

School of Public Health

Syllabus and Course Information



PubH 6363

Design and Analysis of Group-Randomized Trials in Epidemiology Spring 2016

Credits:	3
Meeting Days:	Tuesdays & Thursdays
Meeting Time:	9:45 – 11:00 am
Meeting Place:	Mayo C-381
Instructor:	Michael Oakes
Office Address:	EpiCH WBOB
Office Phone:	612/624-6855
E-mail:	oakes007@umn.edu
Office Hours:	By appointment

I. Course Description

This course provides instruction in the design and analysis of group-randomized trials (GRTs) in epidemiology including the characteristics of GRTs, and their statistical, practical, and ethical issues

II. Course Prerequisites

The course is designed for advanced students in health or related fields (eg, education) who plan to pursue a career in research. Course work in statistics covering analysis of variance and multiple regression is desired (e.g., PubH 6450, 6452, 6454; PubH 6341). An introductory course in research design would be helpful (e.g., PubH 6806 or 6852).

III. Course Goals and Objectives

Students will be able to:

- 1) discuss the purposes of group-randomized trials in epidemiology and public health;
- 2) define the terminology used to describe their research designs;
- 3) explain the components of group-randomized trials including specification of the research question and selection of the proper design, measures, study populations and analysis procedures;
- 4) describe the factors that affect the validity of these trials;
- 5) explain the strengths and weaknesses of several *design* alternatives;
- 6) critique existing trials;

- 7) discuss the strengths and weaknesses of several *analysis* alternatives;
- 8) select an appropriate analysis for a particular design; and
- 9) employ suitable computer software to analyze data from group-randomized trials.

Students who complete this course should be better able to plan, to analyze, and to critically review group-randomized trials in epidemiology, as well as being aware of the difficulties of implementing a GRT.

IV. Methods of Instruction and Work Expectations

The course uses practically all of the relatively textbook (Campbell and Walter, 2014), with some extra material for extending discussion of some topics. Hence, students will have the resources in hand and will be expected to preview as well as going over material covered by presentation and discussion in class-time. Throughout the course assignments of scientific papers reporting on GRTs will be given to expose students to such literature and to give practice in critical review; students will be expected to provide summaries from reading the paper and to be able to summarize the salient points in the paper in brief “pop” quizzes. By meeting in the computer laboratory students will have hands-on experience of running analyses of GRTs using the same dataset as used by Murray.

V. Software, Course Text and Readings

Required Software:

This hands-on course requires students have access to Stata (v14) statistical software. The software may be purchased at a very steep discount from UMN under Stata’s GradPlan program. Stata runs equally well on a Mac or Windows operating system.

Required Text:

David M Murray. (1998) *Design And Analysis Of Group-Randomized Trials*. New York: Oxford University Press.

Text available from Amazon.com or other retailers for approximately \$90.00.

The instructor of this course has several copies to loan students if they do not wish to purchase the text.

Highly recommended as a complementary volume is (not required)::

A Donner and N Klar. *Design and Analysis of Cluster Randomization Trials in Health Research*, London, England: Arnold, 2000

Other *statistical* resources that the student might like to explore (not required):

- MJ Campbell and SJ Walter. 2014. *How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research*. Wiley.
- Anthony S Bryk and Stephen W. Raudenbush (1992), *Hierarchical Linear Models*, Newbury Park:Sage (The authors come from the educational field so the language is different, but the hierarchical formulation of models involving multiple sources of variance is quite readable and complements the textbook).
- *Judith D. Singer (1998), Using SAS PROC MIXED to fit multilevel models, hierarchical models, and individual growth curves, J Educ & Beh Stat 24(4):322-354.*
- *Helen Brown and Robin Prescott (1999), Applied mixed models in medicine, New York:John Wiley and Sons, Ltd.*
- Ramon C Littell, George A Milliken, Walter W Stroup and Russell D Wolfinger, SAS System

for MIXED Models, Cary NC:Sas Institute Inc. 1996.

