2016 University of Florida ● College of Medicine
Department of Health Outcomes and Policy

GMS 6844, Spring 2016

Experimental and Quasi-experimental Research Designs for Community Settings

Time: January 8 – April 15, 2016
Fridays, 9:35 am – 11:30 am
Location: HPNP G-112
Credits:
Instructors: Chris Delcher, Ph.D., Assistant Professor
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Office Hours: Anytime by appointment, just email me.

Course Description

This course provides instruction in: (1) group-randomized trials—experiments where the unit of assignment is an intact social unit (e.g., clinics, schools, communities, rather than individuals), and (2) controlled quasi-experimental trials—longitudinal and time-series experiments (including "natural" experiments) where random assignment is not possible, but high levels of internal validity remain attainable. Data analysis will play an important role in the class.

Audience

This intense concentrated methods course is designed for advanced masters-level and doctoral-level students in medicine, public health, and other health professions, as well as advanced students in public policy, sociology, psychology or other social sciences with plans for a career in research. Prerequisites are a minimum of a graduate course in epidemiology and a graduate course in statistics, and permission of instructor.

Objectives

As a result of this course, students will be able to:

1. Explain key concepts from the philosophy of science that underlie design of research trials.
2. Define the four major types of validity used as the basis for evaluating the strength of a research trial: statistical conclusion validity, internal validity, construct validity, and external validity.
3. Distinguish stronger and weaker research designs in terms of levels of validity.
4. Understand the strengths and limitations of non-equivalent comparison group designs and interrupted time-series designs.
5. Discuss the special considerations in the design, sampling, measurement, implementation, analysis and interpretation of results from group-randomized trials.
6. Identify several alternative research designs for particular scientific questions; evaluate pros and cons of design choices made by published investigators.
7. Demonstrate awareness of special statistical considerations in analyzing data from group-randomized or controlled time-series trials.
8. Perform analysis of a time series of a health-related outcome, interpret the results, and provide discussion of implications

After this course, students will be better able to plan, implement or critically evaluate group-randomized and quasi-experimental research trials, as well as evaluating effects of natural experiments (e.g., policy changes).

Methods of Instruction

The course will operate as an advanced graduate seminar, with students taking an active role in initiating and leading discussions and debates. Attendance and active participation in all class discussions is required, and will be evaluated as part of the student's grade for the course. Students *must* read the required readings *prior* to each class session.

Tests

No exams will be given in this graduate-level seminar course.

Term Paper

There is no term paper in this course.

Assignments

There are three requirements:

1. **Written comments on readings and class discussions.** You *must* read the assigned readings *prior to* each class session, and submit one (minimum) to two (maximum) single-spaced pages of your reactions, thoughts, analysis, comments and questions on the main research design issues raised in the readings. This includes prior to the first class session. **Comments are due via email by 8:30 am on the day of each class session.** Do *not* summarize each reading; instead, tell me what you are *thinking* about what you have read. Your comments should focus on the important conceptual and research design, or analysis implications of the readings. Share what strikes you as new, unexpected, confusing, or particularly important. Discuss implications the authors' ideas, theories, and research findings for *your* work. Organize your comments by each chapter/paper assigned, identifying each with author last name and shortened title. (Student comments will be used to shape class discussions, but time constraints will likely prevent discussion of all issues raised.) Comments are *not* required prior to the following two analysis lab sessions. Note that they *are* required prior to the first class session. All students are expected to participate in each class discussion.
2. **Group activity designing a rigorous study.** At times, you will work in small groups and be given a scenario in which you will need to outline an appropriate study design using optimal design elements. Be prepared to actively participate in the discussion and decisions regarding design elements, threats to validity, and strength of causal inference.
3. **Research proposal and presentation**. A research proposal will be considered for this course, written in an abbreviated format of a NIH proposal, including Specific Aims, Significance, Innovation and Approach sections. You will choose your research topic and the most appropriate study design between a time-series quasi-experimental design or a group-randomized experimental research design. The proposals should be single-spaced and six pages (excluding references). The proposals should be formatted and follow NIH guidelines but can also be converted to a manuscript for class. You will present to the class (15-30 minute presentation using PowerPoint). Sections of the proposal/manuscript will be due throughout the semester.

