

**NUTR 803**  
**Advanced Nutrition Intervention and**  
**Policy Research Methods**  
**Spring 2015**

**Instructors:**

Kyle Burger (ksburger@unc.edu)  
Myles Faith (mfaith@email.unc.edu)

**Course Meetings:**

Wednesday, 2:30 to 4:25 PM  
3100 MHRC

**Office Hours:** By appointment

**Course website:**

<https://sakai.unc.edu/portal/site/802-803>

**Course description**

This course will continue to cover the selected topics in nutrition intervention and policy research design and evaluation covered in the fall session of NUTR 801. Additional topics focused on in this course include implementing intervention research and policy studies. Students will gain familiarity with historical and innovative nutrition trials' design and implementation.

**Course Objectives**

1. Describe different randomization techniques and justification for use, including basic randomization and blinding implementation strategies.
2. Describe the difference between bias and random error and strategies for minimization.
3. Explain factors that are used to select intervention control/comparison groups and how selection of these groups affects the interpretation of a clinical trial.
4. Describe how to determine sample sizes for clinical trials.
5. Describe effective approaches for recruitment and retention of study participants.
6. Describe the data collection requirements of a trial.
  - a. Recommend different questionnaire types and data collection form techniques to ensure quality data.
  - b. Explain how to develop new measures or questionnaires, including assessment of their psychometric properties.
7. List the advantages of intent-to-treat analysis and differentiate its interpretation from that of a other analyses, such as a "completers" analysis.
8. Describe quality assurance procedures for clinical trials.
9. Describe how policy interventions are designed to address nutrition issues
10. Explain the process of policy evaluation, as well as alternative policy and environment strategies that impact public health outcomes.
11. Explain how to support policy recommendations with qualitative and quantitative analyses.
12. Describe dissemination and implementation (D&I) research and understand how D&I studies can be used to promote use of evidence-based programs in real-world settings.

***Prerequisites: Advanced Nutrition Intervention and Research Methods I and II.***

**Assignments**

1. Mid-term exam (10%)
2. Final exam (10%)
3. Lecture (30%)
4. Manuscript Assignment (40%)
5. General class & journal club participation (10%)

## **Lecture**

Students will be assigned to perform with two lecture sessions during the semester. For each of these lectures, students will be responsible for developing/updating lecture slides and materials for use during class, deliver the lecture, answer questions as they arise, and lead discussion as they arise. Students are encouraged to design interactive activities related as they see fit. Students are allowed to organize one outside speaker (3<sup>rd</sup> year PhD +) with the instructor's approval. Students should pull from their experiences with last year's course to improve these lectures and help the presenter modify their presentations.

## **Journal club**

Also, students expected to actively participate in all journal clubs. Students are encouraged to seek out other relevant papers, to add to the scholarship of the discussion. Students are expected to bring at least one discussion question to each journal club.

## **Manuscript Assignment**

The objective of this project is to draft and submit a journal article based on the previous semester's 'impact' project. Aspects of this assignment will include but are not limited to: determination of authorship, identifying a peer-reviewed outlet, identify and summarize previous literature to insure a novel and compelling contribution, drafting the manuscript body, formatting to meet journal requirements, response to instructor feedback, identifying suitable reviewer's, and submission to journal. The end product, to be completed in the spring of 2015, will be a submitted manuscript.

## **Grading**

Students will be evaluated on their ability to:

- Evaluate research papers based on the components of excellence in nutrition intervention and policy research (journal club discussions)
- Facilitate development of a lecture session
- Lead journal article discussion (ratings by course instructors)
- Develop an introduction to public health nutrition research mini-course
- Participate in class discussions, by asking questions, providing comments, and/or answering questions

Grading for the class will be determined as follows:

**H** Student reads and critically engages with all of the assigned material. Participation in discussion and written assignments exhibit the ability not only to apply the material, but also to extrapolate ideas, expand into new areas, and contribute to the body of scholarship in the area. Reserved for truly extraordinary work (i.e., ≥90%).

**P** Student usually reads and engages critically with the assigned material. Able to apply material and extrapolate ideas. Consistently good work done on time (i.e., 76%-89%).

**L** Student reads and engages critically with only some of the assigned material. Able to apply the material and extrapolate ideas in only some instances (i.e., 65%-75%).

