

**Department of Epidemiology and Biostatistics
Epidemiology 9568T
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
Neil Klar nklar@uwo.ca

Office Hours: Email for appointment

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 on Tuesdays with Dr Zwarenstein. Also from weeks 8-13, Dr. Klar will teach statistical analysis for randomized trials (RCTs) on Thursdays

Course Information

Prerequisite: Epidemiology 9566S

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 the 9586T students will be able to explain how to tailor the design of your RCT to take either a pragmatic approach to trial design, to provide evidence to help choose the best treatment option for a real-world situation, or to take a more explanatory approach, which is suitable for testing a causal hypothesis regarding a mechanism of action (a purpose more in line with adding to scientific knowledge than it is with helping choose between interventions). Methods of analysis for RCTs will be taught

by Dr. Klar and will also address the distinction between pragmatic and explanatory RCTs. The prerequisite course (9566S) which is cross listed as the first half of the undergraduate 4715B course focusses on the theory, structure, design and use of randomized controlled trials for evaluation of interventions in human health, such as vaccines or drug treatments.

Course Summary: 9568T (Zwarenstein & Klar) Weeks 8-13

Reading week is February 19-27. Second half T course 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 ⁰ and 2 ⁰ 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 participation and project grades (see below). There will be no exam.

Quizzes/Assignments	30% (design and analysis topics)
Class participation	20% (10% each from Dr. Klar and Dr. Zwarenstein)
1 Project	50% (design or analysis topic)
Total	100%

The project, which can be analysis or design is due April 15.

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.