   Proposal outline:

   I. Specific Aims (1 page or less)
   II. Significance and Innovation (1-2 pages)
   III. Approach (4+ pages)
   IV. Literature cited

   Presentation guidelines:

   You should prepare a well-designed set of slides in a PowerPoint file, which you will use during your presentation and will email to the entire class by 10am the day of your presentation (so people can print

a copy prior to the class, if they wish). Design each visual carefully, to illustrate the main points. Remember the rules for clear, easy to understand, and interesting visuals, such as no more than 12 words per slide (ok, maybe you can break that rule, but only by a couple more words), and prevalent use of diagrams, charts, etc. to illustrate points (avoid too many word-only slides).

Evaluation and Grading

Grades will be based on the written weekly comments on readings (25%), attendance and participation in discussions and group activities (15%); study design and analytic group activities (30%); research proposal and presentation (30%). All deadlines must be met. Any assignment turned in after the deadline will receive one grade below what it would have earned had it been submitted on time. Grades will be assigned as follows:

Letter Grade	Grade Points	Grade Percentage
A	4.0	95-100
A-	3.67	90-94
B+	3.33	87-89
B	3.0	83-86
B-	2.67	80-82
C+	2.33	77-79
C	2.0	73-76
C-	1.67	70-72
D+	1.33	67-69
D	1.0	63-66
D-	.67	60-62
E	0	59 and below

For additional grading policy information, you may visit the web page at:
http://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx.

Class Attendance

Class attendance is required. Excused absences follow the criteria of the UF Graduate Catalogue (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. UF rules require attendance during the first two course sessions, and students also must attend all course sessions of student presentations. Missing more than three scheduled sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students must read the assigned readings *prior to* the class meetings, and be prepared to discuss the material.

Canvas

Course information, readings, and grades are available on Canvas at http://lss.at.ufl.edu/. You must have a Gatorlink account to log on. For more information on using Canvas, see http://lss.at.ufl.edu/help/Student_Faq.

Accommodations for Students with Disabilities

Students requiring accommodations must first register with the Dean of Students' Office. The Dean of Students' Office will provide documentation to the student who must then provide this documentation to the faculty member when requesting accommodation. The College is committed to providing reasonable accommodations to assist students in their coursework.

University of Florida Academic Honesty Statements

"I understand that the University of Florida expects its students to be honest in all their academic work. I agree and adhere to this commitment to academic honesty and understand that my failure to comply with this commitment may result in disciplinary action up to and including expulsion from the University."

"All faculty, staff and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate."

"We, the members of the University of Florida, pledge to hold ourselves and our peers to the highest standards of honesty and integrity."

Citations and Plagiarism

The two key purposes of citation are to: 1) give appropriate credit to the authors of information, research findings, and/or ideas (and avoid plagiarism), and 2) facilitate access by your readers to the sources you use in your research.

Quotations: When directly quoting an outside source, the borrowed text, regardless of the amount, must be surrounded by quotation marks or block quoted. Quoted text over two lines in length should be single-spaced and indented beyond the normal margins. Every quote must include a source—the author, title, volume, page numbers, etc.—whether an internal reference, footnote, or endnote is used in conjunction with a bibliography page.

Paraphrasing or Citing an Idea: When summarizing an outside source in your own words or citing another person's ideas, quotation marks are not necessary, but the source must be included. This includes, but is not confined to, personal communications from other students, faculty members, experts in the field, summarized ideas from published or unpublished resource, and primary methods derived from published or unpublished sources. Use the general concept of "when in doubt – cite."

Plagiarism is a serious violation of the academic honesty policy of the College. If a student plagiarizes others' material or ideas, he or she may receive an "E" in the course. The faculty member may also recommend further sanctions to the Dean, per College disciplinary action policy. Generally speaking, the three keys of acceptable citation practice are: 1) thoroughness, 2) accuracy, and 3) consistency. In other words, be sure to fully cite all sources used (thoroughness), be accurate in the citation information provided, and be consistent in the citation style you adopt. All references should include the following elements: 1) last names along with first and middle initials; 2) full title of reference; 3) name of journal or book; 4) publication city, publisher, volume, and date; and 5) page numbers referenced. When citing information from the Internet, include the WWW address at the end, with the "access date" (i.e., when you obtained the information), just as you would list the document number and date for all public documents. When citing ideas or words from an individual that are not published, you can write "personal communication" along with the person's name and date of communication.

Textbook

Shadish, WR, Cook, TD, & Campbell, DT (2002). *Experimental and Quasi-Experimental Designs for Generalized Causal Inference.* Houghton Mifflin, 2002 (or 2001, 2nd edition). Available at Amazon.com (http://www.amazon.com/Experimental-Quasi-Experimental-Designs-Generalized-Inference/dp/0395615569) and elsewhere; cost about $92.

Schedule of Topics and Readings

1. **1/8/2016 Fri**
2. **1/15/2016 Fri**
3. **1/22/2016 Fri**
4. **1/29/2016 Fri**
5. **2/5/2016 Fri**
6. **2/12/2016 Fri**
7. **2/19/2016 Fri**
8. **2/26/2016 Fri**
9. **3/4/2016 Fri**
10. **3/11/2016 Fri**
11. **3/18/2016 Fri**
12. **3/25/2016 Fri**
13. **4/1/2016 Fri**
14. **4/8/2016 Fri**
15. **4/15/2016 Fri**

Class 1, January 8

Part I: Welcome & review of course

Class 2, January 15

Part I: Introduction to science, experiments and causation; Stages of research—observational to experimental, when to conduct an experiment

Readings: Preface, Ch 1

Class 3, January 22

Part II: Statistical validity; Internal validity, Construct validity; External validity

Readings: Ch. 2

Validity Handout (bring to class)

Class 4

Quasi-experimental designs, Qualities of design for strong causal inference; Review of weak to stronger design features

Readings: Ch 4, 5

Note: In your written comments for the following three readings, please describe the major threats to validity and recommendations for how to redesign the studies to address those threats.

Coady, et al. (2008). Project VIVA: A multilevel community-based intervention to increase influenza vaccination rates among hard-to-reach populations in NYC. AJPH, 98(7), 1314-1321.

Wilcox, et al. (2006). Results of the first year of Active for Life: Translation of 2 evidence-based physical activity programs for older adults into community settings. AJPH, 96(7), 1201-1209.

Veugelers & Fitzgerald (2005). Effectiveness of school programs in preventing childhood obesity: A multilevel comparison. AJPH, 95(3), 432-435.

Class 4, January 29

Design elements continued from above.

Class 5, February 5

Time-series quasi-experimental designs; Applications of time-series designs; Regression discontinuity designs

Readings: Ch 6, 7

Wagenaar, A.C. & Komro, K.A. (2013). Natural Experiments: Research Design Elements for Optimal Causal Inference Without Randomization. In: *Public Health Law Research*. San Francisco: John Wiley & Sons, Inc., pp. 307-324.

View webinar: Wagenaar, A.C. & Komro, K.A. Analyzing Natural Experiments: A Public Health Methods Webinar. Invited Webinar, sponsored by Academy Health, December 14, 2011. http://www.academyhealth.org/Training/ResourceDetail.cfm?itemnumber=7869

Class 6, February 12

Time-series quasi-experimental designs; studies using ARIMA model. Student TED talk proposal.

Delcher, C., Maldonado-Molina, M. M. & Wagenaar, A. C. Effects of alcohol taxes on alcohol-related disease mortality in New York State from 1969 to 2006. *Addictive Behaviors* **37,** 783–789 (2012).

Delcher, C., Wagenaar, A. C., Goldberger, B. A., Cook, R. L. & Maldonado-Molina, M. M. Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program. *Drug Alcohol Depend* (2015). doi:10.1016/j.drugalcdep.2015.02.010

Class 7, February 19

Analysis methods for time-series designs; Interactive lab

NOTE: Bring your laptop with SAS/R ready to use to this class.

