Purpose and Outcome

Course Overview
This course focuses on non-pharmacological rehabilitation intervention approaches to reduce disability and promote participation. Examples of these approaches are therapeutic exercise, the use of technology, and behavioral approaches. Students will learn the spectrum of intervention development and evaluation: from conceptualization and manualizing to testing the intervention feasibility, efficacy, and effectiveness.

Relation to Program Outcomes
Rehabilitation intervention designed to achieve the outcomes of reducing disability and promoting participation is often non-pharmacological based. To develop effective intervention, rehabilitation scientists may draw from multiple theories and combine several treatment components, reflecting the dynamic, complex interactions between the individual and the environment. The course covers the process of developing, planning, and conducting rehabilitation intervention studies at different phases of clinical trials. The course aims to advance students’ knowledge and capacity in developing and evaluating rehabilitation intervention. Students will learn from case examples of published intervention trials targeting various rehabilitation populations across the lifespan. The course is a concentration area for the “Disability, Occupation and Participation” track in the Rehabilitation Science Doctoral program.

Course Objectives and/or Goals
Students will learn to:

- Differentiate the different phases of clinical trials based on the NIH Stage Model for Behavioral Intervention Development
- Identify and appraise key elements in published rehabilitation intervention studies
- Apply theories to guide intervention development and evaluation
- Identify and operationalize “active intervention ingredients.”
- Develop an intervention manual based on the selected research interest
- Evaluate intervention fidelity and create fidelity measurements
- Select proper assessments and time points to measure intervention outcomes
- Select an adequate control/comparison group to evaluate the intervention effect
- Develop an intervention research proposal

Instructional Methods
Active learning means that students need to get involved in the learning process in order to remember and apply new knowledge. Students are encouraged to take ownership of their learning. To facilitate active learning, students in this course will engage in small-group or paired discussions, project presentations, and in-class activities.
What is expected of students?

Students are expected to actively engage in the course throughout the semester and come to class prepared by completing all out-of-class assignments. This preparation gives students the knowledge or practice needed to engage in higher levels of learning during the live class sessions. If students are not prepared for the face-to-face sessions, they may struggle to keep pace with the activities occurring in the live sessions, and it is unlikely that they will reach the higher learning goals of the course. Similarly, students are expected to actively participate in the live class. Their participation fosters a rich course experience for them and their peers that facilitates overall mastery of the course objectives.

Description of Course Content

Topical Outline/Course Schedule (The schedule may be subject to change).

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic(s)</th>
<th>Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1/11</td>
<td>Course overview and introduction to intervention research in rehabilitation sciences</td>
<td>CH 1: Promises and challenges of behavioral intervention research, Wade 2010_Methodological challenges and research in rehabilitation medicine, Wade 2020_interventions in rehabilitation</td>
</tr>
<tr>
<td>2</td>
<td>1/18</td>
<td>Holiday</td>
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<tr>
<td>4</td>
<td>2/1</td>
<td>Using theories to guide intervention development, intervention mapping</td>
<td>CH 4: Theory- A driver of behavioral intervention research, CH 3 (Braden): The theory-driven approach to effectiveness research, Creaves 2016_intervention mapping example</td>
</tr>
<tr>
<td>5</td>
<td>2/8</td>
<td>Assignment due_ “Problem statement and intervention description”</td>
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<tr>
<td>6</td>
<td>2/15</td>
<td>Intervention delivery and standardization: manualization</td>
<td>CH 5: Delivery, CH 6: Standardization</td>
</tr>
<tr>
<td>7</td>
<td>2/22</td>
<td>Selecting control groups and sample considerations</td>
<td>CH 8_Selecting control group, CH 9_Sampling considerations</td>
</tr>
<tr>
<td>8</td>
<td>3/1</td>
<td>Assignment due_ “Intervention manual”</td>
<td>CH 10: Recruitment and retention</td>
</tr>
<tr>
<td>9</td>
<td>3/8</td>
<td>Assignment due_ “Participant recruitment and retention plan”</td>
<td>CH 12: Are treatment effects real, Gearing 2011_What is fidelity</td>
</tr>
<tr>
<td>10</td>
<td>3/15</td>
<td>Assignment due_ “Intervention fidelity description and measures”</td>
<td>CH 7 (Braden) Outcomes-related factors, Coster 2013_Selecting outcome measures for clinical trials and outcome studies</td>
</tr>
</tbody>
</table>

