Department of Epidemiology and Biostatistics
Epidemiology 4715B
Design and Analysis of Clinical Trials

Lecture:
Tuesday 9:30 am - 11:00 am,  K116
Thursday 9:30 am - 11:00 am,  K116

Instructor: Neil Klar
Office Hour: By appointment
E-mail: nklar@uwo.ca
Phone Extension: 86275

Course Information
Undergraduate Pre-requisites: 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. Undergraduate students may seek permission from the Undergraduate 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.

Course Syllabus
The purpose of this course is to introduce students to clinical trials design, analysis and reporting.

Lecture Weeks
1  Jan 2  Course introduction (Jan 5th)
2  Jan. 9  Clinical trials history and ethics
3  Jan. 16  Study question, population, basic designs
4  Jan. 23  Randomization and blinding
5  Jan. 30  Sample size estimation
6  Feb. 6  Baseline assessment, recruitment and data collection
          Feb. 13  Midterm Exam Tuesday (No class Thursday)
7  Feb. 20  READING WEEK
8  Feb. 27  Health-related quality of life
9  Mar. 6  Data analysis: continuous outcomes
10  Mar. 13  Data analysis: binary outcomes
11  Mar. 20  Data analysis: time to event
12  Mar. 27  Monitoring response variables
13  Apr. 3  Data analysis summary and reporting

Course Materials
Methods of Evaluation
The final grade for the course will be allocated as follows:

- Assignments: 30%
- Midterm Exam: 20%
- Class participation: 10%
- Final Exam: 40%

Policy on Accommodation for Medical and Non-Medical Absences
For assignments worth 10% or more, refer to Western University’s Policy on Accommodation for Medical Illness: https://studentservices.uwo.ca/secure/index.cfm.

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_undergrad.pdf.

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/. Information regarding health- and wellness-related services available to students may be found at http://www.health.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. Campus
mental health resources may be found at http://www.health.uwo.ca/mental_health/resources.html

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.

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.