Readings:
Worrall, J. L. (2008). An Introduction to Pooling Cross-Sectional and Time Series Data. Handbook of Longitudinal Research: Design, Measurement, and Analysis. S. Menard. Burlington, MA, Elsevier Inc.**:** 233-248.

Hartmann, D. P., J. M. Gottman, et al. (1980). "Interrupted Time-Series Analysis and its Application to Behavioral Data." Journal of Applied Behavior Analysis **13**(4): 543-559.

Wagenaar, A.C., Livingston, M.D., & Staras, S.S. (2015). Effects of a 2009 Illinois Alcohol Tax Increase on Fatal Motor Vehicle Crashes. American Journal of Public Health, 105 (5).

Also, please review following SAS pages on the ARIMA Model:
http://support.sas.com/documentation/cdl/en/etsug/60372/HTML/default/viewer.htm#etsug_arima_sect003.htm
http://support.sas.com/documentation/cdl/en/etsug/60372/HTML/default/viewer.htm#etsug_arima_sect004.htm
http://support.sas.com/documentation/cdl/en/etsug/60372/HTML/default/viewer.htm#etsug_arima_sect005.htm
http://support.sas.com/documentation/cdl/en/etsug/60372/HTML/default/viewer.htm#etsug_arima_sect010.htm
http://support.sas.com/documentation/cdl/en/etsug/60372/HTML/default/viewer.htm#etsug_arima_sect013.htm

Class 8, February 26

Analysis methods for time-series designs; Interactive lab continued

Class 9, March 4

Analysis methods for time-series designs; Interactive lab continued. Bring your own data!

Class 10, March 11

Randomized experimental design; Group-randomized experimental designs; Applications of group-randomized designs, possible guest lecture (Dr. Alex Wagenaar)

Readings: Ch 8, 9, 10

Optional readings, examples of group-randomized trials: There is a folder in Canvas called "Group-randomized trials example papers" with a dozen or so recent examples of studies using group-randomized designs. Skim them to get a sense how widely applicable the design is.

Class 11 and 12, March 18 and March 25

In-class proposal development and critiques, TBD

Readings:

Hanley, J.A., Negassa, A., et al. (2003). Statistical analysis of correlated data using generalized estimating equations: An orientation. *American Journal of Epidemiology*, 157(4), 364-375.

Murray, D.M., Varnell, S.P. et al. (2004). Design and analysis of group-randomized trials: A review of recent methodological developments. *American Journal of Public Health*, 94(3), 423-432.

Paterson, L. & Goldstein, H. (1991). New statistical methods for analyzing social structures: An introduction to multilevel models. *British Educational Research Journal*, 17(4), 387-393.

Peters, T.S., Richards, et al. (2003). Comparison of methods for analyzing cluster randomized trials: An example involving factorial design. *International Journal of Epidemiology*, 32(5), 840-846.

Also, please review the documentation for SAS PROC GENMOD and this example:
http://support.sas.com/documentation/cdl/en/statug/63347/HTML/default/viewer.htm#statug_genmod_sect065.htm

Class 12, April 1

TBD

Class 13 and 14, April 8 and April 15

Student presentations (proposals due; email PP to class by 9am or bring 7 copies of PP to class—3 to 6 slides per page)

Class wrap-up

Readings:

Shadish, W.R. (2011). Randomized controlled studies and alternative designs in outcome studies: Challenges and opportunities. *Research on Social Work Practice*, 21, 636-643.

Shadish, W.R. (2011). Campbell and Rubin: A primer and comparison of their approaches to causal inference in field settings. *Psychological Methods*, 15, 3-17.

View webinar: Strengths and Weaknesses of Experimental and Quasi-Experimental Designs
http://prevention.nih.gov/mindthegap/shadish.aspx

Other Recommended Resources

Murray, D. (1998). *Design and Analysis of Group-Randomized Trials*. New York: Oxford University Press.

