Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

1. Would you like your application evaluated for a possible exemption?

Yes

Will your study either involve prisoners as participants or be FDA-regulated?

No

In order to be eligible for exemption, your research must fit into one or more of the following categories. Check all of the following that apply, understanding that most research falls into one or two categories.

Category 1

✘ The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and NOT to your location at a university.

And the research specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

✘ Research on regular and special education instructional strategies.

✘ Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

Does your study involve minors under the age of 18?

No

The research involves the use of one or more of the following

✘ Educational tests (cognitive, diagnostic, aptitude, achievement).

✘ Survey procedures.

✔ Interview procedures

✘ Observation of public behavior.

If at least ONE of the following criteria are true:

✔ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

✔ Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

✘ The information obtained is recorded by the investigator in such a manner that participants can readily be ascertained, directly or through identifiers linked to the participants AND there are appropriate provisions in place to protect subject privacy and confidentiality.

Category 3

Research with adults involving Benign Behavioral Interventions (BBI) through one of the following:

✔ Verbal responses

✘ Written responses (including data entry)

✔ Audiovisual recording

And at least one of the following are true:

✔ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects

✔ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

✘ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
If this category is selected, please also explain how the intervention fits the BBI definition: brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and there is no reason to think the subjects will find the interventions offensive or embarrassing.

Category 4

✘ The research involves secondary uses of identifiable private information or identifiable biospecimens.

And one of the following is true:

✘ The identifiable private information or identifiable biospecimens are publicly available.

✘ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

✘ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes."

✘ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Category 5

✘ The project is a research or demonstration project.

Additionally the following must also be true.

✘ The program under study is designed to study, evaluate, improve, or otherwise examine public benefit or service programs.

✘ The research is conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

✘ The Federal department or agency conducting or supporting the research and demonstration projects will establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project will be published on this list prior to commencing the research involving human subjects.

Category 6

✘ The research involves taste and food quality evaluation or is a consumer acceptance study.

Either of the following is true:

✘ Wholesome foods without additives are consumed.

✘ If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following agencies:

Please check which of following

- ✖ The Food and Drug Administration.
- ✖ The Environmental Protection Agency.
- ✖ The Food Safety and Inspection Service of the U.S. Department of Agriculture.

Consent Process for Exemptions

1. While the full regulatory requirements for consent do not apply, some exempt research does involve talking to or interacting with human participants. Under these circumstances, there is still the expectation that you will tell people what you are doing and why, and invite their voluntary participation. If this describes your study, then describe the process for obtaining consent from the subjects. This may or may not include a written consent document or script; if you plan to use a written document, please upload as an attachment as the end of this application process. Example consent document for exempt research.

Participants will be contacted by a representative from their Continuing Care Retirement Community to ask if they would be willing to participate in a telephonic interview regarding their experience of their facility's exercise program. If they agree, their phone number will be given to a research assistant who will contact them by phone. They will be asked to consent to the interview and for the interview to be recorded without any personal identifying information included on the recording. The attached script is provided outlining the details of the interview.

General Information

1. General Information

1. Project Title

Participation, adherence, and associated facilitators and barriers for Otago-based exercise programs in two continuing care retirement communities: an exploratory study

2. **Brief Summary**. Provide a **brief non-technical description** of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: The purpose of this pilot study is to describe program participation, exercise adherence, and associated facilitators and barriers for Otago-based exercise programs in two continuing care retirement communities (CCRCs). The Otago exercise program uses strength and balance exercises and a walking program to reduce falls in older adults.

Participants: Older adults in two continuing care retirement communities who participated in an Otago-based exercise program offered in the community.

Procedures (methods): This pilot study will examine two different exercise programs, a home-based Otago exercise program offered in one CCRC and a group Otago exercise class offered in a different CCRC. Participation will be measured through attendance records for both programs. Exercise adherence for the home-based exercise program will be measured by participants' responses to questions about frequency of exercise in the past week and overall self-report of adherence to exercise recommendations using a 5-point Likert scale. For the group exercise class, exercise adherence will be presumed if records demonstrate class attendance. Facilitators and barriers will be identified through structured interviews conducted with participants from both exercise programs. The pilot study will also explore the differences in facilitators and barriers between these two Otago programs.

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

No

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.
If a change to the Principal Investigator is requested during the course of the study, a PI Change Form must be submitted.

Liaison	Last Name	First Name	Department Name	Role	Detail
University of North Carolina at Chapel Hill (UNC-CH)					
⭐	Mercer	Vicki	Allied Health - Physical Therapy	Principal Investigator	view
	Carter	Katherine	Allied Health Sciences	Study Coordinator	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Allied Health - Physical Therapy

3. Funding Sources

1. Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?
   No

2. Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?
   Yes

Internal UNC Chapel Hill funding

Department Name	Account Number	Detail
N/A	N/A	view

3. Is this research classified (e.g. requires governmental security clearance)?
   No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ✘ Grant Application
- ✘ Industry/Federal Sponsor Master Protocol
- ✘ Student Dissertation or Thesis Proposal
- ✘ Investigator Initiated Master Protocol
- ✘ Other Study Protocol

5. Is this a Clinical Study?
   Check YES if this study involves research using human volunteers that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. Do NOT check yes merely because you are conducting research in a clinical setting or using clinical data.
   Click here for additional definition of "Clinical Study"
   Yes

Will this clinical trial be listed in ClinicalTrials.gov, either by you or the sponsor?
No

Choose the appropriate Phase designation for this clinical trial.

- ✔ Pilot Study
- ✘ Phase I
- ✘ Phase I/II
- ✘ Phase II
- ✘ Phase III
- ✘ Phase IV
- ✘ Other

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH (click for details)

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

   Yes

The next questions will determine if there are HUMAN SUBJECTS (click for details)

2. Will you be obtaining information or biospecimens through intervention or interaction with the individual, and use, study, or analysis of the information or biospecimens? This would include any communication or interpersonal contact between investigator and subject such as using in-person or online questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

   Yes

3. Will you be obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).
   OR
   Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations?

   Yes

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.)

   No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

   No

6. Is the UNC Chapel Hill IRB taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC Chapel Hill? Or you are asking the UNC Chapel Hill IRB to cede review to an External IRB. If so, a reliance agreement will need to be executed prior to conducting any research activities. See guidance.

   No

Location

1. Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States?

   No

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

Many studies have been conducted that examine facilitators and barriers to sustained exercise and physical activity in older adults; however, few examine the Otago program specifically. The Otago Exercise Program is a strength and balance exercise program which has been shown to be effective in reducing falls and injuries associated with falls in high risk older adults and has been recommended by the Centers for Disease Control as an effective program to prevent falls. [1,2] The proposed project will examine participation, adherence, and associated facilitators and barriers for individuals who participated in one of two Otago programs delivered in continuing care retirement community (CCRC) settings. One utilized the full Otago program which includes progressive strength and balance exercises performed at home in addition to a walking program. The second program was an Otago-based group exercise class that was led and supervised by facility staff members.

Very few studies that address exercise facilitators and barriers in older adults include individuals residing in CCRCs. In reviewing prior literature available regarding facilitators and barriers for regular exercise in older adults, there are some

similarities that emerge from prior qualitative studies depending on the setting and patient population. McInnes and Askie performed a systematic review of 24 studies, both qualitative and quantitative, that examined the experience of older adults who had participated in falls prevention programs. These studies included participants who were community-dwelling older adults, patients in rehabilitation wards, and individuals residing in nursing home facilities.[4] Some of the participants in these studies preferred strategies for falls prevention that did not require a behavior change; however, the effectiveness of these types of strategies is unclear.[4] The social value of these programs was reported as a facilitator for participation.[4] Additionally, the authors highlighted the need to confirm with participants what elements of their lifestyle and usual activities they would be willing to change in order to prevent falls, so that participants can be matched to programs that are likely to be beneficial to them.[4] Results of qualitative studies revealed that programs that included a peer role model, were home-based, low intensity, supervised via telephone, occurred with moderate frequency, and were perceived as beneficial, fun, and relevant were likely to have greater participation.[4] Barriers reported in these studies included illness, embarrassment, low self-efficacy, unawareness or denial of personal risk of falling, and fear of falling.[4]

A systematic review conducted by Finnegan et al. examined qualitative and mixed method studies analyzing the experience of community-dwelling individuals, 65 years of age or older, pertaining to their participation in an exercise-based falls prevention program, and their ongoing exercise behaviors.[5] The 14 studies included in the review revealed that the participants' exercise habits were often reflective of their prior exercise behavior.[5] The desire to maintain good health or the presence of ill health were cited as reasons for continued or curtailed exercises respectively.[5] Limited time was also frequently given as a reason for not exercising. Support from family and friends was reported as a motivator when individuals were able to continue exercising with someone following the conclusion of their program; however, in some cases family members were reported to be a barrier when their concerns about the safety of the exercise led to activity restrictions.[5] If participants had met their goal and/or felt that their typical level of activity was sufficient exercise, they often stopped exercising. The social aspect of the program also operated as a motivator for many, while cost of ongoing exercise programs functioned as a barrier.[5]

Sandlund et al. examined uptake and adherence for exercise-based falls prevention programs for community-dwelling older adults in Sweden.[3] They reported that gender did not appear to play a significant role, but it was important to have exercises that where individually tailored to participants.[3] They report that motivators for initiating exercise included treating an injury or medical condition, preserving health, information, and the encouragement of family or a medical provider.[3] Having a knowledgeable and likeable instructor was also a motivator.[3] Barriers reported to inhibit exercise included lack of self-discipline, societal expectations, barriers from the environment, poor health, and the feeling of being fragile or vulnerable.[3] Many participants confirmed that using personal tricks to increase adherence to regular exercise and to make the activity more enjoyable (e.g. listen to music, exercise outside) worked to help motivate them to continue to exercise.[3]

In reviewing the prior literature on this topic, three studies utilized the Otago exercise program or a derivative of the program with their participants. Meyer et al. examined the experience of participants and physiotherapists with a home exercise program for individuals with mild balance dysfunction.[6] The intervention was based on the Otago program and the VHI Balance and Vestibular kit. Participants lived independently or at a retirement village. Again, individualization of the intervention and understanding each individual's unique circumstances were found to enhance adoption of the exercise program.[6] The social benefit of exercising was also reported once again as a motivator. Participants reported that their exercises made them more functionally independent and able to participate in life events functioning as a motivator to continue exercising. Boring or tedious activities discouraged exercising. The ability to exercise on their own schedule in their own homes was a motivator for some.[6]

The Otago program was also used in the study by Arkkukangas et al.[7] They examined facilitators and barriers to completing a home-based exercise program with support for behavioral change.[7] Facilitators for regular exercise included having personal goals that could be achieved through exercise, easy access to exercise, a routine that involved regular exercise, and an environment that is supportive of exercising.[7] Support from the physical therapist and the use of an exercise diary also encouraged exercise adherence. However, some participants reported a negative feeling towards the exercise diary when life events kept them from exercising.[7] Individuals also reported that physical gains such as balance and strength improvements that they noticed after performing their exercises acted as a motivator.[7] The lack of soreness or negative side-effects from the exercises encouraged continued participation in the program.[7] Some individuals reported feeling weak or frail as limiting their daily activities but for some this also supported the need to continue exercising with increased caution and awareness of their surroundings to minimize the risk of falling.[7]

In addition to the previous two studies, Maula et al. studied the experience of community-dwelling individuals who participated in two balance and strength exercise programs, one of which used the Otago home-based exercises.[8] Facilitators identified in this study included enjoyment, physical benefits, and increased physical autonomy.[8] Motivation and self-efficacy with the activities, encouragement from a partner, and converting their exercises into a habit also helped motivate individuals to continue to exercise.[8] Personal illness and being too busy were identified as barriers to exercise.[8] However, the illness of a friend or family member could be perceived as motivational in order to preserve the participant's own health. Depression, negative attitudes toward physical activity, memory impairments, and transportation, cost, or weather impediments could all act as barriers limiting physical activity maintenance.[8]

No studies that examine the experience of individuals living in CCRS who participate in Otago exercises have been identified. CCRCs are a growing industry offering residential opportunities for the expanding older adult population along

the continuum of health care needs. There are approximately 2,000 CCRCs nationwide providing services to 700,000 residents, up from 700 CCRCs in 1986.[9,10] Given that a growing percentage of the older adult population is residing in CCRCs, it is important to know more about how individuals living in these facilities, who may be more limited physically or cognitively, respond to exercise-based interventions and what tools can be used to improve their ongoing participation in exercise-based falls prevention programs, like the Otago program. Examining both a home-based and group-based program utilizing the Otago exercises will provide a better understanding of how exercise setting and social interactions impact the experience of an exercise intervention and adherence over time. Additional research is needed to better understand and promote adherence and participation in programs that prevent falls in individuals living in continuing care retirement communities.

1. Robertson MC, Campbell AJ, Gardner MM, Devlin N. Preventing injuries in older people by preventing falls: a meta-analysis of individual-level data. *J Am Geriatr Soc*. 2002;50(5):905-911. doi:10.1046/j.1532-5415.2002.50218.x
2. Stevens JA, Burns E. A CDC compendium of effective fall interventions: what works for community-dwelling older adults. Center for Disease Control and Prevention. https://www.cdc.gov/homeandrecreationalsafety/pdf/falls/CDC_Falls_Compendium-2015-a.pdf. 2015. Accessed April 9, 2020.
3. Sandlund M, Pohl P, Ahlgren C, et al. Gender perspective on older people's exercise preferences and motivators in the context of falls prevention: A qualitative study. *Biomed Res Int*. 2018;2018:6865156. doi:10.1155/2018/6865156
4. McInnes E, Askie L. Evidence review on older people's views and experiences of falls prevention strategies. *Worldviews Evid Based Nurs*. 2004;1(1):20-37. doi:10.1111/j.1741-6787.2004.04013.x
5. Finnegan S, Bruce J, Seers K. What enables older people to continue with their falls prevention exercises? A qualitative systematic review. *BMJ Open*. 2019;9(4):e026074. doi:10.1136/bmjopen-2018-026074
6. Meyer C, Williams S, Batchelor F, Hill K. Enhancing Adoption of a Home-Based Exercise Program for Mild Balance Dysfunction: A Qualitative Study. *J Aging Phys Act*. 2016;24(1):53-60. doi:10.1123/japa.2014-0035
7. Arkkukangas M, Sundler AJ, Söderlund A, Eriksson S, Johansson A-C. Older persons' experiences of a home-based exercise program with behavioral change support. *Physiother Theory Pract*. 2017;33(12):905-913. doi:10.1080/09593985.2017.1359869
8. Maula A, LaFond N, Orton E, et al. Use it or lose it: a qualitative study of the maintenance of physical activity in older adults. *BMC Geriatr*. 2019;19(1):349. doi:10.1186/s12877-019-1366-x
9. James S. Boomers create surge in luxury care communities. New York Times website. https://www.nytimes.com/2018/12/04/business/retirement/continuing-care-retirement-communities-baby-boomers.html. December 4, 2018. Accessed April 9, 2020.
10. Hermann D, Brod K, Giradi J. Ziegler national CCRC listing and profile. Chicago, IL: Ziegel Capital Markets-Senior Leaving Research. 2009.

A.2. Subjects

A.2.1. Total number of subjects proposed across all sites by all investigators (provide exact number; if unlimited, enter 9999):

20

A.2.2. Total number of subjects to be studied by investigators being provided oversight by the UNC IRB. (provide exact number; if unlimited, enter 9999):

20

A.2.3. If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

Ten individuals will be interviewed from each Otago exercise program to examine their experience pertaining to the outcomes of interest: program participation, exercise adherence, and associated facilitators and barriers.

A.2.4. Do you plan to enroll subjects from these vulnerable or select populations:
If you will include children, prisoners or nonviable neonates or neonates of uncertain viability, please check the appropriate category below and complete the additional sections.

You should check "Pregnant women" if you specifically intend to recruit women who are pregnant or are not excluding pregnant women in biomedical research that is greater than minimal risk. Do not check if you are conducting a survey of the general public or conducting secondary data analysis or chart review not aimed at pregnant women.

Only check UNC-CH Student athletes, athletic teams, or coaches if you have specific plans to enroll these subjects. This is not applicable for intramural or club sports. For definitions and guidance see SOP 1201: Vulnerable subjects in research.

✖ Children (under the age of majority for their location)

Any minor subject who attains the age of majority during the course of the research study must provide consent as an adult, unless consent has been waived, which is requested in section D.3.1.

✖ Pregnant women

✘ Nonviable neonates or neonates of uncertain viability

✘ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)

If an enrolled participant becomes incarcerated during the course of the research, they must be removed from the research project until such time as the IRB (and OHRP for NIH funded projects) approves the study to include prisoners, unless there is an immediate risk to the participant from ending treatments under the protocol.

✘ UNC-CH Student athletes, athletic teams, or coaches

A.2.5. Based on your recruitment plan and target sample population, are you likely to include any of the following as subjects? Select all that apply. This is not applicable to secondary data analysis or chart review.

Based on your responses, the consent form builder will insert the required text into your consent form template.

✘ Decisionally impaired individuals

(e.g., Mini mental state examination (MMSE), Montreal cognitive assessment (MOCA))

✘ Children who are wards of the State (Foster children)

✘ Non-English-speaking individuals

✘ UNC-CH Students

✘ UNC-CH Employees

✘ People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim.
This would include studies that might uncover or expose child, elder or domestic abuse/neglect. (See SOP Appendix A)

A.2.6. If any of the above populations are checked (excluding 'Decisionally impaired individuals' and 'Children who are wards of the State (Foster children)'), please describe your plans to provide additional protections for these subjects.

No Answer Provided

A.2.7. Age range of subjects:

Minimum age of subject enrolled	60
	years
Maximum age of subject enrolled	99
» If no maximum age limit, indicate 99	
	years

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

A.4.1. Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

No

A.4.2. Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

The study will consist of one-time structured telephone interviews with individuals who have already completed or participated in Otago based exercise programs offered at their respective continuing care retirement communities. The interview will take approximately 30 minutes and will follow the attached script. Audio recording of the interview will be taken to allow for review of the contents of the interview at a later time. Interviewees will be selected from program participants who agree to be interviewed.

A.4.3. Will this study use any of the following methods?

✔ Audio Recording

✘ Video Recording

- ✗ Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
- ✗ Pencil and paper questionnaires or surveys
- ✗ Electronic questionnaires or surveys
- ✗ Telephone questionnaires or surveys
- ✓ Interview questionnaires or surveys
- ✗ Other questionnaires or surveys
- ✗ Focus groups
- ✗ Diaries or journals
- ✗ Photovoice
- ✗ Still photography

A.4.4. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

No Answer Provided

A.4.5. Are there cultural issues, concerns or implications for the methods to be used with this study population?

No

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Psychological

- ✗ Emotional distress
- ✓ Embarrassment
- ✓ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.2. Describe any potential psychological risks checked above and what will be done to minimize these risks

Individuals will be asked about their participation and adherence to an exercise program, however, no stigmatizing questions will be asked. Only de-identified participant records will be obtained from the program administrators regarding attendance, and only de-identified information collected during the interviews will be available to the administrators of the exercise program.

A.6.3. Social

- ✗ Loss of reputation or standing within the community
- ✗ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.4. Describe any potential social risks checked above and what will be done to minimize these risks

No Answer Provided

A.6.5. Economic

- ✗ Loss of income
- ✗ Loss of employment or insurability
- ✗ Loss of professional standing or reputation
- ✗ Loss of standing within the community

- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.6. Describe any potential economic risks checked above and what will be done to minimize these risks.

No Answer Provided

A.6.7. Legal

- ✗ Disclosure of illegal activity
- ✗ Disclosure of negligence
- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.8. Describe any potential legal risks checked above and what will be done to minimize these risks

No Answer Provided

A.6.9. Physical

- ✗ Medication side effects
- ✗ Pain
- ✗ Discomfort
- ✗ Injury
- ✗ To a nursing child or a fetus (either through mother or father)

A.6.10. Describe any potential physical risks checked above, including the category of likelihood and severity, and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25 - 50%)
- Likely (approximate incidence of > 10 - 25%)
- Infrequent (approximate incidence of > 1 - 10%)
- Rare (approximate incidence < 1%)

Describe severity of risks using the following grading scale:

- Mild- No disruption to the subject's ability to perform daily activities; may include non-prescription intervention only
- Moderate- Temporary interference with daily activities; may include prescription intervention
- Severe- Interference with daily activities; medically significant but not life threatening
- Life threatening

Examples:

Rare (< 1%) and Severe: blindness
Rare (< 1%) and Mild: dry skin, dry mouth, transient headache

If you are using these terms differently than described above, please provide your study-specific definitions.

Phase 1 trials: Due to limited experience, incidence may be better described as the number of events that have occurred in the total number of animals/humans studied.

No Answer Provided

A.6.11. Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

If participants are deemed in need of medical follow-up or psychological counseling, the program administrator at the participant's CCRC will be notified, and they will follow the existing policies for addressing these concerns that are in place at that facility.

