AH5200: Design & Methodology of Behavioral Trials

University of Connecticut

Fall 2023 – Monday 2p-4:30p

Location: Gentry 232

INSTRUCTOR: Sherry Pagoto, PhD, Professor of Allied Health Sciences

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Office: InCHIP J Ray Ryan Bldg, Room 22 in-person office hours by appointment

PRE-REQUESITES AND ENROLLMENT

Pre-requisites: Instructor consent. Enrollment limited to graduate students. Maximum enrollment: 12.

COURSE DESCRIPTION

This course is intended for graduate students in the health and behavioral sciences, public health or related field AND advanced undergraduate students who are graduate school bound. Preventable diseases, including cardiovascular disease, diabetes and cancer, are the top causes of morbidity and mortality in the US. All are linked to lifestyle behaviors. Behavioral interventions can improve physical and/or mental health using behavioral, social, educational, and cognitive strategies. Randomized trials testing behavioral interventions have unique methodological challenges relative to drug and device trials. This course will cover methodological issues pertinent to behavioral trials including pilot feasibility trials, efficacy trials, effectiveness trials, implementation trials, and dissemination trials. Methodological issues discussed include randomization, control group selection, internal and external validity, treatment receipt and fidelity, adherence, recruitment, intent to treat, and blinding. Students will learn how to design scientifically sound behavioral intervention trials as well as how to critically evaluate behavioral trials published in the literature. 3 credits.

COURSE OBJECTIVES

The goals of the course are achieved through learning activities designed to meet the course objectives. Upon completion of this course, the student will:

1. Understand the steps required in behavioral intervention development and how to implement them.
2. Understand how to design pilot and feasibility studies.
3. Develop a proficiency in constructing research questions and appropriate outcomes for RCTs
4. Understand randomization, how it eliminates bias, consequences of breaking randomization, and the intention to treat principle
5. Develop a proficiency in identifying threats to internal and external validity and methods for maximizing the validity of a trial.
6. Understand the importance of maintaining and assessing treatment fidelity, treatment receipt, and adherence
7. Be able to distinguish between different types of trials (e.g, pilot, efficacy, effectiveness, comparative effectiveness, implementation, and dissemination)
8. Develop skills for composing methodologically-sound specific aims.
9. Be able to identify the control group that is best matched to the research question
10. Develop the ability to detect methodological strengths and weaknesses in trial manuscripts.

COURSE MATERIALS

There is no required textbook for this course. Assignments, handouts, links to assigned readings, and other course materials or resources will be distributed in class or via email, or posted on HuskyCT. Students are expected to check their UConn email daily and HuskyCT at least weekly.

Readings:

1. Czajkowski, SM, Powell, LH, Adler, N, Naar-King, S, Reynolds, KD, Hunter, CM, Laraia, B., Olster, DH, Perna, FM, Peterson, JC, Epel, E., Boyington, JE., Charlston, ME. From ideas to efficacy: the ORBIT model for developing behavioral treatments for chronic diseases. Health Psychology, 2015, 34(10), 971-82.
2. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. Journal of Psychiatric Research 45 (2011) 626e629.
3. Kraemer, HC, Mintz, J, Noda, A, Tinklenberg, J, Yesavage, JA. Caution regarding the use of pilot studies to guide power calculation for study proposals. Arch Gen Psychiatry. 2006; 63(5):484-9.
4. Beets MW, Weaver RG, Ioannidis JPA, Geraci M, Brazendale K, Decker L, Okely AD, Lubans D, van Sluijs E, Jago R, Turner-McGrievy G, Thrasher J, Li X, Milat AJ. Identification and evaluation of risk of generalizability biases in pilot versus efficacy/effectiveness trials: a systematic review and meta-analysis. Int J Behav Nutr Phys Act. 2020 Feb 11;17(1):19.
5. Thorpe, K, Zwarenstein, M, Oxman, AD, Treweek, S, Furberg, CD, Altman, D, Tunis, S, Bergel, E, Harvey, I, Magid, DJ, Chalkidou, K, A pragmatic–explanatory continuum indicator summary (PRECIS): a tool to help trial designers, Journal of Clinical Epidemiology, Volume 62, Issue 5, 2009, 464-475.
6. Courneya, KS. Efficacy, effectiveness, and behavior change trials in exercise research. Int J Behav Nutr Phys Act. 2010,12;7:81. doi: 10.1186/1479-5868-7-81.
7. Landes, S, McBain, S, Curran, GM. An introduction to effectiveness-implementation hybrid designs, Psychiatry Research, Volume 280, 2019, 112513.
8. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Joint Commission Journal on Quality and Patient Safety. 2008 Apr;34(4):228-43. doi: 10.1016/s1553-7250(08)34030-6. PMID: 18468362.
9. Shelton RC, Lee M, Brotzman LE, Wolfenden L, Nathan N, Wainberg ML. What Is Dissemination and Implementation Science?: An Introduction and Opportunities to Advance Behavioral Medicine and Public Health Globally. Int J Behav Med. 2020 Feb;27(1):3-20.

10. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, Ory MG, Estabrooks PA. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. Front Public Health. 2019 Mar 29;7:64.

11. Fontaine KR, Williams MS, Hoenemeyer TW, Kaptchuk TJ, Dutton GR. Placebo effects in obesity research. Obesity (Silver Spring). 2016 Apr;24(4):769-71.

12. Freedland KE. Demanding attention: reconsidering the role of attention control groups in behavioral intervention research. Psychosom Med. 2013 Feb;75(2):100-2.

13. Gold SM, Enck P, Hasselmann H, Friede T, Hegerl U, Mohr DC, Otte C. Control conditions for randomised trials of behavioural interventions in psychiatry: a decision framework. Lancet Psychiatry. 2017 Sep;4(9):725-732.

14. Spring B, Pagoto S, Knatterud G, Kozak A, Hedeker D. Examination of the analytic quality of behavioral health randomized clinical trials. J Clin Psychol. 2007 Jan;63(1):53-71.

15. Pagoto SL, Kozak AT, John P, Bodenlos JS, Hedeker D, Spring B, Schneider KL. Intention-to-treat analyses in behavioral medicine randomized clinical trials. Int J Behav Med. 2009;16(4):316-22. doi: 10.1007/s12529-009-9039-3. PMID: 19319693.

16. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D, Czajkowski S; Treatment Fidelity Workgroup of the NIH Behavior Change Consortium. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 2004 Sep;23(5):443-51.

17. Collins LM, Murphy SA, Strecher V. The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): new methods for more potent eHealth interventions. Am J Prev Med. 2007 May;32(5 Suppl):S112-8.

18. Nahum-Shani I, Smith SN, Spring BJ, Collins LM, Witkiewitz K, Tewari A, Murphy SA. Just-in-Time Adaptive Interventions (JITAIs) in Mobile Health: Key Components and Design Principles for Ongoing Health Behavior Support. Ann Behav Med. 2018 May 18;52(6):446-462.

ASSIGNMENTS

Readings will be assigned each week. You will be expected to have read and be prepared to discuss the assigned articles before class begins. I will usually pose specific questions to students to guide the in-class discussion. You are expected to have the articles with you in class.

Group Presentation. Students will be paired up by common interests to design a series of 5 trials (pilot feasibility, efficacy, effectiveness, dissemination, and implementation). This is a full program of research that would realistically take years to do, but we will envision it in one single semester. Students work together in their groups weekly to design their trials. At the end of the semester each group will present their

trial sequence to the class. Each group can take an hour to present, walking the class through each trial, pointing out methodological challenges and inviting class input to help solve those challenges. To guide group work, I will discuss the trial designs in class and groups will get 30-45 minutes of class time to work in their groups. It is expected that concepts from the course readings will be incorporated into the group project, even if those readings weren't directly discussed in class.

Critiques: We will critique 10 studies published in the literature over the course of the semester. **Students receive a guide of methodological features to address in their critiques and this guide will be used in grading.** Each week, a student will present the article for critique and lead the class discussion. Concepts learned in the readings should be incorporated into critiques. Students will complete a total of 10 critiques. If a student receives a poor grade on a critique or is unable to complete a critique on time, they may redo 1 critique to replace those. Additional critiques are due on the day the final critique is due. Students may request additional critiques at any time during the semester.

