

**Department of Epidemiology and Biostatistics  
Epidemiology 4715B  
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](mailto:merrick.zwarenstein@ices.on.ca)  
Neil Klar [nklar@uwo.ca](mailto:nklar@uwo.ca)

**Office Hours:** Email for appointment

**First half:** Tuesday, Jan. 11 – Thursday, Feb. 17

Dr. Zwarenstein teaches randomized trial design on Tuesdays and Thursdays, online 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.

**Second half:** Tuesday March 1 – Thursday April 7

Video lectures will be online to preview for the second part of Dr. Zwarenstein's randomized control trial (RCT) design class. From weeks 8-13, these will be discussed in person on Tuesdays with Dr Zwarenstein. Also from weeks 8-13, Dr. Klar will teach statistical analysis for randomized trials (RCTs) in person, on Thursdays.

## **Course Information**

**Co-requisite:** Biostatistics 3110B. 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 the first half of this 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, taught by Dr. Zwarenstein. By the end of the second half of this course students will be able to distinguish between two different approaches to designing a trial: the pragmatic approach to provide evidence to help choose the best treatment option for a real-world situation; or the explanatory approach to expand knowledge by testing a hypothesis on the mechanism of action of an intervention. The design choices are different for these two different kinds of RCT and will be discussed in lectures online for preview, and in class. Methods of analysis will be taught in face-to-face lectures on Thursdays in the second half by Dr. Klar.

### **Course Summary: 4715B first half (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 <sup>0</sup> and 2 <sup>0</sup> 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 Summary: 4715B second half (Zwarenstein & Klar) Weeks 8-13**

Weeks 8-13: Reading week is February 19-27. Second half is from March 1- April 7. For Dr Zwarenstein's in-person Tuesday discussions, the lectures will be available online in OWL and should be previewed beforehand to permit more time for interactive learning. Dr Klar teaches statistical analysis for RCTs on Thursdays from 9.30-11.00.

Week	Date	Topic (Discussions: Tues., Dr .Zwarenstein / Lectures: Thurs., Dr. Klar)
8	Mar 1 Mar 3	PRECIS-2 tool, Target populations, generalization and applicability Continuous outcomes
9	Mar 8 Mar 10	Inclusion and exclusion criteria, Recruitment Binary outcomes
10	Mar 15 Mar 17	Setting and organization Crossover trials
11	Mar 22 Mar 24	Intervention and comparator Survival analysis
12	Mar 29 Mar 31	Flexibility of delivery and adherence of participants Interim analyses
13	April 5 April 7	Intensity of follow up, 1 <sup>0</sup> and 2 <sup>0</sup> Outcomes, Analysis Multiple testing

## 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/assignments as well as presentation, participation and project grades (see below). There will be no exam.

Quizzes/Assignments	20% (design and analysis topics)
1 Presentation	10% (design topics)
Class participation	20%
2 Projects	50% (one design topic, second is a design or analysis topic)
<b>Total</b>	<b>100%</b>

**Presentations take place on Tuesdays from wk 2-5 in first half, possibly wk 6 depending on amount of discussion. They may be prerecorded and simply replayed; but discussion will be live. First half project, on trial design is due Feb 20. The second project which can be analysis or design is due April 15. 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**

### [Policy on Academic Consideration for Student Absences](#)

If you are unable to meet a course requirement due to illness or other serious circumstances, you must seek approval for the absence as soon as possible. Approval can be granted either through a **self-reported absence or via the Academic Counselling unit**. Students have two self-reports to use throughout the academic year; absence from course commitments including tests, quizzes, presentations, labs, and assignments that are worth 30% or less can be self-reported. Self-reported absences cover a student for 48 hours (yesterday + today or today + tomorrow). Your instructor will receive notification of your consideration; however, you should contact your instructor immediately regarding your absence. Students are expected to submit missed work within 24 hours of the end of the 48-hour period. Please review Western's [Academic Consideration for Student Absences](#) policy for more details.

If you have used both their self-reported absences or will miss more than 48 hours of course requirements, a Student Medical Certificate (SMC) should be signed by a licensed medical or mental health practitioner and you should contact academic counselling. Academic Counselling will be operating virtually this year and can be contacted at [scibmsac@uwo.ca](mailto:scibmsac@uwo.ca).

## **Special Examinations**

A Special Examination is any examination other than the regular examination, and it may be offered only with the permission of the Dean of the Faculty in which the student is registered, in consultation with the instructor and Department Chair. Permission to write a Special Examination may be given on the basis of compassionate or medical grounds with appropriate supporting documents. To provide an opportunity for students to recover from the circumstances resulting in a Special Examination, the University has implemented Special Examinations dates. These dates as well as other important information about examinations and academic standing can be found [here](#).

## **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, at the following Web site:

[http://www.uwo.ca/univsec/pdf/academic\\_policies/appeals/scholastic\\_discipline\\_undergrad.pdf](http://www.uwo.ca/univsec/pdf/academic_policies/appeals/scholastic_discipline_undergrad.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/>

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. 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. More information and access to services is available on the AEW website:  
[http://academicsupport.uwo.ca/accessible\\_education/index.html](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.

Undergraduate Students requiring academic counselling should contact the Science & Basic Medical Sciences Academic Counselling Office: <https://www.uwo.ca/sci/counselling/>.