Study Protocol Document Cover Page

Official Title of the Study: Home-based Approaches for Subacute Low Back Pain in Active Duty: Randomized, Controlled Trial

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Home-based approaches for subacute low back pain in Active Duty: Randomized control trial

Objective

The *overall objective* of this project is to compare three home-managed treatment regimens for subacute low back pain: Progressive Exercise Plan (PEP), NMES core strength training and standard primary care management (PCM). Each of the treatment arms will be supplemented by PCM and compared to a group receiving standard PCM alone. Our central hypothesis is that the NMES core strength training alone and PEP alone will show significantly greater improvements in muscle strength, pain, mobility/function, daily activity, and quality of life (QOL) than PCM alone in military members with low back pain lasting three to twelve weeks.

Design

This study is a randomized clinical trial with repeated measures over time to compare the effects of NMES and PEP on strength, mobility, symptoms, and QOL in military members with subacute LBP to the effects of a standard primary care management. All groups will participate in the standard primary care management protocol; all groups will have an intensive 9-week program.

Participants will be randomly assigned to 1) NMES core strength training plus PCM, 2) PEP plus PCM and 3) standard primary care management (PCM). We will not randomize participants until after the pre-treatment assessment has been completed. Participants will be familiarized with the test procedures prior to baseline testing, and then assessed again at 3, 6 and 9 weeks. The primary outcome measures are lower back muscle strength, activity, and mobility; and the secondary measures are symptoms/pain and QOL.

Methods

Intervention: The rationale for the number of weeks of intervention and the number and timing of assessments is based on our previous work. NMES was found to increase strength after 36 sessions of training. We will test participants at baseline, 3-weeks, 6-weeks, and 9-weeks when all outcome measures will be tested. The intervention weekly logs to determine pain and difficulty during home exercise, NMES and TENS will be reviewed and adjusted, as necessary. We will have weekly contact with participants during the 9 weeks of the study (baseline – week 9) either by in-person clinic visits, phone checks, text messaging or email.

Standard Primary Care Management (PMC): All participants will receive standard primary care management for subacute LBP. Primary Care Management follows the clinical practice guidelines for low back pain. Service members are to stay as active as possible and progressively increase their activity. Medications prescribed begin with paracetamol and NSAIDs as first-line drugs. Second-line drugs include antidepressants, benzodiazepines, tramadol, and opioids. All participants will receive an information sheet on LBP advising then to remain active and use self-care options such as heat application. To provide an attention control, the PMC only group will receive weekly communication from the study coordinator regarding pain and medication usage.

Progressive Exercise Program (PEP): The primary goal of PEP is to reduce back pain, disability, and improve trunk flexibility, strength, and endurance through controlled, gradual, progressive back exercises. PEP teaches muscle strengthening exercises and self-management strategies to promote back

fitness. The PEP sessions provide the participant with a standardized self-management framework for performing the exercises at home. PEP is performed every other day/week for about ~1 hour over a period of 9 weeks. PEP consists of 3 sequential phases with each phase lasting 3 weeks. As the participant progresses through each phase, the exercises become progressively more difficult and intense, focusing on back stretching and strengthening that progressively load and unload the lumbar spine by means of flexion/extension exercises. During the baseline visit, participants will be provided a handout and given a demonstration of the Phase 1 exercises to be performed at home for 3 weeks. The participant will perform a return demonstration to be sure of proper form and performance of the exercises. At each return 3-week visit, the same parameters (described above) will be used to teach Phase 2 and 3. The PEP group will perform 31 exercise sessions for 60 minutes on alternating days. Pain status will be assessed at each visit.

Data collection: Variables and Their Measurement

Clinical and Demographic Variables: Information will be collected on age, sex, co-morbidities, medication use, use of assistive aids, symptom duration, history of injuries/trauma, changes in frequency, duration and intensity of training, previous surgeries, imaging studies and other self-care methods currently being used to improve pain and/or mobility. Height and weight will be measured without shoes with the head held horizontal and chin parallel to the floor while standing on a flat surface using a calibrated balance beam scale and stadiometer; they will be used to calculate body mass index (BMI: weight in kg divided by square of height in meters). Resting blood pressure (B/P) will be measured in triplicate in a seated position. The lowest of three blood pressure measurements will be recorded. Resting heart rate will be measured using the radial pulse over 1 minute's duration.

Outcome Measures: The primary measures to be studied are lower back muscle strength, physical activity, and mobility; secondary measures are symptoms of LBP and QOL.

Assessment of Torso Muscle Strength: The strength of torso flexion and extension muscles will be measured using a modified version of the U of Michigan strength test system (Workability Systems, West Chester, Ohio) and a Chattanooga-Baseline® HandDynamometer - Digital LCD Gauge - ER™ 300 lb capacity (DJO Global, Chattanooga, Vista, CA USA). For trunk flexion, the participant will stand upright in the testapparatus with buttocks against the padded board and the superior edge set at the level of the iliac crest. The participant is strapped to the apparatus by a canvas belt placed snugly around the chest and under the arms horizontal to the force-measuring dynamometer secured to the apparatus frame. For measurements of trunk extension, the participant stands upright with their lower anterior abdomen against the padded board at the iliac crest level. The belt is placed snugly around the posterior back and runs under the arms horizontal to the dynamometer.

Participants will be instructed to pull against the belt as forcefully as they can without injuring themselves and not to use their arms for support; thus, the force exerted will be by the trunk muscles. For each test, participants will perform two maximal efforts maintaining each voluntary isometric exertion for 5 seconds, separated by 30-second rest; the highest value of the two trials will be accepted in kilograms. All subjects will be given the visual analog scale (VAS) for pain to quantify pain during testing. Reproducibility of maximum exerted forces by repeat testing differed by a mean of 22% extension and 13% flexion. Intra-individual performance ratios differed by a mean of 20% for extension-to-flexion. A reasonable percent variance for strength-testing.

Assessment of Mobility and Physical Activity: Mobility will be measured by these procedures: 2-minute push-up test, 2-minute sit-up test, lumbar trunk muscle test and a 6-minute walk test. Additional physical activity measures will be the monitoring of steps walked and energy expenditure. After completing the tests, a VAS for pain will be administered to quantify pain during the effort.

The 2-minute push-up and sit-up tests will be completed in accordance with the Army APFT protocol, and are similar to that described by the ACSM. Starting in a prone position, the participant is positioned with their hands on the ground (shoulder width apart), toes in contact with the floor, spine parallel to the floor, elbows and hips in extension. The body moves as a single rigid unit and is lowered to the ground until elbows are at 90° angle. The body is then returned to the starting position by pushing the arms up to full extension. A push-up is counted if the elbows were brought to flexion of 90° or greater and then return to full extension, while keeping the body elevated on the toes. The number of push-ups performed in 2-minutes is recorded. The 2-minute sit-up test tests trunk flexion and abdominal endurance. Starting in a supine position, the knee joints are flexed at a 90° angle, with fingers behind the head, soles of the feet and shoulder blades in contact with the floor. With the command to begin, the upper body is raised forward by flexing the abdominal muscles and then lowered. A sit-up is counted if the hands are behind the head, bringing the base of the spine to a vertical position and then returning the shoulder blades to the floor. The number of repetitions performed in 2-minutes is recorded.

The Lumbar Trunk Muscle Test will assess back extension and endurance. Participants will be asked to lie in a prone position while holding the trunk in 15° of extension(sternum off the floor) for as long as they are able. A small pillow will be placed under the lower abdomen and to decrease lumbar lordosis. Participants will be asked to maintain maximum flexion of the cervical spine while contracting the gluteal muscles. The time during which the subject keeps the upper body straight and horizontal is recorded. For subjects who experience no difficulty in holding the position, the test is stopped after 300 seconds (5 minute).

The 6-Minute Walk Test (6-MWT) measures the distance a participant walks at a “fast” pace over a 6-minute period. Participants will “walk as quickly as you can” with the opportunity to stop and rest if required. This test measures functional capacity of walking. Normal reference for healthy adults on the 6-min walk distance has been published.

Physical Activity Measures: Physical activity will be measured using the Fitbit Charge 2 (San Francisco, CA). The Charge 2 is a wrist-worn three-axis accelerometer that measures steps walked, distance traveled, energy expenditure and floors climbed. The unique feature of this device is a wireless function that automatically uploads data to designated mobile phone devices or computers. Batteries are rechargeable and last 5-7 days. Fitbit products use similar accelerometry for all their products. Thus, we assume that each of their products have similar validity and reliability. In our personal experience comparing the Charge to the Jawbone and the well validated Digiwalker, we found very similar accuracy of steps. Subsequently, the device will be worn daily for 9 weeks.

Assessment of Symptoms of Low Back Pain: Pain associated with daily activity (walking, sitting, standing, bending, sport, resting, work) and body functions (pain, sleep, bending, leg weakness, loss of feeling) will be measured by the Clinical Back Pain Questionnaire (CBPS), also known as Aberdeen LBP scale, a 19-item back pain specific self-report questionnaire. Scores range from 0 to 100 with higher scores indicating greater disability.

LBP-related disability and functional limitation will be measured by the Oswestry Disability Index (ODI), a well standardized outcomes questionnaire that is LBP-specific for activities of daily living and degree of disability. The 10-section instrument assesses pain, personal hygiene, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling for those with back pain. Each section contains six statements, ranging from 0 to 5, the final score is calculated using a standard scoring method. The ODI has demonstrated reliability and construct validity in comparison to other pain and disability measures. The Visual Analog Scale (VAS) of pain will be used to assess pain at rest and after activity. Participants will complete this scale following the push-ups, sit-ups, 6-minute walk and the lumbar trunk muscle test. This VAS pain subscale is a 100-mm horizontal line index with descriptive anchors at each end. At the far left (0.0 cm) is "no pain" and at the far right (10 cm) is "worst possible pain". The participant is instructed to place a vertical line at some point between the anchors to describe his/her level of pain.

Assessment of Quality of Life (QOL): The SF-12v2 Health Survey will be used to determine each participant's overall health-related quality of life. It is a shorter version of the MOS 36-item Short Form Health Survey (SF-36) demonstrating similar reliability and maintaining the eight health domains with one or twoquestions per domain. This widely used multidimensional scale has two summary scores for physical and mental health as well as eight subscale scores. In addition, depressive symptoms will be measured by the Centers for Epidemiologic Studies Depression instrument, a self-administered questionnaire that contains 20 items.

Compliance/Adherence to Treatments: Compliance/adherence to the interventions will be measured at multiple levels. Adherence to the standard PCM protocol, PEP and NMES will be computed as the number of home sessions reported on the participant's log divided by the total number of sessions prescribed (daily). Adherence to NMES back training will be defined as the number of sessions achieved in each phase divided by the number of sessions prescribed. The Recovery Back system has a hidden internal compliance timer that records the amount of time the stimulator was used. This time will be compared to the training logs. Individual NMES reliability will be assessed from the total stimulation time recorded in the stimulator compliance monitor and by cross checking with training logs in which participants record their daily stimulation time.

Study population:

To obtain a sample size of 135 adults with subacute LBP (45 per group), we will draw upon Active Duty members and Reserve/National Guard members on active duty status through the physical therapy clinic, family practice clinic and satellite clinics at BACH. All racial, ethnic, and gender groups will be recruited for the study. Active duty members who meet eligibility criteria and agree to participate in the study will be asked to participate.

Inclusion Criteria

The study will be open to all active duty personal who are:

- Active Duty at time of diagnosis.
- LBP greater than 3 weeks and less than 12 weeks since the onset of the episode of LBP;
- age ≥18 and < 45 years; and
- ability to provide freely given informed consent.

Exclusion Criteria

Those who might be at risk of adverse outcomes from the study interventions will be excluded. This includes individuals with

- Eecurrence of LBP that is less than 3 months from prior episode;

- A significant co-morbid medical condition (such as severe hypertension, neurological disorder or pacemaker/defibrillator) in which NMES strength training or unsupervised exercise is contraindicated and would pose a safety threat or impair ability to participate;

- Previous back surgeries;

- Inability or unwillingness to participate in an exercise or strengthening program;

- Pregnancy;

- Vision impairment, where participant is classified as legally blind;

- Unwillingness to accept random assignment; or

- A score of 23 or greater on the Center for Epidemiological Studies-Depression scale (CES-D).

Statistical Methods – See Statistical Analysis Plan.