Informed Consent 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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BLANCHFIELD ARMY COMMUNITY HOSPITAL
CONSENT TO PARTICIPATE IN RESEARCH

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

Principal Investigator: Dr. Laura Talbot; Dr. Samantha Peterson

You may be eligible to take part in this research study. This form gives you important information about the study. Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about, including the risks and possible benefits to you.

Please tell these researchers if you are taking part in another research study.

You do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty. Your decision will not affect your future care at BLANCHFIELD ARMY COMMUNITY HOSPITAL.

1. KEY INFORMATION:

You are being asked to take part in this research study because you have low back pain lasting three to eighteen weeks. This is sometimes referred to as subacute low back pain. With subacute low back pain (LBP), it is important to carefully resume activity and get your back muscles working in order to speed recovery.

Your decision will not affect your future care at Blanchfield Army Community Hospital. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

The purpose of this research study is to examine the effectiveness of three specific therapies for subacute LBP over 9 weeks. The therapies are: 1) Neuromuscular Electrical Stimulation (NMES); 2) Progressive Exercise Plan (PEP); 3) Primary Care Management (PCM) for LBP. The purpose of the study is to see if these three therapies improve: 1) back muscle strength, 2) physical activity level, 3) mobility, 4) LBP symptoms/pain, and 5) quality of life.

Other studies have shown that all therapies are helpful. There has been no study to see if these therapies combined with primary care management provide a benefit for soldiers with subacute LBP. A total of 135 active duty service members are expected to take part in this study, over a period of 3 years.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". This information will be collected as a part of your initial visit.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to be in this study, you will be managed by Primary Care and receive advice/information, over-the-counter analgesics, and modified activity as per their protocol. This treatment is part of what you would have received even if you were not in this study. This is called standard of care. There are some questionnaires, performance tests and back muscle strength testing that will be in addition to your standard of care as part of these appointments. You have a chance of being in one of three different treatment packages which are 9 weeks long. Each treatment package will be evaluated to see if the treatment increases back muscle strength, improves your physical performance and decreases back pain and symptoms.

All participants will be asked to come to the LaPointe clinic per protocol as part of your usual care. During the baseline screening week and weeks 3, 6, and 9, we will measure your back muscle strength and pain level. The initial visit will take about 105 minutes plus an additional 20 minutes if assigned to the NMES or PEP group. Most of these visits will be scheduled, to the best of our ability, with your regular primary care visits but this study will require you to come up to 4 extra times to the LaPointe clinic. The visits for week 3, 6, and 9 will take approximately 70 minutes. Your total time commitment for the study visits is about 5 hours 20 minutes, spaced over a 9-week period with 4 study visits.

The total time commitment for the home treatment will be an additional 31 hours or 30 minutes per day over 9 weeks.

You will also receive a weekly contact for the 9 weeks of the study. This contact will be in the form of a telephone call, text message, or email depending on your preference and on the type or amount of information to be shared. The follow-up calls or texts will ask about how well you are following the program and any safety issues. You will also be asked to rate your back pain. The telephone call or text will end with a reminder of follow-up visits**.** The contact will typically last less than 5 minutes. Total telephonic contact time for the study is expected to be no greater than 45 minutes (5 minutes each week X 9 weeks).

If you agree to be in this study, you will be asked to read and sign this consent form. At the screening visit (week 0), we will verify that you meet the study conditions. The conditions are a diagnosis of low back pain lasting 3 to 18 weeks since the onset of the LBP episode, active duty military at the time of injury, age range of ≥18 to <45 years upon entry into the study and freely give your informed consent. During the screening visit, we will measure your height, weight, and your amount of body fat (body mass index (BMI)). We will also measure your blood pressure and heart rate. We will measure your abdominal fat by using a tape measure and calipers (an instrument consisting of two curved hinged legs, used to measure thickness). We will repeat these measures at weeks 3, 6 and 9.

The screening visit (week 0) testing will take about 105 minutes (1 hour, 45 minutes). During this visit you will also be asked to complete some questionnaires. The questionnaires ask you about your general well-being, current pain level, and mood. You may skip any questions that you do not want to answer. These questionnaires will take about 20 minutes to complete. If any scores are outside our expected range, we will notify your primary care provider.

After completing all initial tests, you will be randomly assigned (similar to the flip of a coin) to one of three groups. The three groups are: 1) NMES with Primary Care Management, 2) PEP with Primary Care Management, and 3) Primary Care Management alone. Your chances of being assigned to any treatment group are equal. If you are assigned to the NMES with primary care management you will receive a battery powered portable Recovery Back□ system with the abdominal and back garments for your home use over the course of this study. If you are assigned to PEP with primary care management, you will receive instructions on progressive exercises for LBP. All participants receive Primary Care Management which includes exercise instruction from their provider or physical therapist. The alternative will be the military Rx3 website link (https://www.hprc-online.org/page/physical-fitness/rx3-rehab-

refit-return-to-duty). All participants will receive a Fitbit Charge 2 to monitor your activity throughout the day.

After the screening visit, you will be asked to come in for follow-up visits at weeks 3, 6, and 9 for testing. During the follow-up visits, all groups will have their back strength tested. If you are assigned to the NMES group, you will be trained to use NMES device and two garments at home. You will alternate using the abdominal NMES garment and the back NMES garment every other day for 30 minutes a day, 7 days a week for 9 weeks (one day Back training, next day Abdominal training). If you are assigned to the PEP group, you will be trained to perform progressive strengthening exercises at home every other day/week for 1 hour for 9 weeks. This training will be an *additional* 20 minutes of home instructions if assigned to the NMES or PEP group. The table below gives an overview on the estimated time for each of the study visits.

Measurement with Time Requirements at Each Visit							
Variable	***Instrument***	***Estimate time***	***Entry***	***Daily***	***3***	***6***	***9***
	Inclusion/Exclusion Criteria	10	X				
	Consent Form	20	X				
Muscle Strength	Back strength during flexion and extension (Nm)	10	X		X	X	X
Physical Activity	Steps walked	–	X	X	X	X	X
	Energy (kcal) expenditure	–	X	X	X	X	X
Mobility	Push-ups (2-minutes)	5	X		X	X	X
	Sit-ups (2-minutes)	5	X		X	X	X
	Lumbar trunk muscle test	5	X		X	X	X
	6-minute timed walk	10	X		X	X	X
Symptoms of LBP	Oswestry Disability Index (ODI)	5	X		X	X	X
	Visual Analog Scale	5	X		X	X	X
	Clinical Back Pain Questionnaire	5	X		X	X	X
Quality of Life	CES-D, SF-12v2 Health Survey	5	X		X	X	X
Clinical Factors	Clinical demographic form	5	X				
Body Composition	Height, weight (BMI), BP, HR, Abdominal Skinfold, Waist circumference	15	X		X	X	X
Adherence	NMES Groups log	5		X			
	PEP Groups log	5		X			
Weekly Totals (minutes)			**105**	**5**	**70**	**70**	**70**
Study Visit Total			**320 minutes**				

The Recovery Back□ system with the abdominal and back garments used for NMES is a small device about the size of a credit card. The NMES group will use abdominal and back garments that have electrodes inside the garment that will be placed on your back/abdomen. A small electrical charge will come from the device through the electrodes which will cause your muscles to contract. The machine is adjustable so that it can cause your muscle to contract in different amounts. You will start at a very low level and progress up slowly over weeks as adjusted by the researcher on this study. The stimulation from the device is not painful. This device has been used in other studies and has been found to help with pain. There may be an odd sensation as your muscle contracts as a result of the machine, but this contraction is not caused by you. In other words, the muscle will contract involuntarily.

You will be given a complete description of how to apply and use this piece of equipment and associated garments when it is given to you. For the Recovery Back□ system, you will be asked to apply and use these devices on your own at home and record this use in a log book. The garment electrodes are re-useable, so they can be used numerous times.

You may experience some discomfort removing the electrodes initially if it sticks to the hair on your torso. However, since the electrodes will be placed in the same spot each time, this discomfort will get less with repeated use. You may also have some skin discomfort with use of the adhesive electrode pads. The position of the electrodes can be moved slightly if this is a problem. This will be explained in detail when you are given a demonstration of the device.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are possible risks from being in this research study. These include: The calipers used to assess abdominal fat may bruise sensitive skin. For the physical performance tests, there is a risk that you may fall during the testing; however, most of the tests are self-paced and are no more risk than daily activities. Finally, you may experience muscle soreness from the strength tests. However, this is only short-term and should disappear within 30 minutes after testing is done. For those in the NMES treatment group, there is a small risk that the electrical muscle stimulation might produce some discomfort with muscle contractions. The skin pads for NMES garments may cause a reddened area on sensitive skin. If the pads become dry, there is a risk of a burn. For the PEP treatment group, post-exercise discomfort such as fatigue, muscle soreness and muscle stiffness may occur with changes in physical activity. There is also a possibility of falling.

A limited amount of study information will be entered into your medical record and this information become part of your medical record. This information could be used for evaluations of military fitness for duty, medical evaluation

boards, and other personnel actions. The information is limited to this consent form with a note stating you are taking part in a research study, the name of the study, group assignment and some interventions performed. This consent form outlines the study assessments, procedures and interventions based on group assignments. At every study visit the study staff will document that you came to the study visit, completed study assessments, and the study intervention was reinforced (based on group assignment).

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

PREGNANCY PRECAUTIONS: It is not known whether neuromuscular electrical stimulation (NMES) can cause birth defects or other problems in an unborn child. If you are pregnant, you cannot take part in this study. Women of childbearing age must take a urine pregnancy test before enrolling if it has been greater than 7 days since your missed period. If the test is positive, you cannot take part in this study. Pregnancy during the time you are receiving neuromuscular electrical stimulation may be a risk to an unborn baby. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy. Detailed testing using the Recovery Back® device has not been done on pregnant women. The maker states that "Safety of NMES for use during pregnancy has not been established." If you are a woman and are in the NMES treatment group, we will take a menstrual history at every visit and perform a urine test to check for pregnancy if you are more than 7 days late. If the test is negative, we will repeat the test if the woman does not start menstruating by the next visit. If the test is positive, the woman will be ineligible to continue in the study if in the NMES groups. If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

There may also be other risks of taking part in this study that we do not yet know about.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military and their dependents), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at Army hospitals or clinics. If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to medical care for your injury at an Army hospital or clinic. Medical care charges will be waived. It cannot be determined in advance which Army hospital or clinic will provide care. If you obtain care for

research-related injuries outside of an Army hospital or clinic, you or your insurance will be responsible for medical expenses.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

The benefits of this study are unknown; however, other studies not involving low back pain with activities have shown NMES and exercise improves muscle strength, function, and back pain. The information we attain may help us learn about strengthening core muscles and pain relief in people with subacute LBP. Still there may be no direct benefit for you participating in this study.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Alternative treatments which could be considered in your case include primary care management alone, physical therapy or a combination of both, as determined by your physician. Your doctor can provide detailed information about the various treatments available to you based on your current medical condition. Not participating in this study is the alternative to participating in this study.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

You will not be paid for your participation in this study. When you complete the study, you may keep the Fitbit Charge 2 activity monitor. If the Fitbit is lost or broken, we will provide a replacement. Once enrolled in the study if you are unable to complete the 9 weeks, you may keep the Fitbit.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Col. (ret) Laura Talbot, RN, PhD is the Overall Principal Investigator of this study and Dr Samantha Peterson, DPT is the On-Site Principal Investigator.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Dr. Laura Talbot at the University of Tennessee Health Science Center at Memphis.

12. SOURCE OF FUNDING:

This study is funded by the TRISERVICE NURSING RESEARCH PROGRAM.

13. LOCATION OF THE RESEARCH:

Blanchfield Army Community Hospital at Fort Campbell, Ky.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement – Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. Procedures to protect the confidentiality of the data in this study include but are not limited to:

The principal investigator will keep your research records. These records may be looked at by staff from the Blanchfield Army Community Hospital, the Regional Health Command-Atlantic (RHC-A) IRB, and the DoD Higher Level Review as part of their duties, University of Tennessee Health Science Center at Memphis, Uniformed Services University Institutional Review Board, Triservice Nursing Research Program (who is funding this study), and other government agencies as part of their normal duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. All records will be kept in a confidential form.

As described in section 5 above, this consent form will be placed, and progress notes will be written in your medical record indicating that you are taking part in a research study, the name of the study, group assignment, and some interventions performed. This consent form outlines the study assessments, procedures and interventions based on group assignments. At every study visit the study staff will document that you came to the study visit, completed study assessments, and the study intervention was reinforced (based on group

assignment). If you agree to participant in this study the limited information described above will be entered into your medical record and this information will become a permanent part of that record. This information could be used for evaluations of military fitness for duty, medical evaluation boards, and other personnel actions.

Please initial the sentences that reflects your choice:

____ I agree to have this limited amount of study related information entered into my medical record.

____ I do not agree to have this study related information entered into my medical record (You will not be able to participate in this study).

Otherwise, only the researchers conducting this study will have access to the records from this study. Your study data from the measurements described in the table above will *not* be placed in the medical records.

Information gained from this study may be used as part of a scientific publication, but you will in no way be personally identified. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study. If you do not complete the full 9 weeks of the study, researchers may still use the information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

A description of this clinical trial will be available on
http://www.ClinicalTrials.gov
as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data. Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. You have a number of options with regard to this request. Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data. The data will be de-identified and reported in aggregate.

17. USE OF INFORMATION AND SPECIMENS

The information that we obtain from you for this study might be used for future studies. We will remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. Specimens are not a part of this study.

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

You do not have an option to decline receiving information about an incidental finding.
A qualified person (usually a member of the research team) will talk to you if there is an incidental finding.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

19. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the principal investigator and return the Recovery Back□ system. If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. CONTACT INFORMATION:

Principal Investigator: Dr. Laura Talbot
Phone: 901-448-3630
Mailing Address:
University of Tennessee Health Science Center
Department of Neurology, College of Medicine
855 Monroe Ave., room 415
Memphis, TN 38163

ltalbot@uthsc.edu

BACH Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Nancy Dallas
Phone: (270) 956-0204

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

(706) 787-8053 or (910) 907-8351
usarmy.belvoir.medcom-rhc-a.mbx.irb-office@mail.mil

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

Please initial the sentences that reflect your choices, and then sign below:

_____ I do not authorize the storage of data collected as a part of this study for future use in research studies.

_____ I authorize the storage of data collected as a part of this study for future use in research studies.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date