Course Information

Welcome to PUBH 52600: Design and Analysis of Randomized Trials in Public Health (CRN 24977)!

Instructor information, along with course announcements and resource materials, is available on the course's Brightspace page. The instructor is available via email on weekdays and will try to respond to your emails as soon as possible (generally within 24-48 hours). When emailing, please place the course number and topic in the subject line of the email (e.g., "PUBH 526 – Homework 2 Question"). This will help tremendously in locating and responding to your emails quickly. The instructor is also available after class or by appointment for questions about the course and course material.

Course Description

Randomized trials provide solid evidence on whether interventions and programs "work" to improve health outcomes. In this three-credit course, students will learn how to design a randomized study, handle practical issues that arise in data collection, analyze data using appropriate methods and good statistical practice, identify limitations to statistical evidence, and interpret and communicate findings in an audience-appropriate way. This is a hands-on statistics course in which students will work with data and build skills using SAS statistical software in preparation for careers as biostatisticians, data scientists, and researchers.

Prerequisite

To be successful in this course, you should have already completed an introductory statistics course and be comfortable with hypothesis testing, simple linear regression, and one-way analysis of variance (ANOVA).

Learning Outcomes

MPH Concentration Competencies: Our Master of Public Health (MPH) program is accredited by the Council on Education for Public Health (CEPH). In addition to CEPH's Foundational Competencies, the Biostatistics Concentration offers students the opportunity to attain depth and expand their knowledge and skills in this designated area. Listed below are the Concentration Competency expectations for students completing this course:

2: Demonstrate mastery of at least one statistical software package commonly used to assess public health issues.

3: Select and apply the most appropriate statistical approaches to address public health issues.

4: Evaluate the limitations of statistical evidence (e.g., validity, reliability, sample size, bias, generalizability).

Learning Resources, Technology, & Texts

There is no required text for this course. For certain topics, required readings and additional resources will be made available on Brightspace. These include:

- Friedman, Furberg, DeMets, Reboussin, Granger (2015) Fundamentals of Clinical Trials, Fifth Edition
- Agresti (2007) An Introduction to Categorical Data Analysis, Second Edition

This course will use SAS (Version 9.4). Sample SAS programs and data sets will be provided on Brightspace. You can obtain SAS at no cost here. Please contact HHS IT at hhshelp@purdue.edu if you need help installing SAS. SAS is also available in campus computer labs. The Department of Statistics has an in-person and virtual help desk that can help with SAS programming.

Evaluation

Your grade in this course will be based on homework (due most weeks on Thursdays at **9:30 AM**), two in-class midterm exams, and an in-person final exam during finals week. All homework will be assigned on and submitted via Brightspace. Each exam focuses on the new course material covered since the previous exam but will contain some earlier material, particularly related to fundamental concepts and good statistical practice.

Homework is an important learning tool in this course. All homework problems will be graded for completeness, and a selected number will be graded for content. Your homework must have the exercises presented in order. The solutions must be clearly readable and easy to follow. These solutions should include all relevant graphs and tables appropriately labeled and described. Any graph or table that is turned in without comment or spans across more than one page will be ignored. You can use a word processor or editor to edit or cut and paste specific software output. You are permitted (and encouraged!) to work together to solve the homework exercises, but each student must write up their own solution to receive credit. Homework assignments will vary in points, but each assignment will be equally weighted, and the lowest homework grade will be dropped in calculating your final grade. The grade breakdown and dates are as follows:

Assignments	Date	Percentage of grade
Homework (lowest dropped)	Due most Thursdays at **9:30 AM**	40
Midterm Exam 1	October 2	20
Midterm Exam 2	November 6	20
Final Exam	TBA	20
Total		**100**

Attendance: Attendance is not monitored in this course. However, you are expected to arrive on time and attend every class. As the content of this course is cumulative, it will be difficult to succeed in this course otherwise. While all course materials will be made available on the course's Brightspace page, taking your own notes, asking questions, and engaging in every class will greatly aid your learning.

Questions about the material are very welcome and encouraged in class. Keeping up with the course will be key to your success in this course. Of course, if you are feeling unwell or are otherwise unable to attend a class period, you can watch the BoilerCast recording on BrightSpace. These recordings can also be useful if you want to review material covered in class. Lectures slides will be shared on Brightspace but cannot cover every point made in class; therefore, it is highly recommended that you take your own notes. The BoilerCast recordings will also attempt to capture material written on the board; however, some material may not be captured, so if you miss a class, please consult your fellow students for notes as needed. It is important that you also regularly check Brightspace for readings, homework, announcements, and other material. **If you are concerned that you are falling behind in this course**, please contact the instructor as soon as possible so we can work together on a solution.

Late work policy: Late homework will not be accepted unless discussed with the instructor, and it will not be possible to submit a homework assignment after solutions have been posted. Rescheduling of exams must be discussed with the instructor. If you foresee that you will not be able to make a deadline (e.g., for a religious observance) or need accommodation to allow you to learn, please contact the instructor as soon as possible.

This said, we all experience challenges. This includes your physical and mental health, illness in your family, the needs of children or elders whom you care for, or any number of other things. **If you find yourself struggling to make a deadline**, please contact the instructor as soon as you are able, and we will work with you to accommodate.