Selecting outcomes - Health Measures-PROMIS, NIH TOOLBOX
University of Florida  
College of Public Health & Health Professions Syllabus

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</tbody>
</table>

### In-class activity: Finalizing outcome measurements and timeline

- Shirley Ryan Rehabilitation Measures Database
- Grid-enabled Measures Database
- Science of Behavior Change Measures

Assignment due: “Outcome measures (description and timeline)”

- Adverse events, protocol violations, and data safety monitoring board
- Role playing of DSMB meeting
- Describe possible adverse events and create a plan for data safety monitoring

- Slutsky 2004_DSMB

Assignment due: “Data safety and monitoring plan”

- Case studies of published trials
  - 3-Step Workout for Life by Liu
  - The CAPABLE trial by Szanton
- Student presentations

Assignment due: “Final intervention study proposal”

- Curran 2012_Effectiveness-implementation hybrid designs
- Collins 2005_MOST strategy
- Almirall 2014_SMART design
- CH 20: Lessons learned from implementing intervention into real world.

### Other readings, links for materials, and learning activities will be posted on the Canvas course website [http://elearning.ufl.edu/](http://elearning.ufl.edu/). Articles are posted in PDF format. PDF Reader/Viewer is required to access these articles.

### References of reading articles


**Recommended Textbooks (Optional):**


**Dr. Liu’s 3-Step Workout for Life publications**


For technical support for this class, please contact the UF Help Desk at:

- Learning-support@ufl.edu
- (352) 392-HELP - select option 2
- https://lss.at.ufl.edu/help.shtml

**Academic Requirements and Grading**

**Assignments**

- Grammar, spelling, structure, clarity, neatness, and legibility will be considered in the grading of all papers, self-evaluations, and presentations.
- All written assignments must be typed (12 pt., double-spaced, 1-inch margin), spell-checked, proofread for grammar mistakes and should conform to the style and reference notation format outlined by the *Publication*
The forum is to help students prepare for class, learn discussion skills, and practice writing skills.

**grading rubric is available on Canvas.**

Case study presentation of published clinical trial.

Intervention fidelity description and measures (due on 3/15): There is no page limit. Students will propose how to measure each type of fidelity and provide examples.

Outcome measures (due on 3/22): In 2-4 pages (exclude references), describe the selected outcome measures, including the psychometrics, the administration and scoring procedure, and timeline of measurements. One of the measures must assess the outcome of disability or participation.

Data safety and monitoring plan (due on 3/29): Students will follow the NIH template, which is provided on Canvas, to develop a data safety and monitoring plan for their own proposed intervention study.

Proposal presentation (due on 4/12, 4/19): Students will prepare a 30-minute presentation of their proposed intervention research. 15-minute Q&A will be followed after the presentation. The grading will be based on the student’s presentation skills (Proper AV set up or handouts, slide/handout content, speak clearly, presentation flow, able to capture the audience’s attention and keep their interest). The grading rubric is available on Canvas.

Peer evaluation of final proposal and presentation (due on 4/23): Each proposal will be assigned to two student reviewers. The student reviewers will provide written feedback. The student reviewers will also provide written feedback to the proposal presentation. Feedback guidelines will be provided to student reviewers for this assignment. The feedback guidelines are available on Canvas. Student reviewers will have the opportunity to share the feedback with the student author after the proposal presentation. Student reviewers will turn in the written feedback to the instructor.

Case study presentation of published clinical trials (on 3/29): Each student will present a case study of clinical intervention trials. The presented studies should be in different phases of the clinical trials, for example, a feasibility study followed by a randomized control trial. Note that some trials may publish details of the intervention as a protocol paper. You should include the protocol paper if available. The 30-minute presentation will cover key elements of intervention learned over the semester (background or rationale for the intervention, theoretical background of the intervention, fidelity information, reporting of adverse events, outcomes measures, results, and lessons learned). The grading rubric is available on Canvas.

Weekly online forum discussion on readings: Each student is required to post two messages on the Canvas forum each week, except the week 1, 2, 6, 12, 14, and 15. The post can be questions, replies, or reflections on that week’s readings. The forum is to help students prepare for class, learn discussion skills, and practice writing skills. The deadline for
posting is the night before the meeting date (Sunday midnight). Students are expected to finish readings before posting on the forum. The grading rubric is available on Canvas.

