

**Department of Epidemiology and Biostatistics
Epidemiology 4715B
Randomized Trial Design**

Lecture and Discussions:

Online synchronous only; recording uploaded after.

Tuesday and Thursday,
09:30 a.m. - 11:00 a.m.

Office Hours: Email for appointment

Instructors:

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Neil Klar

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First half: Jan 12 - Feb 25; Dr. Zwarenstein - randomized trial design on Tue, Thur.
Second half: March 2- April 13; Dr Zwarenstein teaches randomized trial design on Tuesdays and Prof Klar teaches statistical analysis for randomized trials 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 controlled 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. By the end of the second half of this course students will be able to distinguish between two different approaches to designing a trial: a 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. Methods of analysis considered will also address these distinctions.

Course Materials

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

Methods of Evaluation

There will be no exam. The final grade will be made up of the assignments, a presentation and participation grade and a reports grade (see below).

4 Assignments	20% (design and analysis topics)
1 Presentation	15% (design)
Class participation	15%
2 Reports	50%
Total	100%

First design project due Feb 28, second project – can be analysis or design- due April 30
No lectures or assignments in week 6, 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 assignment.

Important Policy Information

1. 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 details of the university's policy on academic consideration for student absences at the above link.

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.

Accommodation for Religious Holidays

The policy on Accommodation for Religious Holidays can be viewed [here](#).

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](#).

Academic Offenses

“Scholastic offences are taken seriously, and students are directed [here](#) to read the appropriate policy, specifically, the definition of what constitutes a Scholastic Offence.

Turnitin and other similarity review software

All assignments will be subject to submission for textual similarity review to the commercial plagiarism detection software under license to the University for the detection of plagiarism. Students will be able to view their results before the final submission. 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 Western University and Turnitin.com.

Accessibility Statement

Please contact the course instructor if you require material in an alternate format or if you require any other arrangements to make this course more accessible to you. You may also wish to contact Accessible Education (AE) at 661-2111 x 82147 for any specific question regarding an accommodation or review [The policy on Accommodation for Students with Disabilities](#).

Correspondence Statement

The centrally administered **e-mail account** provided to students will be considered the individual’s official university e-mail address. It is the responsibility of the account holder to ensure that e-mail received from the University at his/her official university address is attended to in a timely manner. You can read about the privacy and security of the UWO email accounts [here](#).

2. BMSUE Academic Policies and Statements

Rounding of Marks Statement

Across the Basic Medical Sciences Undergraduate Education programs, we strive to maintain high standards that reflect the effort that both students and faculty put into the teaching and learning experience during this course. All students will be treated equally

and evaluated based only on their actual achievement. **Final grades** on this course, irrespective of the number of decimal places used in marking individual assignments and tests, will be calculated to one decimal place and rounded to the nearest integer, e.g., 74.4 becomes 74, and 74.5 becomes 75. Marks WILL NOT be bumped to the next grade or GPA, e.g. a 79 will NOT be bumped up to an 80, an 84 WILL NOT be bumped up to an 85, etc. The mark attained is the mark you achieved, and the mark assigned; requests for mark “bumping” will be denied.

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.

Department & Faculty Offices

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

For undergraduate academic counselling assistance, students will need to speak with the Science & Basic Medical Sciences Academic Counselling Office:

[https://www.uwo.ca/sci/counselling/.](https://www.uwo.ca/sci/counselling/)

3. Support Services

The following links provide information about support services at Western University.

[Academic Counselling \(Science and Basic Medical Sciences\)](#)

[Appeal Procedures](#)

[Registrarial Services](#)

[Student Development Services](#)

[Student Health Services](#)