Critique Presentation. Each student will get a turn to lead the class discussion of an assigned paper. Leading the critique will involve providing a summary of the study and a discussion of the strengths and weaknesses, and then engaging the rest of the class in the discussion.

CLASS PARTICIPATION RUBRIC

It is expected that all students be active participants in class discussions and activities. Students will be asked throughout the semester to evaluate the strengths and limitations of particular datasets for their particular research interests (i.e., populations, risk factors, behaviors, health conditions/diseases). Below is a rubric for class participation that defines high performing behaviors. All students should be consistently performing in the 4-5 range as defined below. For full credit, please ensure that your class participation is at the 5 level.

Category	Scoring					
	5	**4**	3	2	1	0
Peer Interaction	**Actively supports, engages, and listens to peers (ongoing)**	**Most of the time actively supports, engages and listens to peers (ongoing)**	Makes a sincere effort to interact with peers (ongoing)	Limited interaction with peers	Virtually no interaction with peers	No interaction with peers
Preparation	**Arrives fully prepared at every class session**	**Arrives fully prepared at almost every session**	Arrives mostly, if not fully prepared (ongoing)	Preparation is inconsistent	Rarely prepared	Never prepared
Participation	**Plays an active role in discussions (ongoing)**	**Plays an active role in most discussions (ongoing)**	Participates constructively in discussions (ongoing)	Participation is inconsistent	Rarely participates	Never participates
Contribution to Class	**Comments advance level and depth of dialogue**	**Comments occasionally advance the level and depth of the dialogue**	Makes relevant comments that demonstrates understanding of the material	Inconsistent contribution. When prepared or called upon participates constructively in discussions and makes relevant comments	Comments are generally vague or not germane to the discussion. Demonstrates a noticeable lack of interest (on occasion)	Demonstrates a noticeable lack of interest in the material (ongoing)
Group Dynamics	**Group dynamic and level of discussion are nearly always better because of student's presence**	**Group dynamic and level of discussion are often better because of the student's presence**	Group dynamic and level of discussion are occasionally better (never worse) because of the student's presence	Group dynamic and level of discussion are not affected (positively or negatively) by student's presence	Group dynamic and level of discussion are harmed by the student's presence	Group dynamic and level of discussion are significantly harmed by the student's presence

Adapted from "A Participation Rubric," The Teaching Professor 19,3 (March 2005): pgs 4-5.

GRADING CRITERIA AND GRADING SCALE

The course grade will be based on grades on the following components and translated to letter grades.

Grading Criterion	% of Grade
Written critiques	50%
Leading class discussion on critique	10%
Class participation	15%
Group project presentation	25%

Grade	A	A-	B+	B	B-	C+	C	F
Percent	93-100	90-92.9	87-89.9	83-86.9	80-82.9	76-79.9	70-75.9	<70