A.6.12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study?

No

A.9. Identifiers

A.9.1. Check which of the following identifiers you already have or will be receiving, or select "None of the above."

- ✓ Names (this would include names/signatures on consent forms)
- ✓ Telephone numbers

- ✗ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✗ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✗ Fax numbers
- ✗ Electronic mail addresses
- ✗ Social Security numbers
- ✗ Medical record numbers
- ✗ Health plan beneficiary numbers
- ✗ Account numbers
- ✗ Certificate/license numbers
- ✗ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- ✗ Device identifiers and serial numbers (e.g., implanted medical device)
- ✗ Web universal resource locators (URLs)
- ✗ Internet protocol (IP) address numbers
- ✗ Biometric identifiers, including finger and voice prints
- ✗ Full face photographic images and any comparable images
- ✗ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher
- ✗ None of the above

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ✗ with the research data (i.e., in the same data set and/or physical location)
- ✓ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:
A corresponding key assigning a participant number to each participant will be kept in a separate location from the interview data. Interview data and audio recordings will only include the participant number.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

A.10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

Names of participants will only be collected for the purpose of initiating the interview calls and to create a key assigning each participant a number. Each participant number will be used to designate the audio recording for their interview session. The key matching the identification of the participant with their assigned number will be stored separately from the interview data collected.

A.10.2. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

✔ In person
✘ MyChart
Use of MyChart for research recruitment purposes is currently available only to studies which meet specific criteria to participate in a pilot test. Please contact Stephanie Deen if you would like to see if your study meets the criteria for this use.
✘ Participant pools
✘ Presentation to classes or other groups
✘ Letters
✘ Flyers
✘ Radio, TV recruitment ads
✘ Newspaper recruitment ads
✘ Website recruitment ads
✘ Telephone script
✘ Email or listserv announcements
✘ Follow up to initial contact (e.g., email, script, letter)
✘ N/A
✘ Other

If other, please specify

Individuals who are participating or have already participated in an Otago based exercise program at one of the two CCRCs will be contacted by one of the program administrators and asked if they would be interested in participating in a voluntary interview pertaining to their experience with the program.

B.1.2. **Research for Me @UNC**

This public engagement website is intended to improve the transparency and accessibility of research conducted by UNC or UNC-affiliated researchers. It features a comprehensive list of active studies involving direct interaction with participants. All studies must be listed - make a selection below and submit your listing information via the link. View examples

Instructions:

- Choose Basic or Recruitment
- Click on link to open listing submission form in a new tab
- Submit online form, download PDF
- Receive submission confirmation email (PDF also attached)

Special Circumstances: on rare occasions, a study may request that a listing not be published. The acceptable reasons for that request are included as options below. If you feel that you meet criteria for an option other than Basic listing or Recruitment listing, please select that option. Note that upon review, your selection must match information in the rest of your application.

✔ **Basic Listing (Click here to open basic submission form)**

For studies which are recruiting by invitation only, physician referral only, or don't want to be contacted by potential participants. Submit very basic information in lay language.
Improves public transparency of the studies being done at UNC, but no team contact information will be displayed.

✘ **Recruitment Listing (Click here to open recruitment submission form)**

For studies who want to use the listing a free recruitment tool. Submit both basic and recruitment information so that potential participants can express interest in your study. You
control the time frame when study team contact information is visible for recruitment purposes. Site will be promoted to patients and the public. Your listing can be used as a landing
page from other recruitment materials to provide more details.

✘ **Opt-Out:** This study is classified, and even basic information is prohibited from public display

✘ **Opt-Out:** This study involves deception, and would be compromised by public listing

✘ **Opt-Out:** This study is of such a specific and sensitive nature that public listing would compromise participant confidentiality

✘ **Opt-Out:** Enrollment of new participants is complete OR UNC is acting only as the Data Coordinating Center and will not be enrolling participants

View examples, manage submitted listings, find FAQ, and download PDFs at researcherdashboard.unc.edu
Please direct all questions and feedback to Research for Me

B.1.3. Describe how subjects will be identified

Due to the limited size and scope of this project, subjects will be identified only from individuals who are participating or have already participated in Otago based exercise programs offered at two local CCRCs.

