

Stepped wedge cluster randomized trials present advantages, challenges compared to other research methods

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The stepped wedge cluster randomized trial (SW-CRT) is a research methodology that has been growing in popularity, particularly for

pragmatic implementation and dissemination trials. SW-CRTs can have advantages over parallel cluster randomized trials with regards to statistical power. Clusters, such groups of physicians working together in a practice rather than individual physicians, are randomized to a sequence, which determines when—not if—they receive the intervention, which makes this design appealing and relevant for quality improvement and practice transformation initiatives. They also offer a pragmatic approach to providing the intervention to all practices.

For their study published in *The Annals of Family Medicine*, researchers interviewed investigators who conducted cluster randomized trials as part of the EvidenceNOW: Advancing Heart Health Initiative, one of the largest practice-improvement primary care studies funded by the Agency for Healthcare Research and Quality. All interviewees reported that SW-CRT can be an effective study design for large-scale intervention implementations. Advantages include: (1) incentivized recruitment, (2) staggered resource allocation, and (3) statistical power. Challenges included: (1) time-sensitive recruitment, (2) retention, (3) randomization requirements and practice preferences, (4) achieving treatment schedule fidelity, (5) intensive data collection, (6) Hawthorne effect (sites modifying their behavior when made aware that they are being observed), and (7) changes that may occur in primary care clinics over time not associated with an intervention implementation.

The [challenges](#) experienced by EvidenceNOW grantees suggest that certain favorable, [real-world conditions](#) can increase the odds of a successful SW-CRT. Existing infrastructure can support the recruitment of many practices. Strong retention plans are needed to continue to engage sites waiting to start the intervention. Finally, study outcomes should be ones already captured in routine practice—otherwise, funders and investigators should assess the feasibility and cost of data collection.

More information: Ann M. Nguyen et al, Considerations Before

Selecting a Stepped-Wedge Cluster Randomized Trial Design for a Practice Improvement Study, *The Annals of Family Medicine* (2022).
[DOI: 10.1370/afm.2810](https://doi.org/10.1370/afm.2810)

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