UNIVERSITY OF MINNESOTA
School of Public Health

Course Syllabus

PubH 6363-001
Design and Analysis of Group-Randomized Trials in Epidemiology
Spring 2009

Credits:	**3**	
Meeting Days:	**Tuesdays & Thursdays**	
Meeting Time:	**9:45 – 11:00 am**	
Meeting Place:	**Mayo C-381**	
Instructor:	**Michael Oakes**	**Peter Hannan**
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Office Hours:	**By appointment**	**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 required (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;
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 textbook (Murray, 1998), 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. Course Text and Readings

Required Text:

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

Highly recommended as a complementary volume is:

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:

- 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 Med18:855-888.

- 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	Date	Lead Instr	Topic	Chapters	Supplement Readings
1	20-Jan	Michael	Counterfactuals, experimental and observational designs	1	Murray et al 2008
1	22-Jan	Michael	Groups and history of GRT	2	Shadish 2009
2	27-Jan	Michael	Designs, bias and threats to useful inference	3	Susser 1995
2	29-Jan	Michael	Regression in SAS		Oakes 2004
3	3-Feb	Michael	Measures and measurement, precision		Hedges & Hedberg 2007
3	5-Feb	Peter	ANOVA review	4	
4	10-Feb	Peter	Nested XS – Post-test only (OLS and mixed)	5	St. Pierre & Rossi 2006
4	12-Feb	Peter	Lab		
5	17-Feb	Peter	Nested XS – Post-test only; adjusted means	7	McGraw et al 1989
5	19-Feb	Michael	Lab		
6	24-Feb	Peter	Nested XS – Pre/Post analysis		Bloom et al 2007
6	26-Feb	Michael	Lab		
7	3-Mar	Peter	Nested XS – Pre/Post analysis		
7	5-Mar	Peter	Lab		
8	10-Mar	Michael	Review and catch up		Luepker et al 2000
8	12-Mar	Michael	Mid-term exam in class		
9	**17-Mar**		**Spring Break**		
9	**19-Mar**		**Spring Break**		
10	24-Mar	Peter	Nested Cohort – Pre/Post modeling and analysis I	6	Stevens et al 2005
10	26-Mar	Michael			Feldman et al 1998
11	31-Mar	Peter	Nested Cohort – Pre/Post modeling and analysis II	8	Raudenbush et al 2007
11	2-Apr	Peter			Feldman 1997
12	7-Apr	Michael	Statistical power, minimum detectable effect	9	Zucker et al 1996
12	9-Apr	Peter	Lab		Perry et al 2004
13	14-Apr	Guest	Design and implementation of interventions: Guest speaker		Wagenaar et al 2000
13	16-Apr	Guest	Analysis experiences: Guest speaker		Stone et al 1996
14	21-Apr	Peter	Alternative analyses: permutation tests, RC, GEE, etc		Pals et al 2008
14	23-Apr	Peter	Lab		Raudenbush & Sadoff 2008
15	28-Apr	Michael	Catch up	10	
15	30-Apr	Michael	Grant writing & ethics		
16	5-May	Michael	Review and wrap up		
16	7-May	Michael	Final exam in class		

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 (30%), midterm exam (30%), and a final (40%). Students are expected to participate actively in each class and must remain current in their readings throughout the quarter in order to participate fully. Students must achieve at least 2/3 of the marks (67%) in each of the three types of evaluation to be considered for a pass.

Classroom performance on assigned papers will be by agreement between the instructors, and on homework will be graded by one or other of the instructors. Midterm and final will be a consensus grade 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) completed but at a level 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 of 73% to receive a passing score.

Students may change grading options without written permission as specified by the University and without 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, Scholastic Dishonesty and Sexual Harassment Policies
Students are responsible for knowing the University of Minnesota, Board of Regents' policy on Student Conduct and Sexual Harassment found at www.umn.edu/regents/polindex.html.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the Office of Student Academic Integrity (OSAI, www.osai.umn.edu).

The University's Student Conduct Code defines scholastic dishonesty as "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; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis."

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: http://writing.umn.edu/tww/plagiarism/.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to http://tutorial.lib.umn.edu/ and click on "Citing Sources".

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

Disability Statement

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).