NUTR 802
Introduction to Advanced Nutrition Intervention and Policy Research Methods
Spring 2014

Instructors:
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Course Meetings:
Wednesday, 2:00 to 4:00 PM
304 Rosenau

Teaching Assistant:
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Office Hours:
By appointment

Course website:
www.unc.edu/sakai

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.

Assignments.

Assignments include:
1. Mid-term exam (25%)
2. Final exam (35%)
3. Homework assignments (30%)
4. General class participation and one group-led journal club (10%)

Grading

Students will be evaluated on their preparation for and participation in discussion and assignments. As this is a doctoral level course, students are expected to read the assignment before class and come to class prepared to contribute to the discussion. For each week that there is a journal club article assigned, you will submit at least 1 discussion question by Tuesday night. Additionally, you will be responsible for leading one journal club session, in which you incorporate the other students' questions to guide your discussion. Other assignments include graded homework, a midterm exam, and a final exam. Written assignments will be submitted to instructors using the drop box feature in Sakai and are due prior to the start of class on the day they are due. Information about specific assignments will be announced in class and will be posted on Sakai.

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* (3rd 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
8-Jan	Choosing control or comparison groups	Deb/Dianne	Diabetes Prevention Program Research Group. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine, 346(6), 393-403. Kazdin A.E. (2003). Control and comparison groups Research Design in Clinical Psychology (pp. 184-212). Boston: Allyn and Bacon.
15-Jan	Intro to measurement	Deb/Dianne (**Rachel**)	*Designing clinical research:* Chapter 4 DeVellis' *Scale Development: Theory and Applications:* Ch. 1; Ch. 2 pg 14-16
22-Jan	Creating your own measurement: reliability and validity	Lecture: Derek Hales (**Gina**)	DeVellis' *Scale Development: Theory and Applications:* Ch. 3 pgs. 27-29 (through "Coefficient Alpha"), pgs. 38-39 ("Reliability and Statistical Power" section); Ch. 4
		JC: **Melissa**	Hales D. (2013). Development of HomeSTEAD's physical activity and screen time physical environment inventory. International Journal of Behavioral Nutrition and Physical Activity, 10(132).
29-Jan	Sample size & power	Ziya Gizlice (**Melissa**)	*Designing Clinical Research* Chapter 6
5-Feb	Analyzing data from a randomized trial, including intent-to-treat and missing data	Kant Bangdiwala (**Gina**)	<u>Required:</u> Friedman L. M. (1998). Chapter 16: Issues in Data Analysis in Fundamentals of Clinical Trials (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. Plos One, 4(8), e6624. <u>Recommended:</u> Gadbury G. (2003). Modern statistical methods for handling missing repeated measurements in obesity trial data: beyond LOCF. Obesity Reviews, 4(3), 175-184. Murray D.M. (2004). Design and analysis of group-randomized trials: A review of recent methodological developments. American Journal of Public Health, 94, 423-432. Schafer J.L. (1999). Multiple imputation: a primer. Statistical Methods in Medical Research, 8(1), 3-15. Sheean P.M. (2011). Publishing nutrition research: A review of multivariate techniques—Part 1. Journal of the American Dietetic Association, 111, 103-110.
12-Feb	Testing mediation	Lecture: Carmina Valle (Steph)	Lockwood C.M. (2010). Mediation analyses: Applications in nutrition research and reading the literature. Journal of the American Dietetic Association, 110, 753-762.
		JC: **Gina**	Lubans D.R. (2012). Mediators of weight loss in the "Healthy Dads, Healthy Kids" pilot study for overweight fathers. International Journal Behavioral Nutrition and Physical Activity, 9. doi: 10.1186/1479-5868-9-45.

Date	Topic	Leader (navigator)	Readings
19-Feb	Subgroup analyses and other approaches to utilizing your data	Leslie Lytle (**Rachel**)	Assmann S.F. (2000). Subgroup analysis and other (mis)uses of baseline data in clinical trials. The Lancet, 355, 1064-1069. Lagakos S.W. (2006). The challenge of subgroup analyses--reporting without distorting. The New England Journal of Medicine, 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? BMJ, 322, 989-991.
		JC: **Rachel**	Vollmer V.M. (2001). Effects of diet and sodium intake on blood pressure: subgroup analysis of the DASH-sodium trial. Annals of Internal Medicine, 135(12), 1019-28.
26-Feb	Treatment fidelity and process evaluation	Tope Erinosho (**Melissa**)	<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. Health Psychology, 23(5), 443-451. Borrelli B. (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. Journal of Public Health Dentistry, 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. Psychooncology, 20(11), 1193-1201.
		JC: **Cody**	Hardeman W. (2008). Fidelity of delivery of a physical activity intervention: Predictors and consequences. Psychology & Health, 23(1), 11-24.
5-Mar	**MIDTERM**		
12-Mar	**SPRING BREAK**		
19-Mar	Recruitment and retention	Deb/Dianne	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. Annals of Behavioral Medicine, 29, S55-S65. Goldberg, J. H., & Kiernan, M. (2005). Innovative techniques to address retention in a behavioral weight-loss trial. Health Education Research, 20(4), 439-447.
26-Mar	Intro to policy research	Kurt Ribisl (**Sally**) & students	TBD

Date	Topic	Leader (navigator)	Readings
2-Apr	Dissemination & Implementation research	Alice Ammerman (**Sally**)	Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santens RL (2012). Writing implementation research grant proposals: ten key ingredients. Implementation science, 7, 96. 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.
		JC: **Sally**	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).
9-Apr	Policy/Environmental Interventions	Dianne (Steph)	TBD
		JC: **Megumi**	TBD
16-Apr	Course wrap up: Extended class time with special events	Deb/Dianne	
23-Apr	**NO CLASS**		
6-May	**FINAL EXAM**		