

Department of Epidemiology and Biostatistics

Epidemiology 9568T Randomized Trials: Data Analysis Winter 2019

Lecture:

Wednesday 11:30 a.m.-1:00 p.m., KB116

Instructors: Neil Klar

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Office Hours: By appointment**Lab:**

Wednesday, 1 p.m.-2:30 p.m., KB7

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Course Information

Course pre-requisite: Epidemiology 95633 Randomized Trials: Design

Course Objectives

Upon successful completion of this course, students will be able to:

- Carry out and report analyses for randomized trials

Course Materials

LM Freedman, DC Furberg and DL DeMets. *Fundamentals of Clinical Trials* 5th Edition; Springer, 2015.

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

Methods of Evaluation

- 30% - Assignments
- 10% - Class participation
- 60% - Data analysis project

Policy on Accommodation for Medical and Non-Medical Absences

The University's policy on Accommodation for Medical Illness may be found at:

http://www.uwo.ca/univsec/pdf/academic_policies/appeals/accommodation_illness.pdf.

The University has a new policy on Accommodation for Medical Illness, which states that "in order to ensure fairness and consistency for all students, academic accommodation for work representing 10% or more of the student's overall grade in the course shall be granted only in those cases where there is documentation indicating that the student was seriously affected by illness and could not reasonably be expected to meet his/her academic responsibilities.

Documentation shall be submitted, as soon as possible, to the appropriate Dean's office...." (i.e., the Associate Dean, Graduate Studies). This same policy applies for work representing less than 10% of the student's overall grade.

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 by the instructor for either medical or non-medical academic accommodation, then such documentation must be submitted by the student directly to the appropriate Faculty Dean's office and not to the instructor. It will be the Dean's office that will determine if accommodation is warranted.

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:

http://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>)."

Support Services

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. Western has a new Wellness Education Centre located in UCC, room 76.

To help you learn more about mental health, Western has developed an interactive mental health learning module, found here: http://www.health.uwo.ca/mental_health/module.html. This module is 30 minutes in length and provides participants with a basic understanding of mental health issues and of available campus and community resources. Topics include stress, anxiety, depression, suicide and eating disorders. After successful completion of the module, participants receive a certificate confirming their participation.

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/>

Department & Faculty Offices

The Epidemiology & 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 Bachelor of Medical Sciences Office: <http://www.schulich.uwo.ca/bmsc/general-counselling>.

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.

Cell Phone and Electronic Device Policy

The Schulich School of Medicine & Dentistry is committed to ensuring that testing and evaluation are undertaken fairly across all our departments and programs. For all tests and exams, it is the policy of the School and the Department of Epidemiology and Biostatistics that any electronic devices, i.e., cell phones, tablets, cameras, or iPod are strictly prohibited. These devices **MUST** be left either at home or with the student's bag/jacket at the front of the room and **MUST NOT** be at the test/exam desk or in the individual's pocket. Any student found with one of these prohibited devices will receive a grade of zero on the test or exam. Non-programmable calculators are only allowed when indicated by the instructor. The Department of Epidemiology and Biostatistics is not responsible for stolen/lost or broken devices.

Course Schedule

Week	Date	Lecture Topic
1	Feb 27	Health related quality of life
2	March 6	Continuous outcomes
3	March 13	Binary outcomes
4	March 20	Crossover trials
5	March 27	Time to event outcomes
6	April 3	Monitoring response variables
7	April 10	Data analysis summary and reporting