The Application of Stepped-Wedge Cluster-Randomised Controlled Trial Designs in Oncology Research

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What we did

We conducted a systematic review to examine the application of stepped-wedge cluster-randomised controlled trial designs in oncology research

We mapped design features, protocol deviations, and implementation outcomes and strategies

We searched 5 databases in July 2023

What we found

- 15 trials were identified; most were poorly reported
- Trials used a mix of efficacy and implementation outcomes
- 7 (47%) trials evaluated a new model of care
- 9 (60%) trials were conducted in the outpatient setting
- 12 (80%) trials used implementation strategies to deliver the intervention. Most common:
  - Educating and training healthcare professionals (n=12; 100%)
  - Evaluative and iterative strategies (n=5; 42%)
- Protocol deviations were common:
  - Change to trial duration (n=7; 47%)
  - Did not meet sample size targets (n=5; 33%)
  - Change to number of clusters (n=4; 27%)
  - Change to secondary outcomes (n=4; 27%)
- Few trials demonstrated significant effects on the primary outcome (n=6; 40%)

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Stepped-wedge trials bring promise as a methodology to change practice and benefit people affected by cancer when robustly designed and implemented

Greater implementation rigor is required to ensure interventions delivered via stepped-wedge cluster-randomised controlled trials are effective