**F** Student occasionally misses class, does not always read the material, fails to critically engage with it, and is unable or unwilling to apply the material (i.e., below <65%).

## **Honor Code**

Students must observe the Honor Code in all course assignments. You are expected to produce your own work, except where group work is specifically allowed. In all written assignments, you must not plagiarize the work of others. The instrument defining the Honor Code defines plagiarism as "deliberate or reckless representation of another's words, thoughts, or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise." If you have questions about your responsibility under the honor code, please bring them to one of the instructors or consult with the office of the Dean of

Students or the Instrument of Student Judicial Governance. This document, adopted by the Chancellor, the Faculty Council, and the Student Congress, contains all policies and procedures pertaining to the student honor system.

Please include the following pledge on all written assignments: "On my honor, I have neither given nor received unauthorized aid on this assignment."

### **Course Readings**

#### *Required Text:*

Hulley, S. B., Cummings, S. R., Browner, W. S., Grady, D. G., & Newman, T. B. (2007). *Designing Clinical Research* (3<sup>rd</sup> edition). Philadelphia: Lippincott Williams & Wilkins. Available for purchase online and in the UNC Student Store.

#### *Suggested Text:*

Shadish, W.R., Cook, T.D., and Campbell, D.T. (2002). *Experimental and Quasi-Experimental Designs for Causal Inference*. Boston: Houghton Mifflin Co.

Other readings are available electronically on the Sakai website

Date	Topic	Leader (navigator)	Readings
7-Jan	Syllabus/scheduling	Myles/Kyle	
14-Jan	Choosing control or comparison groups	Myles	Diabetes Prevention Program Research Group. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. <i>New England Journal of Medicine</i> , 346(6), 393-403. Kazdin A.E. (2003). Control and comparison groups <i>Research Design in Clinical Psychology</i> (pp. 184-212). Boston: Allyn and Bacon.
21-Jan	Intro to measurement		<i>Designing clinical research</i> : Chapter 4 <i>DeVellis' Scale Development: Theory and Applications</i> : Ch. 1; Ch. 2 pg 14-16
28-Jan	Creating your own measurement: reliability and validity		<i>DeVellis' Scale Development: Theory and Applications</i> : Ch. 3 pgs. 27-29 (through "Coefficient Alpha"), pgs. 38-39 ("Reliability and Statistical Power" section); Ch. 4
		JC	Hales D. (2013). Development of HomeSTEAD's physical activity and screen time physical environment inventory. <i>International Journal of Behavioral Nutrition and Physical Activity</i> , 10(132).
4-Feb	Sample size & power		<i>Designing Clinical Research</i> Chapter 6
11-Feb	Analyzing data from a randomized trial, including intent-to-treat and missing data		<u>Required:</u> Friedman L. M. (1998). Chapter 16: Issues in Data Analysis in <i>Fundamentals of Clinical Trials</i> (pp. 284-322). New York: Springer. Elobeid M. A. (2009). Missing data in randomized clinical trials for weight loss: Scope of the problem, state of the field, and performance of statistical methods. <i>Plos One</i> , 4(8), e6624. <u>Recommended:</u> Gadbury G. (2003). Modern statistical methods for handling missing repeated measurements in obesity trial data: beyond LOCF. <i>Obesity Reviews</i> , 4(3), 175-184. Murray D.M. (2004). Design and analysis of group-randomized trials: A review of recent methodological developments. <i>American Journal of Public Health</i> , 94, 423-432. Schafer J.L. (1999). Multiple imputation: a primer. <i>Statistical Methods in Medical Research</i> , 8(1), 3-15. Sheean P.M. (2011). Publishing nutrition research: A review of multivariate techniques—Part 1. <i>Journal of the American Dietetic Association</i> , 111, 103-110.
18-Feb	Testing mediation		Lockwood C.M. (2010). Mediation analyses: Applications in nutrition research and reading the literature. <i>Journal of the American Dietetic Association</i> , 110, 753-762.

