Clinical Trial Informed Consent Form Posting Required for MOTIVATE to Improve Outcomes for Older Veterans with Musculoskeletal Pain and Depression (IIR 20-256)

NCT#: NCT05220202

IRB last approval: August 3, 2026

INFORMATION SHEET FOR MOTIVATE to Improve Outcomes for Older Veterans with Musculoskeletal Pain and Depression-IIR *VAIRSS #* 1672072

You are being asked to participate in a research study conducted by VA North Texas Health Care System in Dallas and the Michael E. DeBakey VAMC in Houston because you are a Veteran who is older than 60 years of age with musculoskeletal (MSK) pain and depressive symptoms. We are conducting the study to evaluate an intervention (MOTIVATE) to improve physical activity and outcomes in older Veterans with MSK pain and depression. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?
The overall goals of this study are to 1) examine the effectiveness of clinical and behavioral outcomes of MOTIVATE compared to a waitlist control; 2) explore implementation processes for the MOTIVATE intervention, and 3) evaluate preliminary intervention costs to the VA.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?
If you agree to participate, you will be randomly assigned (such as flipping a coin) to the intervention (MOTIVATE) group or a 'waitlist control' group that must wait ~ 6 months to receive the intervention. For participants assigned to the waitlist control, you will not receive the intervention now, but if you are interested, could receive the intervention once you have completed assessments as part of the control group.

For participants assigned to the MOTIVATE intervention arm, trained health coaches will deliver the intervention sessions over the telephone. These weekly phone calls should last 45-60 minutes at a time that is convenient for you. You will also be asked to practice some skills and track your progress during the time in between telephone calls. During this study we will encourage you to increase physical activity by walking and tracking steps (using a pedometer that we send to your home). The health coach or research team may call you in between sessions to remind you of upcoming appointments.

All participants are encouraged to continue with their current musculoskeletal pain and depression treatment plans as recommended by their usual health care providers. You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

All participants, regardless of what group they have been assigned to will be contacted for four outcome assessments (baseline, mid-point, end intervention, 6-months) conducted by a research team member. Each telephone outcome assessment takes approximately 60 minutes to complete. During the second phase of the study, the research team will conduct in-depth interviews with a selected group of participants who were assigned to the MOTIVATE group in efforts to understand what was helpful, what could be improved, and how we can modify our program and protocols to be most helpful to Veterans like you. The audio recordings from these interviews

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will be analyzed at UT Southwestern Medical Center. The audiorecordings of the coaching sessions as well as the in-depth interviews will be stored securely.
The purpose of audiorecording the intervention sessions are to make sure we are delivering the intervention to you as we intended to (fidelity). The interviews will be audiorecorded to be sure we accurately capture the information you provide to us. These audiorecordings will remain confidential and we will remove your personal identifiers as we analyze the data.

ARE THERE ANY RISKS OR DISCOMFORTS?
There are minimal risks related to participating in this study. There is a small potential for loss of confidentiality. To minimize this risk, the information you provide will only be shared with members of the research team. Our research team has extensive training and experience on how to handle data securely, consistent with VA policies and procedures. No reports or publications from the study will use your name or any other information you provide. Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The health coaches encourage mild/ moderate physical activity during MOTIVATE. There is minimal risk of physical injury due to falls as you become more active. However, the health coach will focus on safely increasing walking and fall prevention strategies. The amount of activity we are asking you to do is considered standard of practice and not strenuous activity that could result in injury. Other possible risks are loss of time, participant burden and resulting fatigue. Discussing pain or depression may result in further psychological distress. You may decline to answer any of the questions, take a break, or stop your participation at any time. Participation in this study is voluntary and deciding not to take part will not affect the health care you receive. There is no economic or legal risk in this study.

In the unlikely event that you are injured as a result of taking part in this study, the VA (not you or your insurance) will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures. This program is not asking participants to do anything beyond what is considered standard of care.

ARE THERE ANY BENEFITS?
Your participation may benefit others in the future by contributing to the researchers understanding that will improve the intervention and process of delivering the intervention. Your participation in the health coaching sessions may personally help you.

WHO WILL SEE MY INFORMATION?
The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Institutional Review Board, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?
You will receive $20 vouchers for completing each of the 4 assessments for a total of potentially $80 if you complete all assessments of the study. If you are selected to take part in the in-depth

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interview about your impressions of the program, you will receive an additional $20.

WHO CAN I TALK TO ABOUT THE STUDY?
In the event of a research related injury or if you have any questions, comments, or concerns about the research, please contact [redacted] at the VA North Texas Health Care System.

If you have any questions about whether this is a VA North Texas Healthcare System approved research study, you may contact the [redacted].

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Script for telephone screening once patient receives the Opt-Out letter (within 5 days):

Voicemail script:

Good morning/ afternoon, this is a message for Mr/Ms. [--]. My name is [your name] calling from the Dallas/Houston VA. I wanted to follow-up with you about the MOTIVATE program we sent you a letter about. Please give us a call at your convenience: [redacted] Thank you.

If you reach a person:

Hello, is Mr/s. [name of patient] available?

[If patient is unavailable] OK, may I leave a message for them to return my call? I'm calling from the Dallas/Houston VA about a research study they may be interested in.

[If speaking to correct patient] This is [your name] from the Dallas/Houston VA calling to follow up to see if you received a letter that we mailed you about the MOTIVATE program- focused on older Veterans with pain and depression?

[If no, they did not receive]: I can tell you more information about the program now, if this is a good time. I can also re-send the letter to you.

[If now is not a good time, but they would like to receive more information another time, find out when a good time to call them back will be and make a note of this in the tracking document].

[If yes, they did receive]: Would now be a good time for me to tell you more about the program and answer any questions that you might have? I'd like to briefly explain the study and why you are being asked to participate.

[If patient says no, they are not interested in hearing more about the program]: May I ask you the reason why you are not interested? I'd be happy to answer any questions that you might have?

[If patient still remains uninterested despite further information]: Ok, thank you very much for your time. Have a nice day.

[If patient is interested in hearing more about the program]:

Verbal Consent Script:

We are conducting a research study with Veterans who are at least 60 years of age with musculoskeletal pain and depression. We are interested in evaluating an intervention (MOTIVATE) to improve physical activity and outcomes in older Veterans with MSK pain and depression. This program, consisting of 8 sessions spread out over 12-20 weeks, is completely remote; you will not need to come into the VA for additional visits.

Your participation in this research study is voluntary.

If you agree to participate, you will be randomly assigned (such as flipping a coin) to either the intervention (MOTIVATE) group or the waitlist control group. For participants assigned to the waitlist control group, this means that you will not receive the intervention now, but if you are interested, could receive the intervention once you have completed all outcomes assessments.

For participants assigned to the MOTIVATE group, trained health coaches will deliver the intervention sessions over the telephone. These weekly phone calls should last 45-60 minutes at a time that is

convenient for you. You will also be asked to practice some skills and track your progress during the time in between telephone calls. During this study we will encourage you to increase physical activity by walking and tracking steps (using a pedometer that we send to your home). The health coach or research team may call you in between sessions to remind you of upcoming appointments.

All participants are encouraged to continue with their current musculoskeletal pain and depression treatment plans as recommended by their usual health care providers.

All participants, regardless of what group they have been assigned to will be contacted for four outcome assessments (baseline, mid-point, end intervention, 6-months) conducted by a research team member. Each telephone outcome assessment takes approximately 60 minutes to complete. During the second phase of the study, the research team will conduct in-depth interviews with a selected group of participants who were assigned to the MOTIVATE group in efforts to understand what was helpful, what could be improved, and how we can modify our program and protocols to be most helpful to Veterans like you. The audio recordings from these interviews will be analyzed at UT Southwestern Medical Center.

The coaching session as well as the in-depth interviews will be audio recorded and stored securely. We audio record the intervention sessions to make sure we are delivering the intervention to you as we intended to (fidelity). The interviews will be audio recorded to be sure we accurately capture the information you provide to us. These audio recordings will remain confidential and we will remove your personal identifiers as we analyze the data. The audiotapes may be used for any purpose relevant to research and medical education, within the discretion of the Principal Investigator.

The expected duration of your participation for outcome assessments is six months and each takes roughly 60-90 minutes to complete. These data will be collected and stored on a research-specific electronic database behind a password protected VA firewall. Additionally, upon completion of each outcomes assessment, you will receive a voucher, valued at $20. If you are selected to take part in the in-depth interview during the second phase of this study, you will receive an additional $20.

There are minimal risks related to participating in this study. Still, there is a small potential for loss of confidentiality. To minimize this risk, the information you provide to me will be shared with members of our research team, including VA Connecticut Healthcare System in West Haven, Connecticut and Puget Sound Health Care System in Seattle Washington for data management and analysis. Our research team has extensive training and experience on how to handle data securely, consistent with VA policies and procedures. No reports or publications from the study will use your name or any other information you provide. Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The health coaches encourage mild/ moderate physical activity during MOTIVATE. There is minimal risk of physical injury due to falls as you become more active. However, the health coach will focus on safely increasing walking and fall prevention strategies. The amount of activity we are asking you to do is considered standard of practice and not strenuous activity that could result in injury. Other possible risks are loss of time, participant burden and resulting fatigue. Discussing pain or depression may result in further psychological distress. You may decline to answer any of the questions, take a break, or stop your participation at any time. Participation in this study is voluntary and deciding not to take part will not affect the health care you receive. There is no economic or legal risk in this study.

In the unlikely event that you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-

compliance by a study participant with study procedures. This program is not asking participants to do anything beyond what is considered standard of care.

Do you have any questions for me before we move on?

Do you agree to participate in the MOTIVATE study?

If you are interested, we have a few questions to make sure you are a good fit for the program. Proceed to Eligibility Screener.

[If patient is eligible]: Mr/Ms. [--], it sounds like you would be a great fit for the program. We look forward to working with you. The next steps include performing a **baseline assessment (we will arrange a separate phone call in the next week)** and then **randomize** you to one of the 2 groups we discussed. We are looking forward to getting started!

Please call us with any questions that you might have: [redacted]

Thank you for your time.

If needed, can offer summary of several study related details:

- In this program, you will either be **randomized** to the active intervention (MOTIVATE) or a wait list control group.
- If you are randomized to the **wait list control group**, you will eventually receive the intervention, if you choose to.
- As part of the intervention group, the health coach will call you over the telephone for **a total of 8 telephone sessions.**
- We will need for you to have a **reliable telephone** to take part in these sessions.
- We would like for you to try to complete the 8- session program within **20 weeks**.
- You will also **receive four telephone calls to ask you about outcomes,** at the beginning, middle and end of the program, then an interview and call 6 months later: for which you will receive **compensation in the form of a $20 voucher**, resulting in a total of up to $80 if you complete those assessments. If you are selected for in in-depth interview by the team, you will receive another $20.
- You **do not get paid for your work with the health coach**.