**Participation:** Students are expected to attend the class online and fully participate in class. Students should inform the instructor and others ahead of time if likely to be late or absent, and arrange to cover their own responsibilities, which includes turning in the make-up work on time and requesting an extension for an assignment deadline. Please review the university attendance policies here. The grading rubric for participation is available on Canvas.

**Grading**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Due date</th>
<th>% of final grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem statement and intervention description</td>
<td>2/8</td>
<td>5%</td>
</tr>
<tr>
<td>Intervention manual</td>
<td>3/1</td>
<td>15%</td>
</tr>
<tr>
<td>Participant recruitment and retention plan</td>
<td>3/8</td>
<td>5%</td>
</tr>
<tr>
<td>Intervention fidelity description and measures</td>
<td>3/15</td>
<td>5%</td>
</tr>
<tr>
<td>Outcome measures (description and timeline)</td>
<td>3/22</td>
<td>5%</td>
</tr>
<tr>
<td>Data safety and monitoring plan</td>
<td>3/29</td>
<td>5%</td>
</tr>
<tr>
<td>Case study presentation of published clinical trials</td>
<td>3/29</td>
<td>10%</td>
</tr>
<tr>
<td>Final written intervention study proposal</td>
<td>4/5</td>
<td>20%</td>
</tr>
<tr>
<td>Proposal presentation</td>
<td>4/12, 4/19</td>
<td>10%</td>
</tr>
<tr>
<td>Peer evaluation of final intervention study proposal and presentation</td>
<td>4/23</td>
<td>5%</td>
</tr>
<tr>
<td>Weekly online forum discussion on readings</td>
<td>Weekly (Monday midnight)</td>
<td>5%</td>
</tr>
<tr>
<td>Participation (in-class discussion and activities)</td>
<td>weekly</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Point system used (i.e., how do course points translate into letter grades).

<table>
<thead>
<tr>
<th>Percentage Earned</th>
<th>Letter Grade</th>
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</thead>
<tbody>
<tr>
<td>93-100</td>
<td>A</td>
</tr>
<tr>
<td>90-92</td>
<td>A-</td>
</tr>
<tr>
<td>87-89</td>
<td>B+</td>
</tr>
<tr>
<td>83-86</td>
<td>B</td>
</tr>
<tr>
<td>80-82</td>
<td>B-</td>
</tr>
<tr>
<td>77-79</td>
<td>C+</td>
</tr>
<tr>
<td>73-76</td>
<td>C</td>
</tr>
<tr>
<td>70-72</td>
<td>C-</td>
</tr>
<tr>
<td>67-69</td>
<td>D+</td>
</tr>
<tr>
<td>63-66</td>
<td>D</td>
</tr>
<tr>
<td>60-62</td>
<td>D-</td>
</tr>
<tr>
<td>Below 60</td>
<td>E</td>
</tr>
</tbody>
</table>

Please be aware that a C- is not an acceptable grade for graduate students. The GPA for graduate students must be 3.0 based on 5000 level courses and above to graduate. A grade of C counts toward a graduate degree only if based on credits in courses numbered 5000 or higher that have been earned with a B+ or higher.
More information on UF grading policy may be found at:
https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/

Assignment Make-Up Policy
Assignments and learning activities are expected to be turned in on the scheduled date and time or the arranged scheduled date and time. Students who miss a class will be required to complete a two-page summary of assigned readings. If a new due date is not arranged, assignments submitted after the scheduled date and time will have a 10% deduction of graded points for each 24 hours after the due date and time. If arranged, assignments submitted after the new arranged due date will have a 10% deduction of graded points for each 24 hours after the due date and time. Late assignments should be submitted via the Canvas assignment tab.

Please note: Any requests for make-ups due to technical issues MUST be accompanied by the UF Computing help desk (http://helpdesk.ufl.edu/) correspondence. You MUST e-mail to or notify the instructor within 24 hours of the technical difficulty if you wish to request a make-up.

Policy Related to Required Class Attendance
Be punctual and prepared at the beginning of class. Attendance is an essential and required. Any student arriving more than 15 minutes late, or leaving more than 15 minutes early, will be required to complete the make-up assignment. If students cannot attend a class, the students must notify the instructor by email or phone prior to the class meeting date or within 48 hours after the class. Students will lose 10% of the total attendance points for every class missed for unexcused absences.