Use of large language models (LLMs) and other artificial intelligence (AI) in this course: You may use AI in this course. Personally, there are situations where I have found these tools helpful for my learning and understanding. However, you should know that I put all assignment and exam questions through at least one AI program before they are posted. In general, I've found that AI-generated responses either lack the depth that will be expected in this course or make outright mistakes. You therefore need to check all AI output critically, and you are responsible for the work you submit. Also, be careful that you do not use these tools as a crutch that prevents you from truly learning the material and understanding the concepts covered in this course.

Grading Scale

Your final grade will be calculated as a percentage according to the table in the Evaluation section above. Below is the lowest final percentage required to achieve a given letter grade. The instructor reserves the right to revise these cutoffs downward (for example, to allow someone getting a final grade of 89% to receive an A-), but the cutoffs will never be revised upward.

Grade	Lowest Final Grade (%)
A+	98
A	92
A-	90
B+	87
B	82
B-	80

C+	77
C	72
C-	70
D+	67
D	62
D-	60
F	<60

Incompletes

A grade of incomplete (I) will be given only in unusual circumstances. To receive an "I" grade, a written request must be submitted (check with your graduate program advisor about deadlines) and approved by the instructor. The request must describe the circumstances, along with a proposed timeline for completing the course work. Submitting a request does not ensure that an incomplete grade will be granted. If granted, you will be required to fill out and sign an "Incomplete Contract" form that will be turned in with the course grades. Any requests made after the course is completed will not be considered for an incomplete grade.

Course Topics and Schedule

Our course will cover the topics listed below. Please see the course page on Brightspace for details, class materials, and any updates.

- Principles and components of a randomized controlled trial
- Ethical considerations
- Hypothesis testing
- Comparing two or more groups
- Model diagnostics
- Power calculations
- Hypothesis tests regarding means
- ANCOVA and effect modification
- Randomized complete block designs
- Random effects/multilevel models
- Cluster randomized designs
- Crossover designs
- Repeated measures
- Factorial designs
- Meta-analysis

Academic Integrity

Academic integrity is one of the highest values that Purdue University holds. Please see the University's website for details on University Policies and Statements, including Use of Copyrighted Materials. Effective learning environments provide opportunities for students to reflect, explore new ideas, post opinions openly, and have the freedom to change those opinions over time. Students and instructors are the authors of the works they create in the learning environment. As authors, they own the copyright in their works subject only to the

University's right to use those works for educational purposes. Students may not copy, reproduce, or post to any other outlet (e.g., YouTube, social media sites, or other open media sources or websites) any work in which they are not the sole or joint author or have not obtained the permission of the author(s).

Accessibility

Purdue University strives to make learning experiences as accessible as possible. The Disability Resource Center is there to help and reachable at drc@purdue.edu or by phone: 765-494-1247. We'll work with you to create an accessible learning environment.

Mental Health Statement

If you find yourself beginning to feel some stress, anxiety and/or feeling slightly overwhelmed, try Therapy Assistance Online (TAO), a web and app-based mental health resource available courtesy of Purdue Counseling and Psychological Services (CAPS)**.** TAO is available to all students at any time by creating an account on the TAO Connect website, or downloading the app from the App Store or Google Play. It offers free, confidential well-being resources through a self-guided program informed by psychotherapy research and strategies that may aid in overcoming anxiety, depression, and other concerns. It provides accessible and effective resources including short videos, brief exercises, and self-reflection tools.

If you need support and information about options and resources, please contact or see the Office of the Dean of Students. Call 765-494-1747. Hours of operation are M-F, 8 a.m.- 5 p.m.

If you find yourself struggling to find a healthy balance between academics, social life, stress, etc., sign up for free one-on-one virtual or in-person sessions in West Lafayette with a Purdue Wellness Coach at RecWell. Student coaches can help you navigate through barriers and challenges toward your goals throughout the semester. Sign up is free and can be done on BoilerConnect.

If you're struggling and need mental health services: Purdue University is committed to advancing the mental health and well-being of its students. If you or someone you know is feeling overwhelmed, depressed, and/or in need of mental health support, services are available. For help, such individuals should contact Counseling and Psychological Services (CAPS) at 765-494-6995 during and after hours, on weekends and holidays, or by going to the CAPS offices in West Lafayette or Indianapolis.

Emergency Preparation

In the event of a major campus emergency, course requirements, deadlines, and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances beyond the instructor's control. Relevant changes to this course will be posted onto the course website or can be obtained by contacting the instructor via email. You are expected to read your @purdue.edu email on a frequent basis.

Purdue's Emergency Preparation and Planning website covers topics such as Severe Weather Guidance, Emergency Plans, and a place to sign up for the Emergency Warning Notification System. I encourage you to download and review the *Emergency Preparedness for Classrooms document*.

Course Evaluation

During the last two weeks of the semester, you will be provided with an opportunity to give feedback on this course and your instructor. Purdue uses an online course evaluation system. You will receive an official email from evaluation administrators with a link to the online evaluation site. You will have up to 10 days to complete this evaluation. We value your feedback and will use it to improve the course in future semesters.

Disclaimer

This syllabus is subject to change. All changes will be posted as announcements on Brightspace.