Brooke Army Medical Center
CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator: MAJ Bryan Pickens, PT, DPT, DSc

Protocol Title: SMART Stepped Care Management for Low Back Pain in the Military Health System

Key Information: This section provides a one-page summary of the information outlined in this consent form. More information will be provided to you on the pages that follow.

Voluntary Participation	You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study.
Purpose	The purpose of this study is to explore and compare a variety of current treatment practices for chronic low back pain and what value they add based on how and when they are delivered.
Duration	You will be in the study for up to 1 year.
Procedures	While you are in the study, you will be assigned to attend several appointments that may include physical therapy, a mindfulness training program, and/or a holistic self-management program. You will also be asked to follow up with the research team either in person, electronically and/or by phone at approximately 8 weeks, 18 weeks (4 months), 26 weeks (6 months), and 1 year from your initial enrollment. The follow-ups will allow us to understand how your symptoms and quality of life change over time.
Why might you want to participate in this research (benefits)?	There is no guarantee you will receive any benefit from being in this study other than knowing the information may help future patients. The information we gather from this study may help us better manage patients with low back pain in the future. The treatment provided may also help you manage your symptoms.
Why might you choose not to participate in this research (risks)?	The **main** risks from being in this study are: • Possibly experiencing some increased pain or muscle soreness from exercising. Though unlikely, it is always possible someone could gain access to your personal information in documents stored by the researcher team. • Some of the questions asked may make you uncomfortable.
What are the alternatives to participating?	Alternative treatments and/or procedures that may be available to you include: self-management strategies and seeing other medical providers. You can talk with your primary care provider about these options. Choosing not to take part in this research study is also an option.
Payment	You will not be paid for your participation in this study.

1. PROTOCOL TITLE: SMART Stepped Care Management for Low Back Pain in the Military Health System

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 Brooke Army Medical Center or any other medical clinic where you are already authorized to receive care.

2. 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 seeking care for your back pain. The purpose of this study is to learn about different combinations of treatment strategies for chronic back pain that are not based on medication. Your participation in the study may last up to one year.

There will be about 1200 people taking part in this study overall.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, we need to confirm that you qualify for the study. Some of the information needed may be collected from your medical record. We may also conduct an additional exam and ask you questions about your medical history and current health.

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

If eligible to participate in the study, you will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a 50% chance of being assigned to either of the two groups.

Both groups involve components of care that you could be receiving from medical providers even if you didn't participate in the study. We are looking at how they might compare to each other and how effective they can be in the long term. These options include being seen by a physical therapist to determine your plan of care, seeing a health coach that will help guide you through a program designed by Army Medicine to deliver holistic care (which means focusing on other components that influence your health, such as sleep, nutrition and physical activity), or a program focused on mindfulness (this includes mental exercises and activities to improve your awareness, understanding, and coping with pain and associated discomforts).

This study has two phases. The initial phase will last about 6 weeks, with as many as 3 visits per week and as few as 1 visit every 2-3 weeks. Appointment frequency will vary based on your treatment plan, and will be determined by the medical provider that is managing your care. If it is determined that an additional treatment approach is necessary, you will be randomized a second time to one of two different groups. The second phase could last another 8 weeks (from 3 visits per week to 1 visit every 2-3 weeks). We will ask you to adhere to the schedule we provided you. Not everyone will receive the same treatment.

You will also be asked to follow up with the research team at approximately 8 weeks, 18 weeks (4 months), 26 weeks (6 months), and 1 year from your initial enrollment. Follow-ups can be conducted in person, electronically via a data collection web service, or by regular mail. We will email, mail, or text a link to access the surveys that need to be filled out. We estimate it will take approximately 5 to 20 minutes to fill out the surveys. Some of this data might already be available to the research if you filled it out for other reasons (in other clinics). If we are able to access it, then we will not have you fill it out again. To ensure your follow up is complete in a timely manner we will send reminder notices over mail, email, phone, and or text message, whichever you prefer. These follow-ups will allow us to understand how your symptoms and quality of life change over time.

We will also review your medical records so that we can evaluate the care you have had for your back pain (for example, information about your prescriptions for pain medications, visits to other providers, number and types of X-rays and MRIs, etc.). This will help us understand how different treatment decisions might be influencing your progress. We will review medical records in the year leading up to enrollment and the year you are enrolled in the study. Medical care will be automatically collected by the investigators from the TRICARE medical database that tracks and stores health care for beneficiaries. This will include all care in the TRICARE Network. If you are on active duty, we will also pull the number of limited duty days related to your back pain during the one year before and the one year follow-up periods.

