Department of Epidemiology and Biostatistics  
Epidemiology 9566S  
Randomized Trial Design

**Lectures with Discussion:**
Online only, recording uploaded after.  
Jan 12 - Feb 25*

Tuesdays and Thursdays,  
09:30 a.m. - 11:00 a.m.

* No lectures or assignments in week 6 (Feb 15-19; reading week)

**Instructor:** Merrick Zwarenstein  
E-mail: merrick.zwarenstein@ices.on.ca

**Office Hours:** Email for appointment

**Course Information**
**Co-requisite:** Biostatistics 9521B. Unless you have either the requisites for this course or written special permission to enroll in it, you may be removed from this course and it will be deleted from your record. Graduate students may do so through the Graduate Chair. This decision may not be appealed. You will receive no adjustment to your fees in the event that you are dropped from a course for failing to have the necessary prerequisites.

**Objectives:**
Randomized controlled trials are experiments comparing the effects of different interventions in humans. By the end of this course students will understand the theory, structure, design and use of randomized controlled trials for evaluation of interventions in human health, such as vaccines or drug treatments.

**Course materials:**
All materials will be provided online in OWL.

**Methods of Evaluation:**
There will be no exam. The final grade will be made up of two assignments, a presentation, a participation grade and a report grade (see below).

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<tr>
<th>Component</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>2 Assignments</td>
<td>20% (design topics only)</td>
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<tr>
<td>1 Presentation</td>
<td>30%</td>
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<tr>
<td>Class participation</td>
<td>10%</td>
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<tr>
<td>1 Final Report</td>
<td>40% (due: week 7, Feb 28)</td>
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<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
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Technology Requirements
You are responsible for all required course materials and announcements posted to the course’s OWL website. Please ensure after the first class that when you log in you are able to access the course site. A copy of the course outline will be available on both OWL and the departmental website. You are also responsible for obtaining access to zoom, with an internet connection and a computer that permits your participation in discussion and presentation.

Statement on Copyright and Audio/Video Recording
All of the remote learning sessions for this course will be recorded. The data captured during these recordings may include your image, voice recordings, chat logs and personal identifiers (name displayed on the screen). The recordings will be used for educational purposes related to this course, including evaluations. The recordings may be disclosed to other individuals participating in the course for their private or group study purposes. Please contact the instructor if you have any concerns related to session recordings.

Participants in this course are not permitted to record the sessions, except where recording is an approved accommodation, or the participant has the prior written permission of the instructor. You must always ask permission to record another individual and you should never share or distribute recordings.

Course material produced by faculty is copyrighted and to reproduce this material for any purposes other than your own educational use contravenes Canadian Copyright Laws.

Policy on Accommodation for Medical and Non-Medical Absences
All non-medical absences must be approved in advance. In the case of an unexpected absence on compassionate grounds, documentation may be requested. If documentation is required for either medical or non-medical academic accommodation, then such documentation must be submitted by the student to the instructor.

Statement on Academic Offences
Scholastic offences are taken seriously and students are directed to read the appropriate policy, specifically, the definition of what constitutes a Scholastic Offence:
https://www.uwo.ca/univsec/pdf/academic_policies/appeals/scholastic_discipline_grad.pdf
All required papers may be subject to submission for textual similarity review to the commercial plagiarism detection software under license to the University for the detection of plagiarism. All papers submitted for such checking will be included as source documents in the reference database for the purpose of detecting plagiarism of papers subsequently submitted to the system. Use of the service is subject to the licensing agreement, currently between The University of Western Ontario and Turnitin.com (http://www.turnitin.com).
Computer-marked multiple-choice tests and/or exams may be subject to submission for similarity review by software that will check for unusual coincidences in answer patterns that may indicate cheating.
Support Services
As part of a successful student experience at Western, we encourage students to make their health and wellness a priority. Western provides several on campus health-related services to help you achieve optimum health and engage in healthy living while pursuing your degree. For example, to support physical activity, all students, as part of their registration, receive membership in Western’s Campus Recreation Centre. Numerous cultural events are offered throughout the year. Please check out the Faculty of Music web page http://www.music.uwo.ca/, and our own McIntosh Gallery http://www.mcintoshgallery.ca/. Information regarding health- and wellness-related services available to students may be found at http://www.health.uwo.ca/

Registrarial Services: http://www.registrar.uwo.ca
USC Student Support Services: http://westernusc.ca/services/
Student Development Centre: http://www.sdc.uwo.ca/
SGPS Life & Community web page: https://grad.uwo.ca/life_community/self/index.html

Students seeking help regarding mental health concerns are advised to speak to someone they feel comfortable confiding in, such as their faculty supervisor, their program director (graduate or undergraduate chair), or other relevant administrators in their unit. Students who are in emotional/mental distress should refer to Mental Health@Western http://www.uwo.ca/uwocom/mentalhealth/ for a complete list of options about how to obtain help.

Student Accessibility Services
Western is committed to achieving barrier-free accessibility for all its members, including graduate students. As part of this commitment, Western provides a variety of services devoted to promoting, advocating, and accommodating persons with disabilities in their respective graduate program.

Graduate students with disabilities (for example, chronic illnesses, mental health conditions, mobility impairments) are encouraged to register with Student Accessibility Services, a confidential service designed to support graduate and undergraduate students through their academic program. With the appropriate documentation, the student will work with both SAS and their graduate programs (normally their Graduate Chair and/or Course instructor) to ensure that appropriate academic accommodations to program requirements are arranged. These accommodations include individual counselling, alternative formatted literature, accessible campus transportation, learning strategy instruction, writing exams and assistive technology instruction.

Department & Faculty Offices
The Epidemiology and Biostatistics main office is located in K201 in the Kresge Building on Main campus.