Building Capacity to Evaluate Group-Level Interventions by Stephen W. Raudenbush (University of Chicago) and Howard Bloom (MDRC):
http://sitemaker.umich.edu/group-based/home

Blitstein, J.L., Hannan, P.J., Murray, D.M., Shadish, W.R. (2005). Increasing the degrees of freedom in existing group randomized trials through the use of external estimates of intraclass correlation: The DF* approach. *Evaluation Review, 29*(3), 241-267.

Blitstein, J.L., Murray, D.M., Hannan, P.J., Shadish, W.R. (2005). Increasing the degrees of freedom in future group randomized trials: The df* approach. *Evaluation Review, 29*(3), 268-286.

Flay, B.R., Biglan, A., Boruch, R.F., Castro, F.G., Gottfredson, D., Kellam, S., Moscicki, E.K., Schinke, S., Valentine, J.C., & Ji, P. (2005). Standards of evidence: Criteria for efficacy, effectiveness and dissemination. *Prevention Science*, 6, 151-175.

Pals, S.L., Murray, D.M., Alfano, C.M. et al. (2008). Individually Randomized Group Treatment Trials: A Critical Appraisal of Frequently Used Design and Analytic Approaches. *American Journal of Public Health, 98* (8), 1418-1424.

Varnell, S., Murray, D.M., Janega, J.B., & Blitstein, J.L. (2004). Design and analysis of group-randomized trials: A review of recent practices. *American Journal of Public Health, 94*(3):393-399.1-2 Others

Resources for preparation of 6-page abbreviated proposals:

Specific Aims
Discuss the broad, long-term objectives and goals of the research proposed. Second, be sure to list the very *specific* few research questions or hypotheses to be tested in the proposed study. One page is recommended for NIH, *1 page or less for the class assignment*.

Significance and Innovation
Explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Two to three pages are recommended for NIH, *1-2 pages for the class assignment.*

Approach
Describe the research design, conceptual or clinical framework, methods, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methods and its advantage over existing methods. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss how threats to validity are addressed by the design. Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Nine pages are usual for this section. *For class, four pages are required for this section (see outline above).*

Proposal Outline (6 pages, single-spaced; note per NIH rules you may use margins as small as ½ inch to maximize space)

A. Specific Aims (1 page or less)
    a. Broad, long-term objectives and goals of proposed research
    b. List very specific few research questions or hypotheses to be tested
B. Significance and Innovation (1-2 pages)
    a. Critically evaluate existing knowledge
    b. Specifically identify gaps that this project is intended to fill
    c. State concisely the importance and health relevance of the proposed research
    d. Explain why concepts and methods are novel to the research field.
    e. Focus on innovation in study design and outcomes.
C. Approach (4 pages or more)
    a. Introduction: summary of design and methods
    b. Study design
        i. Overview of study design (include diagram of the design)
        ii. Overall timeline for baseline and follow-ups
    c. Target population, eligible study sample, recruitment, retention strategies

d. Intervention description
    i. Theory/conceptual model
    ii. Description
    iii. Implementation
e. Evaluation Overview
    i. Outcome and intermediate measures
        1. Description of each measure
        2. Data collection protocol (for each measure)
    ii. Process measures to measure intervention implementation
f. Analysis Methods
    i. Description of specific statistical analysis models that will be performed (usually including an equation illustrating it)
    ii. Rationale for why analysis is appropriate
    iii. Discussion of how analysis will account for nesting of individuals within units within study condition, if appropriate
g. Statistical Power Analysis
    i. Show how the study as designed has enough power to find an effect of the magnitude reasonably expected or hypothesized
h. Summary of design, discuss any limitations of study, and highlight how design features address threats to validity

D. Literature cited
    a. Use AMA or APA guidelines, be accurate and consistent

Reference/citation guidelines:

APA:
http://www.cws.illinois.edu/workshop/writers/citation/apa/

http://owl.english.purdue.edu/owl/resource/560/01/

AMA:
http://www.ajph.org/misc/ama_references.shtml

http://www.findlay.edu/NR/rdonlyres/DB5BCD1B-07AA-4BC6-A62B-3C962CBAA3CD/0/AMAStyleGuide.pdf