Study Title: Occupational Impacts of Compound Resistance Training in Community-Dwelling Older Adults

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Background and Rationale

Resistance training offers many benefits for community-dwelling elderly adults, impacting physiological, cognitive, psychological, and functional domains. Existing research highlights the importance of utilizing resistance training as an intervention to counteract age-related declines such as loss of muscle mass, decreased strength, and diminished cognitive function. The evidence indicates significant improvements in muscle mass, strength, sleep, fluid cognition, and overall quality of life, all of which contribute to enhanced functional performance and reduced risk of injury. Despite the robust findings supporting resistance training in older adults, its integration into occupational therapy practices remains underexplored. This study will aim to bridge this gap, emphasizing the occupational therapy perspective and its potential to provide holistic, person-centered resistance training interventions to improve functional performance. The utilization of compound movement resistance training within this project will establish new pathways for occupational therapy professionals to support the health and independence of community-dwelling elderly adults (Coelho-Júnior et al., 2021; Cranmer & Walston, 2022; Gupta et al., 2022; Lai et al., 2023; Macaulay et al., 2021; Marzuca-Nassr et al., 2024; Syed-Abdul et al., 2022; Voulgaridou et al., 2023).

Specific Aims

This study aims to assess the impact of compound resistance training on the ability of adults age 65 and older to participate in desired daily activities, their satisfaction with their level of participation, and their overall mental health.

Study Design and Procedures

This is a quasi-experimental pre-test post-test study. Following initial screening for eligibility via inclusion and exclusion criteria, and completion of informed consent discussion and signed form, subjects will complete an initial assessment. This assessment will consist of a semi-structured interview, completion of the Patient Health Questionnaire (PHQ-9) and Perceived Stress Scale (PSS), and completion of the Canadian Occupational Performance Measure (COPM) with guidance from principal investigator, who has been trained in administration of this occupational therapy field-specific assessment.

Intervention will take place over the course of 10 weeks, with individual sessions occurring twice weekly for one hour per session with each participant. Each session will consist of personalized strength training sessions, utilizing programming with a focus on compound, multi-joint movements, in keeping with existing literature on the subject. The nature of the exercises will be submitted for IRB review in a separate document (*Intervention Guide*). Each session will be designed based upon the PI's evaluation of each individual participant with customized interventions. The PI will record specific

exercises prescribed and completed, including volume, load, and Rate of Perceived Exertion (RPE) from subject report. Ongoing reassessment will be conducted from session to session with changes made in intervention throughout. At completion of the 10-week study, subjects will complete a reassessment with the same measures from the initial assessment, the PHQ-9, the PSS, and the COPM. Subjects will also be asked to re-answer the questions from the semi-structured interview.

Study Population

20 participants will be enrolled in this study. Up to 60 individuals may engage in the consent process to obtain 20 participants in the research activities.

Inclusion Criteria

- Adult age 65 or older
- Living independently in a community dwelling, such as a house or apartment
- Able to complete basic daily tasks (i.e. dressing, toileting, transfers) without assistance from another person
- Access to transportation to and from sessions for this study
- Able to attend two, one-hour sessions per week for the duration of the study
- Has a membership to Silver Sneakers, Silver and Fit, and/or Renew Active, or are willing to obtain a paid membership to Washington Regional Center for Exercise

Exclusion Criteria

- Personal history of stroke or heart attack
- Limb amputation
- Heart failure or arrythmias
- Presence of brain or aortic aneurism
- Active cancer
- Major illness
- Physical activity contraindicated as instructed by a physician
- Active drug abuse
- Moderate to severe cognitive impairment

Potential subjects will be located in the following ways:

- Handing out and/or posting fliers in community settings such as churches, local senior centers, and/or other public places such as grocery stores or shopping malls
- Advertising on social media platforms (Instagram and Facebook)

In some cases, potential subjects will respond to posted fliers. In these cases, initial contact with the study team will be made by the subject via phone or email.

Risks and Benefits

A risk to study participants is the potential for loss of confidentiality of study data.

Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

Another risk to participants is injury or medical event relating to exercise.

Measures to protect subjects include adequate facilities at site of intervention, such as a well-maintained space and equipment that is regularly inspected for safety. An AED is also available in the facility. Provisions for emergency treatment available in the location also include a level 2 trauma center hospital located less than 1 mile from the facility. Appropriately qualified PI will be conducting this study, with qualifications including certification in Barbell Rehab Method and Basic Life Support CPR, as well as classroom and clinical education in occupational therapy assessment and intervention. Trained fitness professionals are also employed on site and will be present throughout the intervention.

Potential benefits include:

- Improved ability for subjects to participate in desired daily activities
- Improved mental health of subjects
- Improved physical health of subjects
- Improved subject knowledge of exercise options, safety, form, and benefits

Data safety will be monitored by the PI and reviewed every 30 days for risk trends.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study.

Names will be coded in recorded data, with the key to the code kept separately. Each participant will be identified by a number (e.g. "Participant 2") in all recorded data. The key linking the recorded data to the participants will be destroyed at the end of the study. Data will be stored via UAMS-monitored database, UAMS BOX, and made accessible only to the PI and Sub-Investigator.

At the conclusion of the study, the data will be retained for 7 years in UAMS BOX according to UAMS administrative policy before destruction.

Multisite Research

This study has one PI. The PI is responsible for all data collection, data management/storage, protocol modification, and submission of amendments to IRB. UAMS is the Reviewing IRB. University of Arkansas Fayetteville and Washington Regional Medical Center are Relying Institutions.

Fitness professionals that will be onsite are employed by Washington Regional Medical Center. They will not be part of the research team, nor will they participate in the consent, data collection, or data analysis. Their role is strictly an added safety component of additional trained individuals present at the facility during intervention, however not involved in the study directly.

No research elements will be conducted by University of Arkansas Fayetteville or Washington Regional Medical Center entities. The PI is a student in a dual-enrolled program within both UAMS and UAF. One employee at the Washington Regional Medical Center (facility manager) will serve as a site mentor and content expert for advising the PI throughout the study, though not conducting any data collection, data analysis, or partaking in consent procedures.

The PI retains responsibility for overseeing protocol implementation, including adherence to IRB-approved protocol in intervention implementation and for maintaining all data confidentiality. PI will retain responsibility for reporting any adverse events, including data related adverse events.

Data Analysis

Data from the objective assessments conducted in this study will be analyzed using statistical analysis to determine if a clinically significant difference exists between the pre- and post-test scores for each assessment. The threshold for clinical significance is 5 points on the PHQ-9 (Kroenke et al., 1999). There is limited research published on the minimal clinically important difference (MCID) for the PSS, however it is estimated to be about 4 points (Drachev et al., 2020). In prior research with community-dwelling older adults, the MCID for the COPM was found to be 3 points for both performance and satisfaction sections (Tuntland et al., 2016).

Themes in subjective data will be coded and analyzed from identification of any changes in subjects' interviews.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the IRB as required.

There will be no compensation for subjects for participation in this study.

The informed consent of each subject, using IRB-approved consent materials, will be obtained before that subject begins any study procedures. All subjects for this study will be provided a consent form on paper describing this study in language understandable to the study population. Consent materials will provide sufficient information for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain what the subjects need to know about the study, including study requirements, study risks and benefits. The consent process will take place in person at the facility prior to beginning initial session, on the same day or up to several days prior to the start of the study. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject**,** and the person obtaining the consent. The participant will receive a paper copy of the signed consent form, and the informed consent process will be documented in the research record.

The consent process will be documented separately via a written note in the research for each subject.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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