- Murray DM and Wolfinger RD (1994), Analysis issues in the evaluation community trials: progress toward solutions in SAS/STAT MIXED, Journal of Community Psychology CSAP Special Issue 140-154.
- Murray DM, Hannan PJ, Wolfinger RD, Baker WL and Dwyer JH (1998), Analysis of data from group-randomized trials with repeat observations on the same groups. Stats. In Medicine 17:1581-1600.
- Murray DM and Hannan PJ (1990), Planning for the appropriate analysis in school-based drug-use prevention studies. J Consulting & Clinical Psych 58(4):458-468. Murray DM, Hannan PJ, and Zucker D (1991) Analysis issues in school-based health promotion studies. Health Education Quarterly.
- Murray DM, Hannan PJ, and Baker WL (1996), A Monte Carlo study of alternative responses to intraclass correlation in community trials: Is it ever possible to avoid Cornfield's penalties?, Evaluation Review 20(3):313-337.
- Hannan PJ and Murray DM (1996), Gauss or Bernoulli? A Monte Carlo comparison of the linear mixed model and the logistic mixed model analyses in simulated community trials with a dichotomous outcome variable at the individual level, Evaluation Review 20(3):338-352.
- Koepsell TD, Martin DC, Diehr PH, Psaty BM, Wagner EH, Perrin EB, and Cheadle A (1991), Data analysis and sample size issues in evaluations of community-based health promotion and disease prevention programs: A mixed-model analysis of variance approach. Journal of Clinical Epidemiology 44(7):701-713.
- Zucker DM (1990), An analysis of variance pitfall: The fixed effect analysis in a nested design. Educational and Psychological Measurement 50:731-738.
- Annette J. Dobson (2002), An introduction to generalized linear models, 2nd ed. New York:Chapman and Hall/CRC (paperback).
- Lisa M Sullivan, Kimberley A Dukes, and Elena Losina (1999), Tutorial in Biostatistics: An introduction to hierarchical linear modeling, Stats Med 18:855-888.
- Harvey Goldstein, William Browne and Jon Rasbash (2002), Tutorial in Biostatistics: Multilevel modeling of medical data, Statistics in Medicine 21:3291-3315.
- Zhou X, Perkins AJ, and Hui SL (1999), Comparison of software packages for generalized linear multilevel models, The American Statistician 53:282-290.

VI. Course Outline/Weekly Schedule

Week	Day	Date	Topic	Stata?	Chapters	Supplement Readings
1	Tuesday	19-Jan	Groups and history of GRT		1	Hannan 2006
1	Thursday	21-Jan	Groups and history of GRT		2	
2	Tuesday	26-Jan	Designs, bias and threats to useful inference		3	Susser 1995
2	Thursday	28-Jan	Concepts for GRTs			
3	Tuesday	2-Feb	Concepts for GRTs			
3	Thursday	4-Feb	Designs, bias and threats to useful inference		4	VanderWeele 2008
4	Tuesday	9-Feb	Sohota Discussion		5	
4	Thursday	11-Feb	10 Common Mistakes Discussion			
5	Tuesday	16-Feb	Introduction to Stata for GRTs	Y	7	
5	Thursday	18-Feb	Nested XS – Post-test only (OLS and mixed)	Y		
6	Tuesday	23-Feb	Nested XS – Post-test only (OLS and mixed)	Y		
6	Thursday	25-Feb	Designs, bias and threats to useful inference			
7	Tuesday	1-Mar	Nested XS – Post-test only; adjusted means	Y		
7	Thursday	3-Mar	Process Evaluation	Y		McGraw et al 1989
8	Tuesday	8-Mar	The ethics of group trials			
8	Thursday	10-Mar	No Class - Take Home Mid-term Exam			Macklin 2014; Hutton 2001
9	Tuesday	15-Mar	Spring Break			
9	Thursday	17-Mar	Spring Break			
10	Tuesday	22-Mar	Nested XS – Pre/Post analysis	Y	6	
10	Thursday	24-Mar	Nested XS – Pre/Post analysis	Y		
11	Tuesday	29-Mar	Nested Cohort – Pre/Post modeling and analysis	Y	8	
11	Thursday	31-Mar	Nested Cohort – Pre/Post modeling and analysis	Y		
12	Tuesday	5-Apr	Statistical power, minimum detectable effect		9	Hannan 2006
12	Thursday	7-Apr	Statistical power, minimum detectable effect			Feldman 1997
13	Tuesday	12-Apr	Alternative analyses: permutation tests, RC, GEE, etc	Y		
13	Thursday	14-Apr	Alternative analyses: permutation tests, RC, GEE, etc	Y		
14	Tuesday	19-Apr	Non-randomized group "trials"			
14	Thursday	21-Apr	Non-randomized group "trials"			
15	Tuesday	26-Apr	Guest speaker on GRT Intervention designs		10	Eldridge & Kerry 2012
15	Thursday	28-Apr	Advanced Designs (eg, Step Wedge)			Pals et al 2008
16	Tuesday	3-May	Messy Designs			Kelly et al 2014
16	Thursday	5-May	Review and Wrap Up			

