Module Specification (Distance Learning)

In collaboration with University of London International Programmes

1. Title:	**Cluster Randomised Trials**
2. Module code:	CTM209
3. Institution:	Faculty of Epidemiology and Population Health London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT http://www.lshtm.ac.uk/eph
4. Module Organiser:	Natasha Larke
5. Mode of study:	Distance learning
6. Type:	Elective module
7. Duration and dates:	Deadlines if taken as part of a formal award: Application deadline: 30 June each year Registration deadline: 31 August each year Course registration duration: Up to 5 years Course starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed) Deadlines if taken as an individual module (i.e. not registered for formal award): Application deadline: 31 August each year Registration deadline: 30 November each year Registration duration: 2 years Module study starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed).
8. Credit points:	15 credit points will be awarded on successful completion of this module at Masters level (Level 7).
9. Notional Learning Hours (NLH):	On average the module should take about 150 hours to complete, consisting of the following: Computer-Assisted Learning (CAL) sessions: 40 hours Additional reading time: 24 hours Assignments: 14 hours Self-directed learning: 72 hours.
10. 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.
11. Learning objectives:	On completing 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.
12. Content:	This module consists of 10 CAL sessions: 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 in cluster randomised trials Reporting and interpretation of results from cluster randomised trials Summary.
13. Learning Methods:	Learning is self-directed against a detailed set of learning objectives, identified at the start of each chapter, using the materials provided. These consist of a module textbook which lists a range of activities including focused reading. Student support is available from the module tutors through the web-based discussion forum in which students are encouraged to participate. In addition, module tutors provide written feedback on the submitted assessed assignment. The course uses Computer-Assisted Learning (CAL) material to introduce and explain the principles and methods covered in the module. It is important that all the CAL sessions are completed and understood at each step before progressing with further sessions.
14. Assessment procedures:	Formal assessment of the module will be by an assessed assignment(20%) and by a two-hour unseen written examination (80%). Examinations are normally held in a student's country of residence, in one of over 650 examination centres worldwide. They are arranged mainly through Ministries of Education or the British Council. A local fee will be payable. A list of examination centres can be found at http://www.londoninternational.ac.uk/current_students/general_resources/exams/exam_centres/index.shtml. If students fail an examination at the first entry they will be allowed one further attempt, the following year.
15. Prerequisites:	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 Course Director, students must study CTM208 *Further Statistical Methods in Clinical Trials* OR EPM304 *Advanced Statistical Methods in Epidemiology* (or module *2412 Advanced Statistical Methods in Epidemiology* via blended learning study at the School) before studying this module. Module CTM202 may also be useful but is not a

	pre-requisite. Students should have access to Microsoft Excel 97 or later. Those wishing to study this module must have regular access to the internet as this module is taught online and through web-based discussions. Students must meet the standard of English required to study this course. See http://www.lshtm.ac.uk/prospectus/english.html.
16. Attendance:	No maximum number
17. Selection, if applicable:	This module is one of the optional modules available to those studying the MSc Clinical Trials course but may also be studied by those registered for the MSc Epidemiology course, subject to Course Director approval. Those studying for the PG Diploma in Clinical Trials under the credit framework scheme may also choose to study this module. Alternatively, it may be taken as an Individual Module.
18. Fees:	For current schedule of fees see http://www.londoninternational.ac.uk/fees/schedules/lshtm.pdf.
19. Scholarships:	MSc only – see http://www.lshtm.ac.uk/prospectus/funding/ for details.
20. External accreditation:	None
21. Application process:	Applications are managed by the University of London International Programmes (website: http://www.londoninternational.ac.uk/).
22. Further enquiries:	Enquiries may be emailed to distance@lshtm.ac.uk.