MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2023-24
Module Code	CTM209
Module Title	Cluster Randomised Trials
Module Organiser(s)	Natasha Larke, Som Kumar Shrestha
Contact Email	CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine
FHEQ Level	Level 7
Credit Value	**CATS** 15 **ECTS** 7.5
HECoS Code	100962 : 100473
Mode of Delivery	Distance Learning
Mode of Study	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 may need to spend some time familiarising themselves with terminology before they can successfully complete any of the CT elective modules. Except with the special permission of the Programme Director, a student 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.) 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)	There is no cap on the number of students who can register for this distance learning module.
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.
Module Description	The module seeks to develop key knowledge, understanding and skills needed in the design, ethical conduct, analysis, and reporting of cluster randomised trials. A particular emphasis is placed on developing skills in analysing data, and interpreting the results, from cluster randomised trials.
Duration	Distance learning module studies begin in early October. Students may start their studies at any time once they gain access to Moodle and therefore the study materials, and work through the material until the AA submission deadline on 12th May.
Last Revised (e.g. year changes approved)	2023

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

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • equip students with the key knowledge, understanding and skills needed in the design, ethical conduct, analysis, and reporting of cluster randomised trials.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. Demonstrate an understanding of the key features of cluster randomised trials and when this type of trial may be appropriate 2. Critically evaluate design strategies for cluster randomised trials, including sample size requirements 3. Demonstrate skills in analysing data, and interpreting the results, from cluster randomised trials 4. Understand and address ethical issues specific to cluster randomised trials 5. Demonstrate skills in reporting the methods and results 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 • Rationale for cluster-randomisation and choice of clusters • Matching, restricted randomisation and alternative designs • Cluster randomised trials: sample size • Analytical principles and cluster-level analysis of CRTs • Analysis of individual level data • Analysis of pair-matched and stratified CRTs • Ethical issues, Data Monitoring and Interim Analysis of CRTs • Reporting and interpretation of results from cluster randomised trials • Summary.

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
Learning is self-directed against a detailed set of learning outcomes using the materials provided. To support their self-directed learning, students are strongly encouraged to: • post questions for tutors or fellow students and participate in the module-specific discussion board forums available on Moodle. • submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs. • work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade. • learn from written feedback from tutors on submitted AAs. • join real-time tutorials online, or via recorded video tutorials focusing on preparing for assignments. • 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 optional formative assessments, one self-assessed (SAFA) and the other tutor-marked with feedback (TMFA) and one summative written assessed assignment (AA). The FAs have the same word-length and format as the AA, to build skills, and encourage students to engage with the study materials. They encourage M-level thinking through questions which challenge students to consult study materials and to analyse and problem-solve. They support attainment of ILOs by collectively testing across 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: students will be able to answer the questions successfully in fewer words. For all CTM209 assessments the application of key learning to scenario-based questions to develop practical skills directly applicable in real cluster randomised 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 5000 words	100	1, 2, 3, 4 and 5

Formative assignments for this module can be submitted only once annually, no later than **31 March** and must be submitted via the online Assignment Management System.

Time-limited examinations for DL modules are held once a year, mostly in June (including resits).

Examinations are held in accordance with University of London's annual guidance but in 2023/24 they are likely to be held online.

Please note that a separate examination fee may be payable in addition to the module fee. Further details will be communicated as soon as the final decisions are known.

Resitting assessment
Resits will accord with the LSHTM's Resits Policy

Resources

Essential resources

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

- Computer Assisted Learning (CAL) materials provided electronically through the online learning site Moodle, for self-directed study
- Stata datasets.
- E-books as below
- 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; 3 1: 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 with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London website.