COURSE POLICIES

- Class Participation – It is expected that all students will be active, inquisitive, and contributing participants. While there is no formal attendance policy, class attendance is expected and strongly encouraged. Class meetings will be recorded and posted in the event that a meeting is missed. Be mindful that engaging in the discussion makes class a more stimulating experience for everyone so do your best to jump in on the discussion.
- Make-up Policy – Reasonable accommodations will be done in response to student requests to complete work missed by absence resulting from observation of religious holidays or extra-curricular/co–curricular activities performed in the interest of the university and/or those that support the scholarly development of the student (e.g., attending a professional conference). Such accommodations will be made in ways that do not dilute or preclude the requirements or learning outcomes for the course. Students anticipating such a conflict must inform their instructor in writing within the first three weeks of the semester, and prior to the anticipated absence, and must take the initiative to work out with the instructor a schedule for making up missed work.
- Turning in Work Late – Critiques are due before class starts the day the critiqued article is to be discussed. It is expected that all work will be submitted on time. Late critiques will result in full loss of credit for the assignment.
- Use of Electronic Devices in Class – Students will **not** need to have open laptops in class given the discussion oriented nature of class. Students are asked to bring hard copies of any materials they need to aid in their presentations and their participation in discussion. An open laptop will likely negatively impact a student's participation grade.
- Seeking Help from the Instructor – Students are encouraged to seek help from the instructor during class or breakouts with questions about course content or procedures, and for assistance on group projects. The instructor will answer questions via email or arrange a time to meet in-person or via phone. Students can expect the instructor to reply to emails within one business day. Students are encouraged to plan ahead when seeking assistance. Note that last-minute requests for meetings may not always be granted.
- Addressing the Instructor – The instructor is happy to be addressed as "Sherry," "Dr. Pagoto," or "Professor Pagoto," as each student feels comfortable. The instructor uses the pronouns she/her/hers.
- Working Collaboratively – Science is collaborative, and being able to effectively work in interdisciplinary teams is an important professional skill. Some exercises will be designed to be completed in pairs or small groups.
- Plagiarism – Please note that copying and pasting verbatim from any source and using in written assignments is plagiarism.
- University Policies – Instructors and students in this course will conduct themselves in accordance with University policies, including but not limited to the Policy Against Discrimination, Harassment and Inappropriate Romantic Relationships, the Sexual Assault Reporting Policy, policies relating to the support of students with disabilities, and policies relating to academic integrity (plagiarism). To review current statements of these policies, please see http://provost.uconn.edu/faculty-and-staff-resources/syllabi-references/

CHANGES TO THE SYLLABUS

Information contained in the course syllabus (other than grading criteria and grading scale) may be subject to change without advance notice as deemed appropriate by the instructor. The instructor will notify students of any changes during class and electronically (via email and/or HuskyCT) and will distribute an updated syllabus on HuskyCT.

COURSE SCHEDULE

Class	Date	Topic	Critique DUE	Reading Assignment
1	8-28	Introduction and syllabus Why Behavioral RCTs?		Gautret et al 2020 (critique article)

				Czajkowski et al. 2015
NO CLASS	9-4	LABOR DAY		
2	9-11	A Selected History of Behavioral Randomized Clinical Trials and What We Have Learned Behavioral intervention development (ORBIT Model) Critiques	Gautret et al 2020	Netter et al 2022 (critique article) Leon & Kraemer 2011 Kraemer et al. 2006 Beets et al 2020
3	9-18	Designing and conducting pilot feasibility trials Critiques	Netter et al 2022	Kvillemo et al 2016 (critique article) Thorpe et al. 2009 Courneya, et al 2010
4	9-25	Trial Types Part 1: Efficacy vs Effectiveness Critiques	Kvillemo et al 2016	Ma et al 2013 (critique article) Landes et al 2019 Feldstein et al 2008
5	10-2	Trial Types Part 2: Implementation Critiques	Ma et al 2013	Godino et al 2016 (critique article) Shelton et al 2020
6	10-9	Trial Types Part 3: Dissemination Critiques	Godino et al 2016	Foa et al 2020 (critique article) Glasgow et al 2019
7.	10-16	CBPR Critiques	Foa et al 2020	Buller et al 2012 (critique article) Fontaine et al 2016 Freedland 2013

				Gold et al 2017
8	10-23	Control Groups Critiques	Buller et al 2012	Allen et al 2010 (critique article) Spring et al 2007 Pagoto et al 2009
9	10-30	Retention, Intent to Treat Principle, CONSORT Critiques	Allen et al 2010	Domar et al 2000 (article) Bellg et al 2004
10	11-6	Treatment Fidelity, Treatment Receipt, Participant Adherence, Participant Burden Critiques	Domar et al 2000	Cucciare et al 2021 (critique article) Collins et al 2007 Nahum-Shani et al 2018
11	11-13	Adaptive Designs (JITAI, MOST and SMART)	Cucciare et al 2021	
NO CLASS		THANKSGIVING BREAK		
12	11-27	Group presentations		
13	12-4	Group presentations		
-		FINALS WEEK/NO CLASS		