# Module Specification

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Cluster Randomised Trials</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM209</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Natasha Larke, Clemence Leyrat, Kathy Baisley</td>
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<tr>
<td>Contact email</td>
<td>The LSHTM distance learning programmes and modules are run in collaboration with the University of London (UoL). Enquiries may be made via their Student Advice Centre at: general <a href="https://london.ac.uk/contact-us">https://london.ac.uk/contact-us</a> email-form click <a href="https://london.ac.uk/contact-us">here</a> (Enquiries from face-to-face i.e. London-based LSHTM MSc or research students regarding study of DL modules should be emailed to <a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>)</td>
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<tr>
<td>Home Faculty</td>
<td>Epidemiology and Population Health London School of Hygiene &amp; Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a></td>
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<tr>
<td>Level</td>
<td>This module is at Level 7 (postgraduate Masters level) of the QAA <a href="https://www.qaa.ac.uk/">Framework for Higher Education Qualifications</a> in England, Wales &amp; Northern Ireland (FHEQ).</td>
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<tr>
<td>Credit</td>
<td>LSHTM award 15 credits on successful completion of this module.</td>
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<tr>
<td>Accreditation</td>
<td>Not currently accredited by any other body.</td>
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<tr>
<td>Keywords</td>
<td>Cluster randomised trials.</td>
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## AIMS, OBJECTIVES AND AUDIENCE

### Overall aim
To understand the key features in the design, analysis and reporting of cluster randomised trials. Trials in which individuals are randomised in groups (clusters) are being increasingly utilised, especially in the fields of infectious diseases, implementation research, and public health and complex interventions. This module will consider the advantages and disadvantages of the use of cluster trials, with particular emphasis on statistical considerations for their design and analysis, as well as the implications for informed consent and reporting.

### Intended learning outcomes
By the end of this module, students should be able to:
- describe the key features of a cluster randomised trial and explain what impact these have on the design and analysis of cluster randomised trials
- evaluate in what circumstances cluster randomised trials may be more suitable or practical than individually randomised trials
- recommend a sensible design for a cluster randomised trial using information on a given study question and setting
- calculate sample sizes for cluster randomised trials
- perform and interpret appropriate statistical analysis of data from cluster randomised trials with different designs
- evaluate ethical issues specific to a given cluster randomised trial
- discuss the requirement and role of data monitoring in cluster randomised trials
- prepare an appropriate report of the methods and results of cluster randomised trials.

**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.

**CONTENT**

**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, LEARNING AND ASSESSMENT**

**Study resources provided or required**

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
- Online reading
- Stata datasets.

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 and learning methods**

- Learning is self-directed against a detailed set of learning objectives 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.
  - Students are strongly encouraged to submit a Formative Assignment (FA), for which personalised written feedback is available. This is not compulsory and does not contribute to the overall module grade.
  - Students are provided with written feedback on submitted AAs.
  - There are at least two real-time tutorials available on Moodle for students to obtain additional tutor support: one for feedback on a 2nd Formative Assignment, and one for assessed assignment (AA) preparation.
  - Students are encouraged to make use of LSHTM online library resources.
  - Students are provided with Examiners’ Reports giving previous AA questions and specimen answers.

**Assessment details**

Formal assessment of the module will be by two AAs each worth 50% of the module marks.

To pass the module, students will need to achieve an overall gradepoint average of 2, including at least a gradepoint of 1 in each AA.
If students fail the module overall, they are allowed one further attempt at the failed element(s).

Prior to September 2018, students were required to sit an unseen written examination (80% of module marks) and submit an assessed assignment (20% of module marks). A student registered for CTM209 prior to 1 September 2018 who has completed one element of assessment but not the other (i.e. the unseen written examination or the assessed assignment) prior to 1 September 2018 must complete both elements of assessment. If a student registered for module CTM209 prior to 1 September 2018 and has obtained a GPA of less than 1.0 on the assessed assignment or the unseen written examination, or both, prior to 1 September 2018, then the failed element(s) must be resat.

| Assessment dates | The Formative Assignment for this module can be submitted only once annually, no later than 31st March and must be submitted via the online Assignment Management System. The two AAs for this module can be submitted separately at different times, or at the same time if the student prefers. The two Assessed Assignments for this module can be submitted only once annually, no later than 12th May and must be submitted via the online Assignment Management System. |
| Language of study and assessment | English (please see 'English language requirements' below regarding the standard required for entry). |

**TIMING AND MODE OF STUDY**

**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.

**Dates**
Tutorial support (via the online discussion forums or ctsupport@lshtm.ac.uk) is available from the beginning of October until the AA submission deadline.

**Mode of study**
By distance learning.

**Learning time**
The notional learning time for the module totals 150 hours, consisting of:
- **Directed self-study** (reading and working through the provided module material) ≈ 60 hours
- **Self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 30 hours
- **Assessment, review and revision** ≈ 60 hours.

**APPLICATION, ADMISSION AND FEES**

**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.)

Those wishing to study this module must have regular access to the internet to access the module study materials, participate in module-specific discussions and tutorials on Moodle, benefit from online library facilities and submit assignments.
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<tr>
<th><strong>English language requirements</strong></th>
<th>A strong command of the English language is necessary to benefit from studying the module. Applicants whose first language is not English or whose prior university studies have not been conducted wholly in English must fulfil LSHTM’s English language requirements, with an acceptable score in an approved test taken in the two years prior to entry. Applicants may be asked to take a test even if the standard conditions have been met.</th>
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<tr>
<td><strong>Student numbers</strong></td>
<td>There is no cap on the number of students who can register for this distance learning module. The number of students actively studying this module varies, but typically approx. 15 students register for the module per year.</td>
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| **Student selection** | This module is available to be studied by students on the following distance learning programmes: PG Diploma Clinical Trials, MSc Clinical Trials, MSc Epidemiology. 
Alternatively, students may register for this as an “individual module”.
This module is also open to students registered on LSHTM face-to-face (i.e. London-based) MSc programmes (subject to programme-specific limitations) and research degree students. |
| **Fees** | The current schedule of fees can be viewed at [https://www.lshtm.ac.uk/study/fees-funding/tuition-fees/tuition-fees-and-expenses-2018-19](https://www.lshtm.ac.uk/study/fees-funding/tuition-fees/tuition-fees-and-expenses-2018-19) |
| **Scholarships** | Scholarships are not available for individual modules. Some potential sources of funding are detailed on the LSHTM website. |
| **Admission deadlines** | Applications for LSHTM distance learning programmes and modules are managed by the University of London. To apply to take either a formal award (i.e. PG Certificate, PG Diploma or MSc) or an individual module, click on the red Apply Now tab [https://london.ac.uk/courses/clinical-trials](https://london.ac.uk/courses/clinical-trials)

Key deadlines are as follows:
Application deadline: 31st October each year
Registration deadline: 30th November each year

*Please note:* The academic year starts on Monday 1st October 2018. 
Students who register after 1st October should note that module welcome and Collaborate sessions held in October are recorded, but they cannot request an extension to assignment submission deadlines as a result of registering later than 1st October.

In-house LSHTM research degree students wishing to study this module should note information given in the mixed mode study option link at [https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx](https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx)