NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)
November 13, 2023; 3:00-4:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Kevin McBryde (NCCIH), Kayla Mehl (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Damon Seils (Duke University), Kayte Spector-Bagdady (University of Michigan), Kevin Weinfurt (Duke University), Ben Wilfond (University of Washington)
- Demonstration Project team: Janelle Maddox-Regis (Johns Hopkins University), Richard Skolasky (Johns Hopkins University), Megan Singleton, Kevin McLaughlin (Johns Hopkins University)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
Brief review of Demonstration Project	Meeting attendees received the Research Strategy and Data Sharing and Management Plan for ARBOR-Telehealth with the meeting agenda (see supplementary material attached). Stephanie Morain facilitated the discussion. Core members, ARBOR-Telehealth team members, and staff from the NIH Pragmatic Trials Collaboratory Coordinating Center introduced themselves. The ARBOR-Telehealth team members present included co–principal investigators Richard Skolasky and Kevin McLaughlin, along with Janelle Maddox-Regis (associate director of the IRB Reliance Program at Johns Hopkins Medicine) and Megan Singleton (director of the Human Research Protection Program at Johns Hopkins Medicine). **Project overview**: Kevin McLaughlin gave an overview of the project. The goal of ARBOR-Telehealth is to evaluate the use of a telehealth physical therapy strategy for patients who present to primary care clinics with low back pain in rural communities, compared with usual care. A secondary aim of the study is to compare the effectiveness of the risk-stratification approach (described below). **Healthcare system partners**: TidalHealth (Maryland)		

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
	NIH Institute Providing Oversight: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) **Study design**: The study is proposed to be a 2-arm pragmatic trial of adults being seen in primary care clinics for low back pain. Participants will be assigned by individual randomization to either telerehabilitation or usual care. Participants in the usual care arm will receive physician advice standardized via an educational website. Participants in the intervention arm will be stratified into low-risk, medium-risk, and high-risk categories using a measure of psychosocial risk for self-reported disability from persistent low back pain. Patients in the low-risk group will receive remote therapeutic monitoring; patients in the medium-risk group will receive physical therapy telehealth visits; and patients in the high-risk group will receive psychologically informed physical therapy telehealth visits. Block randomization from within risk categories will ensure there are equal risk strata in each arm. **Outcomes**: The primary outcomes are self-reported disability from persistent low back pain and opioid use after 8 weeks of treatment. Secondary outcomes include use of other healthcare resources related to low back pain, including physical therapy outside the study.		
Status of IRB approval	The study will use the Johns Hopkins Medicine IRB as the single IRB of record. TidalHealth, the partnering healthcare system, is a member of the Johns Hopkins Clinical Research Network and will be added as a reliance partner.		
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. Study activities during the planning phase are being conducted under a waiver of consent. In the implementation, the study team plans to use an oral consent script with a waiver of documentation of consent. However, this will depend on the determination about whether the study is considered minimal risk. Kayte Spector-Bagdady asked whether the effectiveness of the risk-stratification strategy will be compared within the intervention arm. Richard replied that the study's primary analysis will compare usual care with telerehabilitation overall. The study team is also interested in an exploratory analysis of effectiveness that compares patients in each arm matched on risk category. David Magnus asked		

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
	whether the use of an unvalidated risk-stratification strategy might influence the determination of whether the study meets the regulatory criteria to be considered minimal risk. Richard replied that there is evidence to support the use of the risk-stratification strategy to identify people who are at risk for poor outcomes. Assignment to a risk category will not be reported back to the primary care physician and, therefore, should not influence routine clinical care. David asked whether the risk category assignment will be shared with the participants themselves, as this could ultimately influence their routine clinical care. There was agreement that it would be best for individual participants not to know their risk category assignment. Richard thanked the group for this point and noted that the study team is still working on the language about how to describe the study and the risk stratification to participants. Megan Singleton noted that, if the study is not determined to meet the regulatory criteria to be considered minimal risk, there are remote consent options to consider.		
Privacy (including HIPAA)	The TidalHealth clinical data acquisition team will prepare a monthly report of patients who meet the study's eligibility criteria and will transmit this data via a secure, IT-managed REDCap platform. The study will need a waiver of HIPAA authorization to view this dataset. The study team will have access to protected health information, because the recruitment process will include sending letters to individual participants with an opt-out option. Eligible patients who do not opt out will be contacted for a scripted telephone screening. Interested patients will then receive the oral consent script.		
Monitoring and oversight	NIAMS will assemble a data and safety monitoring board and has asked the study team to provide names of potential members. Stephanie referred the study team to the Data and Safety Monitoring chapter of the Living Textbook: https://rethinkingclinicaltrials.org/chapters/ethics-and-regulatory/data-and-safety-monitoring/introduction-data-and-safety-monitoring/.		
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters	None.		

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER

Research Strategy

A. Significance and Scientific Premise

A.1 The Burden of Chronic Low Back Pain: Chronic LBP is the leading cause of disability globally, affecting more than 500 million individuals annually, with a nearly 20% increase in prevalence over the past 2 decades.[3] In the US, approximately 80% of adults experience at least 1 episode of LBP during their lifetime, and 25% of adults report low back pain that lasted at least 1 day during the past 3 months.[22] LBP also accounts for approximately 5% of all physician visits[23,24] and is the costliest health condition in the US, accounting for an estimated $135 billion in spending, exceeding diabetes, heart disease, and Alzheimer's disease, and increasing at the second fastest rate of any health condition during the past decade.[25] Despite intensive clinical efforts and high levels of healthcare expenditure, the prevalence of chronic LBP continues to be high, with reports indicating that 6% of adults in the US experience chronic LBP and that this rate is steadily increasing.[26,27] These statistics demonstrate that, ***despite significant spending, the prevalence of chronic LBP continues to rise, indicating that current management techniques are ineffective.***

A.2 The Role of Chronic Low Back Pain in the Opioid Epidemic: Opioid use disorder has reached all-time highs in the US over recent years. In 2018, a reported 46,802 individuals died of opioid-related drug overdoses, with 14,795 (32%) of these overdoses events including prescription opioids.[28] Additionally, nearly 27 million people were estimated to be living with opioid use disorder worldwide, with the highest rates of opioid use disorder being observed in the US.[3] The US prescribes opioids at a higher rate per capita than any other country in the world, accounting for 68% of opioid consumption globally.[29]

Ineffective management of LBP contributes directly to the opioid crisis. For example, from 2000-2010, opioid prescribing for non-cancer pain nearly doubled to 20% of all physician visits, with studies showing that LBP was the leading diagnosis associated with opioid prescription [26,30,31]. Moreover, studies have shown that a diagnosis of LBP increases the likelihood that patients will receive high doses of opioids (≥180mg morphine) compared to other conditions that are commonly treated with opioids.[32] These rates of opioid prescription for LBP continue to rise, despite a lack of evidence for long-term effectiveness.[33] ***These statistics demonstrate the role of chronic LBP in the US opioid epidemic and support the urgent need for more effective treatment methods for chronic LBP to decrease reliance on opioid pain management.***

Supplementary Material

A.3 Evidence for Physical Therapy for Treating Low Back Pain: Physical therapy has been found effective in reducing LBP related pain and disability. As such, it is recommended as the first line of treatment for LBP in most clinical practice guidelines.[34] Studies have shown that timely access to physical therapy leads to significant decreases in pain and disability compared to usual care for patients with LBP.[35] Access to physical therapy has also been shown to decrease downstream utilization of other LBP-related services and procedures. Importantly, studies have shown that patients who attend physical therapy shortly after a LBP-related physician office visit are 38% less likely to be prescribed opioids than patients who do not attend or delay starting physical therapy until later.[4,5] These same patients also experience a significant reduction in risk that they will receive advanced imaging (48% reduction), injections (44% reduction), or surgery (41% reduction).[4,5] By reducing downstream utilization, these studies have shown that timely initiation of physical therapy after LBP-related physician office visits can reduce the cost of LBP-related healthcare by over 40%.[4,5] Combined with the data supporting the clinical effectiveness of physical therapy for LBP, ***these findings support the use physical therapy as the first line of treatment for patients with chronic LBP and indicate it may be protective against opioid use.***

A.4 Barriers to Attending Physical Therapy in Rural Areas: While physical therapy has been shown to be an effective treatment for LBP, only 7-13% of patients with LBP go on to receive physical therapy services.[4,5] This low rate of physical therapy utilization by patients with LBP is likely related to barriers surrounding access (i.e., wait times, cost) and logistics (i.e., missed work time, transportation).[8-11,36] These barriers are amplified in rural parts of the country where studies on physical therapy employment distribution have found that there are 40% fewer physical therapists per capita in rural geographic regions compared to more urban regions.[12] These results go hand-in-hand with results indicating that African-Americans with chronic LBP living in rural parts of the US are significantly less likely to receive physical therapy than similar individuals living in more urban areas.[37] It is possible that rural-urban disparities in physical therapy access contribute to the disproportionate amount of opioid prescriptions and use observed in rural areas of the US.[13,38] ***There is an urgent need for studies addressing rural-urban disparities in access to physical therapy.***

A.5 Emergence of Digital Approaches to Physical Therapy: The COVID-19 pandemic has facilitated the rapid emergence of telerehabilitation.[15,39] Prior to the pandemic, outpatient physical therapy was delivered almost exclusively in-person. However, since the pandemic began, policy changes on the state and federal level have led to major expansions in the way that physical therapy is delivered to patients outside of clinic. Not only does this include the ability of physical therapists to provide care using telehealth visits,[40] but also through the use of an asynchronous form of telerehabilitation referred to as Remote Therapeutic Monitoring (RTM).[41] Using this

approach, patients are provided with treatment (i.e., exercise routine) through a digital treatment platform accessed via website or mobile application. This platform also allows patients to report their progress back to their physical therapist by completing questionnaires and by logging their exercise sessions. Physical therapists then utilize the feedback provided by their patients through the digital treatment platform to update their treatment program and plan of care. This approach eliminates the requirement for scheduled physical therapy visits (in-person or via telehealth visit) and facilitates a more independent approach to physical therapy.

Advancements in telerehabilitation stand to improve access to physical therapy for patients in rural communities by reducing or eliminating many barriers that restrict access to in-person care. However, as these represent brand new approaches to physical therapy, few studies have examined their effectiveness and it is unclear how these approaches should be implemented by healthcare systems. As such, ***studies are needed that examine the effectiveness of telerehabilitation for chronic LBP and methods for implementation in rural settings.***

A.6 Addressing Healthcare Access Limitations with Telehealth: Telehealth, defined as delivery of health care via remote technologies, has long been viewed as a means of improving access to healthcare among those living in rural communities, but logistical and policy-related barriers have historically limited uptake of these services by providers.[42-44] A confluence of recent technology advancements, expansion of broadband coverage, and policy changes spurred by the pandemic have eliminated many barriers and led to rapid uptake of telehealth by patients and providers. As telehealth has become more widely accepted by patients and providers, studies have shown that telehealth can improve access to healthcare for patients with a variety of conditions including heart disease, kidney failure, mental health conditions, musculoskeletal conditions, and several others.[43,45-49].

Importantly, recent studies have found that 85-92% of individuals in the US have access to the internet through either a smartphone or other type of connected device.[50] The number of individuals with connected devices has also steadily increased annually over the past several years, meaning that the proportion of individuals without internet access is likely to continue to decrease. Given widespread and growing access to the internet and reduced barriers to telehealth, ***it is likely that telehealth will play an important role in expanding access to healthcare for patients in rural communities and other underserved populations.***

A.7 Clinical Effects of Telerehabilitation for Low Back Pain: Telerehabilitation stands to improve access to physical therapy and to allow for more patient-centered approaches to physical therapy for patients with chronic LBP. However, given that telerehabilitation has only recently emerged as an option for patients seeking physical therapy services, little research has been conducted to examine its effectiveness or acceptability among patients with chronic LBP. Our study team has provided some of the first research findings pertaining to telerehabilitation for patients with chronic LBP since the expansion of telerehabilitation during the pandemic. For example, a recent study that included members of our study team found that physical therapy delivered using telehealth visits resulted in meaningful reductions in LBP-related disability and improvements in physical function for patients with chronic LBP.[51] Importantly, this study also found that patients reported high levels of therapeutic alliance with their physical therapist, which has been shown to have a strong influence on patient outcomes among patients receiving physical therapy for chronic musculoskeletal pain.[52]

Supplementary Material

There have also been studies published prior to the pandemic that support the use of telerehabilitation for patients with LBP. For example, two systematic reviews conducted in 2021 found that physical therapy provided using telehealth visits resulted in non-inferior outcomes compared to in-person physical therapy for patients with a variety of conditions, including those with LBP.[53,54] An additional systematic review found that digital self-management approaches were feasible and may provide symptom reduction for patients with LBP.[55] Together, these systematic reviews show that telerehabilitation is feasible and can provide symptom relief for patients with LBP. However, the interventions included in these reviews are heterogenous and the majority of included studies were small pilot or feasibility studies. Furthermore, most of these studies were conducted outside of normal clinical settings and do not include implementation data, which is needed to inform efforts to integrate telerehabilitation into routine clinical care. Larger studies embedded within clinical settings are needed to examine the effectiveness and implementation of telerehabilitation for patients with LBP.

Research surrounding patients' perceptions of telerehabilitation is also important as the value that patients ascribe to telerehabilitation may influence their likelihood to attend treatment sessions and to fully engage in the intervention. A recent study by members of our study team utilized survey data from an ongoing clinical trial of patients with chronic LBP to analyze patient acceptance of telerehabilitation.[16] The results of this study indicated that more than half of respondents were willing or neutral about attending telehealth physical therapy with older and Black respondents being more likely to attend telehealth physical therapy.[16] An additional study led by Dr. Skolasky found that patients with chronic LBP considered telehealth to be an acceptable form of physical therapy, with patients reporting advantages to telehealth physical therapy that included convenience, time savings, and personalization of care.[16] The results of the study by Dr. Skolasky are in line with the results from a systematic review of qualitative studies that also found telehealth services to be acceptable by patients with orthopaedic conditions.[56] These results are important as patients are unlikely to actively engage with physical therapy plans

of care delivered through telehealth in they are not accepting of this approach. Patient engagement is paramount in physical therapy given the emphasis placed on active treatment interventions (i.e., exercise). ***Taken together, these studies provide early evidence that telerehabilitation is likely an effective approach to physical therapy and is considered an acceptable approach for patients with chronic LBP.***

A.8 Risk-Stratified Approaches to Physical Therapy for Patients with Low Back Pain: A substantial body of evidence points to the large influence of psychosocial factors on patient-centered outcomes among those with LBP. Elevated levels of depression, fear avoidant beliefs, and pain catastrophizing have each been independently associated with worse outcomes among patients with LBP.[57-61] For example, a systematic review with meta-analysis published in 2022 found that depressive symptoms were associated with self-reported disability and worse recovery among patients with chronic LBP.[61] The authors also found depressive symptoms were associated with greater levels of healthcare utilization among patients with LBP. Two systematic reviews examining the influence of fear avoidant beliefs on outcomes among those with LBP found that patients with elevated fear avoidant beliefs experiences increased pain intensity, higher self-reported disability, and worse work-related outcomes (i.e., sick days).[59,60] Two additional systematic reviews found pain catastrophizing to be associated with delayed recovery and predictive of worse pain and disability among those with LBP.[57,58]

Physical therapy clinical practice guidelines for LBP suggest that physical therapists use composite measurement tools to screen for psychosocial factors that may influence patient outcomes.[62] One of the most commonly used composite tools used to assess the presence of psychosocial risk factors among patients with LBP is the STarTBack Screening Tool (SBST). Designed to assess the risk of persistent disability for patients with LBP, the SBST consists of 9 items to categorize patients as having high, medium, or low-risk for persistent disability or other poor outcomes.[63] Several prospective studies have shown the SBST to be predictive of LBP-related outcomes including response to physical therapy, pain, disability, and healthcare utilization.[63-65]

A stratified care model using the SBST to guide conservative treatment of LBP has been shown to be clinically and cost effective in the United Kingdom (UK).[20,66] In this approach, all patients with LBP (assuming no red flags for serious pathology) are referred to physical therapy for treatment. Those identified as low-risk by the SBST receive a single education and advice session with medium- to high-risk patients receiving follow up sessions at a frequency determined by the treating physical therapy. During these follow up sessions, medium-risk patients receive standard physical therapy while the high-risk group receives additional psychosocial interventions during their sessions, also provided by the physical therapist. Compared to usual care in a randomized clinical trial, those receiving stratified care experienced significantly greater improvements in disability at 4- and 12-months.[20] The stratified group also experienced a greater mean health benefit, measured by quality of life years, compared to the usual care group.[20] This care model has been implemented in multiple other countries with similar results.[67,68] ***Our risk-stratified telerehabilitation approach is largely based on this stratified approach to in-person physical therapy, which has been shown to be feasible and to lead to clinical superior and cost-effective outcomes among patients with LBP.***

Supplementary Material

While previous studies of stratified care for patients with LBP have shown promising results, there are several important limitations to consider. First, stratified care models have primarily been implemented by primary care providers in the UK, where the healthcare system differs greatly from the US.[20,66] While smaller studies have found similar approaches to be feasible in the US, larger efforts to implement stratified care among US primary care providers have met significant challenges, including low provider (i.e., physician) adherence to stratified care protocols.[19,69] It has been speculated that low adherence to stratified protocols by primary care providers in the US was due to time constraints and physician workflow limitations. We plan to address this limitation by moving the responsibility to risk stratify patients from physicians to the physical therapists who will be providing care to the patient. This will also improve the generalizability of our results as many patients self-refer to physical therapy without a physician referral.[70,71] A second limitation of previous stratified care models is that patients considered to be low risk for persistent disability were provided with advice only and no follow up sessions. While the majority of these patients are expected to recover from LBP by simply remaining active, some patients will not recover and are likely to benefit from physical therapy, especially those with chronic LBP.[65] We plan to address this limitation by remotely monitoring low-risk patients using pain and disability measures. This approach will allow us to identify patients not responding to this approach and prevent poor outcomes by intervening with additional telehealth interventions. ***In addition to adapting this model to be delivered remotely, we are confident that these adjustments will improve upon previous risk-stratified care models, resulting in a more feasible and effective model than those that have been tested previously***.