Date	Topic	Leader (navigator)	Readings
		JC	Wingo B.C. (2013). Self-efficacy as a Predictor of Weight Change and Behavior Change in the PREMIER Trial. <i>Journal of Nutrition Education and Behavior</i> , 45(4), 314-321.
25-Feb	Subgroup analyses and other approaches to utilizing your data		Assmann S.F. (2000). Subgroup analysis and other (mis)uses of baseline data in clinical trials. <i>The Lancet</i> , 355, 1064-1069. Lagakos S.W. (2006). The challenge of subgroup analyses--reporting without distorting. <i>The New England Journal of Medicine</i> , 354(16), 1667-1669. Freemantle N. (2001). Interpreting the results of secondary end points and subgroup analyses in clinical trials: Should we lock the crazy aunt in the attic? <i>BMJ</i> , 322, 989-991.
		JC	Lytle L.A. (2011). Examining the Relationships Between Family Meal Practices, Family Stressors, and the Weight of Youth in the Family. <i>Annals of Behavioral Medicine</i> , 41, 353-362.
4-Mar	<b>MIDTERM</b>		
11-Mar	<b>SPRING BREAK</b>		
18-Mar	Treatment fidelity and process evaluation		<u>Required:</u> Bellg A.J. (2004). Enhancing treatment fidelity in the health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. <i>Health Psychology</i> , 23(5), 443-451. Borrelli B. (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. <i>Journal of Public Health Dentistry</i> , 71, S52-S63.  <u>Recommended:</u> Robb S. (2011). Ensuring treatment fidelity in a multi-site behavioral intervention study: Implementing NIH Behavior Change Consortium recommendations in the SMART Trial. <i>Psychooncology</i> , 20(11), 1193-1201.
		JC	Hardeman W. (2008). Fidelity of delivery of a physical activity intervention: Predictors and consequences. <i>Psychology &amp; Health</i> , 23(1), 11-24.
25-Mar	Recruitment and retention		Coday, M., Boutin-Foster, C., Sher, T. G., Tennant, J., Greaney, M. L., Saunders, S. D., & Somes, G. W. (2005). Strategies for retaining study participants in behavioral intervention trials: Retention experiences of the NIH Behavior Change Consortium. <i>Annals of Behavioral Medicine</i> , 29, S55-S65. Goldberg, J. H., & Kiernan, M. (2005). Innovative techniques to address retention in a behavioral weight-loss trial. <i>Health Education Research</i> , 20(4), 439-447.

Date	Topic	Leader (navigator)	Readings
1-Apr	Intro to policy research		<p><u>Required:</u> Sanson-Fisher, Robert W., et al. (2014). "Evaluation of Systems-Oriented Public Health Interventions: Alternative Research Designs." Annual Review of Public Health, 35, 9-27.</p> <p><u>Recommended:</u> Brownson, Ross C., et al. (2006). "Researchers and policymakers: travelers in parallel universes." American journal of preventive medicine 30(2), 164-172.</p>
8-Apr	Dissemination & Implementation research		<p>Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santens RL (2012). Writing implementation research grant proposals: ten key ingredients. Implementation science, 7, 96.</p> <p>Tabak RG, Khoong EC, Chambers DA, Brownson RC (2012). Bridging research and practice: models for dissemination and implementation research. American journal of preventive medicine, 43(3), 337-350.</p>
		JC	Allen P. (2013). Promoting state health department evidence-based cancer and chronic disease prevention: a multi-phase dissemination study with a cluster randomized trial component. Implementation Science, 8(141).
16-Apr	Policy/Environmental Interventions		<p>Story M, Kaphingst KM, Robinson-O'Brien R, Glanz K. (2008). Creating Healthy Food and Eating Environments: Policy and Environmental Approaches. Annual Review of Public Health, 29, 253-72.</p> <p>Alkon A, Crowley AA, Neelon SE, Hill S, Pan Y, Nguyen V, Rose R, Savage E, Forestieri N, Shipman L, Kotch JB. (2014). Nutrition and physical activity randomized control trial in child care centers improves knowledge, policies, and children's body mass index. BMC Public Health, 14(1):215.</p>
		JC	Levy DE, Riis J, Sonnenberg LM, Barraclough SJ, Thorndike AN. (2012). Food choices of minority and low-income employees: a cafeteria intervention. American Journal of Preventive Medicine, 43(3):240-8.
22-Apr	Course wrap up: Extended class time with special events	Myles/Kyle	
29-Apr	<b>NO CLASS</b>		
	<b>FINAL EXAM</b>		