Chapter refer to the text Design and Analysis of Group-Randomized Trials (Murray, 1998) Oxford U.P.

VII. Evaluation and Grading

Evaluation will be based on class participation and pop-quizzes throughout the course (40%), mid exam (25%), and a final (35%). Students are expected to participate actively in each class and be current in their readings throughout the semester in order to participate fully.

Classroom performance on assigned papers will be by agreement between the instructors, and or homework will be graded by one or other of the instructors. Midterm and final will be a consensus arrived at by the two instructors. Letter grades or S/N grades are available. A grade of "C" or higher is needed for an "S."

Written assignments are expected to be typed, including mathematical equations, and submitted in pdf format.

S/N option must complete all assignments to a C level (73%).

Letter grade will be determined by total effort as follows:

70-72	C-
73-76	C
77-79	C+
80-82	B-
83-86	B
87-89	B+
90-94	A-
95-100	A

F (or N) – Represents failure (or no credit) and signifies that the work was either (1) not completed or of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (for incomplete).

S – Achievement that is satisfactory will be expected to complete all assignments and receive a minimum 73% to receive a passing score.

Students may change grading options without written permission as specified by the University or a penalty during the initial registration period or during the first two weeks of the semester. **The grading option may not be changed after the second week of the term.**

Course Evaluation

Beginning in fall 2008 the SPH will collect student course evaluations electronically using a software system called CoursEval. The system will send email notifications to students when they can access and complete their course evaluations. Students who complete their course evaluations promptly will be able to access their final grades just as soon as the faculty member renders the grade. All students will have access to their final grades two weeks after the last day of the semester regardless of whether they completed their course evaluation or not. Student feedback on course content and faculty teaching skills are important means for improving our work. Please take the time to complete a course evaluation for each of the courses for which you are registered.

Incomplete Contracts

A grade of incomplete "I" shall be assigned at the discretion of the instructor when, due to extraordinary circumstances (e.g., documented illness or hospitalization, death in family, etc.), the student was prevented from completing the work of the course on time. The assignment of an "I" requires that a contract be initiated and completed by the student before the last day of class, and signed by both the student and instructor. If an incomplete is deemed appropriate by the instructor, the student in consultation with the instructor, will specify the time and manner in which the student will complete course requirements. Extension for completion of the work will not exceed one year (or earlier if designated by the student's college). For more information and to initiate an incomplete contract, students should go to: www.sph.umn.edu/grades.

University of Minnesota Uniform Grading and Transcript Policy

A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable)

For full-semester courses, students may change their grade option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e. summer and half-semester courses) can be found at onestop.umn.edu.

Course Withdrawal

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Student Services Center at sph-ssc@umn.edu for further information.

Student Conduct Code:

The University seeks an environment that promotes academic achievement and integrity, that is protective of free inquiry, and that serves the educational mission of the University. Similarly, the University seeks a community that is free from violence, threats, and intimidation; that is respectful of the rights, opportunities, and welfare of students, faculty, staff, and guests of the University; and that does not threaten the physical or mental health or safety of members of the University community.