A.9 Conceptual Models Informing Telerehabilitation Approaches for Low Back Pain

The biopsychosocial model for LBP expanded understanding of the influence of cognitive, behavioral, and environmental characteristics factors on health and health outcomes in patients that experience low back pain (**Fig 1**). The application of this model to the understanding of the LBP experience and impact has been an important advance in the field. Previously, the biomedical model focused on the relationship between symptoms

and a discoverable tissue injury or disease process that led to an over-medicalization of the pain experience and increased reliance on invasive diagnostic and treatment procedures.[72,73] The biopsychosocial model recognizes that an individual's pain experience and disability level can be influenced by cognitive, behavioral, and environmental factors.[74] This broader focus supports a multi-dimensional approach to our understanding of diagnosis, treatment, and assessment of LBP.[74,75] While there is broad support for management of chronic LBP that is consistent with the biopsychosocial model, challenges in addressing psychological factors and in engaging patients to manage their chronic LBP have been identified.[76]

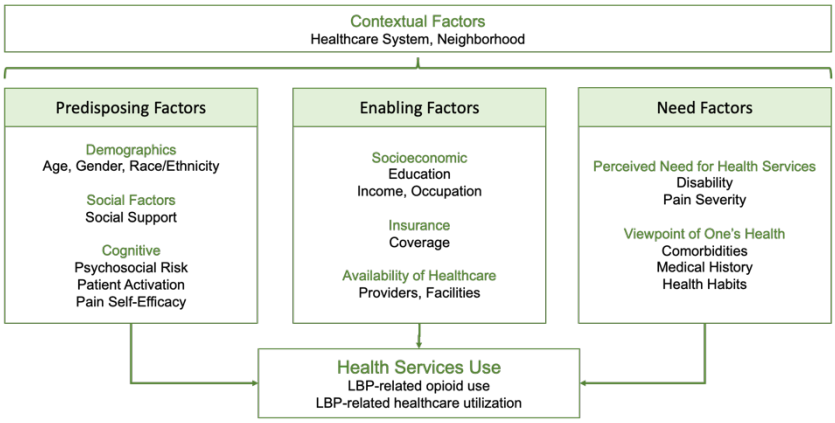

Figure 1. Consolidated framework to guide intervention and measurement strategies

Social cognitive theory provides an understanding of how cognitive, behavioral, and social factors drive changes in human behavior.[77] When applied to our understanding of person factors driving adaptive health behavior changes, cognitive and behavioral factors emphasize the roles that risk perception, outcome expectancies, and self-efficacy[78] play to support engagement in physical therapy care and home exercise, increase participation in daily activities, and reduce the need for opioid or other invasive treatments.[79] Social (or environmental factors) influence LBP behavior and outcomes through the availability of and access to appropriate and timely treatment.

In the original Behavioral Model, Andersen posited that people's utilization of health services was directly related to their predispositions to use services, barriers and facilitators, equitable access to use, and the need for care.[80] The utilization of physical therapy services to treat LBP is related to a person's predispositions to use healthcare resources, barriers and facilitators to accessing those resources, personal characteristics, and equitable access. The key attributes to be measured are person-oriented attributes (the person actively takes part in the process) and person-environment attributes (the person is informed about the health condition and the treatment strategies are tailored to the person's values, needs and environment).[81,82]

Supplementary Material

A.10 Conceptual Models Informing Implementation of Risk-Stratified Telerehabilitation for Chronic Low Back Pain: The pipeline from discovery of evidence-based interventions to their implementation in clinical practice is estimated to be 17 years. While there are many proposed solutions to close this gap, one approach has been to embed strategies that support implementation within effectiveness trials.[83] The current project will delivery evidence-based physical therapy care to patients with chronic LBP using telerehabilitation, with treatment protocols specifically designed to address their psychosocial risk for persistent symptoms or other poor health outcomes. The design of this pragmatic clinical trial will incorporate a Hybrid I effectiveness-implementation design that is guided by the RE-AIM (Reach-Effectiveness-Adoption-Implementation-Maintenance) framework.[84] The Reach, Effectiveness, and Maintenance are individual level factors; whereas, Adoption and Implementation are staff and setting factors. Understanding conditions that would influence the adoption and implementation of risk-stratified telerehabilitation for the treatment of patients with chronic LBP has been informed by the Consolidated Framework for Implementation Research (CFIR).[85] Our implementation strategy is consistent with Implementation Mapping[86] and our measurement strategy has been guided by Proctor's taxonomy for implementation research (**Fig 2**).[87]

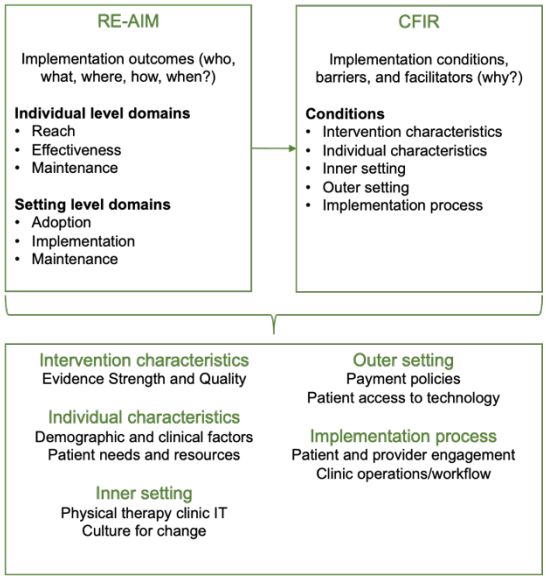

Figure 2. Consolidated framework (RE-AIM and CFIR) to guide implementation.

A.11 Summary of Significance and Scientific Premise: The current project will likely be the first to examine a stratified approach to telerehabilitation for chronic LBP based on an individual's psychosocial risk for poor outcome. While there is sufficient evidence supporting use of traditional in-person physical therapy for the care of patients with chronic LBP,[34,35,88-90] telerehabilitation has only recently emerged as an option for patients and HCS's. While telerehabilitation has great potential to increase access to physical therapy and improve outcomes of patients with chronic LBP in rural communities, research is urgently needed to examine effectiveness of this

approach prior to wider implementation. We have chosen to focus on chronic LBP given its major impact on patient function, opioid consumption, and contributions to healthcare spending in the US.[25] We will embed our study intervention within a community HCS (TidalHealth), spanning two rural counties on the Maryland Eastern Shore. As such, the project is aligned with the NIH Interagency National Pain Strategy to address disparities (i.e., rural-urban) and promote equitable pain care for vulnerable populations, and develop health system interventions aimed at preventing and treating chronic pain.[91] This aligns with the NIH-wide Research Plan on Rehabilitation placing emphasis on research of telerehabilitation strategies to overcome access barriers.[92]

