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**A Novel ‘Helix’ Crossover Randomised Study Design: Methodological Description and Potential Application to Implementation Research**

**Presenting Authors**

Mr Mitchell Sarkies

**Affiliation**

1. Monash University
2. Monash Health

**Country of residence**

Australia

**Objectives/aims**

Frequently, the benefits of new evidence are not successfully implemented due to difficulties applying traditional research methodologies to implementation settings. Randomised controlled trials are the gold standard for evaluating healthcare outcomes, but are not always practical for the implementation phase of knowledge transfer. We propose a novel ‘helix’ crossover randomised study design where crossover is employed, but contamination is averted through use of different health contexts in which to test the implementation strategy.

**Methods**

The helix design is a category of crossover randomised design where the independent variable (implementation strategy) has two or more levels evaluated across an equivalent number of health context areas (e.g. falls prevention or language interpreting) using the same dependent variable. Unlike a conventional crossover design, the different levels of independent variable do not need to be delivered to the individual participant or participating health service sequentially. They can be delivered simultaneously because each level of the independent variable uses a different health context within each individual participant or participating health service to avoid the effect of treatment “contamination” from exposure to the intervention or control condition.

**Main findings**

An example application of the helix design is presented in a hypothetical research implementation study to demonstrate the pragmatic comparison of ‘video-based’ and ‘written-based’ evidence summary research implementation strategies for changing self-reported clinical practice in community acquired pneumonia and nutrition in critically ill patient health contexts.