Requirements for class attendance and make-up exams, assignments, and other work in this course are consistent with university policies that can be found at: https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

Excused absences must be consistent with university policies in the Graduate Catalog (http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#attendance). Additional information can be found here: https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

Student Expectations, Roles, and Opportunities for Input
Expectations Regarding Course Behavior

Doctoral-level students are expected to exhibit the highest level of professional behavior in the classroom. These are the minimum behavioral standards that I expect to see in this class and some examples of how each behavior might be evaluated:

1. Dependability—regular class attendance and punctuality, turning in assignments on time
2. Responsibility—actively participating in class, putting forth your best effort in discussions and assignments, notifying instructor for late/missing class or assignments
3. Expectations regarding presentations: The presenting student is expected to arrive early such that the class presentation can begin at the start of the class period. All other students are expected to arrive on time. Cell phones, tablets and laptops may be used to search for materials related to the presentation and topic, but for no other purpose. Cell phones must be silenced. During discussions, students are expected to behave professionally and be respectful of each other’s opinions.

Communication Guidelines

1. Communication—appropriate communication with instructors, support staff, guests and other students, receiving and giving constructive feedback
2. Respect for others—appreciating different points of view, being courteous to instructors, support staff, guests and other students, avoiding distracting behavior during class (including talking, cell phone usage, web surfing, texting)
3. Tips for online discussion
   a. Writing a post
      - Express yourself clearly. This means using complete words and sentences and avoiding jokes.
      - Develop a clear thesis, argument (opinions are not arguments), or question.
      - Encourage discussion. If you are the first to post, strive to encourage discussion (e.g., “what do you think?” “does anyone share the same view?”). Remember to check back later.
   b. Responding to other posts
      - Add value to the conversation. Don’t simply just say “I agree” or “I disagree.” Describe why you agree and your rationale. State precisely the point you agree or disagree with. For example, “I disagree with that the researchers should include fidelity measures in feasibility studies because the intervention is in the “prototype” phase…”
      - Politely critique a position on an issue but not the person.

In-class Technology

Student’s use of laptops during class is reserved for relevant coursework. Phones are to be silenced and put away. Answering texts and phone calls during class is prohibited. Students are expected to refrain from surfing the internet, online shopping, emailing or using social media during class.

Academic Integrity

Students are expected to act in accordance with the University of Florida policy on academic integrity. As a student at the University of Florida, you have committed yourself to uphold the Honor Code, which includes the following pledge:

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

You are expected to exhibit behavior consistent with this commitment to the UF academic community, and on all work submitted for credit at the University of Florida, the following pledge is either required or implied:

“Oh my honor, I have neither given nor received unauthorized aid in doing this assignment.”

It is your individual responsibility to know and comply with all university policies and procedures regarding academic integrity and the Student Honor Code. Violations of the Honor Code at the University of Florida will not be tolerated. Violations will be reported to the Dean of Students Office for consideration of disciplinary action. For additional information regarding Academic Integrity, please see Student Conduct and Honor Code or the Graduate Student Website for additional details:
https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/
http://gradschool.ufl.edu/students/introduction.html
Please remember cheating, lying, misrepresentation, or plagiarism in any form is unacceptable and inexcusable behavior.

**Online Faculty Course Evaluation Process**

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at [https://gatorevals.aa.ufl.edu/students/](https://gatorevals.aa.ufl.edu/students/). Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via [https://uflbluea.com/ufl/](https://uflbluea.com/ufl/). Summaries of course evaluation results are available to students at [https://gatorevals.aa.ufl.edu/public-results/](https://gatorevals.aa.ufl.edu/public-results/).

**On Campus Face-to-Face**

We will have face-to-face instructional sessions to accomplish the student learning objectives of this course. In response to COVID-19, the following policies and requirements are in place to maintain your learning environment and to enhance the safety of our in-classroom interactions.

