NUTR 801/803
Quantitative Nutrition Intervention Research Methods (801)
Nutrition Intervention Hot Topic Seminar (803): Cognitive/Mindful-based Eating Interventions
Fall 2015

Instructors:
Kyle Burger (kyle_burger@unc.edu)

Course Meetings:
Thursday, 12:30 to 3:15 PM

TA: Cody Neshteruk (cneshter@live.unc.edu)

Office Hours: By appointment

Course website:
https://sakai.unc.edu/portal/site/nutr801_fa15

Course description
This course will focus on the critical thinking associated with the fundamental design of nutrition intervention and policy research including: theoretical foundation of health promotion, conceptualization of research questions, aims & hypothesis writing, critical aspects of study design and sample selection of nutrition clinical and community trials. The secondary purpose of this course is critically evaluate new methodologies in nutrition intervention research.

Course Objectives
1. Evaluate common designs for controlled clinical trials for addressing community nutrition research questions and understand the advantages and disadvantages of different study designs.
2. Identify the components necessary for an appropriate research aims and hypothesis.
3. Describe constructs of behavior change theories, justification and degree of use.
4. Define internal and external validity and describe the importance of each in development, testing, and dissemination of intervention trials. Also, describe strategies to limit threats to internal validity.
5. Identify strengths and weakness of various research designs, describe appropriate design selection as a function of rigor, research aim, and feasibility
6. Describe different randomization techniques and understand the importance of randomization and the role of inclusion/exclusion criteria on limiting bias.
7. Define the difference between an intervention group and a control (or comparison) group, how such differences affect the interpretation of a clinical trial and possible ethical concerns.
8. In terms of measurement tools and their development, discuss psychometric properties (internal consistency, temporal reliability), and data driven techniques of measurement development
9. Describe dissemination and implementation (D&I) research and understand how D&I studies as well as policy and environment strategies that can be used to promote use of evidence-based programs in real-world settings.
10. Describe how to determine sample sizes and selecting the appropriate test statistics for clinical trials.
11. Describe quality assurance procedures for clinical trials.
12. Describe differences between clinical and statistical significance, and the utility of effect sizes. Understand advantages/disadvantages of intent-to-treat analysis, mediation, moderation, subgroup analyses

Assignments/Grading
1. Mid-term exam (25%)
2. Final exam (30%)
3. Presentations (25%)
4. Class participation (20%)

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. Other assignments include, a midterm exam, and a final exam. Any written assignments will be submitted to instructors using via email or 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.

Presentations Students will be expected to present (via PowerPoint, Prezi, Keynote etc…) one of the hot topic articles. Following the format of presentations at scientific meetings, the presentation should be no longer than 12 minutes followed by 5-7 minutes of question from the audience. The presentation should explain all aspects of the article from background to discussion, present display items of results and provide thought beyond what is in the text of the article (e.g., different interpretation of the results, additional analyses you would have run). The goal isn't to be simply critical of study design or methods, but understand the article enough present and defend questions as if it was your own data. Audience members are expected to ask insightful and thoughtful 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* (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

Course Schedule

Date	Topic	Section	Readings
20-Aug	Introduction & study basics	Material	**Introduction; Choosing research topics and formulating research questions; Basic study designs**
		Discussion	
		Hot Topic	*Overview & Assign presentation dates, 'p hacking'*
27-Aug	Aims, Populations, & Outcomes	Material	**Writing aims & hypotheses; Choosing study populations and outcomes**
		Readings	Designing Clinical Research Chap. 2,3,5
		Hot Topic	Thorgeirsson, Kawachi (2013) Behavioral Economics
3-Sep	Theoretical Foundations of Behavior Change	Material	**Role of theory in intervention research**
		Readings	Glanz PDFs
		Hot Topic	Roberto, Kawachi (2014) Am J Prev Med
10-Sep	Measurement I	Material	**Selecting measurement tools; Internal & external validity; Generalizability**
		Readings	Designing clinical research: Chapter 4 Shadish, Cook, & Campbell, 2002. Chap 2,3
		Hot Topic	List, Samek (2015) Jour Health Economics
17-Sep	Measurement II	Material	**Scale development processes, Internal consistency; Temporal reliability**
		Readings	Designing Clinical Research Chap. 15 DeVellis' *Scale Development: Theory and Applications:* Ch. 3 pgs. 27-29 (through "Coefficient Alpha"), pgs. 38-39 ("Reliability and Statistical Power" section); Ch. 4
		Hot Topic	Alberts, Thewissen, Raes (2012) Appetite
24-Sep	Research Design I	Material	**Basic research designs; Randomization, RCT, Factorial designs**
		Readings	Designing Clinical Research Chap. 7, 8
		Hot Topic	Forman et al (2013) Obesity
1-Oct	**MIDTERM**		

8-Oct	Research Design II	Material	**Group randomized designs; Choosing control or comparison groups; Research ethics**
		Readings	Kazdin A.E. (2003). Control and comparison groups Research Design in Clinical Psychology (pp. 184-212). Boston: Allyn and Bacon. Designing Clinical Research Chap. 9,10,14.
		Hot Topic	Gregg, Callaghan, Hayes, Glenn-Lawson (2007) J. Consult. Clin. Psychol.
15-Oct	**Fall Break**		
22-Oct	Research Design III	Material	**Policy/Environmental-level Intervention; Dissemination & Implementation Research**
		Readings	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. 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.
		Hot Topic	Kocovski, Fleming, Hawley, Huta, Antony (2013) Behavior Research and Therapy
29-Oct	Practical Statistics I	Material	**Sample size and power calculations; Choosing *a priori* test statistics**
		Readings	Designing Clinical Research Chapter 6 G*Power
		Hot Topic	Kristeller, Wolever, Sheets (2013) Mindfulness
5-Nov	Quality Control		**Recruitment and retention; Treatment fidelity and process evaluation; Data Management**

			Borrelli B. (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. Journal of Public Health Dentistry, 71, S52-S63. 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.
		Hot Topic	Stice, Yokum, Burger, Rohde, Shaw, Gau (2014) Physio and Behavior
12-Nov	Practical Statistics II	Material	**Significance (clinical vs. statistical) & Effect sizes; Intent-to-treat & missing data in analyses; Mediation, moderation & causality; Subgroup analyses**
		Readings	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.
		Hot Topic	Giuliani, Calcott, Berkman (2013) Appetite
19-Nov	**Final**		
26-Nov	**Thanksgiving**		