

Study Title: Occupational Impacts of Compound Resistance Training in Community-Dwelling Older Adults
PI (researcher): Alexis Skalberg
Institution: University of Arkansas for Medical Sciences

Key Information for The Study:

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

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer for a research study about strength training in older adults (age 65+). By doing this study, we hope to learn how this type of exercise can help you in your daily life and make your overall mental health better.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study. The contact information is on page 9 of this form.

What will happen if I join the study?

If you join, your part in this research will last about 1 hour per day, 2 days per week, over 10 weeks in the year 2025.

During the study, we will ask that you:

- Go to 2 one-on-one training sessions per week
- Participate in safe, individualized strength exercises with occupational therapy student with relevant certifications
- Fill out brief pen-and-paper assessments at the beginning and end of the study

Do I have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. If you decide to take part in the study, it should be because you really want to volunteer.

What do I need to know to decide if I should join this study?

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

Main reasons to join the study

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- ✓ Known health benefits resulting from exercise
- ✓ Increased knowledge of exercise form, safety, and use of equipment
- ✓ Individual, personalized training sessions
- ✓ You may see improvements in your ability to participate in your daily activities and/or in your overall mental health

Main reasons not to join the study

- ✓ The exercises in this study may be difficult at times
- ✓ You will have to commit 2 hours of your time to this study every week for 10 weeks
- ✓ You may be sore from exercising on days in between sessions

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care from UAMS or Washington Regional Medical Center if you are not in the study.

- We are asking you to be in a research study. You do not have to join the study.
- You can still get your medical care from UAMS or Washington Regional Medical Center even if you are not in the study.
- Take as much time as you need to read this form and decide what is right for you.

University of Arkansas for Medical Sciences Informed Consent Form

Why am I being asked to be in this research study?

- We want to learn more about compound resistance training (multi-joint exercises) in older adults (age 65+).
- By doing this study, we hope to find out whether or not compound resistance training helps people improve their daily lives or how they feel mentally.

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- We are asking people like you, who are adults 65 and older living in the community, to help us.
- 20 people 65 years old or older will be part of this study.

What if I don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

What will happen if I say yes, I want to be in this study?

First, we found out that you qualify to be in the study. We asked if you met these criteria below:

- You are age 65 or older
- You reside in the greater Northwest Arkansas area in a private community dwelling, such as a house, apartment, or independent living community.
- You can complete all basic daily tasks (i.e. bathing, toileting, dressing, transfers) without help or supervision
- You have no medical history that would make this type of exercise unsafe, including but not limited to the following:
 - Personal history of stroke or heart attack
 - Limb amputation
 - Heart failure or arrhythmias
 - Presence of brain or aortic aneurism
 - Active cancer
 - Major illness
 - Physician instruction to avoid exercise
 - Active drug abuse
 - Moderate to severe cognitive impairment
- You are able to attend 2 sessions weekly for 10 weeks and have reliable transportation
- You have a Silver Sneakers, Silver and Fit, and/or Renew Active membership, or willing to get a paid membership at Washington Regional Center for Exercise

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If you qualify, we will do these things:

- Ask about your day-to-day life and routines, current physical activity level, any exercise and/or sport history you may have, and what you hope to get out of this study
- You do not have to answer any questions you do not want to answer, except for your current physical activity level, as it changes your starting point with the exercises in this study.
- The intervention in this study will be exercises like squats, lunges, overhead pressing, and hinge movements with weights. These exercises will be moderate intensity.
- Each one-on-one session will be personalized to your current level and will increase over time specifically to you and your body.
- Each session will last about 1 hour and there will be 2 sessions per week over the course of 10 weeks.
- The tests involved in this study will be 2 mental health questionnaires and one occupational therapy assessment that we will talk through together and answer based on your current happiness with how you are performing your daily activities.
- The questionnaires and assessment should take between 20 and 30 minutes in total. Each questionnaire and assessment will be completed both when you start the study and at the end of the 10 weeks.

How long will I be in this study?

You will be in this study for 10 weeks. It will include 20 visits that will take place twice per week.

What if I say no, I do not want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at UAMS.

What happens if I say yes but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at UAMS or Washington Regional
- If you decide to stop being in the study, you should let the researcher know verbally, by email, or by phone as soon as possible.

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Will it cost me anything to be in the study?

To be in this study, you must have Silver Sneakers, Silver and Fit, Renew Active, OR a paid membership to Washington Regional Center for Exercise. Some insurance plans include Silver Sneakers, Silver and Fit, and/or Renew Active. Washington Regional Center for Exercise charges \$35 per month for access to their facility.

You or your insurance company will be responsible for the costs of your regular medical care, as usual.

Will I be paid for being in the study?

No. You will not be paid for being in this study.

Will being in this study help me in any way?