- You are required to wear approved face coverings at all times during class and within buildings. Following and enforcing these policies and requirements are all of our responsibility. Failure to do so will lead to a report to the Office of Student Conduct and Conflict Resolution.
- This course has been assigned a physical classroom with enough capacity to maintain physical distancing (6 feet between individuals) requirements. Please utilize designated seats and maintain appropriate spacing between students. Please do not move desks or stations.
- Sanitizing supplies are available in the classroom if you wish to wipe down your desks prior to sitting down and at the end of the class.
- Follow your instructor’s guidance on how to enter and exit the classroom. Practice physical distancing to the extent possible when entering and exiting the classroom.
  - Course materials will be provided to you with an excused absence, and you will be given a reasonable amount of time to make up work ([https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/](https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/)).

**Policy Related to Guests Attending Class**

Only registered students are permitted to attend class. However, we recognize that students who are caretakers may face occasional unexpected challenges creating attendance barriers. Therefore, by exception, a department chair or his or her designee (e.g., instructors) may grant a student permission to bring a guest(s) for a total of two class sessions per semester. This is two sessions total across all courses. No further extensions will be granted. Please note that guests are not permitted to attend either cadaver or wet labs. Students are responsible for course material regardless of attendance. For additional information, please review the Classroom Guests of Students policy in its entirety: [https://facstaff.phhp.ufl.edu/services/resourceguide/PHHP-Classroom-guest-policy-20180629.pdf](https://facstaff.phhp.ufl.edu/services/resourceguide/PHHP-Classroom-guest-policy-20180629.pdf)

**SUPPORT SERVICES**

**Accommodations for Students with Disabilities**

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center by visiting [https://disability.ufl.edu/students/get-started/](https://disability.ufl.edu/students/get-started/). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester. The College is committed to providing reasonable accommodations to assist students in their coursework.
Counseling and Student Health

Students sometimes experience stress from academic expectations and/or personal and interpersonal issues that may interfere with their academic performance. If you find yourself facing issues that have the potential to or are already negatively affecting your coursework, you are encouraged to talk with an instructor and/or seek help through University resources available to you.

- The Counseling and Wellness Center 352-392-1575 offers a variety of support services such as psychological assessment and intervention and assistance for math and test anxiety. Visit their web site for more information: http://www.counseling.ufl.edu. On line and in person assistance is available.

- You Matter We Care website: http://www.umatter.ufl.edu/. If you are feeling overwhelmed or stressed, you can reach out for help through the You Matter We Care website, which is staffed by Dean of Students and Counseling Center personnel.

- The Student Health Care Center at Shands is a satellite clinic of the main Student Health Care Center located on Fletcher Drive on campus. Student Health at Shands offers a variety of clinical services. The clinic is located on the second floor of the Dental Tower in the Health Science Center. For more information, contact the clinic at 392-0627 or check out the web site at: https://shcc.ufl.edu/

- Crisis intervention is always available 24/7 from:
  Alachua County Crisis Center:
  (352) 264-6789
  http://www.alachuacounty.us/DEPTS/CSS/CRISISCENTER/Pages/CrisisCenter.aspx

Do not wait until you reach a crisis to come in and talk with us. We have helped many students through stressful situations impacting their academic performance. You are not alone so do not be afraid to ask for assistance.

Inclusive Learning Environment

Public health and health professions are based on the belief in human dignity and on respect for the individual. As we share our personal beliefs inside or outside of the classroom, it is always with the understanding that we value and respect diversity of background, experience, and opinion, where every individual feels valued. We believe in, and promote, openness and tolerance of differences in ethnicity and culture, and we respect differing personal, spiritual, religious and political values. We further believe that celebrating such diversity enriches the quality of the educational experiences we provide our students and enhances our own personal and professional relationships. We embrace The University of Florida’s Non-Discrimination Policy, which reads, “The University shall actively promote equal opportunity policies and practices conforming to laws against discrimination. The University is committed to non-discrimination with respect to race, creed, color, religion, age, disability, sex, sexual orientation, gender identity and expression, marital status, national origin, political opinions or affiliations, genetic information and veteran status as protected under the Vietnam Era Veterans’ Readjustment Assistance Act.” If you have questions or concerns about your rights and responsibilities for inclusive learning environment, please see your instructor or refer to the Office of Multicultural & Diversity Affairs website: www.multicultural.ufl.edu

Writing Studio

The new Writing Studio is committed to helping University of Florida students meet their academic goals by becoming better writers. The Writing Studio is a free service for current UF graduate and undergraduate students. Students have the opportunity to work one-on-one with a consultant on issues specific to their own particular development. To schedule one-on-one tutorials, please visit https://writing.ufl.edu/writing-studio/