As a student at the University you are expected adhere to Board of Regents Policy: *Student Conduct Code*. To review the Student Conduct Code, please see: http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf.

Note that the conduct code specifically addresses disruptive classroom conduct, which means "engaging in behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning. The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities."

Use of Personal Electronic Devices in the Classroom:

Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. To this end, the University establishes the right of each faculty member to determine if and how personal electronic devices are allowed to be used

in the classroom. For complete information, please reference:
<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Scholastic Dishonesty:

You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis. (Student Conduct Code: http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf) If it is determined that a student has cheated, he or she may be given an "F" or an "N" for the course, and may face additional sanctions from the University. For additional information, please see:
<http://policy.umn.edu/Policies/Education/Education/INSTRUCTORRESP.html>.

The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: <http://www1.umn.edu/oscai/integrity/student/index.html>. If you have additional questions, please clarify with your instructor for the course. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam.

Makeup Work for Legitimate Absences:

Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Such circumstances do not include voting in local, state, or national elections. For complete information, please see:
<http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html>.

Appropriate Student Use of Class Notes and Course Materials:

Taking notes is a means of recording information but more importantly of personally absorbing and integrating the educational experience. However, broadly disseminating class notes beyond the classroom community or accepting compensation for taking and distributing classroom notes undermines instructor interests in their intellectual work product while not substantially furthering instructor and student interests in effective learning. Such actions violate shared norms and standards of the academic community. For additional information, please see: <http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Sexual Harassment:

"Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment in any University activity or program. Such behavior is not acceptable in the University setting. For additional information, please consult Board of Regents Policy:
<http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf>

Equity, Diversity, Equal Opportunity, and Affirmative Action:

The University will provide equal access to and opportunity in its programs and facilities, without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression. For more information, please consult Board of Regents Policy:
http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EO_AA.pdf.

Disability Accommodations:

The University of Minnesota is committed to providing equitable access to learning opportunities for all students. The Disability Resource Center Student Services is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations.

If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DRC at 612-626-1333 or drc@umn.edu to arrange a confidential discussion regarding equitable access and reasonable accommodations.

If you are registered with DS and have a current letter requesting reasonable accommodations, please contact your instructor as early in the semester as possible to discuss how the accommodations will be applied in the course.

For more information, please see the DS website, <https://diversity.umn.edu/disability/>.

Mental Health and Stress Management:

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance and may reduce your ability to participate in daily activities. University of Minnesota services are available to assist you. You can learn more about the broad range of confidential mental health services available on campus via the Student Mental Health Website: <http://www.mentalhealth.umn.edu>.

The Office of Student Affairs at the University of Minnesota:

The Office for Student Affairs provides services, programs, and facilities that advance student success, inspire students to make life-long positive contributions to society, promote an inclusive environment, and enrich the University of Minnesota community.

Units within the Office for Student Affairs include, the Aurora Center for Advocacy & Education, Boynton Health Service, Central Career Initiatives (CCE, CDes, CFANS), Leadership Education and Development – Undergraduate Programs (LEAD-UP), the Office for Fraternity and Sorority Life, the Office for Student Conduct and Academic Integrity, the Office for Student Engagement, the Parent Program, Recreational Sports, Student and Community Relations, the Student Conflict Resolution Center, the Student Parent HELP Center, Student Unions & Activities, University Counseling & Consulting Services, and University Student Legal Service.

For more information, please see the Office of Student Affairs at <http://www.osa.umn.edu/index.html>.

Academic Freedom and Responsibility: *for courses that do not involve students in research:*

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

** Language adapted from the American Association of University Professors "Joint Statement on Rights and Freedoms of Students".*

Student Academic Success Services (SASS): <http://www.sass.umn.edu>:

Students who wish to improve their academic performance may find assistance from Student Academic Support Services. While tutoring and advising are not offered, SASS provides resources such as individual consultations, workshops, and self-help materials.