We anticipate that risk-stratified telerehabilitation will result in superior clinical outcomes compared to an education control, while eliminating many of the barriers that patients face when seeking traditional in-person care. Our hypothesis is based on two (2) key findings from previous studies. First, matching patients with tailored physical therapy protocols based on risk of persistent disability (measured by the SBST) has been shown to be efficacious in the treatment of patients with LBP.[19,93,94]Second, there is a growing body of evidence that suggests telerehabilitation is at least as effective as traditional in-person care and can reduce or eliminate many of the barriers that patients face when seeking physical therapy services.[95]

We are uniquely positioned to conduct this study based on our experience in this area. For example, our study team conducted one of the first studies of telerehabilitation for patients with chronic LBP and has produced several publications on this topic.[16,96,97] Our study team was directly involved in conducting one of the largest studies of risk-stratified physical therapy to date.[18] The cumulative experience gained by our study team in conducting these studies, paired with expertise in physical therapy, rehabilitation psychology and implementation science, will provide the foundation needed to successfully design and implement the proposed study.

A.12 Alignment of Project with RFA and NIAMS Priorities: Our project is in response to RFA-NR-23-001 (HEAL Initiative: Prevention and Management of Chronic Pain in Rural Populations). It responds directly to this funding announcement in 5 keys areas. First, this study will be conducted in partnership with a rural HCS (TidalHealth), allowing us to examine “real world” effectiveness and implementation of our study intervention among patients living in rural communities. Second, per the funding announcement, we have identified a community partner with expertise in rural healthcare delivery that will provide important input as we finalize the design of our study intervention and implementation plans during the UG3 phase, as well during the implementation and evaluation of our results during the UH3 phase of the project. Third, our study has selected outcomes relevant to this patient population (i.e., pain, disability) as well as specific to the HEAL initiative (i.e., opioid use). Fourth, we have selected a hybrid effectiveness-implementation study design that will allow more rapid translation of our results into clinical practice. Finally, we have chosen to focus on the treatment of patients with chronic LBP, a condition of interest listed by the funding announcement as well as by NIAMS as a research priority.

Supplementary Material

B. Innovation

This study is innovative because it combines the concepts of risk-stratification and telerehabilitation. While there have been studies examining the use of stratified care for patients with LBP, none have included the use of telerehabilitation. And, likewise, the few studies that have examined telerehabilitation for patients with LBP have not utilized any form of risk stratification to tailor therapy to individual patients. Our study combines the strengths of risk-stratification (i.e., enhanced clinical outcomes) with the strengths of telerehabilitation (i.e., improved access to care) to deliver a treatment protocol that has the potential to expand access to physical therapy while maximizing clinical effectiveness.

This study is innovative as it includes two different forms of telerehabilitation, physical therapy telehealth visits and RTM. Previous studies have examined each approach independently, but few if any have examined the use of both these care-delivery mechanisms based on the needs of individual patients.[16,55] This is an important line of inquiry given that these both represent new care-delivery options for physical therapists and there is little to no research available to guide clinical decisions surrounding which form of telerehabilitation different types of patients are more or less likely to benefit from. By matching patients with treatment approaches based on psychosocial risk levels, using a widely available screening tool (SBST), this study stands to provide valuable guidance to HCSs and individual clinicians seeking to utilize telerehabilitation for patients with chronic LBP.

Our treatment approach is innovative because it is scalable. While the version of the SBST that we will use in this study is specific to chronic LBP, recent studies have found that modified versions of the SBST can reliably measure psychosocial risk and predict physical therapy outcomes for patients with conditions in other body regions, including the knee, shoulder, and neck.[98,99] Because our treatment protocols are stratified based on psychosocial risk rather than physical impairments specific to the lumbopelvic region, we anticipate that the results of this study will be translatable to other body regions and that these results will inform the development of similar risk-stratified telerehabilitation approaches for patients with other chronic musculoskeletal conditions, such as chronic neck pain or knee osteoarthritis.

Our study is innovative because it has been designed to allow for rapid translation of our findings into practice. Historically, research findings have not be efficiently translated into clinical practice.[100] While this is impacted by a number of factors, a major reason for slow and incomplete translation of research findings into practice is the absence of implementation variables in most efficacy and effectiveness studies. To address this limitation, we have elected to use a hybrid effectiveness-implementation study design (Type 1) that will allow us to simultaneously collect information on implementation variables while examining the effectiveness of risk-stratified telerehabilitation for patients with chronic LBP.[83] If our intervention is shown to be effective, these efforts will provide a framework for program sustainability at our partner HSC, allowing them to continue providing risk-stratified telerehabilitation for patients with chronic LBP after the completion of the study. In addition, our careful attention to barriers and facilitators to implementation guided by the Consolidated Framework for Implementation Research will provide an implementation strategy for other rural HSCs wishing to adopt this approach to management of chronic LBP populations.

C. Preliminary Work

C.1 Preliminary Work Training Physical Therapists to Provide Psychologically Informed Physical Therapy: The team has considerable experience and expertise in developing, delivering, and assessing the adequacy of training for physical therapists to provide psychologically informed physical therapy (PIPT) for patients with LBP.

Summarize relationships between pain neuroscience, pain models, and development chronic low back pain
Identify patients at high risk for transitioning from acute to chronic low back pain
Apply targeted treatment for patients at high risk for transitioning from acute to chronic low back pain
Recognize effective communication skills and be able to implement as a key component
Differentiate key principles and application between graded activity and graded exposure
Review Low Back Pain Clinical Practice Guidelines to become familiar with ICF-based classifications; symptoms; impairments; and intervention strategies
Be able to implement PIPT practice principles for patients with low back pain

Table 1. Learning Objectives for PIPT in TARGET Trial

Dr. Wegener (Co-I) is a rehabilitation psychologist at the Johns Hopkins University who has worked on the development of training protocols for the delivery of PIPT for patients with LBP presenting to primary care as part of the PCORI-funded TARGET trial (NCT03859713).[101] The TARGET trial was a multisite, pragmatic, cluster-randomized clinical trial studying patients with acute LBP seeking care from a primary care provider with elevated psychosocial risk for persistent disability (NCT02647658).[17] Dr. Wegener collaborated with a multidisciplinary team representing physical therapy and clinical psychology to develop a pragmatic training program that was tested and modified using an iterative process to enhance optimal effects intended to be implemented during routine clinical practice (**Table 1**). PIPT training was delivered in a 1-day format with a flipped classroom format and post-treatment booster sessions with each physical therapist being provided course materials (i.e., workshop content, including specific descriptions and scenarios pertaining to PIPT interventions such as patient-centered communication, pain coping skills, patient education, activity-based intervention, impairment-based intervention, and treatment monitoring components). Treatment fidelity checklists were integrated into the EHR to assess fidelity. The team trained nearly 500 physical therapists at 5 national trial sites to deliver PIPT to patients with LBP at elevated risk for transition to chronic pain.

Supplementary Material

MPIs Drs. Skolasky and McLaughlin (MPIs) have both been directly involved in efforts surrounding the development and implementation of a training program for physical therapists to provide evidence-based treatment for patients with chronic LBP as part of the PCORI-funded OPTIMIZE trial. The OPTIMIZE trial is an ongoing pragmatic clinical trial with a SMART design at the University of Utah (lead), Johns Hopkins Medicine, and Intermountain Healthcare. Physical therapists in this study provide evidence-based physical therapy for chronic LBP consisting of patient education, exercise instruction, and manual therapy, tailored to the needs of individual patients based on examination findings and psychosocial risk factors. Participating physical therapists receive an initial 8-hour training with quarterly 1-hour telephone booster sessions over the course of the trial. Physical therapists were provided manuals and online resources outlining core components for the evidence-based treatment. The OPTIMIZE study is ongoing with more than 200 physical therapists trained to date.

C.2 Preliminary Work with Physical Therapy Telehealth Visits for Patients with Low Back Pain: The MPI (Dr. Skolasky) has worked closely with colleagues at the University of Utah and Intermountain Healthcare to adapt an in-person physical therapy protocol for patients with chronic LBP to be delivered using telehealth visits.[101] This work involved training physical therapists to deliver a physical therapy protocol that focused on education and exercise, tailored to participants' clinical presentations based on the treatment-based classification system

decision-making algorithm.[102] Adaptations to in-person evaluation procedures to accommodate the use of telehealth visits included consideration of privacy, distractions, and safety in the patient's environment. Assessments of impairments in mobility, strength and flexibility were adapted to use observation instead of hands-on techniques. Adaptations to the treatment procedures included removing the manual therapy component and supplementing the exercise and education components of care with commercially available patient education and exercise video modules (Medbridge Inc., Seattle, WA) that could be tailored to the patient and accessed through a mobile app or web-based platform to facilitate participants' self-management in between telehealth visits.

Working Alliance Domain	Mean (SD)	Median
Goal Subscale (Patient perception of agreement with therapist on treatment goals)	16.5 (4.3)	18
Task Subscale (Patient perception of agreement with therapist on tasks to accomplish treatment goals)	15.6 (4.3)	17
Bond Subscale (Patient perception of a personal bond with their therapist made up of reciprocal positive regard)	16.7 (4.2)	19
TOTAL WAI-SR Score	48.8 (12.2)	54

Table 2. Working alliance scores at the 10-week assessment among participants who received telehealth physical therapy (n=77). Maximum score is 20 for the subscale scores and 60 for the total WAI-SR score.

We have completed an observational trial nested within a larger pragmatic trial (NCT05103462) to examine implementation and effectiveness outcomes of this adapted physical therapy telehealth protocol for patients with chronic LBP (n=126).[16] Implementation outcomes included acceptability, appropriateness, feasibility, and fidelity. We demonstrated high working alliance between therapists and patients, with patients endorsing meaningful reductions in LBP-related disability and improvements in physical function (**Table 2**)[51]

	Overall	≥50% Improvement	<50% Improvement	P-Value
SBST Category, N (%)				
Low	16 (16.3)	5 (31.2)	11 (13.4)	0.04
Medium	53 (54.1)	10 (62.5)	43 (52.4)	
High	29 (29.6)	1 (6.3)	28 (34.2)	
Anxiety (PROMIS-29), mean (SD)	54.3 (10.5)	49.2 (10.9)	55.2 (10.2)	0.04
Pain Self-Efficacy, mean (SD)	32.9 (12.3)	38.4 (10.5)	31.8 (12.3)	0.05
NPRS, mean (SD)	5.6 (1.8)	4.5 (1.6)	5.8 (1.8)	0.01

Table 3. Changes in Oswestry Disability Index scores 10-weeks after initiation of telerehabilitation for chronic LBP (N=98). Changes scores dichotomized to +/- 50% improvement to reflect substantial clinical benefit. NPRS: Numerical Pain Rating Scale; SBST: STarTBack Screening Tool

Supplementary Material

Drs. McLaughlin and Skolasky (MPIs) have also recently completed a secondary analysis of this data, with significant trends indicating patients with lower psychosocial risk per the SBST are more likely to experience substantial clinical benefit (≥50% reduction in LBP-related disability) from standard telerehabilitation for chronic LBP than patients with higher levels of psychosocial risk (**Table 3**) (in review). During this analysis, we also identified other baseline factors associated with substantial clinical benefit from telerehabilitation, including pain self-efficacy, anxiety, and pain severity. This analysis also indicated that a tailored approach is required for patients with high psychosocial risk for persistent disability, which was not included in the previous study.

C.3. Preliminary Work with Remote Therapeutic Monitoring for Patients with Musculoskeletal Pain

During the early stages of the COVID-19 pandemic, outpatient rehabilitation clinics were forced to restrict in-person visits for infection control purposes. During this time, orthopaedic surgery clinics at Johns Hopkins Medicine began to offer access to an RTM platform for patients with non-operative musculoskeletal pain (Limber Health). Between May 2020 and June 2022, 318 patients were enrolled on the Limber Health digital treatment platform. This included patients with shoulder (51%), knee (44%), hip (3%), and low back (2%) pain. Once provided access to the digital treatment platform, patients interacted with the platform an average of 19.7 (standard deviation (SD) 36.7) times during their episode of care. Patients experienced an average decrease in pain of 3.8 points (SD 7.3) measured using PROMIS-Pain Interference computer adaptive test (CAT). In addition to reduction in pain, these patients experienced improvements in physical function. Those with shoulder pain experienced an average improvement in function of 2.6 points (SD 7.8) measured using the PROMIS – Upper Extremity Function CAT. All other patients experienced an average improvement in function of 4.3 points (SD 7.8) measured using the PROMIS – Physical Function CAT. Assuming a minimal clinically important difference (MCID) of 5 points for each condition and PROMIS measure[103] we found that 38% of patients with shoulder conditions experienced improvements in upper extremity function that surpassed the MCID. We also found that 43% of those with knee, hip or low back pain experienced improvements in function that surpassed the MCID. We also observed that 38% of all patients experienced improvements in pain interference that surpassed the

MCID. Data shows that RTM delivered using a commercially available digital treatment platform was feasible, patients engaged with the platform regularly, and experienced improvements in pain and physical function. The patients utilizing the digital treatment platform in this dataset were not stratified in any way and it is likely that targeting specific patient groups, like in the proposed study, may have resulted in superior clinical outcomes. The proposed study will assist in elucidating the types of patients most likely to respond well to this approach.

C.4. Preliminary Work with EHR-Based Recruitment Strategies: Our research team is currently collaborating on a pragmatic clinical trial of non-pharmacologic treatments for patients with chronic LBP that has developed robust systems that support EHR-based screening and recruitment, treatment initiation and retention, and fidelity assessment. The investigators at each site, including Dr. Skolasky at Johns Hopkins, have worked with their respective clinical data acquisition teams to optimize the clinical utility of their respective EHRs. Using these tools, the research teams were able to identify all potentially eligible patients who had presented to primary or specialty outpatient clinics meeting certain ICD-10 diagnostic coding consistent with non-specific low back pain and absent for red-flag conditions for screening and recruitment. All enrolled participants were identified in the EHR with a study specific ID to allow automated reports to be generated indicating scheduled, completed, and canceled intervention visits to monitor treatment initiation and retention. Finally, provider checklists were built into the EHR to support fidelity monitoring of key intervention components delivered at each session.

In summary, this project builds on the established experience that the research team has leveraging the EHR to conduct high-level clinical research. Our team plans to work closely with our rural HSC partner, who uses the same EHR platform (Epic), in order to facilitate similar methods for patient recruitment, treatment initiation and retention, and fidelity assessment using their EHR.

Supplementary Material

D. Approach

D.1 Summary of Design and Study Organization: Our goal is to improve patient-centered outcomes and decrease opioid consumption among patients with chronic LBP living in rural communities. This project focuses

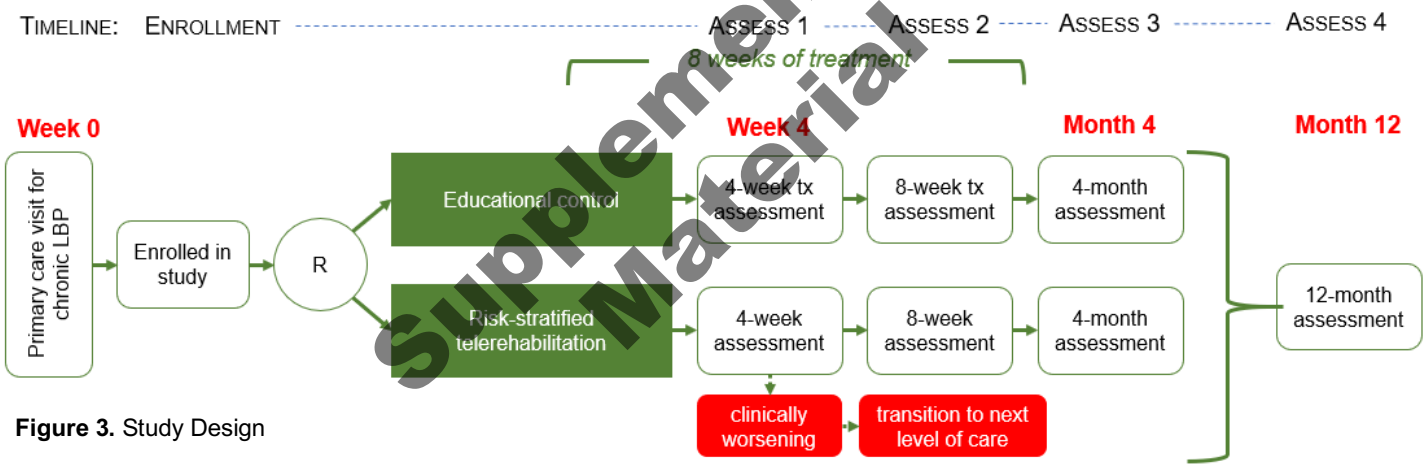

Figure 3. Study Design

on chronic LBP given its prevalence, negative impact on function (i.e., disability)[22-24,26,104], and the high rates of opioid consumption observed among patients with chronic LBP.[26,31] Our research strategy is to expand access to physical therapy for patients with chronic LBP by providing a patient-centered approach to telerehabilitation that leverages evidence on psychosocial risk for poor outcomes to provide effective treatment focusing on education, exercise, and monitoring of patient-reported outcome measures.

Based on our conceptual framework (**Figs 1 and 2**), we will use a risk-stratified approach to providing physical therapy that will match patients with a specific telerehabilitation protocol based on known psychosocial risk for persistent disability, measured by the SBST. We anticipate that providing physical therapy using telerehabilitation will reduce or eliminate many of the barriers associated with receiving in-person physical therapy, leading to increased utilization of physical therapy services, which will in turn lead to superior clinical outcomes (less pain, disability), and decreased utilization of opioids for pain management. To test these hypotheses, we will conduct a hybrid effectiveness-implementation study of our risk-stratified telerehabilitation approach compared to an educational control provided over 8 weeks using a pragmatic randomized single-blind clinical trial, embedded within a rural HCS on Maryland's Eastern Shore (TidalHealth).

Following baseline assessment, all participants will be individually randomized to receive telerehabilitation or standard education (**Fig 3**). Patients assigned to the educational control group will receive access to a study

website with evidence-based advice on self-management techniques for chronic LBP and education on the importance of remaining active and maintaining a healthy lifestyle (i.e., adequate sleep, healthy diet).

Those assigned to the risk-stratified telerehabilitation will receive care based on their risk category, as determined by the SBST including RTM (low-risk), standard physical therapy telehealth visits (medium-risk), and PIPT telehealth visits (high-risk) (**Table 4**). All telerehabilitation interventions will be delivered by a trained physical therapist at TidalHealth.

