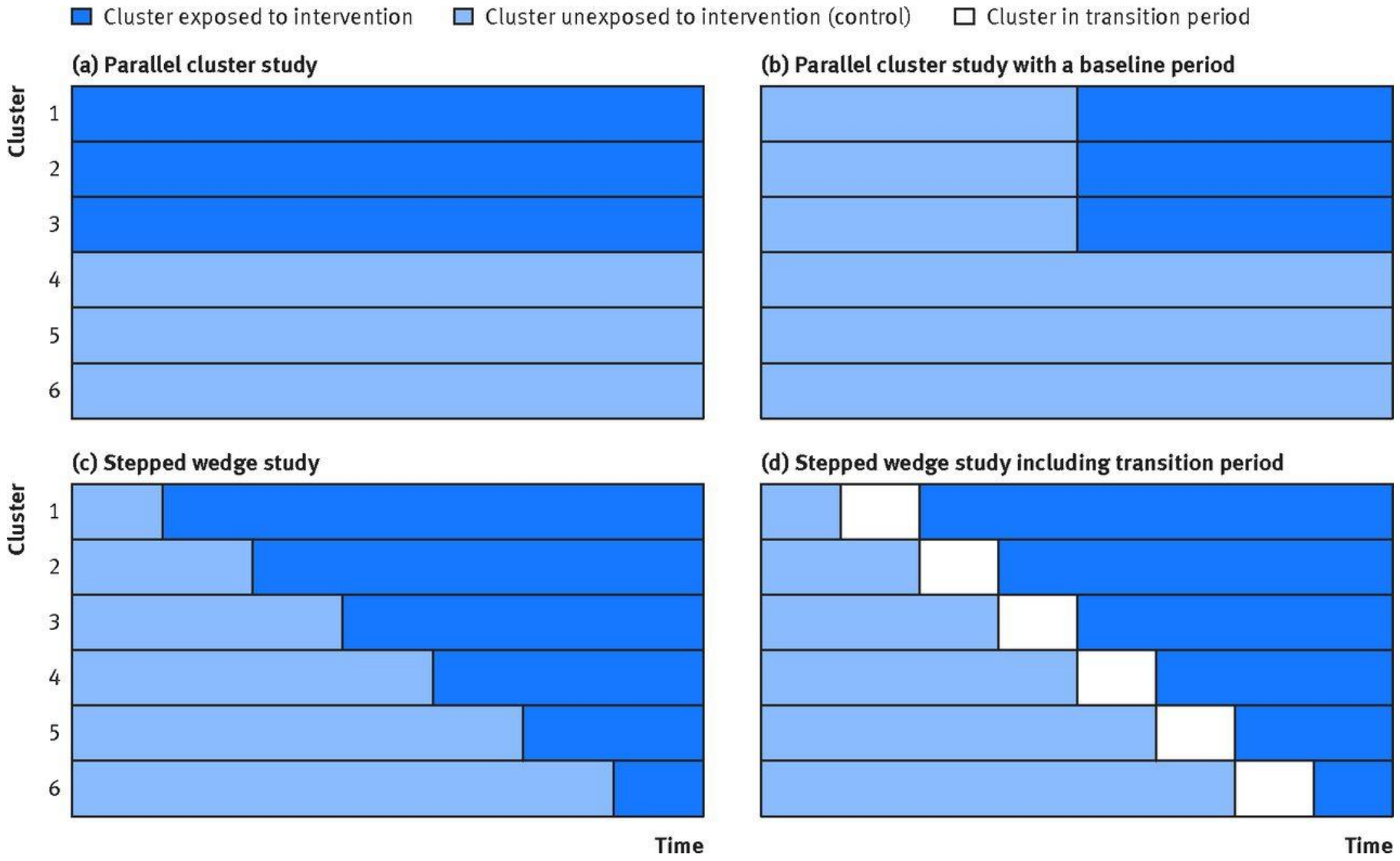
A conventional parallel cluster study (with variations) and the stepped wedge study design.



