



MODULE SPECIFICATION

Academic Year	2026-27
Module Code	CTM209
Module Title	Design and Analysis of Cluster Randomised and Stepped Wedge Trials
Module Organiser(s)	Natasha Larke, Joe Biggs
Contact Email	For students studying University of London Awards (initial registration 2025/2026 and prior years: Enquiries may be made via their Student Advice Centre at: Student Advice Centre. For students studying LSHTM awards (registration in 2026/2027 and onwards) : Enquiries should be emailed to CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health
FHEQ Level	Level 7
Credit Value	CATS 15 ECTS 7.5
Mode of Delivery	Distance Learning
Mode of Study	One week Intensive in-Person or Intensive online Followed by directed self-study, through online materials via the Virtual Learning Environment
Language of Study	English
Pre-Requisites	All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules. Students who do not have a background in clinical trials or epidemiology may need to spend some time familiarising themselves with terminology before they can successfully complete any of the CT elective modules. You will need a working knowledge of standard statistical methods used in epidemiological analyses (e.g. linear, Poisson and logistic regression) and of clinical trials. Except with the special permission of the Programme Director, MSc Clinical Trials students must study CTM208 Further statistical methods in clinical trials or EPM304 Advanced statistical methods in epidemiology before studying CTM209. (Students

	must not be registered for, and must not study, both CTM208 and EPM304 because the content of both modules overlaps.). The course is taught primarily in R, but detailed explanations of how to implement the methods will be provided in both Stata and R. Course participants should have either a basic knowledge of R or a solid knowledge of Stata. Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.
Accreditation by Professional Statutory and Regulatory Body	Not currently accredited by any other body.
Module Cap (Maximum number of students)	While there is no formal enrolment cap for the CTM209 module and the associated SDAC short course, we reserve the right to limit numbers based on staffing levels or facility capacity. Places will be allocated on a first-come, first-served basis; therefore, CTM209 students are encouraged to register early to guarantee admission. Generally, students who complete their elective registration by October 1st are successfully admitted to the module, although late registration at the discretion of the MO/PDs will usually be considered, given that students will not begin studies on this module until June/July.
Target Audience	Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials, MSc Epidemiology. Also open to any other student who meets pre-requisites for the module and who wishes to learn about Cluster Randomised Trials and stepped wedge trials.
Module Description	This course will provide a clear understanding of how to design and analyse cluster randomised trials and stepped wedge trials. The module covers key principles such as when to use these trials, potential issues when designing them, the statistical methods and skills needed to analyse the data, and how to interpret the findings.
Duration	Students begin their studies in end June/start July 2027. Students are required to attend live sessions from 9.30 (BST) to 17:00 (BST) either in-person or online for the full 5 days of teaching. Students then continue to work on their formative assessments, working to 17 th July deadline. Tutor feedback on the formative assignment will be returned by the 31 st July and students then work to submitting their AA by September 1 st .

Last Revised (e.g. year changes approved)	February 2026
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For students studying UoL awards (initial registration in 2025/2026 and prior years)

Programme(s)	Status
This module is linked to the following programme(s)	
PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Elective
PGDip/MSc Epidemiology (Distance Learning - University of London Worldwide)	Elective

For students studying LSHTM awards (registration in 2026/2027 and onwards)

Programme(s)	Status
This module is linked to the following programme(s)	
PGDip Clinical Trials (Distance Learning)	Elective
MSc Clinical Trials (Distance Learning)	Elective
PGDip Epidemiology (Distance Learning)	Elective
MSc Epidemiology (Distance Learning)	Elective

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: provide students with an understanding of the key concepts and ethics for conducting cluster randomised and stepped wedge trials; and skills in designing and analysing trials with these designs

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: - Describe the key features of cluster randomised and stepped wedge trial designs and evaluate in what circumstances these designs may be more suitable or practical than individually randomised trials; - Critically evaluate design strategies for a cluster randomised trial using information on a given study question and setting, including when a stepped-wedge design should be considered; - Perform, justify and interpret sample size calculations for parallel and stepped-wedge cluster randomised trials, accounting for diverse trial endpoints and the impact of between-cluster variation and cluster size;

Module Intended Learning Outcomes

4. Perform and interpret appropriate statistical analysis of data from cluster randomised trials with different designs and trial endpoints;
5. Evaluate ethical issues specific to a given cluster randomised trial;
6. Appraise and apply international standards for the monitoring and reporting of cluster randomised trials.

