

**Department of Epidemiology and Biostatistics
Epidemiology 9566S
Randomized Trial Design
Winter 2022**

Lecture and Discussions: 09:30 a.m. – 11.00 a.m. Tuesdays and Thursdays, HSA H062

Instructors:

Merrick Zwarenstein merrick.zwarenstein@ices.on.ca

Office Hours: Email for appointment

Tuesday, Jan. 11 – Thursday, Feb. 17

Dr. Zwarenstein teaches randomized trial design on Tuesdays and Thursdays, with online classes until at least end January. Video lectures will be uploaded to OWL for previewing from Jan 10.

From weeks 2-6, Tuesdays will be a synchronous Zoom interactive discussion on the above-mentioned previewed lecture material, readings, and take-home quizzes. Also on Tuesdays, starting in Week 2, each student will give one online 5-minute presentation to the class describing and critiquing a randomized trial that each of you will select from a list of COVID-19 trials that I will upload by Jan 10. Thursdays will be a face-to-face interactive discussion in class of questions related to the lectures, quizzes and other activities.

Reading week: Feb 19-Feb 27

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 trials are experiments comparing the effects of different interventions in humans. By the end of this graduate course (cross listed with and same content as first half of 4715B undergraduate course) students will be able to describe the theory, structure,

design and use of randomized controlled trials for evaluation of interventions in human health, such as vaccines or drug treatments. This course, taught by Dr. Zwarenstein, focusses on internal validity. This course is a prerequisite for and complement to Epidemiology 9586T which focusses on external validity of RCTs.

Course Summary: 9566S (Zwarenstein) Weeks 1-6

Week	Date	Topic
1	Jan 11 Jan 13	The magic of randomization: Course introduction Randomization: Individual/Crossover/Factorial/Cluster/Stepped wedge
2	Jan 18 Jan 20	Background and rationale for trial; Research question Target and study populations; Inclusion and exclusion of participants
3	Jan 25 Jan 27	Recruitment and Setting Intervention, Comparator, Allocation concealment and blinding
4	Feb 1 Feb 3	Measurement: Baseline, 1 ^o and 2 ^o Outcomes Data collection and Organisation of the trial
5	Feb 8 Feb 10	Qualitative, Economic and Pilot studies History and ethics
6	Feb 15 Feb 17	Internal and External Validity; pragmatic and explanatory approaches PRECIS 2 tool

Course Materials

All course materials will be provided on the course's OWL website.

Methods of Evaluation

The final grade will be made up of take-at-home online quizzes as well as presentation, participation and project grades (see below). There will be no exam.

Quizzes	10% (design topics)
1 Presentation	20% (design topics)
Class participation	20%
Project	50% (design topic)
Total	100%

Presentations take place on Tuesdays from wk 2-5, possibly wk 6 depending on amount of discussion. They may be prerecorded and simply replayed; but discussion will be live. The project on trial design is due Feb 20. No lectures or assignments in week 7, reading week.

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 participation in discussion and presentation of your analysis of a published RCT.

Western Academic Policies and Statements

Absence from Course Commitments

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.

Copyright and Audio/Video Recording Statement

Remote learning sessions for this course may 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.

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/>.

Registrarial Services: <http://www.registrar.uwo.ca>
USC Student Support Services: <http://westernusc.ca/services/>
Academic Support and Engagement: <http://academicsupport.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 Chair), or other relevant administrators in their unit. Health and Wellness-related information and services are available at <https://www.uwo.ca/health/>.

Students who are in emotional/mental distress should refer to Mental Health@Western <https://www.uwo.ca/health/> for a complete list of options about how to obtain help.

Accessible Education Western (AEW)

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 strongly encouraged to register with Accessible Education Western (AEW), a confidential service designed to support graduate and undergraduate students through their academic program. With the appropriate documentation, the student will work with both AEW 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.

More information and access to services is available on the AEW website: http://academicsupport.uwo.ca/accessible_education/index.html

Department & Faculty Offices

The Department of Epidemiology and Biostatistics is located on the third floor of the Western Centre for Public Health & Family Medicine (PHFM) on Western University's Main Campus.