Hemming et al. BMJ 2015;350:bmj.h391

Reasons for using a stepped wedge trial design

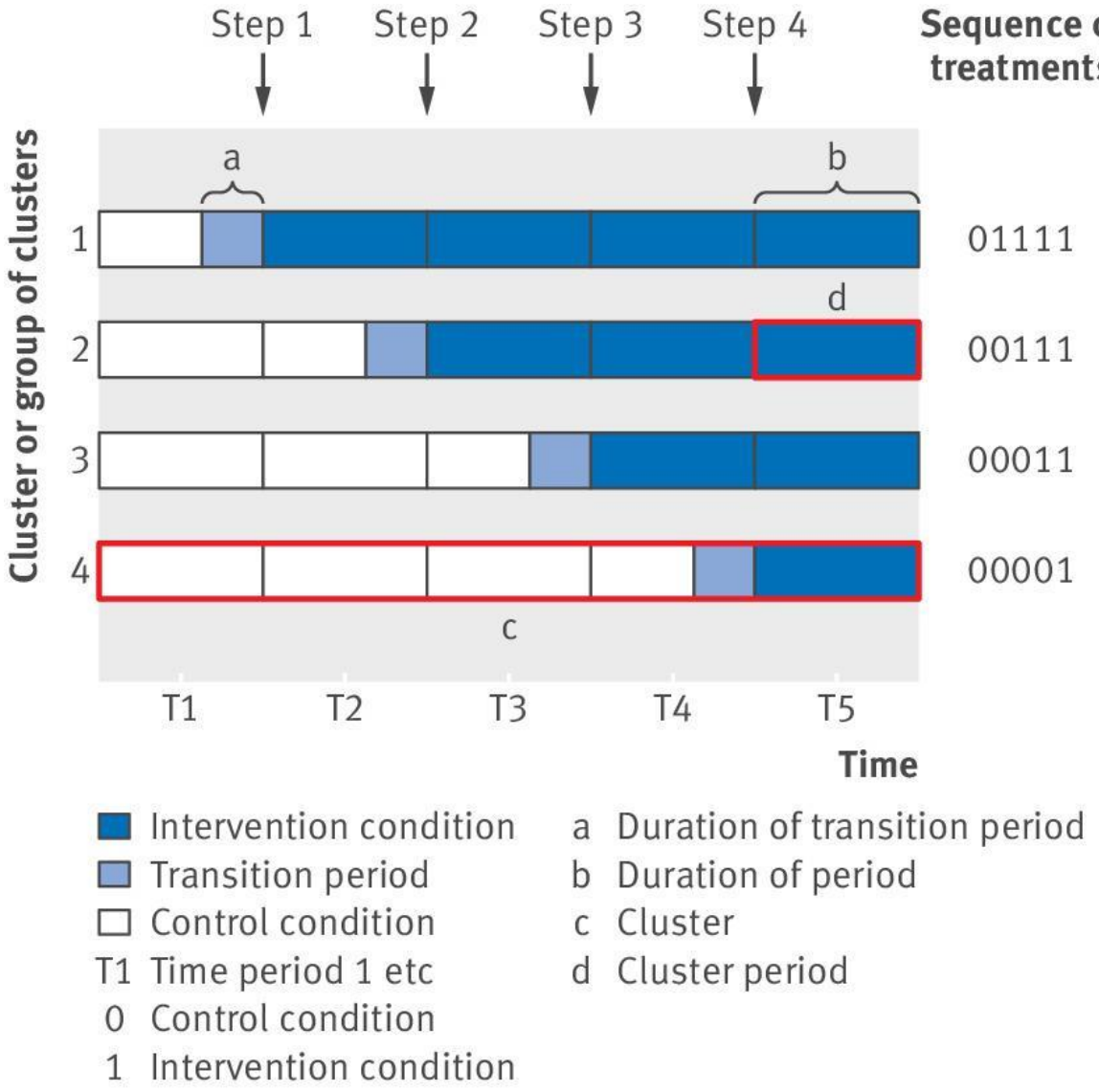
Ethical

Statistical

Social/political

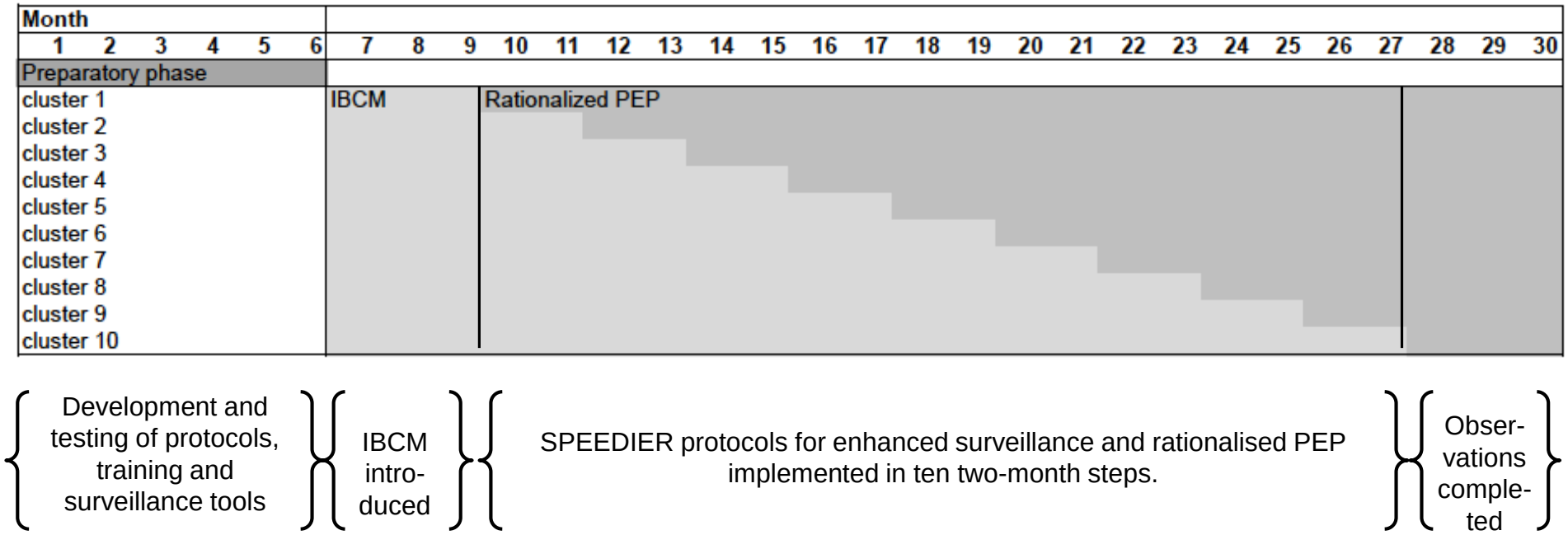
Logistical

The standard stepped wedge cluster randomised trial



Karla Hemming et al. BMJ 2018;363:bmj.k1614

The SPEEDIER stepped wedge cluster randomised trial.



Concept	Description	Why important	Mitigating strategies
Imbalance with respect to time	Observations under control condition are on average taken earlier than observations under the intervention	May cause confounding by secular trends	Allow for confounding in sample size calculation and analysis
Repeated measures on same clusters	Measurements are repeated over time within each cluster, on same or different participants	May lead to complex correlation structures	Allow for intra-cluster correlations in sample size calculation and analysis
Within cluster contamination	Clusters are exposed to both intervention and control conditions	Some participants may be exposed to both conditions	Avoid delayed assessment of outcomes
Delayed treatment effects/transition periods	There may be a delay before effect of intervention is realised	Estimate of effect may be attenuated	Allow a transition period before measurements are taken
Time by treatment effect interactions	Effects may strengthen or wear off over time post-intervention	For a permanent (rather than one-off) intervention, refinement/learning may strengthen effect over time	Analysis should examine how treatment effects change over time
Sampling of observations	Trials may involve complete enumeration, random sampling within cluster or recruitment into the trial	Recruitment may incur risk of bias	Complete enumeration
Continuous or discrete time measurements	Observations may be accrued continuously or at discrete points in time (e.g. repeated cross sectional surveys)	Where outcomes are accrued in discrete time, they are more likely to be measured in discrete time intervals	Collect exact timings of outcomes
Justification of study type	Staggered exposure of intervention requires justification	Leads to risk of bias and may involve exposing greater numbers of clusters	Submit to approved research ethics committee

CONSORT Checklist for Stepped Wedge Trials

Supplementary materials 3: 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.	
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	
	2b	Specific objectives or hypotheses.	
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.	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	
Participants	4a	Eligibility criteria for clusters and participants.	
	4b	Settings and locations where the data were collected.	
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.	
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	
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).	
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	
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.	
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	
	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.	
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	
	11b	If relevant, description of the similarity of treatments.	
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.	
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	

(Continued)

Proposal

Proposal/protocol

Not relevant

Proposal/protocol

Proposal/ protocol

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).	
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	
	14b	Why the trial ended or was stopped.	
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	
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.	
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.	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	
Other information			
Registration	23	Registration number and name of trial registry.	
Protocol	24	Where the full trial protocol can be accessed, if available.	
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	
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.	

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.