Being in the study may or may not help you, personally. But even if it does not help you, it may help people 65 and older in the future. What we learn may help in the following ways:

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

What are the risks of being in this study?

The risk of joining this study are:

- Injury or soreness related to resistance training

There are also things about being in the study that might affect you, such as:

- The questions asked in the questionnaires may make you sad or upset.
- You will have to do challenging exercises regularly throughout this study, which may make you tired or uncomfortable
- You will have to get transportation to and from the facility for each session
- If you plan to travel outside the NWA area for more than one week during the study period, this may affect your ability to be in the study.

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There is also the risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

What if I get sick or hurt while I am in this study?

- If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid and emergency care. This treatment will be billed to you or your insurance company. No other form of payment is available.
- If you feel sick, please notify the head researcher so we can reschedule your session(s).
- If you are not here and get hurt, and you think it is because of the study, do these things:
 - ✓ call your doctor – or if an emergency, call 911
 - ✓ give your doctor or ER staff
 - The name of this study – Occupational Impacts of Compound Resistance Training in Community-Dwelling Older Adults
 - the name of the head researcher for this study – Alexis Skalberg
 - A copy of this form if you have it
 - This treatment will be billed to you or your insurance company. No other form of payment is available.

Reminder:

You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

What are the alternatives to being in this study?

You do not have to be in this study.

If you decide not to join this study, you have the following other options:

- Seek paid personal training through a fitness center or other facility
- Join a senior center and enroll in group fitness classes
- Workout on your own at home or in a gym

Can I be taken out of the study even if I want to continue?

Yes, the head researcher can take you out of the study if:

- You do not follow study instructions.

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- It is not in your best interest to continue.
- The study is stopped for any reason.

What information will be collected about me in the study?

We will only collect details we need for the study. We may collect the following information from you:

- General contact and background information about you, such as name, age, and phone number
- Medical information about you, such as relevant medical history and answers to questionnaires
- Personal information, such as your daily life routines, habits, and/or activities

We need these details to improve the safety and personalization of the exercises we have you do during this study and to help us schedule sessions at times that work for you.

Who will see this information? How will you keep it private?

- The lead researcher and UAMS faculty advisor will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off information that we collect from you during the study. We will give your information a code, so that no one can identify you.
- When we share the results of the study in presentations or published articles, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are
 - ✓ OHRP (Office for Human Research Protections), a federal agency
 - ✓ UAMS Institutional Review Board
 - ✓ University of Arkansas Fayetteville Institutional Review Board
 - ✓ Washington Regional Medical Center Review Board
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

How study staff may share your information:

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We may share your health information with:

- Staff at the University of Arkansas for Medical Sciences (UAMS), including:
 - The research study staff
 - The UAMS Institutional Review Board (IRB)
 - Other institutional oversight offices
- Companies that work with us on the research, such as:
 - Washington Regional Medical Center
- People outside of UAMS who make sure we do the research the right way, such as:
 - The U.S. Office for Human Research Protections

We think everyone involved with research understands how important it is to keep your health information private. But people outside of UAMS may not have to follow the same laws UAMS follows to protect your health information.

How long this authorization lasts:

When you sign this form, you agree to let us collect, produce, and share health information about you as we describe in this form. Your authorization ends on November 22, 2032 (7 years after the end of the study).

How to cancel (revoke) your HIPAA authorization:

If you sign this form and decide later that you do not want us to use your health information for the research, you can cancel (revoke) your HIPAA authorization. To do so, you must either send a letter to the Principal Investigator at the name and address at the top of this form or send an email to irb@uams.edu. Your letter or email must include:

- The study title (from the top of this form)
- A statement saying you changed your mind and are ending your “HIPAA Research Authorization”
- Your signature

After we get the letter or email, we will take you out of the study and stop collecting your health information. But we may still use and share your health information we collected before we got your letter.

If you quit the study, it will not change any care or benefits you receive from UAMS or Washington Regional Medical Center.

Will you tell me the results of the study?

Yes. Once the study is done, we will send you a summary of all the results and what they mean. We will also send you your individual results from the study.

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What if new information comes up about the study?

We will tell you if we learn anything that may change your mind about being in the study.

What if I have questions?

- Please call the head researcher of the study – Alexis Skalberg (469) 525-2213 – if you
 - ✓ have any questions about this study
 - ✓ feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 and leave a message that will be returned during normal work hours.

By signing the document, I am saying:

- ✓ I agree to be in the study.
- ✓ Study staff may share my information as described in this form.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.

I know that:

- ✓ I can stop being in the study at any time and nothing bad will happen to me.
- ✓ I can still get medical care at UAMS or Washington Regional Medical Center no matter what I decide.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my legal rights by signing this form.

I agree to be part of this study:

Your name (please print)

Your signature

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Date

Printed name (person obtaining consent)
consent)

Signature (person obtaining

Date