HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: Lumbar Stabilization Exercises and Neuromuscular Electrical Stimulation: An Investigation of Muscle Size and Function in Older Adults with Chronic Low Back Pain

Principal Investigator
Name: J. Megan Sions, PT, DPT, OCS
Department/Center: Biomechanics and Movement Science: Department of Physical Therapy
Contact Phone Number: (302) 831-8893
Email Address: megsions@udel.edu

Advisor (if student PI):
Name: Dr. Gregory E. Hicks, PT, PhD
Contact Phone Number: (302) 831-2690
Email Address: ghicks@udel.edu

Other Investigators:
Teonette Velasco, MPT, PT, OCS
Tara Jo Manal, DPT, PT, OCS, SCS

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the HSRB. Should any unanticipated problems involving risk to subjects, including breaches of guaranteed confidentiality occur during this project, I will report such events to the Chair, Human Subjects Review Board immediately.

1. **Is this project externally funded? YES**
   If so, please list the funding source: If so, please list the funding source: APTA: Promotion of Doctoral Studies I Scholarship

2. **Project Staff**

Please list personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
J. Megan Sions, PT, DPT, OCS	Principal investigator/graduate student	YES
Gregory E. Hicks, PT, PhD	Advisor	YES
Teonette Velasco, MPT, PT, OCS	Research Assistant	YES
Tara Jo Manal, DPT, PT, OCS, SCS	Researcher	YES
Martha Callahan	Research Coordinator	YES
Leigh Shrewsbury Liza Walker	Scheduling Staff Scheduling Staff	YES YES

Matthew Bertinato	Undergraduate Assistant	YES
Cameron Hui	Undergraduate Assistant	YES
Erin Thomas	Undergraduate Assistant	YES
Alicia Ferrier	Undergraduate Assistant	YES
Karen Hillsley	Undergraduate Assistant	YES
Nicole Tomaselli	Undergraduate Assistant	YES
Megan Byrne	Undergraduate Assistant	YES
Alexandra Cangero	Undergraduate Assistant	YES
James Townsend	Undergraduate Assistant	Will complete before starting
Paul Schulze	Undergraduate Assistant	Will complete before starting
Alexia Hay	Undergraduate Assistant	Will complete before starting

3. **Special Populations**
Does this project involve any of the following:
Research on Children? NO
Research with Prisoners? NO
Research with any other vulnerable population (please describe)? NO

4. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

Rehabilitative Ultrasound Imaging (US) is a procedure used to evaluate skeletal muscle size and function to inform clinical practice. US has been shown to be a reliable and valid tool for measuring changes in trunk muscle (i.e. abdominal and back muscle) size and activity during sub-maximal contractions in younger populations. Younger adults with low back pain as compared with healthy adults without pain demonstrate smaller back muscle size, lower back muscle activity, and greater back muscle asymmetry (differences in right side compared with left side).

No trials are published evaluating muscle adaptations using US in response to clinical treatments for low back pain in the older adult population. Increased muscle size and improved muscle symmetry have been reported in younger adults with low back pain who participate in low back stabilization exercises. These exercises use voluntary contractions of the back muscles with prolonged hold times and low loads. Neuromuscular Electrical Stimulation (NMES) is a treatment modality that increases muscle activity when voluntary activity is impaired and increases muscle size. Most studies assessing muscle size and activity in response to NMES have been conducted in the knee muscles (i.e. the quadriceps), while the impact of NMES on the back muscles remains relatively unexplored. Given the potential to evaluate back muscle size and activity with US, this assessment tool may be used to document muscle adaptations to a clinical intervention in older adults with low back pain.

The purpose of this study is to conduct a 6-week clinical trial to determine if NMES plus lumbar stabilization exercises is superior to lumbar stabilization exercises for improving back muscle size, activity, and side-to-side (i.e. right side versus left side) symmetry in older adults with chronic low back pain (i.e. low back pain of greater than 3 months). Muscle size, activity, and symmetry will be assessed using US before and after the treatments to determine if the treatments positively impact muscle. Secondary clinical measures of success will include improvements in physical, psychological, and social function pre- to post-treatment.

5. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

Overview: Participants will be enrolled in a 6-week clinical trial through the University of Delaware Physical Therapy Clinic to collect preliminary data for future investigations. Participants will undergo

a baseline, standardized physical examination as well as ultrasound imaging (US) assessment. Participants will be randomly assigned to one of two treatment groups: 1) lumbar stabilization exercises and moist heat applied to the low back; or 2) lumbar stabilization exercises with neuromuscular electrical stimulation (NMES). Treatment frequency will be two times per week for six weeks. Following the six-week clinical trial, the participant will undergo a standardized, follow-up physical evaluation and repeat US by the examiner.

Ultrasound Imaging: Ultrasound images, which will take less than 30 minutes, will be obtained using a MyLab 25 portable ultrasonography unit (Biosound Esaote Inc., Indianapolis, IN) with a 3.5-5.0 MHz curvilinear transducer (i.e. probe) and analyzed using MyLab software. Brightness mode will be used to attain images of the low back muscles, including the lumbar multifidi. Multifidi images will be obtained using the L4/5 facet joint as a reference point with the transducer (i.e. probe) longitudinally placed and angled toward the spine. Images will be taken at rest and with a contralateral straight leg raise to determine muscle activity, which will be calculated as percent thickness change. Percent thickness change will specifically allow determination of L4/5 multifidi muscle activity. Transverse placement of the transducer will capture the L4 low back muscle cross-sectional area at rest. Cross-sectional area measurements of the back muscles will be performed by tracing just inside the border of the muscle. Side-to-side muscle symmetry will be determined using the equation: (% difference =[(largest side value/smallest side value)*100]-100).

Self-Report Measures: Participants will complete a demographics intake sheet, sign a consent for treatment*, and complete a past medical history checklist* (*required documentation of UD PT Clinic). The standardized physical therapy evaluation will include questions regarding back pain, potential hip pain complaints, and low back pain-related functional limitations. Participants will be asked to complete questionnaires that assess pain, the impact of pain on function, and fear-beliefs related to back pain presence as part of the criteria for inclusion in the study. The additional pain, health, and mood questionnaires will be administered:

1) Pain Diagram: Participant identifies the location(s) and type(s) of pain on a human diagram, which will assist with screening for pain below the knee that may be related to the back, as well as understanding participant pain complaints.

2) Medical Outcomes Short Form 36 (SF-36): The SF-36 is a comprehensive, generic questionnaire, which evaluates health-related quality-of-life. Lower SF-36 scores have been linked to delayed recovery in individuals with low back pain.

3) Cumulative Illness Rating Scale (CIRS): Given the potential for multiple co-morbidities among older adults and that medical diagnoses unrelated to pain may contribute to compromised functional status in the older adult, we will administer the CIRS to document health-related quality-of-life.

4) Geriatric Depression Scale: Short-Form (GDS): We will include the GDS for mood assessment, given the strong associations between chronic pain and depression in older adults and poor physical performance and depression.

Objective Measures: The standardized physical therapy examination will include the following:

1) Vital Signs: Participant heart rate, respiratory rate, and blood pressure will be assessed to determine appropriateness for participation in exercise.

2) Anthropometric Measurements: Height, weight, waist circumference, and hip circumference will be taken. These body measurements have been shown to affect muscle size during US assessments.

3) Hip Screen: As concurrent pathology at the hip and the spine is not uncommon among older adults, participants will be screened for hip pathology. In addition to questioning regarding hip pain and morning stiffness, participants will undergo the following measures, which are part of clinical classification criteria for hip osteoarthritis:

    a. *Hip Flexion Range-of-Motion:* With the participant lying on his/her back, using a standard goniometer (measurement device) and bony landmarks of the hip and thigh, knee-to-chest passive range-of-motion will be taken to the nearest degree for each limb.

    b. *Hip Internal Rotation Range-of-Motion:* With the participant lying on his/her stomach, using a standard goniometer (measurement device), the examiner will bend the knee to 90 degrees and rotate the hip until the point just before pelvic movement. Bony landmarks will include the midpoint of the knee cap and the front of the lower leg, with right and left measurements taken to the nearest degree.

4) Lumbar Active Range-of-Motion: The following clinical measures are theorized to capture spine flexibility:

    a. Side-Bending: An inclinometer (measurement device similar to a carpenter's level) is applied between the spinous processes of T9 and T12 (at the lower rib cage). The participant is instructed to lean to the right as far as possible with the fingertips reaching down the side of the thigh. The measurement is repeated to the left.

    b. Total Flexion: The inclinometer is centered over the interspinous space of T12/L1 (just below the rib cage). The participant is instructed to bend forward as far as possible without bending the knees.

    c. Pelvic Flexion: The inclinometer is centered over the S2 spinous process (below the belt line), and the participant is instructed to bend forward as far as possible without bending the knees.

    d. Extension: The inclinometer is centered over the interspinous space T12/L1 (just below the rib cage). The participant is instructed to bend backwards as far as possible without bending the knees.

