# Design & Analysis of Cluster Randomised and Stepped Wedge Trials



## Overview

This course will provide a clear understanding of the design and analysis of cluster randomised trials and stepped wedge trials. These trials are increasingly used to evaluate health and social interventions. They require specific methods of statistical analysis. This course will include the rationale for using these designs, specific design issues, the randomisation process, sample size calculations, analytical methods, ethical considerations, and trial reporting and interpretation. We will include case studies from low-, middle- and high-income settings. Participants will gain practical experience of data analysis using the computer package Stata.

# Course objectives

By the end of this course, attendees will be able to critique and apply a range of appropriate design approaches and analytical methods for cluster randomised and stepped wedge trials. The course will cover:

- Key concepts of cluster randomised trials, including measures of betweencluster variation and the rationale for cluster randomisation
- Design of cluster-randomised trials, including stratification and randomisation procedures
- Calculation of sample size
- Analysis of cluster randomised trials using both cluster-level summaries and individual-level data (random effects models and generalised estimating equations)
- Design and analysis of stepped wedge trials
- Ethical considerations, data monitoring and reporting of CRTs

## Teaching Methods

Teaching will take place through a blend of pre-recorded video lectures and hands-on, live, practical sessions. Participants will be expected to have watched the video lecture before the related practical. There will be a strong emphasis on the practical exercises where participants will have hands-on experience using Stata to analyse illustrative datasets from a variety of trials.

Live practical sessions will run each day of the course. These live sessions will take place from approximately 10.00am to 4.00pm British Summer Time (BST). The live sessions will take place online using Zoom.

## **Entry Requirements**

We require students to have experience of the use of Stata for standard epidemiological analyses (e.g. linear, Poisson and logistic regression) and a working knowledge of clinical trials and statistics.

## Attendance

This short course is studied online on a fulltime basis for one week. Most participants should expect to spend approximately 7 hours a day on the course.

## Key information



#### Course organisers:

Jennifer Thompson and John Bradley



#### Fees for 2021:

£1,400



#### Contact email:

shortcourses@lshtm.ac.uk



#### Find out more and apply:

www.lshtm.ac.uk/study/courses/ short-courses/cluster-randomised-trials