Indicative Syllabus

Session Content

The module is expected to include sessions addressing the following topics:

- Introduction and key concepts in cluster randomised trials
- Design of cluster-randomised trials, stratification and randomisation procedures
- Choosing a design Strategy and sample size
- Analyses of CRTs using cluster-level summaries
- Analyses of CRTs using individual level data (mixed effects models)
- Further methods of analysis of CRTs
- Introduction to stepped wedge trials
- Analysis of stepped wedge trials
- Design of stepped wedge trials
- Ethical considerations, Data Monitoring and reporting of CRTs

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	60	40%
Self-directed learning	30	20%
Assessment, review and revision	60	40%
Total	150	100

Teaching and Learning Strategy

The contact time component of the learning time will involve full-time study for one week. This includes live lectures and live, interactive, small-group practicals. This contact time will have a hybrid format and students can choose to attend in person in London or join online. This contact time is delivered via the [Short Course “Design and Analysis of Cluster Randomised and Stepped Wedge Trials”](#). By studying alongside this group of external professionals and practitioners, this module offers a unique opportunity for students to collaborate, network, and gain diverse perspectives on trial design from those currently working in the field. Comprehensive study materials are released during the week of the course. All sessions are recorded and uploaded to the course Moodle page, allowing for convenient review and revision.

In addition to contact time, students are also expected to learn through self-directed study and are provided with a textbook and reading lists to facilitate this.

The module adopts an 'Assessment as Learning' philosophy, recognising that a significant portion of the student learning occurs during the assessment cycle. By providing opportunities for formative assessment and learning, we ensure that the time spent on assignments is not merely evaluative but serves as an opportunity for deep conceptual engagement and practical skill acquisition.

To support their learning, students are expected to:

- submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs. This assessment design adopts a “feed-forwards” approach, which emphasises the importance of feedback that feeds forward into the summative assessment task
- work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided.
- learn from written feedback from tutors on submitted FAs
- make use of LSHTM online library resources.
- make use of Examiners’ Reports which include previous assessed assignment questions and specimen answers.

Assessment

Assessment Strategy

The assessment strategy for CTM209 is designed to support progressive student learning through two formative assessments, one self-assessed (SAFA) and the other tutor-marked with feedback (TMFA) and one summative written assessed assignment (AA). The FAs build skills, and encourage students to engage with the study materials. The FAs encourage M-level thinking through questions which challenge students to consult study materials, to analyse, and problem-solve. They support attainment of ILOs by collectively testing across

Assessment Strategy

the range of learning outcomes. The AA is designed to test whether students are going beyond reiteration of the materials, and using M-level skills of criticality, and wider reflection. The word limits give sufficient text allowance to demonstrate these skills within a succinct and focused writing style. For all CTM209 assessments the application of key learning to scenario-based questions to develop practical skills directly applicable in real cluster randomised and stepped wedge trials. On this module past AA papers, (with specimen answers where appropriate), are also available for practice and self-assessment.

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Intended Module Learning Outcomes Tested
Assessed Assignment	Maximum word length of 4000 words	100	1, 2, 3, 4 and 5

Resitting assessment

Resits will accord with [Chapter 8b](#) of the LSHTM Academic Manual.

Resources

Essential resources

The following materials are provided to students after registration for this module once a year in June/July:

- Course notes, lecture slides and practical exercises. Previous recordings of live lectures are provided.
- Datasets for statistical analysis
- E-books as below
- Articles, papers and online reading.

E-books

- Hayes RJ, Moulton LH. *Cluster Randomised Trials*. Chapman & Hall/CRC; 2017

Examples of online reading

- Campbell MKP. Consort 2010 statement: extension to cluster randomised trials, *BMJ*. 2012 Winter 12;345.
- Cheung YBJ. A simple approach to test for interaction between intervention and an individual-level variable in community randomized trials, *Tropical Medicine & International Health*. 2008;13(2):247–55–.
- Copas AJ, Lewis JJ, Thompson JA, Davey C, Baio G, Hargreaves JR. Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches. *Trials*. 2015 Aug 17;16(1):1.
- Hayes R, Bennett S. Simple sample size calculation for cluster-randomized trials. *International Journal of Epidemiology*. 1999;28(2):319–26.
- Bennett S, Parpia T, Hayes R, Cousens S. Methods for the analysis of incidence rates in cluster randomized trials. *Int J Epidemiology*. 2002; 31: 839-846.
- Weijer CG. The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials, *PLoS Med* [Internet]. Vol. 9. 2012

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for online discussions forums etc.) and the LSHTM online library resources.

Teaching for Disabilities and Learning Differences

The module-specific site on Moodle provides students with access to the module learning materials and online reading list (containing both essential and recommended readings), and additional resources including supplementary exercises and optional lecture recordings (where appropriate). All materials posted up on Moodle areas, including computer-based sessions, have been made accessible where possible. The LSHTM Moodle has been made accessible to the widest possible audience, using a VLE that allows for up to 300% zoom, permits navigation via keyboard and use of speech recognition software, and that allows listening through a screen reader.

For Students studying University of London Awards (initial registration 2025/2026 and prior years):

For students with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London Worldwide website at: [Inclusive practice and Access arrangements | University of London](#)

For Students Studying LSHTM awards (registration 2026/2027 and onwards):

For students who require learning or assessment adjustments and support this can be arranged through the Student Support Services – details and how to request support can be found on the [LSHTM Disability Support pages](#).