5) Passive Straight Leg Raise: The participant lies on his/her back with the legs straight. An inclinometer is positioned on the shin and the examiner lifts the leg to the maximally tolerated straight leg raise position, records the degrees of elevation, and repeats with the opposite leg. Degrees of elevation may be decreased in individuals with low back pain.

6) Single-Limb Stance: Single-limb stance is a clinical measure that may be used to assess trunk muscle, functional coordination in individuals with non-specific low back pain. The individual is asked to stand on a single leg while bending the opposite hip toward the stomach.

7) Modified Biering-Sorensen Back Endurance Test (mBSBET): The participant will lie on his/her stomach with the waist-line aligned with the edge of the table. The lower half of the body will be strapped to the table with three belts located at the ankles, back of knees, and hips. The participant will rest their upper body on a chair and then will move to assume a horizontal upper trunk position with the arms folded across the chest for up to four minutes. Decreased hold times are found in older adults, when compared to younger adults.

8) Timed Up and Go (TUG): The TUG is associated with low back pain-related disability. The TUG test asks that the individual rise from a standard chair with armrests, walk 3 meters, turn around, walk back to the chair and sit down, while timed.

9) Short-Physical Performance Battery: This battery, which includes tasks that stress the trunk, has been used to evaluated leg performance in individuals with back pain. It includes: (1) repeated chair stands, (2) balance testing, and (3) the 8-Feet Walk Test.

10) Functional Reach: This measure is used to assess anterior-posterior (front-to-back) trunk stability. Starting with the shoulder elevated to 90 degrees, the participant will "reach as far forward as possible, without losing his/her balance, touching the wall, or taking a step."

11) 6-Minute Walk Test: The 6-Minute Walk will be used to objectively document decreased walking capacity, a common complaint among individuals with chronic low back pain. Participants will be asked to "cover as much ground as possible walking up & down the hallway for 6 minutes.

Treatment: The lumbar stabilization program will include exercises targeting the back muscles in three positions: standing, prone (belly), and quadruped (hands and knees). See attachment for the proposed exercise program. Participants will be asked to perform their home program on the five days that they do not attend physical therapy and return exercise compliance logs. NMES to the low back muscles (i.e. spinal extensors) will be applied at the parameters previously used in the knee muscles at the maximal tolerable intensity, which results in a full, sustained isometric contraction of the back muscles. NMES treatment time will be 10 seconds of contraction followed by 50 seconds of rest for 15 contractions. Pad placement will be just below the waist line, with 2, 2X2 inch pads, on either side of the spine. Participants will be positioned on their belly with 2 pillows under their stomach to level the spine and secured to a table using a belt that crosses the buttock. Participants will be able to stop the NMES by pushing the STOP button, if at any point in time the NMES becomes more than he/she can tolerate. For those who do not receive NMES, moist heat will be applied for 15 minutes in a position of comfort for the participant. Regardless of group assignment, each treatment session will be about 1 hour.

Re-Evaluation: Participants will be asked to undergo a follow-up evaluation within 7 days of their final treatment session. The follow-up evaluation will include standardized physical therapy evaluation tests and measures as well as repeat ultrasound imaging. This session will last about 2 hours.

6. **STUDY POPULATION AND RECRUITMENT**

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information. Attach all recruitment fliers, letters, or other recruitment materials to be used.

This study will use a sample consisting of 36, English-speaking and English-reading, older male and female adults (ages 60-85 years) with chronic low back pain, i.e. pain of greater than 3 months duration. All participants will be recruited through advertisements, physician offices affiliated with the University of Delaware (UD) Physical Therapy (PT) Clinic, and local community centers near UD. During the examination, potential participants must have 2/4 of the following for inclusion, based on previous work by Hicks et al, which outlined clinical predictors of success with a trunk muscle stabilization exercise program:

1) Fear-Avoidance Beliefs Questionnaire (FABQ) Physical Activity Sub-Scale score ≥9: The FABQ is a measure of an individual's beliefs regarding the impact of physical activity and work on his/her low back pain. The FABQ is comprised of two sub-scales: physical activity

and work. Higher FABQ scores have been shown to predict pain and disability in individuals with chronic low back pain.

2) Aberrant Movement: Aberrant movement may be classified as any one of the following: (1) an "instability catch", defined as deviation from the plane of movement during flexion or extension; (2) "thigh climbing", which is defined as using the hands and pushing on the thighs to assist in obtaining an upright trunk position; (3) a "painful arc of motion", when flexing or returning to upright from a flexed spinal position; or (4) "reversal of the lumbopelvic rhythm", where the trunk is first extended and then the hips and pelvis extend to bring the body upright from a flexed position.

3) Posterior-to-Anterior Segmental Hypermobility: The participant will lie on his/her stomach and the examiner will apply a posterior-to-anterior (back-to-front) force over the spinous processes from S1 to T12 (just below the belt-line to the rib cage). The available mobility will be graded hypermobile (too much motion), normal, or hypomobile (too little motion).

4) Positive Prone Instability Test: The participant will lie on his/her stomach with the legs off the edge of the table and the feet resting on the floor. The examiner will apply a posterior-to-anterior pressure at each spinous process (T12-S1). Any provocation of pain will require the participant to lift their legs off the floor while the pressure is reapplied to the painful level. If the pain subsides with elevation of the legs, this is considered a positive test.

Describe what exclusionary criteria, if any will be applied.

(a) Exclusion criteria for participants includes (1) history of low back surgery; (2) recent trauma (i.e. motor vehicle accident, fall, etc.); (3) receipt of services for low back pain within the last 6 months; (4) non-ambulatory or severely impaired mobility (i.e. use of an assistive device greater than a cane); (5) severe hearing or visual impairment; (6) non-mechanical low back pain; (7) neurological disorder; (8) presence of an acute illness; (9) diagnosis of scoliosis; (10) symptoms related to the back below the knee; (11) presence of a pacemaker; (12) participation in R21 clinical trial ongoing at the UD PT Clinic; or (13) the inability to participate in the study for the full six weeks for any known reason (i.e. moving away, extended vacation). Potential participants will also be excluded if during the evaluation any of the following are found:
    (1) score < 24 on the Folstein Mini-Mental State Examination (MMSE): As scores greater than or equal to 24 may identify individuals who are cognitively intact, this screening tool will exclude those older adults with questionable reliability (i.e. consistency) on the self-report questionnaires secondary to cognitive impairment.
    (2) Modified Oswestry Low Back Pain Questionnaire (mOSW) score < 14 percent: This questionnaire will exclude those individuals with chronic low back pain who demonstrate minimal low back pain-related disability. Individuals with minimal disability may not be representative of those seeking outpatient physical therapy services for their back pain.
    (3) Facial Pain Scale-Revised (FPS-R) "worst" low back pain rating in last 24 hours of < 3/10: Pain rating ≥ 3/10 is being used in the hopes of recruiting a group of individuals who may be representative of those likely to seek clinical services for their low back pain. Also, all FPS-Rs ("current", "best", and "worst") will be used to document the impact of treatment on self-reported pain.
    (4) Inability to tolerate lying on belly with legs straight: This is a requirement for our standardized position for ultrasound.

Describe what (if any) conditions will result in PI termination of subject participation.

The PI or treating therapist may terminate subject participation if at any time vital signs preclude participation or it is determined that further participation is unsafe for the individual. If during treatment symptoms worsen, i.e. the participant begins to experience symptoms below the knee

related to the back that are unresponsive to the current treatment, participation may be terminated.

7. **RISKS AND BENEFITS**

Describe the risks to participants (risks listed here should be included in the consent document). If risk is more than minimal, please justify.

Participants may experience muscle soreness a day or two following testing or treatment. In fact, post-treatments, short-lived soreness is a positive response and a sign of appropriate exercise intensity. Muscle strains are possible during exercise, but due to the use of body-weight only during exercises there is very little risk for injury. For those participants who receive neuromuscular electrical stimulation (NMES) to the back, there exists the potential for equipment malfunction, which could result in a skin burn. However, the equipment is highly reliable and due to the short "on" time (i.e. 10 seconds), the risk of burns is decreased. There is also a potential for minor skin irritation (i.e. skin redness) should the participant have an allergic reaction to the adhesive used in the self-adhesive electrodes. For those who receive moist heat, there is a small risk for a skin burn. However, moist heat packs are routinely used in physical therapy, and the therapist will take all precautions to decrease this risk.

What steps will be taken to minimize risks?

The therapist will ensure that the participants use appropriate form during lumbar stabilization exercises to minimize the risk of muscle strains. Exercises will be progressed in accordance with standard exercise progression rules related to post-exercise soreness. The therapist will take every precaution to ensure safety during the use of NMES, by cleansing the skin, checking the skin post-treatment, etc. The therapist will also position the unit so that the participant may push the STOP button, should at any point the NMES feel different than in previous treatments or be too much for the participant to handle. For those receiving moist heat, the risk of a skin burn will be minimized by ensuring adequate towels are placed between the heat pack and the participant's skin. The participant will be instructed to notify the therapist if the heat is too intense, so that additional towels may be added.

Describe any direct benefits to participants. Participants will receive comprehensive evaluations by a licensed physical therapist that will provide the participant with detailed information regarding their low back pain.

Evaluations and treatments will be at no cost to the participants.

Describe any future benefits to this class of participants.

The information obtained from the study will be used to guide future physical therapy treatments and assist in identifying potential predictor factors of outcomes following rehabilitation for older adult patients with chronic low back pain.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

As this is a small study, we will not establish an external Data Safety and Monitoring Board. We do have a Data Safety and Monitoring Plan. Dr. Gregory Hicks, J. Megan Sions, and Teonette Velasco will meet twice a month to discuss study progress and issues related to participant safety, subject recruitment, subject confidentiality, and data management. J. Megan Sions will be responsible for communication with other members of the research team regarding meeting discussions. The occurrence of adverse events or breaches in confidentiality will be monitored for each participant on an ongoing basis throughout the study. If an adverse event occurs, it will be reported immediately to

the University of Delaware Human Subjects Review Board.

8. **COMPENSATION**
Will participants be compensated for participation? Participants will not be compensated for participation, but we will pay for parking for the pre- and post-evaluation sessions.
If so, please include details. Not applicable

9. **DATA**
Will subjects be anonymous to the researcher? NO
If subjects are identifiable, will their identities be kept confidential? YES

How and how long will data be stored? Data will be securely stored indefinitely in the University of Delaware Physical Therapy Department for future/additional research. All data collected will be held in locked files in areas accessible only to research personnel. Data will be de-identified at the conclusion of the study to protect subject identity.

How will data be destroyed? Not applicable

How will data be analyzed and reported?
Statistical Analysis: Data will be de-identified and will be analyzed using appropriate statistical software packages. To determine if six weeks of lumbar stabilization exercises plus neuromuscular electrical stimulation (NMES) to the low back extensors is superior to lumbar stabilization exercises, we will analyze the data, preserving the randomization of participants to groups. We will test for baseline similarities in group demographics, anthropometrics (body measurements), pain-intensity, functional mobility, and low back pain-related disability to assess the success of the randomization of the participants. Data will be analyzed using statistics to assess for between group differences followed by appropriate follow-up statistical tests. The primary outcome measures in this preliminary investigation will include muscle measurements as obtained with ultrasound imaging. Secondary outcome measures will include clinical measures of physical, psychological, and social function.

Reporting: Results will be disseminated through written publications in reputable medical journals and professional presentations. Results will be part of the dissertation document of J. Megan Sions.

10. **CONFIDENTIALITY**
Will participants be audiotaped, photographed or videotaped during this study? NO

How will subject identity be protected? The risk of breaching subject confidentiality will be minimized by identifying all participants by code numbers and by securing all data in locked files accessible only to research personnel. Neither the participant's name nor any identifying information will be used in any publication or presentation resulting from this study.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy). NO

11. **CONSENT and ASSENT**
__X__ Consent forms will be used and are attached for review.
____ Additionally, child assent forms will be used and are attached.
____ Consent forms will not be used (Justify request for waiver).

12. **Other IRB Approval**
Has this protocol been submitted to any other IRBs? NO
If so, please list along with protocol title, number, and expiration date. Not applicable

13. **Supporting Documentation**

Please list all additional documents uploaded to IRBNet in support of this application.

1) Demographics Intake Sheet
2) Consent for Treatment/Past Medical History Checklist (UD PT Clinic Requirements)
3) Fear Avoidance Beliefs Questionnaire-Physical Activity Sub-Scale
4) Folstein Mini-Mental State Examination
5) Modified Oswestry Low Back Pain Questionnaire
6) Facial Pain Scale-Revised (X 3)-“current” pain, “best” pain, & “worst” pain
7) Pain Diagram
8) Short-Form 36
9) Cumulative Index Rating Scale
10) Geriatric Depression Scale
11) Short Physical Performance Battery
12) Exercise Program
13) Recruitment Flier with tabs
14) Recruitment Brochure