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

If you choose to take part in this study: the risks for this study are minimal.

Although efforts are made to protect your research study records, there is always a risk that someone could access the personal information in your records stored by the research team.

All of the treatments that are being evaluated as part of this study are used already in standard clinical care, meaning you could receive any of them even if you were not a participating in this study. Medical providers use these treatments and others based on their personal preference for what they think might be most appropriate. Due to randomization, you may or may not receive the same treatment plan that you might have received if you were not in the study. You will always be able to discuss your individual situation with either your physical therapist or your primary care provider at any time during the study and can always opt for a different treatment after discussing it with your primary care provider.

Some of the questions asked may make you uncomfortable. You can choose to skip or not answer any questions.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a participant in this research study are that you may receive relief and experience improvement in your back symptoms. However, there is no guarantee that you will get better or benefit from being in this research. The researchers hope the information learned may help providers better manage patients with low back pain in the future.

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

There may be other options for treatment. Alternative treatments and/or procedures that may be available to you include: self-management strategies and seeing other medical providers. You should talk with your personal primary care provider (if applicable) about these options. Choosing not to take part in this research study is also an option.

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

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

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

10. WHO IS CONDUCTING THIS RESEARCH?

The Center for the Intrepid, Department of Rehabilitation Medicine, Brooke Army Medical Center, in collaboration with the University of Utah, is conducting this clinical trial with funding and oversight by the National Institutes of Health (NIH).

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

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

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 online 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 of the Brooke Army Medical Center (BAMC), members of the Institutional Review Board (IRB) (a committee responsible for protecting research participants), members of the research team at the University of Utah who are helping with the research study, the National Institutes of Health (NIH) (the sponsor of the study) 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: All paper copies of study files will be stored in a locked cabinet in a locked room. The consent form that identifies you by name will be stored in a locked cabinet. All research materials will be

coded with a unique identifier (not your DoD ID) to protect your identity. The data file linking your name and code number will be accessible only to the researchers that work within DoD, and your data will be entered into a computer file by this code number. If your data is used in scholarly presentations or journal articles, the investigators will protect your anonymity by reporting only aggregate data (e.g. group means) where appropriate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov . This web site will not include information that can identify you. At most, the web site will include a brief 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 never 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.

With the exception of the dates on which you provide research data (to include any adverse events), study investigators outside of DoD (NIH and the University of Utah) will only have access to your de-identified data. This means they can receive research data, but nothing at all that is linked to private information. Members of the research team within the DoD will have access to your de-identified data.

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

In some cases, we will use 3rd party services to communicate by text message and/or email with you (for example, to send surveys or communication). This means that we may have to enter your name, email address, and phone number into 3rd party platforms. Your information will only be placed within accounts that belong to the research team and that only the research team has authorized access to; however, it will be kept in the storage maintained by the 3rd party service and subject to their security policies. This information will never include other personal health or private information. You can always opt out in the future if you change your mind by notifying the Principal Investigator.

13. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify the Principal Investigator. The contact information is included below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available 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 DoD hospitals or DoD clinics.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

14. 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 in writing. Your condition will continue to be treated in accordance with acceptable standards of medical treatment. You may be asked if you wish to provide further data collection from routine medical care. The data collected prior to your withdrawal, and the healthcare utilization data from medical records, will still remain part of the study database and will not be removed, unless you also ask for it to be removed.

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 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 he 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.

15. 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: MAJ Bryan Pickens
Phone: 210-808-2247
Mailing Address:
Jennifer Moreno Clinic
Garden Avenue #1179
JBSA Fort Sam Houston 78234

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:

Mailing Address:
RHC-C IRB Office, Brooke Army Medical Center
ATTN: MCHE-ZQ, Department of Quality and Safety
3551 Roger Brooke Drive
Fort Sam Houston, Texas 78234-6315
Phone: 210-916-2598

16. LONG TERM USE OF DATA

Once information that personally identifies you is removed from your data, then your data may be used for future research studies or given to other researchers for future research studies without your permission to do so. Any future research using your retained de-identified data that is not related to this initial study will still require ethics approval by the Institutional Review Board before it is used. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

SIGNATURE OF PARTICIPANT

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.

_____

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