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## MODULE SPECIFICATION

<b>Academic Year (student cohort covered by specification)</b>	2020-21
<b>Module Code</b>	CTM202
<b>Module Title</b>	Trial Designs
<b>Module Organiser(s)</b>	Natasha Larke, Kerry Dwan
<b>Contact Email</b>	<a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>
<b>Faculty</b>	Epidemiology and Population Health London School of Hygiene & Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a>
<b>FHEQ Level</b>	Level 7
<b>Credit Value</b>	<b>CATS</b> 15 <b>ECTS</b> 7.5
<b>HECoS Code</b>	100962 : 100473
<b>Mode of Delivery</b>	Distance Learning
<b>Mode of Study</b>	Directed self-study, through online materials via the Virtual Learning Environment
<b>Language of Study</b>	English
<b>Pre-Requisites</b>	All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules, including a knowledge of basic statistics relevant to clinical trials. 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. Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.
<b>Accreditation by Professional Statutory and Regulatory Body</b>	Not currently accredited by any other body
<b>Module Cap (Maximum number of students)</b>	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. 65 students register for the module per year.
<b>Target Audience</b>	Elective 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 trial designs.
<b>Module Description</b>	This module seeks to develop an understanding of the key features of a variety of trial designs and provide students with the opportunity to critique their appropriate use. The appropriate application of statistical principles to trial design and analysis will be discussed. Appropriate interpretation of trial results and analysis according to the trial design are also considered.
<b>Duration</b>	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 start of the June examinations (although assessment submission deadlines which are earlier than this must be observed).
<b>Last Revised (e.g. year changes approved)</b>	2020

<b>Programme(s)</b>	<b>Status</b>
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

## Module Aim and Intended Learning Outcomes

<b>Overall aim of the module</b>
The overall module aim is to: <ul style="list-style-type: none"> <li>familiarise students with a variety of trial designs and their fundamental characteristics, and provide students with the opportunity to demonstrate their appropriate use.</li> </ul>

<b>Module Intended Learning Outcomes</b>
Upon successful completion of the module a student will be able to: <ol style="list-style-type: none"> <li>demonstrate knowledge of the key features of trial designs used to evaluate interventions</li> <li>critically evaluate which trial design is most appropriate to the research question</li> <li>demonstrate application of statistical principles to trial design and analysis</li> <li>interpret the results from the analysis of trials according to the trial design.</li> </ol>



## Indicative Syllabus

### Session Content

The module consists of 8 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:

- Introduction
- Early Phase Trials
- Cluster RCTs
- Non-Inferiority/Equivalence Trials
- Cross-Over Trials
- Factorial Trials and Other Multi-Armed Trials
- Adaptive Design Trials
- Other Designs

## 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
<b>Total</b>	<b>150</b>	<b>100</b>

### 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.
- work through the Self Assessed Mock Examination (SAME), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade.



### Teaching and Learning Strategy

- learn from written feedback from tutors on submitted AAs.
- join real-time tutorials via Collaborate, available on Moodle, to obtain additional tutor support: at least two tutorials are available, one focusing on assignments, and one for exam preparation.
- make use of LSHTM online library resources.
- make use of Examiners' Reports which include previous assessed assignment and examination questions and specimen answers.

## Assessment

### Assessment Strategy

The assessment strategy for CTM202 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), a summative written assessed assignment (AA) and a formal examination. The FAs and AAs have the same word-length and scenario-based short question format 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 reflect 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 limit gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. The examination questions are also written to test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AAs, but may be answered without recourse to the study materials. For all CTM202 assessments the application of key learning to scenario-based questions encourages students to develop the skill of using core learning to respond to real-life problems encountered in the design, conduct, analysis and interpretation of different clinical trial designs. On this module two past AA papers, and three past examination papers, all with specimen answers, 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	The Assessed Assignment has a maximum word length of 2000 words	20	<b>1-4</b>
Examination	2 hours 15 minutes	80	<b>1-4</b>



### 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
- Text book as below
- E-book as below
- Online reading as below

#### *E-books*

- Senn S. *Statistical Issues in Drug Development* (2nd edition). (2007) Wiley, Chichester.

#### *Text book*

Wang D, Bakhai A. (2005). *Clinical Trials: A Practical Guide to Design, Analysis and Reporting*. REMEDICA (Only sent to students who did not study CTM101.)



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### **Essential resources**

#### *Examples of online reading*

- Adamson J, Cockayne S, Puffer S, Torgerson DJ. Review of randomised trials using the post-randomised consent (Zelen's) design. *Contemp Clin Trials*. 2006 Aug; **27**(4): 305-19.
- Bhatt DL, Mehta C. Adaptive Designs for Clinical Trials. *N Engl J Med*. 2016 Jul 7; **375**(1):65-74. doi: 10.1056/NEJMra1510061.
- Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. *BMJ*, 2019; 366:14378
- Jones B, Lewis J, Ebbutt E. Trials to assess equivalence: the importance of rigorous methods. *BMJ*. 1996; **313**: 36-9
- Hayes RJ, Alexander NDE, Bennett S, Cousens SN. Design and analysis issues in cluster-randomized trials of interventions against infectious diseases. *Statistical Methods in Medical Research*. 2000; **9**(2): 95-116.
- Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. 2007 Feb; **28**(2): 182-91.
- Mills EJ *et al.* [Design, analysis, and presentation of crossover trials](#). *Trials*, 2009. **10**: p. 27.
- Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006 Mar 8; **295**(10): 1152-60.
- Sedgwick P. Randomised controlled trials with full factorial designs *BMJ* 2012; **345**:e5114

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for web-based 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 Worldwide website at

<https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements>