MADIGAN ARMY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

PRINCIPAL INVESTIGATOR: **German Grinshpun, DO,**
german.grinshpun.civ@health.mil, 253-968-5968

KEY INFORMATION FOR PROTOCOL: Investigating Medical Massage Therapy for Patients with Sub-Acute Lower Back Pain

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

The purpose of this study is to compare medical massage therapy and routine clinical care treatments for the management of low back pain. By doing this study, we hope to learn about medical massage therapy as a modality for the treatment of subacute low back pain and its effects on pain, prescription medication utilization, and medical restricted duty days.

If you choose to take part in this study, procedures will include completing questionnaires and being randomly assigned to receive treatment in one of two study groups: either (1) provider directed care only, or (2) provider directed care and medical massage therapy and education. Your participation in this research will last about 16 weeks.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

The possible benefits to you as a research participant in this research study are reduced pain, decreased utilization of prescription medications, and shorter duration of medical restricted duty days. However, there is no guarantee that you will benefit from being in this research.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

While massage therapy is considered to be safe and is well-regarded, there is a chance that you may experience discomfort, muscle/joint injury, soreness, muscle stiffness, bruising, fatigue, blood pressure fluctuations, temporary headaches, dizziness, nerve irritation, pain, inflammation, or worsening of pre-existing injuries.

All available measures to minimize risks from massage therapy will be taken in accordance with standard protocols, including utilization of properly licensed, trained, and certified therapists.

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.

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

There may be other options for treating your low back pain. You should talk with your personal physician (if applicable) about these options.

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.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have at Madigan Army Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Dr. German Grinshpun. If you have questions, suggestions or concerns about the study, his contact information is: 253-968-5968, and mailing address: 9040 Jackson Avenue, Tacoma, WA 98431.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the MAMC IRB Office at: 253-968-3524, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research 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 in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

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

You are being asked to take part in this research study because you are an active-duty service member, between the ages of 18-64 (inclusive), and you are experiencing subacute low back pain. The purpose of this research study is to learn about medical massage therapy for the treatment of low back pain. The duration of participation per visit will vary depending on which study group you are randomized to; however, the average visit can be expected to last approximately one hour.

There will be up to 220 people taking part in the study at Madigan, over a period of 1 year.

At the end of this research study the clinical results, including research results about you will be shared with you, at your request

2. 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 may have been collected as a part of your regular medical care.

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

If you agree to participate in this research and once you have read and signed this consent form and all of your questions have been answered you will be asked to complete the following study procedures:

Initial Baseline Visit for All Subjects (approximately 60 minutes):
You will be asked to complete three questionnaires to collect your contact information, demographics, and self-reported measures of your low back function and pain. Then you will be randomly assigned to one of two study groups:

(1) Provider directed care only

OR

(2) Provider directed care plus medical massage therapy.

Randomization is a process like flipping a coin and means you will have an equal chance (50/50) of being assigned to either of the two groups.

Study Subjects in both groups are asked to refrain from any invasive interventions such as spine injections, dry needling, acupuncture, cupping, and trigger point injections for the duration of your participation in the study. If you receive any

invasive treatment while you are participating in the study, please let the study team know so it can be documented.

Study Treatment:

Provider Directed Care Only Group (approximately 30 minutes):
If you are randomized to this group, the routine clinical care treatment modalities you will receive to address your low back pain will be at the discretion of your regular healthcare provider and may vary in type and length of time to complete.

Provider Directed Care Plus Medical Massage Therapy Group (approximately 90 minutes):
In addition to the routine clinical care treatment modalities, you will receive to address your low back pain, at the discretion of your regular healthcare provider (which may vary in type and length of time to complete), you will also receive weekly medical massage therapy and education sessions in your home (approximately 60 minutes).

The study team will provide your name and contact information to Zeel, a company serving as the service provider that will be facilitating the massages and education sessions provided in this study. Zeel is a technology-enabled health and wellness platform that allows patients to schedule massages through an expansive nationwide network of 12,000 health and wellness providers.

Zeel will contact you to schedule your combined massage and education sessions. Additionally, before you receive the medical massage therapy and education sessions, Zeel Support will contact you via email to ask you to review their standard notice of privacy practice and sign a consent for treatment from Zeel via Docusign.

You will receive the massage and education sessions in your home once a week for 12 weeks (or, up to 16 weeks to accommodate temporary changes in your schedule or location). Your massage therapy and education sessions will be administered by a licensed massage therapist who has been trained in medical massage therapy in schools accredited by the Commission on Massage Therapy Accreditation.

You will be asked to have a 6’ x 10’ space cleared in your home to allow for the massage table to be set up. The medical massage therapist will bring all equipment required, such as the massage table, bolsters, and hypoallergenic lotion. During the first visit, the medical massage therapist will ask questions to better understand your health profile, will explain the treatment process and complete your medical massage therapy treatment plan.

During the medical massage treatment, you will remain clothed. You will be asked to wear loose-fitting clothing that allows for access to the treatment area and enables a full range of motion. If clinically appropriate, the medical massage therapist may ask your permission to access areas underneath clothing – including shoulders, lower

back, and thighs – as part of the pain management protocol. The massage therapist will tailor treatment and education based on your individual needs. There will be 5-10 minutes of targeted education during the massage session. The topics for education and content that will be shared include the following: anatomy and physiology, breathing and relaxation techniques, hydration, posture, passive stretching, active mobility, core stability exercises, and ergonomic adjustments.

Follow-Up Data Collection (approximately 60 minutes):
Regardless of which study group you are randomized to you will be asked to complete weekly self-report assessments of your low back function and pain for 16 weeks. These assessments may be completed either in-person or remotely from any location using a personalized survey link that the study team will email to you. The study team will give you reminder phone calls, texts, and/or emails using your preferred contact method. In-person follow-up visits will be requested and scheduled if you miss any appointments to help keep you on track with the study protocol.

Your study participation will end after you have completed the 16-week follow-up visit.

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

There may be other options for treating your low back pain. Alternative treatments and/or procedures that may be available to you include spine injections, dry needling, acupuncture, cupping, trigger point injections or other treatments available as care as directed by your medical provider. You should talk with your personal physician (if applicable) about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

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

No, you will not receive any compensation for participating in this study.

6. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

German Grinshpun, DO
Interdisciplinary Pain Management Center (IPMC)
Madigan Army Medical Center

9040 Jackson Ave
Tacoma, WA 98431
(253) 968-5968
german.grinshpun.civ@health.mil

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

   Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your de-identified research data.

   As the sponsor of this research, the Department of Defense (DoD) may have access to your research data in accordance with DoDI 3216.02.

9. **SOURCE OF FUNDING:** Research funding is provided from the DoD Defense Health Agency (DHA) through USU.

10. **LOCATION OF THE RESEARCH:** Interdisciplinary Pain Management Center (IPMC), Madigan Army Medical Center

11. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**:

    Zeel is a for-profit company facilitating the medical massages delivered in this study. Zeel is engaged as the service provider, and while they will not be in charge of participant selection, nor data analyses, they do have a vested interest in the outcomes of this study to understand if massage therapy can assist with preventing the progression of subacute low back pain.

12. **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.

    The research team will keep your research records. These records may be looked at by staff from the Madigan Human Research Protection Office, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their 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.
Procedures to protect the confidentiality of the data in this study include but are not limited to:

- Your research data will be identified only by a unique coded study ID and not by your name, DoD ID, or other protected identifier. Only the research staff will have access to the file which links your identifiable personal information with the study ID number. This file will be password protected and stored on a server which requires CAC access and is only accessible by the research staff and will never be printed.

- All paper research records will be stored in a locked cabinet inside of a locked room accessible only by authorized staff. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by USU in Bethesda, MD. No identifiable information will be entered into REDCap.

- Once your coded data is entered in REDCap, it will only be accessible by authorized study team members and oversight officials, MAMC IRB, and authorized staff from MIRROR, which is based out of the Department of Physical Medicine & Rehabilitation at USU and is serving as the data coordinating center for this study. MIRROR/USU will not have access to your identifiable information.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

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

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.

The local study team will keep this signed consent form for six (6) years following study closure, and your coded research forms will be kept for five (5) years following study closure. The master list which connects your identity with your unique study code will be permanently deleted by the local study team at study closure. The PI will ensure adherence to the records destruction schedule.

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

Information gained from your participation in this research study may 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

13. USE OF INFORMATION

The investigators have requested to save selected data collected from your participation in this research study for possible use in future research. 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. This future research may be in the same area as the original study or it may be for a different kind of study.

If you consent to participate in this study, your de-identified data, meaning that all of your personal identifiers have been removed, that was collected as part of this research may be kept for future research or given to others for future approved research studies.

****If you would NOT like your de-identified data collected as part of this research to be kept for possible future research, you should not consent to participate in this research study.****

Your de-identified research data will be securely sent to MIRROR and stored at USU alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

Any future research using your retained data will require a research protocol for the proposed study reviewed and approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or an Exempt Determination Official (EDO). The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

14. 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.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email using the contact information provided in this document. If you decide to no longer participate in this research study, the researchers may keep and analyze all data that was collected during your participation in this study. However, no additional data will be collected after the time of your withdrawal.

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.
The principal investigator of this research study may terminate your participation in this research study at any time if they determine 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.

16. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: German Grinshpun, DO
Phone: 253-968-5968
Mailing Address: Madigan Army Medical Center
Interdisciplinary Pain Management Center (IPMC)
9040 Jackson Ave
Tacoma, WA 98431

Madigan Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office staff and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study. Please contact the Madigan HRPP Office at: 253-968-0149, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

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.

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

IRB NUMBER: 226029
IRB APPROVAL DATE: 02/05/2026