STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN

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

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The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

Title:	MOTIVATE: Moving to Improve Chronic Back Pain and Depression in Older Adults
Principal Investigator:	Una Makris, MD- Principal Investigator
Funding Source:	Institutional funds

Purpose and Objectives

The overarching goal of this study is to evaluate a tele-based behavioral change intervention for older adults (aged 50 years and older) with chronic low back pain (cLBP) and comorbid depression, and to ultimately assess its effect on cLBP-related disability and depressive symptoms.

Specific Aims: Behavioral interventions for older adults with comorbid chronic low back pain (cLBP) and depression are urgently needed. Our group developed a telephone delivered intervention targeting behavioral constructs common to both cLBP and depression in older adults: MOTIVATE (Moving to Improve Back Pain and Depression in Older Adults). Further, we emphasize individualized values, goals and motivations to change behavior- all relevant for sustaining behavior change. We now seek to 1) evaluate the feasibility of MOTIVATE in a diverse older adult population, and 2) inform future research and trial design choices by eliciting feedback from key stakeholder groups. These results will inform methods and procedures for use in a large-scale, R01 level hybrid (Type 1) effectiveness-implementation randomized controlled trial (RCT).

Aim 1: Evaluate the feasibility of implementing MOTIVATE (n=25) vs. waitlist control (n=25) among older adults with comorbid cLBP and depression.

Aim 2: Ascertain key barriers and facilitators to implementing MOTIVATE in a diverse older population in primary care. We will conduct semi-structured interviews with 10 participants, 5 clinicians, and the health coach, to explore factors critical to eventual uptake of MOTIVATE, e.g., acceptability, adoption, sustainability.

Background and Current Practice

Chronic low back pain (cLBP) in older adults is a major public health problem with significant consequences. Annual costs related to back pain exceed $100 billion, and will rise with the aging population. While the population of older adults is rapidly rising, we lack evidence based options in this population because older adults are often excluded from randomized controlled trials for various reasons including multi-morbidity, polypharmacy, frailty and fragmented social support systems.

My prior work analyzing 13+ years of data shows that older adults are more likely to develop recurrent back pain if they suffer from depressive symptoms. The relationship between cLBP (>3 months) and depression is well established: both are risk factors for the others' onset, influence each other's

treatment, and have adverse reciprocal effects on quality of life, disability, and health care costs. Because cLBP and depression are mutually exacerbating, efforts to improve outcomes for both require effective co-management.

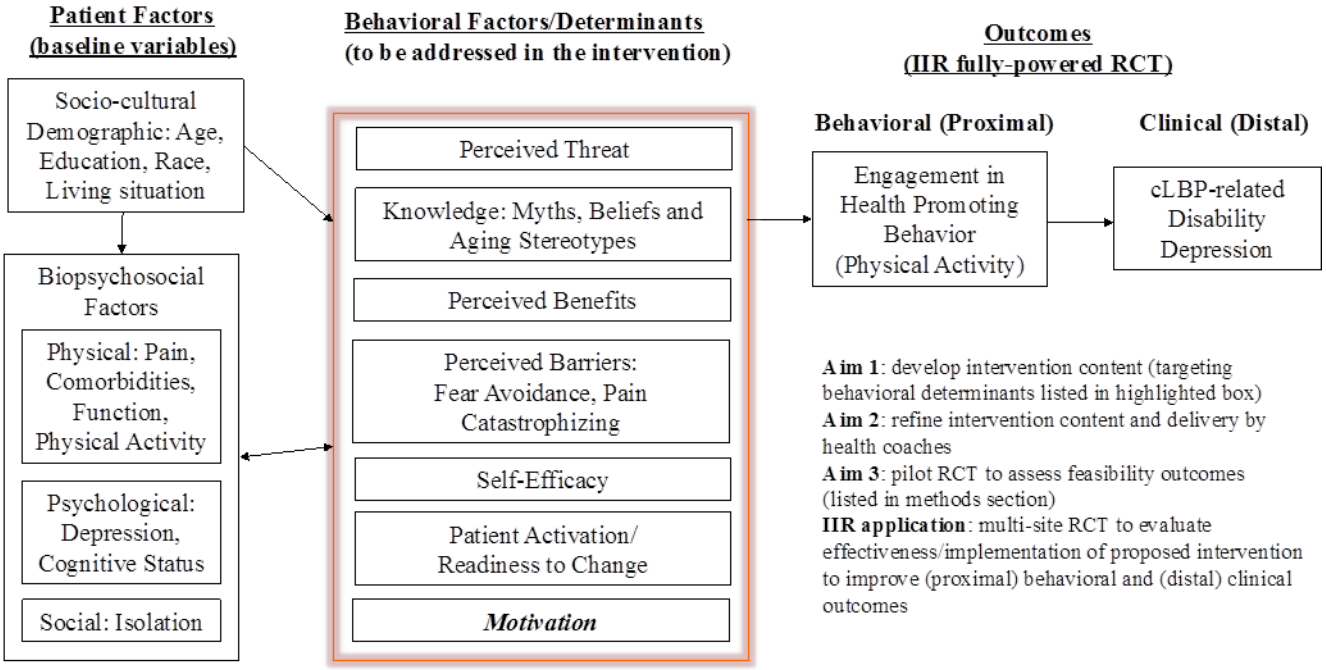
Pharmacological management alone has limited effectiveness in older adults. Both cLBP and depression respond well to techniques designed to improve physical/emotional self-management behaviors. Older adults deserve particular attention as there is growing literature that decision making strategies and motivations to change differ from younger populations. Interventions that target age-appropriate motivations, among other behavioral determinants, are ideal for these chronic conditions.

Older adults urgently need effective behavioral interventions that simultaneously target cLBP and depression. Multiple studies demonstrate the effectiveness of non-pharmacological therapies in improving chronic pain outcomes, including therapies based on cognitive behavioral principles and/or movement-based strategies (exercise and physical therapy). We know that physical activity is effective (alone or as augmentation therapy) for adults with depression. A recent publication provides evidence that biopsychosocial multi-component interventions are more effective for patients (average age 45) with cLBP as compared to placebo or physical treatments. However, older adults are consistently excluded from studies for various reasons, mostly having to do with multi-morbidity and polypharmacy. There are no multicomponent tele-based behavioral interventions specifically in older adults with cLBP and depression. Because cLBP and depression are mutually perpetuating and exacerbating, a critical piece of this research is to identify and target interrelated behavioral determinants (i.e., beliefs, fear avoidance, self-efficacy, and motivation) that play a role in older adult's behavior and subsequent outcomes.

Overview of Proposed Intervention

The suggested intervention is grounded in health behavior theories and builds on prior interventions for chronic pain and mental illness in medically complex older adults. Our conceptual model includes patient characteristics, potential reciprocal relationships between the listed constructs, and emphasizes motivation to change as a key behavioral determinant (Figure 1). One-way arrows show that baseline socio-cultural variables, rarely modifiable, influence biopsychosocial factors (i.e. the way an older adult may experience pain) which in turn influence behavioral determinants. The extent and status of specific behavioral determinants may influence/modify specific baseline biopsychosocial factors, as well as both proximal and distal outcomes.

Figure 1: Conceptual Model for Proposed Intervention



Consistent with a recently published model for developing behavioral treatments for chronic diseases, Figure 1 represents a model pathway by which our behavioral intervention is hypothesized to improve behavioral and, ultimately, clinical outcomes. By eliciting and targeting specific behavioral determinants (highlighted box) we will facilitate engagement in a health promoting behavior (physical activity) and ultimately improve cLBP and depression clinical outcomes (disability and depression scores). The behavioral determinants listed in Figure 1 are relevant for both cLBP and depression and include prominent constructs from the health belief model-perceived threat, perceived benefits, barriers, and self-efficacy-as well as from the trans-theoretical model-readiness to change. Consistent with clinical practice, older adults with cLBP and depression exhibit variability in the behavioral determinants listed. To increase intervention potency, the intervention targets both cLBP and depression behavioral determinants and seeks to improve outcomes in both conditions.

Compared to their younger counterparts (aged 49 and younger), older adults appear to be motivated to engage selectively with information that is relevant, positively framed, and fits with their personal goals. For example, when making choices, older adults tend to review and remember relatively more positive than negative information as compared to younger adults. To develop the most robust intervention for this population, we must tailor intervention content recognizing that older adults have unique beliefs, [mis]perceptions, as well as different preferred delivery of the material as compared to younger individuals. Data suggest that positively-framed messages, for instance emphasizing benefits of walking, are more effective than negatively-framed messages, emphasizing risks associated with not walking, in promoting and activating older adults to walk more. Our intervention content and messaging will target these unique motivations to engage in behavioral change.

Health coach delivered behavioral interventions have been shown to be effective in older adults with chronic pain. A health coach, broadly, is defined as a supportive mentor who motivates, educates, and supports clients to achieve their health goals through lifestyle and behavior adjustments. The health coach for this study will have experience with chronic pain and depression. These prerequisites will ensure that the health coach has exposure to principles of motivational interviewing, patient activation, and goal setting. The health coach will receive additional training in motivational interviewing and delivery of the proposed intervention as intended. As proposed in Figure 1, the intervention will be delivered via telephone or video-assisted technology (tele-based) by a health coach using modules that target the listed potential behavioral determinants that specifically focus on how older adults are uniquely motivated to change. The health coach will educate participants, use motivational interviewing to enhance perceived benefits, reduce barriers to participating in recommended behaviors, and assess motivations and readiness to change. Once a participant is ready for action, the health coach will use motivational coaching as well as goal setting and action planning techniques to facilitate behavioral change.

This study protocol is intended to evaluate the tele-based behavioral change intervention in a larger randomized sample.

Study Design

In aim 1, we will assess the feasibility of a tele-delivered behavioral change intervention among older adults (aged 50 and older) with cLBP and depression. Fifty participants will be randomly assigned to one of two groups, behavioral intervention arm (n=25) versus the waitlist control arm (n=25). The active intervention will include eight tele-delivered health coach sessions and three tele-based outcome assessments. Each tele-based outcome assessment is roughly 45-60 minutes, and will be conducted by a member of the research team and will be recorded for research purposes. Each intervention session will be delivered by a trained health coach over a period of 10-20 weeks (up to 5 months total, accounting for additional time between sessions if needed). Aim 2 will involve one, in-depth, telephone-based, semi-structured interview at 6 months post-intervention. The health coach/research coordinator will identify participants who are at higher risk for drop-out, less engaged, or particularly successful at achieving behavioral change. The purpose of this interview is to learn about the barriers and facilitators to successful intervention delivery and integration within primary care, participant retention and acceptability from the clinician, patient, and health coach perspective. We will explore factors that are critical to eventual uptake of MOTIVATE; informed by Proctor's Framework of Implementation Outcomes we will focus on acceptability, adoption, appropriateness and sustainability of MOTIVATE. Semi-structured interviews with patients will be occur over the telephone, while clinician semi-structured interviews can occur over the telephone or at a location convenient for the participant-most likely to occur on a UTSW or Parkland location.

The first session will introduce the participant to the health coach and the program, establish rapport, and measure baseline physical activity. The following six sessions address behavioral determinants, followed by a final session designed to be a booster session to the overall program.

An Omron pedometer (product name, Walking style One 2.0; type, HJ-320-E) will be provided to each participant for the assessment of physical activity. The Omron pedometer will be set up by a member of the research team (e.g., stride length, setting date/time) and will be mailed to the participant's home address between sessions one and two. Participants will not be required to mail the Omron pedometer back, nor will they incur out-of-pocket costs if lost, damaged, or stolen. Each participant will receive a courtesy phone call when the pedometer is mailed and will be asked to call the research coordinator when it arrives. The research team will provide technical assistance and instructions to the participant regarding use. The pedometer is intended to be worn on the waist band, daily, with the exception of times when the participant may shower or bathe. The research team will verbally instruct the participant on how to press the mode and memory buttons in order to provide weekly step counts for tracking physical activity. The participants will be prompted by the health coach or research staff to report step counts during subsequent weekly tele-based coaching sessions.

Since we are interested in better understanding feasibility of the intervention as compared to the waitlist control, and how behaviors are sustained over time, the study involves extended follow-up to six months. We will use these extended follow-up data to better understand differential attrition as well as preliminary formative implementation evaluation. Using purposive sampling, we will conduct ~ 16 in-depth semi-structured interviews, 10 participants, 5 clinicians, and the health coach. Each interview will occur post-intervention and will include key stakeholders from the following groups: study participants from each arm of the pilot study, the health coach, primary care providers (including clinic leadership, geriatricians, and clinical psychologists- will be identified by the PI's professional network and via snow ball sampling), and will be audio recorded (on LRX 40 USB or UTSW digital logger) for research purposes. Each audio recording will, thereafter, be transferred to a secure folder, behind the UTSW firewall and deleted from the audio recording device. . The research staff will select participants identified as higher risk for drop-out, less engaged, or were particularly successful at achieving behavioral change. The purpose of the final interviews is to learn about the barriers and facilitators to successful intervention delivery and participant retention from the perspectives of the enrolled patients, health coach, and providers. Interview topics will borrow from components of the well-established framework, Promoting Action on Research Implementation in Health Services (PARiHS). Semi-structured interview strategy is informed by two PARiHS dimensions: *context*-how the microsystem (UTSW and or Parkland) impacts behavioral change uptake, for example, potential facilitators to intervention implementation; *facilitation*-identifying specific ways to augment the likelihood of implementation. Table 1 outlines the structure of the interview questions.

Table 1. Key Informant Interview Topics Based on PARiHS Framework of Evidence, Context, and Facilitation		
PARiHS Dimension: Evidence	PARiHS Dimension: Context	PARiHS Dimension: Facilitation
▪ Perceptions about the strength and motivation for personalized goal-setting ▪ Perceptions about how well goal-setting is accepted by adults ▪ Perceptions of how goal-setting affects current practices or can be integrated into routine work flows ▪ Perceptions of how patient activation can be applied to improve outcomes ▪ Perceptions of how motivations to change and identifying meaningful goals can be aligned	▪ Availability of resources to carry out personalized goal-setting ▪ How training and fidelity assessment for personalized goal-setting fit with work demands ▪ Past experiences with collaborating with other health care providers on self-management or goal-setting ▪ Existing channels of communication for input and feedback among health care providers regarding goal-setting and self-management	▪ How to align roles in the project with existing responsibilities ▪ Perceptions about what successful implementation will require from staff, patients, and clinicians ▪ Perceptions of skills, attitudes, and beliefs about internal facilitators and study team ▪ Plans for establishing formal communication routines between study team, health care providers and other personnel

Criteria for Inclusion of Participants

Participant Selection

An initial data pull using patients' electronic medical records (EMR) will identify a pre-screen list of potentially eligible patients. Potential participants will include only those with an International Classification of Diseases-10 (ICD-10) code for back pain and depression. Further eligibility criteria are as follows:

Inclusion Criteria

- Aged 50 and older
- English- speaking
- Working telephone
- Capable of participating in home-based activity
- Chronic low back pain with intensity of 4 or higher on 10 point scale
- At least one doctor visit for cLBP in the two years
- UTSW General Internal Medicine (GIM) or Parkland internal medicine/primary care clinic or community outpatient clinic patient with scheduled clinic appointment within 2 years of enrollment date
- Self-reported low back pain (+/-radiation) in the past 3 months that interferes with daily activities on most days

- Depression, PHQ-9>10 stable (per chart review, no psychotic or suicidal ideation; confirmed over telephone or video-assist)

Exclusion Criteria:

- Aged 49 or less
- No telephone
- Not English speaking
- Unwilling to be randomized to either study arm
- Self-reported, uncorrected hearing or visual disturbance precluding ability to participate in telephone sessions or read pedometer screen
- Cognitive impairment, assessed by Memory Impairment Screen
- Lumbar surgery within the last year
- Self-reported dependence on wheelchair, bed-bound, or severe balance impairment (unable to participate in physical activity intervention)
- Illness requiring hospitalization within the last 3 months (e.g., fall, gout attacks, stroke, heart attack, heart failure, or surgery for blocked arteries)
- Suicidal ideation or prior psychotic episodes requiring hospitalization within the last year

Recruitment Strategy and Informed Consent Process

A waiver of consent for recruitment will be sought for identifying patients in the EMR, delivery of an invitation letter, and screening of potentially eligible participants aged 50 and older with an ICD-10 code for back pain and depression. We are also filing a waiver/alteration of HIPPA request to conduct the tele-delivered intervention and outcome assessments. Such a waiver is justified as minimal risk is anticipated; the waiver will not adversely affect the rights or welfare of participants.

Identified patients will be mailed an invitation letter signed by the principal investigator requesting their participation. The letters will describe the research study, describe what time involvement the project would require, and provide a local number to refuse contact. Letters will only be written in English as non-English speaking patients are ineligible for enrollment.

UTSW Strategy

The first recruitment method involves identifying when potentially eligible participants have appointments in UTSW GIM primary care clinic. The GIM provider will introduce the study and a research staff member to the patient during their clinic visit. The research staff member will then provide a detailed study overview and verbally consent the participant if interested, and ask a series of eligibility screening questions

The second recruitment method involves direct provider referral. Dr. Makris will provide a flyer to be posted in GIM primary care clinics (see attached to this IRB protocol submission) with a study synopsis and eligibility criteria. If the participant is interested in learning more, he/she may call the number

provided on the flyer. Additionally, with the HIPAA waiver, the participant's provider may notify Dr. Makris via secure email to call the potential participant. Dr. Makris or a member of the research team will speak with the participant, either in person at a GIM clinic appointment or by telephone, and will provide a study overview, the study risks and potential benefits, obtain verbal consent, and ask a series of eligibility screening questions.

Parkland Strategy

The first recruitment method involves obtaining a list of Parkland internal medicine patients > 50 years old, with ICD-10 codes for chronic lower back pain and depression. Next we will review these lists for appropriateness to enroll in this program. Next we will send opt out letters as previously outlined and then the research team will screen these patients for eligibility.

The second recruitment strategy involves Parkland internal medicine providers refer directly to the research team who screens for eligibility.

The third recruitment strategy is that Parkland internal medicine providers refer patients to the existing Parkland internal medicine behavioral health consult. The current Internal Medicine team member (social worker) at Parkland already screens these referrals for appropriateness and will screen these internal consults for our criteria of age > 50, chronic lower back pain, and depression. If positive the patient will be referred to our research team for further eligibility screening.

The fourth randomization method is for patients who are referred to the Parkland integrative pain clinic (typically on opioid and benzodiazepines) and who are screened internally by Dr. Lee. If appropriate, Dr. Lee will refer directly to our research team for further eligibility screening.

Study Procedures

Eligible participants will be randomly assigned to the waitlist control group (n=25) or the intervention (n=25) by applying a set of computer-generated random numbers. Since we are interested in better understanding feasibility of the intervention as compared to the waitlist control, and how behaviors are sustained over time, this study involves extended follow-up to 6 months. The waitlist control arm will receive usual care and will be offered the active intervention if they chose to once the active arm has completed the intervention.

If randomized to the intervention arm, a binder containing the intervention study material will be sent to the participant's home address. The study binder will include a manual to serve as a guide for the patient to follow during each tele-delivered session with the health coach and activity tracker to document step counts and impact on pain and depression. Appointment reminders will be mailed prior to each intervention session. Depending on the content of the session, these reminders may also include a list of the participant's values, goals, and action plan as discussed during prior sessions. Additional session reminders will be delivered via telephone in addition to mailed appointment reminders.

A research team member, not the health coach, will call each participant for outcome assessments at baseline, mid-intervention and post-intervention, regardless of intervention arm assignment. These data

will be collected using UTSW REDCap, a secure web application that can be used to distribute and manage online survey tools and databases. Upon study completion, semi-structured interviews will elicit stakeholder and participant perceptions of health coach recommendations and use of action plans (see **Table 1** for key informant interview topics).

Database Management

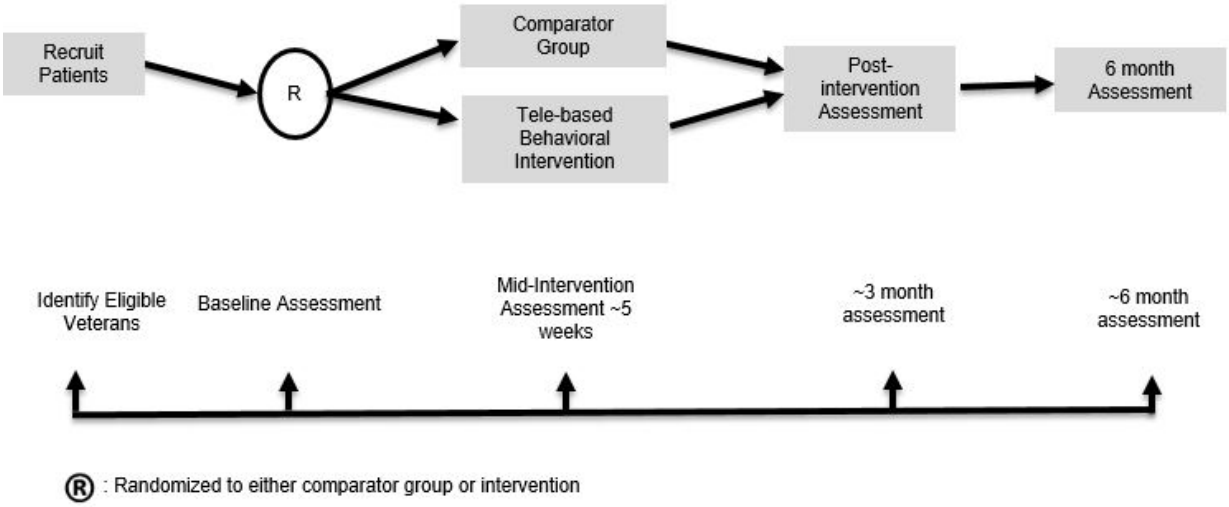
The UTSW Redcap has been programmed with the specific outcomes assessments for this project, and we will use Redcap to document all electronic data management activities including tracking of screening, recruitment, and progress through the intervention and assessments. The study data will be stored on the UTSW network or on the REDCap survey website. The data from health coaching tele-sessions (i.e. goals set by participants, achievement of goals, barriers to achieving desired goals) will be entered into a parallel health coaching manual (word document) that will be IRB approved and stored behind the UTSW firewall in the study secure research folder.

Study data will be stored within password protected data management programs, on password protected computers. Only IRB approved study personnel will have access to study data. All research staff will be trained in the appropriate safeguarding of confidential data and in the protection of human participants. At the end of the study, after analyses are complete, all study data will be de-identified, and the identifying key will be destroyed per UTSW and Parkland policies and regulations. The health coach will have restricted access to the study database; he/she will also have access to EMR as needed.

Outcome Assessments and Data Collection

Using age >50, ICD-10 codes for chronic back pain and depression as criteria, an initial data pull from patients' EMR will yield a list of potentially eligible prospective study participants. The research team will pre-screen this list of potentially eligible patients for recruitment. As outlined in section **Recruitment Strategy and Informed Consent Process,** participant recruitment may occur in-person or by tele-based method and will include an introduction to the study and **verbal consent.** Upon completion of consent, a research staff member will further screen for eligibility and arrange a separate telephone call for a baseline assessment. As seen in the **Figure 2** below, a research team member, not the health coach, will complete all outcome assessments via telephone using structured data collection tools at baseline, mid-point (~ 5 weeks), end-point (~ 10 weeks), and 6 months post-intervention. A subset of the participants from the trial will be invited for an in-depth, semi-structured interview, as discussed above (Aim 2), to better understand implementation and sustainability of behavior uptake.

All study-related data from the assessments will be entered into a UTSW REDCap database at: https://ais.swmed.edu/redcap/. Only de-identified data will be entered in REDCap. The health coach or a research staff member will obtain daily versus weekly step counts from study participants as appropriate depending on the session content and activity tracker assignment.



Outcome Measures

For aim 1 researchers will collect relevant demographic and clinical data either from patient EMR data abstraction or directly from the participant during a tele-delivered session. The research team will also collect various data points at specific intervals throughout the study duration using REDCap outcome assessment tools. A description of outcome assessment tools are included below. For aim 2, researchers will ascertain key barriers and facilitators to implementing MOTIVATE in a diverse older population in primary care and will explore factors critical to eventual uptake of MOTIVATE, e.g., acceptability, adoption, sustainability. The in-depth, semi-structured interviews will include a discussion guide with prompts focusing on acceptability, adoption, appropriateness, and sustainability of implementing MOTIVATE with older adults in primary care. All of these categories are relevant to patients, clinicians, and leadership, though nuances will emerge during interviews. We will stop conducting interviews once we reach thematic saturation and no further responses/ themes are provided.

Feasibility Outcomes

Feasibility outcomes, including recruitment and fidelity, will be collected and are intended to inform future grant proposals for a fully powered hybrid effectiveness/implementation award. All health coaching tele-sessions will be audio recorded using a telephone recording adapter (Model: LRX 40 USB) or audio recorders built into the telephones in DPDS. 20% of study sessions will be assessed using a fidelity checklist to ensure that the intervention is being delivered as intended. The fidelity checklists will be submitted along with this IRB. The purpose of the fidelity checklists is to verify that the objectives and core concepts for each session are being delivered as intended to the participants. Feasibility outcomes include, enrollment rates across GIM primary care and Parkland internal medicine/primary care clinic or community outpatient clinics, intervention adherence (measured as number of sessions the participant engaged in), and retention rate.

Primary outcomes for future effectiveness trial will be assessed:

• Physical function/ self-reported disability will be measured by the Roland Morris Disability Questionnaire (RMDQ). The RMDQ is valid, reliable and responsive to change in community dwelling patients with cLBP. Pain disability is important because this is a major treatment target in patients with chronic pain.

• Depression will be measured using the validated PHQ-9. A PHQ-9 cutoff score of >10 will signify clinically meaningful symptom burden (sensitivity and specificity =88% for major depressive disorder).

Secondary outcomes include physical, psychosocial consequences associated with cLBP and depression:

• Pain interference and pain behavior will be measured using NIH PROMIS instruments.

• Pain intensity will be measured with the PEG Three-Item Scale, which assesses average pain intensity, interference with enjoyment of life, and interference with general activity on a scale from 0 to 10).

• Quality of life will be measured with the well-validated PROMIS Global Health scale (physical and mental health).

• Social functioning is an important contributor to disability in those with depression and chronic pain. We will measure social isolation using PROMIS measures.

• Current medications (regularly scheduled and as-needed) will be collected at baseline and subsequent assessments from the EMR and then confirmed with the participant over the tele. Participants are also asked if they are taking additional medications. As described, we will create four “yes/no” variables reflecting medication use: acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), opioids (including tramadol), and other agents such as anti-depressants used specifically for pain (versus depression), gabapentin, other anticonvulsants, corticosteroids, topical anesthetic and capsaicin preparations.

• Variables abstracted from the electronic medical record include (baseline, 3, 6): opioid use, psychotropic medications, hospitalizations, clinic visits (including mental health appointments), and unexpected clinic visits (included emergency department and/or urgent care clinics). These are important health utilization outcomes that will be explored in future studies.

Proximal/behavioral outcomes:

• Physical activity: We will evaluate overall physical activity level using a portable, lightweight, Omron HJ-320 pedometer. Participants will wear the pedometer clipped to their right lateral waistband for 24 hours per day for seven consecutive days (except during shower or water activities) to obtain five complete days of physical activity data. This will be explained in detail at the time of recruitment call. More details about the device and instructions for use are included for IRB review.

Other measures associated with achieving behavioral and clinical outcomes:

- Program satisfaction will be assessed during the end assessment. Including 1) To what extent has the study coach met your needs? 2) In an overall sense, how satisfied are you with the services that you have received with the MOTIVATE program? 3) If your friend or family member had pain and depression, would you recommend the MOTIVATE program to them? 4) Did the MOTIVATE program help motivate you to become active? 5) Did the MOTIVATE program help you understand the connection between pain, depression and activity? 6) Did the MOTIVATE program help you link goals to your values?

• Arthritis Self-efficacy scale is a 10 point Likert scale that measures the belief or confidence the participant has to perform 8 specific activities or tasks, based on arthritis.

• Physical activity contemplation ladder.

• Expectations of the intervention are asked with the following three questions: 1) How likely is this program to improve my ability to walk? 2) How likely is this program to improve my back pain? 3) How likely is this program to improve my depression/mood?

• Global impression of change will be assessed using the Patient Global Impression of Change Scale, a 7-point scale (1 = No change (or condition has gotten worse) to 7 = great deal better and a considerable improvement that has made all the difference) asking participants to rate their change (if any) in pain since starting the study.

• Pain Stages of Change Questionnaire (PSOCQ) evaluates attitudes, intentions, and behaviors consistent with stages of change for pain self-management.

• Therapeutic alliance will be assessed using the Working Alliance Inventory Short-Form will measure therapeutic relationship between patients and therapist (health coach in our study). To allow the therapeutic relationship to develop, participants will complete this assessment starting at 5 weeks.

- Sleep will be measured using the PROMIS Sleep SF 6-item.
- Resilience will be assessed using Connor Davidson Resilience Short Form: CDRISC 10 item.
- Claims/Billing and Healthcare Utilization: As part of the pilot study we are requesting claims billing data (from insurers) as well as administrative data from EMR or other UTSW or Parkland data sources to include the following data domains: all visits (outpatient, inpatient, ED visits, urgent care, physical therapy), procedures (in/outpatient; injections, surgery), imaging, and medications and their associated diagnosis/procedure codes (which our research team will use to determine if pain, degenerative joint disease, depression-related).

Table 2. Demographic and Clinical Data Points and Outcome Assessment Instruments						
DATA	**SOURCE**	**PRE-SCREEN**	**SCREEN**	**BASELINE**	**MID**	**END**
Sex	EMR	X		X		
Age 50+	EMR	X		X		
ICD-10 back pain	EMR	X				
ICD-10 depression	EMR	X				
History of suicidal ideation	EMR	X				
Psychotic or suicidal hospitalization w/ past year	EMR	X				
Telephone	EMR Phone	X				
Inclusion/Exclusion Criteria						
50 or older (confirm)	Phone		X			
(Clbp confirm) Low back pain (+/- radiation) on most days for the past 3 months?	Phone		X			
(Clbp confirm) Does your back pain limit your ability to do activities around the home or activities that you enjoy?"	Phone		X			
Rate pain level in past week (Scale 0-10)	Phone		X	X	X	X
Self-report hearing/visual challenges	Phone		X			
Lumbar surgery within past year	Phone		X			
Recent illness/diagnosis of concern	Phone		X			
Bed bound	Phone		X			
Use of wheelchair around the house	Phone		X			
Safety & Physical Activity	Phone		X			
Cognitive Screener	Phone		X			
Patient Health Questionnaire (PHQ-9)	Phone		X	X	X	X
Self-Report Demographics and Other Clinical Variables						
Race/Ethnicity	EMR Phone			X		
Education	EMR Phone			X		
Marital Status	EMR Phone			X		
Living situation	EMR Phone			X		
Address	EMR Phone			X		

Charleston Age Comorbidity Calculator	EMR			X		
Body mass index	EMR			X		
Medication list	EMR Phone			X		
Pain injections at ER/outpatient in the last month	EMR			X	X	X
Med/mental/PT appointments (related to Clbp/depression) or ED/urgent care visits within the last 6 months	EMR Phone			X	X	X
Financial situation	Phone			X		
Most frequented primary care clinic location	Phone			X		
Short Michigan Alcoholism Screening Test (SMAST)	Phone			X		X
Drug Use Questionnaire (DAST)	Phone			X		
Expectation of Intervention	Phone			X		
Pain Screen Tool (PEG)	Phone			X	X	X
Self-Efficacy Arthritis	Phone			X	X	X
Roland Disability Quest: Rating Scale for Low Back Pain	Phone			X	X	X
Pain Catastrophizing Scale (PCS-EN)	Phone			X	X	X
Fear Avoidance Beliefs Questionnaire (FABQ)	Phone			X	X	X
Physical Activity Contemplation Ladder	Phone			X	X	X
Exercise Questionnaire	Phone			X	X	X
General Health Questions	Phone			X	X	X
Pain Stage of Change	Phone			X	X	X
PROMIS 1.2 Global Mental Health	Phone			X	X	X
PROMIS 1.2 Global Physical Health	Phone			X	X	X
PROMIS SF 1.1 Pain Behavior	Phone			X	X	X
PROMIS SF 2.0 Social Isolation	Phone			X	X	X
PROMIS 2.0 Physical Function	Phone			X	X	X
PROMIS Sleep 6-item	Phone			X	X	X
Med List and Med/Mental/PT Appointments	Phone			X	X	X
Future Time Perspective (Time Horizons?)	Phone			X		X
Global Impression of Change	Phone				X	X
Working Alliance Survey	Phone				X	X
Connor Davidson Resilience Short Form: CDRISC 10 item	Phone			X	X	X
Patient Satisfaction Question	Phone					X

Semi-structured Interviews

Upon intervention completion, among a subset of the participants only, a member of the research team, not the health coach, will conduct face-to-face or telephone based, in-depth, semi-structured interviews prompting responses concerning helpfulness of skills taught, overall satisfaction, and motivation uptake as related to the information presented in the intervention. Semi-structured interviews with patients will occur over the phone, while clinician semi-structured interviews can occur over the telephone or at location convenient for the participant-most likely to occur on a UTSW or Parkland location. The interviews will also help identify barriers and facilitators to delivering a successful intervention. Interview topics will use the PARiHS framework previously outlined in Table 1.

Analysis

Feasibility outcomes will be measured by recruitment rates, adherence, retention, and intervention fidelity. We will add prompts during the semi-structured interviews that focus on how participants, if applicable, achieved an increase in physical activity. For example, did they build more walking-based activities in their daily routine (walking to the store rather than driving) or did they add new activities to accumulate more steps? We will also inquire about whether goals achieved were congruent with motivations to change behavior and how these motivations may influence sustained behavior. Fidelity assessment, as described above, will result in feedback to the health coaches and will ensure that the health coaches deliver the intervention as intended.

Analysis of the aim 2 qualitative data will be consistent with methods used in our prior research, using the constant comparative method. Interviews will be audio recorded and professionally transcribed. The qualitative data will be managed for coding and analysis of salient themes using NVIVO software, available to staff in Dr. Makris' group. These results will inform procedural modifications and trial design decisions for a larger scale RCT to further evaluate MOTIVATE.

Proposed Analyses

Exact binomial method will be used to estimate rates of recruitment, intervention adherence, retention, and drop-out along with the corresponding 95% confidence intervals. Multiple levels of treatment retention will be defined, including partial intervention completion (% who do not complete all sessions), intervention dropout (% who dropout of intervention but continue to do assessments), research dropouts (% who remain in intervention, but do not complete assessments), and intervention + research dropouts (% who do not complete intervention or assessments). We will further break down the enrollment and retention calculations by examining enrollment/retention differences by treatment group, health coach, sex, age, race/ethnicity, and initial cLBP and depression severity using cross-classification tables.

As exploratory analyses, pre- and post-improvement in disability (RMDQ) and depression (PHQ-9) scores, as well as secondary and intermediate outcomes, from baseline to three months will be compared based on a two-sample t-test or Wilcoxon rank-sum tests between the two groups. The difference in improvement will be estimated and the 95% confidence interval will be reported. We will

estimate the preliminary effect size and variance of effect for the above outcomes. Linear mixed models will be used to assess whether there is a difference in the above outcomes over time within and between the two groups. We will include distance (in miles) from a UTSW or Parkland facility as a covariate in the exploratory outcome analyses, as suggested by reviewer.

We will describe, for the subset of participants receiving the intervention, whether physical activity (proximal outcome) and clinical outcomes (disability and depression scores) change over time based on the 1) proportion of the total sessions completed, and 2) the proportion of individual sessions completed. This will help us estimate optimal dose of the intervention (for example, whether completion of 4 vs. 7 vs. 8 of 10 sessions produces similar outcomes) and may inform which specific sessions are absolutely critical. SAS (version 9.3, Cary, NC) statistical software will be used.

Our formative evaluation may help to identify parts of the process that need refinement to maximize the feasibility and extension of the project to different sites in the future. Also part of the formative evaluation process will be to understand how implementation factors influence the optimal dose of our intervention. This evaluation may highlight which intervention components (or active ingredients) resulted in a change in behavior or other outcome result and potentially why (barriers/facilitators of change from an implementation standpoint).

Potential Risks

The risks to the study are minimal. The research involves a tele-delivered program by a health coach over 10-20 weeks followed by an interview; hence, there is minimal risk of physical injury. Participants will be asked to be more physically active and track their steps with a pedometer. As they become more active there is a risk of fall and injury. However, the health coach will focus on safely increasing walking and fall prevention strategies. The amount of activity we are asking participants to do is considered standard of practice and not strenuous activity that could result in injury. Another possible risk to patients is loss of time and potential breach of confidentiality. Risks include participant burden and resulting fatigue. There is no economic or legal risk in this study. To prevent or minimize any potential risks, patients may stop the interview at any point during this study if they feel any distress.

Discussing pain or psycho-social factors including comorbid depression may result in further psychological distress. There is no economic or legal risk in this study. To prevent or minimize any potential risks, the participant may stop the health coaching, assessments, or interview process at any time.

Since we will be recruiting older adults with comorbid depression, we have a plan in place should a participant be found to have worsening mental health conditions(s). If the participant develops worsening depressive symptoms during this study, the PCP will be notified to make appropriate follow-up or evaluation with Mental Health. In the case of suicidality endorsed, as standard measures at UTSW and Parkland, we will provide the suicide hotline (800-273-TALK)) and a local 24/7 crisis hotline (214-828-1000), warm transfer to mental health specialist, follow-up with mental health services, and communication with the primary care physician. If the participant endorses suicidal or homicidal ideation during an in-person interview, the participant will be escorted to the Emergency Department

for in-person psychiatric evaluation. The PI will be immediately notified of any de-escalation of mental health conditions.

A protocol will be in place should the study team identify a potential participant who reports or develops suicidal ideation. For safety purposes, the protocol is as follows: any patient identified as having suicidal ideation during this screening process will be referred to Dr. Makris, their respective Emergency Department, and referred to a national hotline (800-273-TALK) or the local hotline (214-828-1000). Using a pre-established protocol, Dr. Makris will contact the participant and make arrangements for immediate mental health assessment and treatment based on the participant's symptoms. All suicidal patients will be provided with the suicide crisis hotline number, regardless of other immediate clinical interventions. Furthermore, participants with severe psychiatric diagnoses (as specified among the exclusion criteria) or prior documented inpatient admissions for suicidal ideation will be excluded and not enrolled in the study.

Procedures to Maintain Confidentiality

All electronic data will be stored within password protected data management programs, on password protected computers. All research staff will be trained in the appropriate safeguarding of confidential data and in the protection of human participants. At the end of the study, after analyses are complete, all study data will be de-identified, and the identifying key will be destroyed per UTSW policies and regulations.

All print information will be stored in locked files. The print information will be destroyed one year after the study completion date. Personally identifying data (name, address, and phone number) will be obtained from the UTSW and Parkland EMR system for the purpose of identifying potential participants and conducting calls in a secure password-protected database. Only members of the research team will have access to this information. All electronic information (survey database) will be stored on password-protected files on secure network servers. Identifiers will be destroyed after the study completion. Only IRB approved study personnel will have access to study data.

We anticipate that our procedures to minimize risk of confidentiality will be highly effective. In the unlikely event of loss of patient confidentiality, we will have a procedure in place for responding in timely and appropriate manner. The study participant who experiences loss of confidentiality will be informed by the Principal Investigator (Una Makris, MD) in writing and by phone of the loss of confidentiality. UTSW and Parkland clinical leadership, the IRB, and participant will be informed in the case of such an occurrence.

Payment to Participants for Their Participation

For this study, we will provide incentives to all the participants who will be recruited (n=50). Each participant will receive a modest incentive after completion of each data collection assessment. Participants will be paid $15 after completion of each outcomes assessment (this does not include the intervention health coaching sessions), and after completion of the in-depth interview, if selected. This will include assessments at baseline, mid-intervention at ~ five weeks, post intervention at ~10 weeks,

six-month interviews, and in-depth interview (only if selected) for a total of potentially $60-75 if they complete all assessments of the study.