B.1.4. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

Administrators for both of the exercise programs will contact participants and prior participants from these two programs and ask if they would be willing to be interviewed regarding their experience with the program. Once they have received verbal consent, the participants telephone contact information will be shared with the research team. Due to resource limitations only 10 individuals from each program will be interviewed. There is a high likelihood that the projected number of subjects will be identified given the number of individuals who have participated in these exercise programs. One program has had approximately 40 participants and the other has had approximately 16.

Part C. Existing Data, Records, Specimens

C.1. Data Sources

C.1.1. What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'):

✗ Medical records in any format.

ALERT: You must check both boxes: 1) Medical records in any format and 2) Electronic medical record using Epic, or you/your study team will not be granted access to Epic for research purposes.

✗ Electronic medical records using Epic, WebCIS or other electronic system

✗ Carolina Data Warehouse for Health (CDW-H) (for UNC and its affiliates only)

✗ Carolinas Collaborative Data Request and Review Committee (DRRC)

✗ Paper medical records

If you access the medical records of fewer than 50 patients under a full or limited waiver of HIPAA, submit a copy of your IRB approval letter and a completed Research Disclosure Form to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at : 919-595-5591 or 919-966-1225 or 919-595-5580.

✗ Data already collected from another research study

Were the investigators for the current application involved in the original collection?	--

✗ Patient specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess?	--

✓ Data already collected for administrative purposes

✗ Student records (You will need to satisfy FERPA requirements: see SOP 3101, section 3.1 for guidance)

✗ UNC Dental Records

✗ Data coming directly from a health plan, health care clearinghouse, or health care provider?

✗ Publicly available data

✗ Other

✗ None of the above

For EACH data source checked above, provide a description of the data, proposed use, how data were collected (including consent procedures), and where data currently reside.

Aggregate, de-identified data regarding program attendance, and demographic information regarding gender, age, and use of assistive devices will be requested from the two program administrators who already have this information collected in their files for the purpose of tracking utilization of their programs. These values will be used to describe the sample population as a whole; individual demographic information will not be linked to interview data.

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., pathology dept, tissue bank, original researcher):

Program administrators from both programs have agreed to share the requested data for this research project.

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

No

C.2. Coding and Data Use Agreements

C.2.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."

Yes

Will any of the personnel involved in this study (this includes collaborators providing data or specimens, personnel listed on grants, co-authors, and faculty advisors) have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples?

No

Answer the questions below to identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:

Data use agreement with custodian of data (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	No
Note: For Data Use Agreements, Non-Clinical Agreements, or Clinical Agreement Amendments, please submit the New OIC RRF and draft materials via email to OIC@unc.edu	--
Data are publicly available?	No
Honest broker (centralized custodian who controls data and will not release codes or IDs)?	Yes
Other	No

Do ALL of these data, records or specimens exist at the time of this application?

Yes

Attachments

This submission requires the following attachments

Document Type
Interview Questionnaire Survey

This submission includes the following attachments

File Name	Document Type
Interview Script.1.docx	Interview Questionnaire Survey

view attachments

Addenda

Data Security Requirements

view addenda

If Principal Investigator of this study is a Student or Trainee Investigator, the Faculty Advisor certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 2 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 4/12/2020 10:09:17 PM

Vicki Mercer

The expectation is that this approval is being given on behalf of the head of the Department, Division, or Center. If the chair or director is an investigator on this project or otherwise conflicted in approving it, the Vice-Chair or Chair's designee should review it. By approving, you are certifying the following on behalf of your department, division or center:

- This research is appropriate for this Investigator and our department
- The investigator(s) are qualified to conduct the research
- There are adequate resources (including financial, support and facilities) available
- For units that have a local review committee for pre-IRB review, this requirement has been satisfied
- I support this application, and hereby submit it for further review

This study proposes research that has been determined to include Security Level 2 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

- If you are approving for other purposes (e.g., CTRC, DSMB, IBC, PRC, RSC, or other review committees), you affirm the following: The proposed submission is approved and may be forwarded for IRB review.

Department Approval Signatures:

By signing in the appropriate space, the Department Chairperson(s) is indicating only that he/she has seen and reviewed this submission

Department: Allied Health - Physical Therapy

Signature: Electronic Signature Received **Date:** 4/12/2020 10:51:07 PM

Name & Title: Wanqing Zhang, Research Assistant Professor