Study Title:	Quantifying the Trainability of Peripheral Nerve Function in Young and Older Adults.
NCT number:	N/A
Date:	9/9/2024

CONSENT FORM

Quantifying the Trainability of Peripheral Nerve Function in Young and Older Adults

Key Information

- **Study Purpose:** Nerve speed has shown to decline in older adults and may consequently affect one's quality of life. As such, identifying interventions to improve peripheral nerve function may be useful in avoiding these negative outcomes. Resistance training may be one intervention to counteract these deficits. Therefore, the purpose of this study is to determine if resistance training elicits positive adaptations to the nerves of the hand muscles in both young and older adults.

- **Major Procedures of the Study:**
  - ***EMG –*** sensors will be placed over the forearm muscles of both arms to measure muscle activity.
  - ***Nerve Stimulation*** – we will provide short electrical stimulations to the nerve of the arm to cause the muscles to contract.
  - ***Voluntary contractions*** – we will ask you to perform three of maximal handgrip contractions with each arm.
  - ***Ultrasound –*** ultrasound images will be taken of your forearm muscles.
  - ***Manual dexterity tasks –*** we will ask you to perform a series of tasks that assess your bimanual dexterity.
- **Study Population:** Apparently healthy adults 18-100 years old.
- **Duration of Participation:** This study is two visits over a 4-week period, which should take 2-2.5 hrs each visit.
- **Exclusion Criteria for Training groups:** ○ If you have been notified by a physician to refrain from exercise due to cardiovascular issues.
  - Known orthopedic or neuromuscular limitations, or illness of the upper extremities. ○ Known neuromuscular disorders.
  - Individuals that are experiencing a fever (> 100.4° F) or have identified as symptomatic on the COVID-19 screening questionnaire may not participate at this time.
- **Exclusion Criteria for Control groups:** ○ If you have been notified by a physician to refrain from exercise due to cardiovascular issues.
  - Known orthopedic or neuromuscular limitations, or illness of the upper extremities. ○ Known neuromuscular disorders.
  - Individuals that are experiencing a fever (> 100.4° F) or have identified as symptomatic on the COVID-19 screening questionnaire may not participate at this time.
- **Time Commitment:** Participants will be in one two groups: training group or a control group. The training group will be asked to perform an at-home intervention completing a series of hand grip exercises over a 4-week period, 3 times per week (12 training sessions). There will also be 2 testing visits lasting 2-2.5 hrs each. Participants in the control groups will visit the lab for 2 testing visits lasting 2-2.5 hrs each over a 4-week period.
- **Significant Risks**: None.
- **Potential Benefits:** Participants will gain a better understanding of their peripheral nerve function.
- **Compensation:** Participants in the training group will be provided a kit with strength training devices for the hand. They will use this kit for their training during the study, and will be allowed to keep the equipment. Participants in the control group will also be provided a free training kit, but after completion of the study.

Approved:
Expires: N/A
Protocol #: IRB-22-270

Background Information

You are invited to be in a research study of peripheral nerve function in young and older adults. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Your participation is entirely voluntary.

This study is being conducted by:

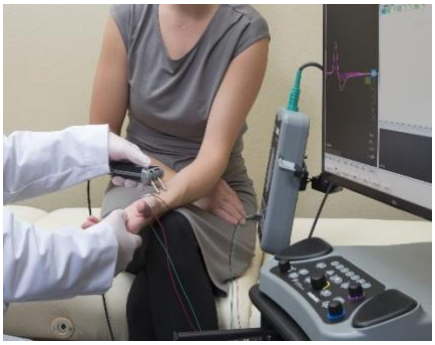
Principal Investigator: JoCarol Shields, PhD student
Supervising Professor: Dr. Jason DeFreitas, Associate Professor in Health & Human Performance

Procedures

If you agree to be in this study, we would ask you to do the following things:

EMG:
Electromyography (EMG) noninvasively measures the electrical activity of muscles using electrodes placed on the skin over the muscles of interest. In this study, the electrodes will be placed over the forearm muscles. To ensure accurate readings, the areas on the skin of the forearms might need to be shaved, lightly abraded, and cleansed with rubbing alcohol. The preparation of the skin only takes ~5 minutes, and the sensors will remain in place for the duration of the protocol (estimated 2-2.5 hrs).

Peripheral Nerve Stimulation:
Peripheral nerve stimulation, is a noninvasive technique for evoking or stimulating contractions of the muscles. In this case, the peripheral nerve that activates the muscle of interest is electrically stimulated with 2 metal, round prongs (an example of a handheld stimulator is shown in the photo to the right). The electrical stimulation will be delivered to the skin of the arm, over the nerve, at different intensities, and may cause brief, but slight discomfort. While completely safe, some participants feel a very brief sensation, often described as similar to a pinch, at the higher intensities.



Voluntary contractions:
Participants will be asked to perform three maximal handgrip contractions with each arm. Prior to the contractions, participants will perform 2-3 warm-up contractions at about half of their maximal effort. Upon directions, participants will take a deep breath in and raise the hand dynamometer to a 90-degree angle and contract maximally while exhaling each breath. Each contraction will last 4-5 seconds with strong verbal encouragement given by the research team, and one minute of rest given between each trial.

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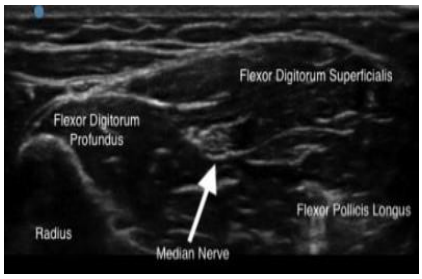
Ultrasound:
Muscle size, quality and architecture of the forearm will be assessed using a diagnostic ultrasound machine. For the assessment, your forearm will be place on a cushioned table. Water-soluble gel will be placed on the surface of their skin at the site of each muscle prior to assessment in order to avoid compression or depression of the muscle. During the assessment, a probe connected to the ultrasound device will be placed on the skin at the site of each muscle to view and capture images.



Manual dexterity tasks:
Each participant will be asked to perform the Minnesota hand dexterity Test. This involves a placing test and a turning test that examines bimanual dexterity. The placing test requires participants to place blocks one by one on the board with their dominant hand while timed. During the turning tests, participants take the block from the right top corner with their left hand and turn it over and place it in the hole with their right hand while timed.

Resistance training:
Participants assigned to the training group will be asked to complete an athome intervention with instruction and guidance given by the research team. Participants will perform a series of exercises 3 times per week for fourweeks (12 training sessions). The training sessions will last in duration between 30-45 minutes with a progressive overload in resistance each week. These sessions will include the use of a specialized hand grip band and hand grip ring. Frequent check-in communication will be conducted by the research team.

Risks and Benefits of being in the Study

The study involves the following foreseeable risks: As is the case with any test involving maximal physical exertion, there is a risk of musculoskeletal injury and discomfort to the hands, wrists, or forearms during testing. There is a chance that your muscles may be sore and tired following testing. On rare occasions, participants note joint pain following testing. A series of warm-up contractions will be administered to help avoid injuries. Physical activity also causes temporary blood pressure elevation (because you will be performing strenuous exercise and/or moving around). The likelihood of lightheadedness or fainting is moderate to minimal. Additionally, alcohol and drug use have been shown to exacerbate muscle damage and swelling. Therefore, it is advised that you refrain from using these substances throughout the duration of the study.

EMG and Nerve Stimulation:
This is a small risk that redness or swelling could develop from the EMG electrodes that will be placed on your forearms, the nerve stimulation probe, or the EMG skin preparation (shaving, abrading, and cleansing). The test may cause some itching or slight discomfort at these sites.

In case of injury or illness resulting from this study, emergency medical treatment will be available (CPR certified investigators and 911). No funds have been set aside by Oklahoma State University to compensate you in the event of illness or injury. It is important to note that you are free to withdraw from the study at any time without prejudice or penalty.

What Steps Are Being Taken to Reduce Risk of Coronavirus Infection?

The following steps are being taken to address the risk of coronavirus infection:

- **Screening:** Researchers and participants who show potential symptoms of COVID-19 (fever, cough, shortness of breath, etc.) will NOT participate in this study at this time.

- **Physical distancing**: Whenever possible, we will maintain at least 6 feet of distance between persons while conducting the study.
- **Disinfecting materials:** We will clean and disinfect surfaces between participants, using an EPA registered disinfectant or a bleach solution (5 tablespoons of regular bleach per gallon of water) for hard materials and by laundering soft materials. Disinfected materials will be handled using gloves, paper towel, plastic wrap or storage bags to reduce the chance of re-contamination of materials.
- **Electronics:** Alcohol-based wipes or sprays containing at least 70% alcohol will be used to disinfect shared touch screens, mice, keyboards, etc. Surfaces will be dried to avoid pooling of liquids.

The benefits to participation are: Participants will gain a better understanding of their peripheral nerve function. Additionally, those participating in the training groups have the potential to see changes in hand grip strength as result of resistance training. Moreover, this study may help the researchers learn more about peripheral nerve function and may help develop future therapies for populations with motor nerve disorders (e.g. amyotrophic lateral sclerosis, spinal muscular atrophy, etc.).

Compensation

Participants in the training group will be provided a kit with strength training devices for the hand. They will use this kit for their training during the study, and will be allowed to keep the equipment. Participants in the control group will also be provided a free training kit, but after completion of the study.

Confidentiality

The information that you give in the study will be handled confidentially. Your data will be assigned a code number which will have no link to your identifying information. Your name will not be used in any report. This Informed Consent form, and the Health History Questionnaire, will be the only documentation kept with your identifiable information. They will be stored in a file cabinet or drawer in a locked office for a minimum of 3 years after the completion of the study, after which they will be destroyed. Your data collected as part of this research project will be strictly under the code number assigned to you, which cannot be linked back to your identity, and will be used or distributed for future research studies.

Voluntary Nature of the Study

Your participation in this research is voluntary. There is no penalty for refusal to participate, and you are free to withdraw your consent and participation in this project at any time. The alternative is to not participate.

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Oklahoma State University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at 386-341-1524, jocarol.shields@okstate.edu. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (405) 744-3377 or irb@okstate.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Indicate Yes or No:

I give consent for my coded data to be used in future research studies: [ ] Yes [ ] No

Approved:
Expires: N/A
Protocol #: IRB-22-270

Signature:_____ Date: _____

Signature of Investigator:_____ Date: _____