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Short- and long-term effects of progressive resistance exercise on muscle and bone mass, physical and mental performance and balance compared to age-matched non-exercising middle-aged and older adults

Submission date
17/02/2023

Recruitment status
Recruiting

Registration date
02/03/2023

Overall study status
Ongoing

Last Edited
02/03/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Aging results in the loss of muscle, bone, strength, physical and mental performance, endurance, flexibility, and balance. These changes also affect one's ability to function in everyday life (for instance, to do yard work, or buy and transport groceries). Abundant research evidence demonstrates that, regardless of age, many of the harmful physical and mental of aging can be reduced, prevented, or even reversed with exercise. However, there are few multi-year experimental exercise studies in middle-aged and older adults. The current study investigates the short and long-term effects of progressive resistance exercise on muscle and bone mass, physical and mental function, and balance in aging.

Who can participate?
People over the age of 40 years who are committed to completing a monitored exercise program three times per week

What does the study involve?
Participants self-select into an experimental exercise or control non-exercising group. Physical function, cognitive performance, and balance data are collected every 14 weeks, and muscle and bone mass data are collected at the start of the study and after 42 weeks. Participants in the experimental group exercise three times per week. Once they complete the 42-week exercise program, they complete the cycle again with heavier loads. This pattern is completed as long as they stay enrolled in the study.

What are the possible benefits and risks of participation?
There is a small risk of injury, muscle soreness or cramping, acute cardiovascular event, bruising, low blood sugar, motion sickness from VR cognitive testing, exposure to infectious disease, and radiation exposure (equal to living one day of life in Denver, CO). Overall, these risks are similar

to any individual who exercises, though they might be mitigated due to the constant monitoring of the exercise by the research investigators. Participants in the experimental group are expected to benefit by accruing new or maintaining current muscle and bone mass, improving or preserving physical and cognitive performance, and improving balance. Participants in the control group will benefit from the comprehensive assessments.

Where is the study run from?
University of Houston - Clear Lake (USA)

When is the study starting and how long is it expected to run for?
August 2021 to August 2033

Who is funding the study?
University of Houston - Clear Lake (USA)

Who is the main contact?
Dr William E. Amonette, amonette@uhcl.edu

Contact information

Type(s)
Principal investigator

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Study information

Scientific Title
Longitudinal study of aging, health, and human performance: the skeletal muscle matters protocol

Study objectives
Middle-aged and older adults engaging in long-term progressive resistance exercise will experience reduced muscle loss, less falls, improved cognition, balance and functional performance compared to age-matched controls who do not engage in formal strength training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2021, the Committee for the Protection of Human Subjects at the University of Houston - Clear Lake (Bayou Building, 2531, 2700 Bay Area Blvd, Box 44, Houston, TX, 77058-1002, USA; +1 (0)281 283 3015; Sponsoredprograms@uhcl.edu), ref: 02-22-003

Primary study design
Interventional

Study design
Non-randomized controlled trial (between-within design)

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Aging and skeletal muscle loss

Interventions
Participants self-select into an experimental exercise or control non-exercising group. Physical function, cognitive performance, and balance data are collected every 14 weeks, and muscle and bone mass data are collected at the start of the study and after 42 weeks. Participants in the experimental group exercise three times per week. Once they complete the 42-week exercise program, they complete the cycle again with heavier loads. This pattern is completed as long as they stay enrolled in the study.

Intervention Type
Other

Primary outcome(s)
Skeletal muscle mass and bone mineral density measured with dual x-ray absorptiometry every 42 weeks

Key secondary outcome(s)
1. Force and power output measured with force plates during the sit-to-stand test every 14 weeks
2. Total time to complete the Timed-up-and-go test measured every 14 weeks
3. Time to complete and number of steps measured in the forward 10-meter walk test performed every 14 weeks
4. Time to complete and number of steps measured in the backward 10-meter walk test performed every 14 weeks
5. Sway magnitude measured with a computerized dynamic posturography device during a sensory organization text every 14 weeks
6. Total distance walked during the 6-minute walk test completed every 14 weeks
7. Cognitive function measured with Bell's test, mini-cognitive assessment, Trails A&B, the Digit-Symbol, and Navigation measured every 14 weeks
8. Daily workout volume-load measured using the weight lifted multiplied by the sets and repetitions
9. The number of falls documented monthly

10. Blood pressure measured monthly with a sphygmomanometer
11. Body weight measured monthly with a digital scale

Completion date
01/08/2033

Eligibility

Key inclusion criteria
1. At least 40 years of age
2. Have the ability to perform lower- and upper-body exercises
3. Commit to exercise 2-3 times per week (experimental group only)
4. Free from overt neurologic disease or injury

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Sex
All

Key exclusion criteria
Overt neurologic disease or inability to ambulate safely without assistance

Date of first enrolment
15/01/2022

Date of final enrolment
15/01/2032

Locations

Countries of recruitment
United States of America

Study participating centre
University of Houston - Clear Lake
Health and Human Performance Institute
2700 Bay Area Blvd
Houston

United States of America
77058

Sponsor information

Organisation
University of Houston - Clear Lake

ROR
https://ror.org/01t817z14

Funder(s)

Funder type
University/education

Funder Name
University of Houston

Alternative Name(s)
The University of Houston, Houston Junior College, University of Houston–University Park, U of H, Houston, UH, HJC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication. Upon signing the Informed Consent form approved by the Committee for the Protection of Human Subjects at the University of Houston - Clear Lake, each subject will be assigned a number from 1 –500. All data will be catalogued and stored with the use of this number. Data will be kept in a locked office, in a locked file cabinet, or on a password-protected computer in a password protected file. Only the principal investigator and co-investigators will have access to these data during the experiment. Every effort will be made

to maintain the confidentiality of the study records. The data collected from the study will be used for educational and publication purposes. However, the data will be maintained such that no data will be linked to an individual. In the event that any publications result from this evaluation, no personally identifiable information will be disclosed without prior consent. For federal audit purposes, subjects' documentation for this research project will be maintained and safeguarded by the principal investigator for a minimum of three years after completion of the study. After that time, the subjects' documentation may be destroyed.

IPD sharing plan summary

Published as a supplement to the results publication