

INFORMATION SHEET

Official title: MOTIVATE: Moving to Improve Chronic Back Pain and Depression in Older Adults

NCT number: NCT03914469

IRB Approved date: 05-23-22



Study Information Sheet

MOTIVATE: Moving to Improve Chronic Back Pain and Depression in Older Adults

Principal Investigator: Una Makris, MD
Associate Professor, Department of Internal Medicine
University of Texas Southwestern Medical Center

Funding Agency/Sponsor: Institutional Funds

Why is this study being done? Researchers at the UT Southwestern Medical Center and Parkland are conducting a pilot, randomized control trial to assess an intervention to improve physical activity and outcomes in older patients with chronic low back pain and depression. We are interested in testing a tele-based behavior change intervention delivered by a trained health coach.

Why am I being asked to take part in this research study? You are being asked to participate in this study because you are at least 50 years of age with chronic low back pain and depression. We expect approximately 50 participants.

What is involved in this study? The primary purpose of this study is to develop and evaluate a tele-based behavioral change intervention for older adults with chronic low back pain and comorbid depression, and to assess the intervention's effect on physical activity, chronic low back pain, and depressive symptoms. Each study participant is randomly assigned to one of two groups, either the behavioral intervention group or the waitlist control group. You may also be invited to take part in a phone interview to learn about your experience with the study. All phone calls will be audio recorded. If you agree to join the study, we will mail you a \$15 gift card after you complete each phone assessment and/or interview.

What if I do not want to participate? Participating in this study is voluntary. You may refuse to answer any question, take a break, or stop your participation at any time. However, answering the questions implies that you volunteer to participate and deciding not to take part will not affect the health care you receive.

What are the risks of the study? Any time patient information is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; though, this cannot be guaranteed. This information will only be shared with research personnel involved in this study.

Whom do I call if I have questions or problems? If you have any questions about the project please call the study coordinator at 214-645-3638. For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

Before you agree to participate, please ensure that you have read the information provided above, your questions have been answered to your satisfaction, and you have freely decided to participate in this research study.