This study uses a pragmatic approach, allowing physical therapists to focus on exercise interventions that they consider appropriate based on examination findings and patients' treatment response. At 4-weeks of treatment, participants in the risk-stratified telerehabilitation group will be assessed to determine early treatment response. Patients in the low and medium-risk groups who experience worsening of LBP-related disability (ODI decline from baseline of ≥6 points) will be transitioned to the next highest level of care. For example, a patient in the low-risk group who reports a ≥6-point decline in disability (per the ODI) after receiving 4 weeks of RTM will be transitioned to receive standard physical therapy telehealth visits (*see section D.6.2 for more information*).

SBST risk group	Matched Treatment
Low risk	Remote therapeutic monitoring
Medium risk	Standard physical therapy telehealth visits
High risk	Psychologically informed physical therapy telehealth visits

Table 4. Risk categories and match treatment approaches

We will collect patient reported outcome measures to examine the effectiveness of risk-stratified telerehabilitation compared to an educational control after 8 weeks of treatment (**UH3 Aim 1**). The planned primary study outcome is LBP-related disability assessed using the Oswestry Disability Index (ODI). NIH-PROMIS physical function (PROMIS-PF) will serve as key secondary outcomes, with pain intensity (PEG Scale) and health-related quality of life (HRQoL, PROMIS 29 v2.0 Profile) serving as exploratory outcomes. All outcomes will be assessed at baseline and at 8-, 16-, and 52-weeks. Importantly, we will also compare downstream LBP-related opioid use among patients in each group following the completion of the 8-week intervention at 16- and 52-weeks, using patient surveys and data extracted from the EHR (**UH3 Aim 2**). We will include other LBP-related healthcare utilization (i.e., physician office visits, injections, diagnostic imaging) as a secondary outcome for this aim.

We have employed a Type I Hybrid effectiveness-implementation design[100] for the current project that emphasizes the evaluation of clinical effectiveness but allows for the collection of important implementation variables that can be used to inform future studies and quality improvement efforts surrounding telerehabilitation for patients with musculoskeletal pain. The implementation variables that we have chosen to focus on are based on the RE-AIM framework and Proctor's taxonomy of implementation research outcomes (acceptability, adoption, feasibility, and fidelity) (**UH3 Aim 3**). These variables will be examined using a mixed-methods approach that includes patient and providers surveys, semi-structured interviews, focus groups, and key process metrics. We believe that our risk-stratified telerehabilitation approach is scalable to patients with other types of musculoskeletal conditions and that these implementation outcomes will inform efforts to adapt the model to patients with conditions other than chronic LBP.

Supplementary Material

Our study has two phases. The first is a 1-year UG3 (Planning) Phase that will be used to finalize and refine important aspects of the study including intervention protocols, implementation strategies, outcomes collections, sample size, and statistical analysis plans. The second is a 4-year UH3 (Clinical Trial) Phase used to examine effectiveness of our treatment approach and to collect important implementation data used to inform future efforts in this area.

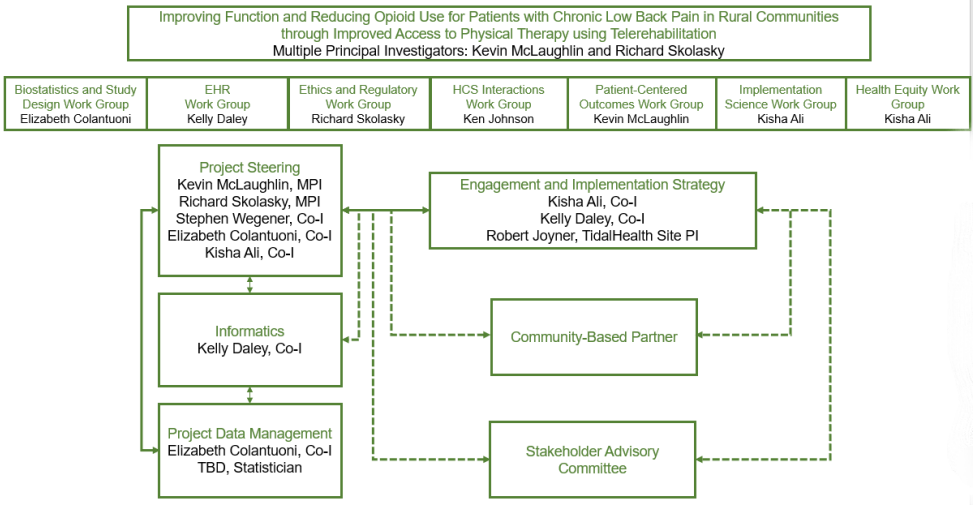

Figure 4. Organizational Framework

D.2 Expertise of Study Team: Team members from Johns Hopkins Medicine and TidalHealth provide the requisite experience and expertise to conduct the proposed project and to fully engage with work groups across the NIH Pragmatic Trials Collaboratory. We have developed an organizational framework (**Fig 4**) to oversee key components of the UG3 (Planning) and UH3

(Clinical Trial) Phases. Member and structure will be finalized in Year 1 during the UG3 (Planning) Phase.

Dr. Skolasky began his research career through AHRQ-funded research (R03HS016106) that examined the role that patient activation played in engagement in physical therapy and home exercise.[105,106] That experience was critical in the development and testing of Health Behavior Change Counseling (HBCC) to increase patient activation and to improve rehabilitation engagement and health outcomes in patients undergoing lumbar spine surgery (AHRQ, R01HS017990).[107-110] He is currently site-PI on a PCORI-funded trial to optimize the sequencing of non-pharmacologic treatments for patients with chronic LBP (the OPTIMIZE trial). This study, conducted with the University of Utah (lead) and Intermountain Healthcare, randomizes patients to physical therapy, cognitive behavioral therapy, or mindfulness-oriented recovery enhancement using a SMART design. Dr. Skolasky has collaborated with researchers and clinicians in the Departments of Orthopaedic Surgery and Physical Medicine & Rehabilitation and the Johns Hopkins Community Partners to develop and test interventions to understand the role of patient activation and health behavior and outcomes and to support treatment of patients with chronic LBP that are directly relevant to the current proposal.

Dr. McLaughlin is a residency and fellowship trained physical therapist with over 10 years of clinical experience treating patients with chronic LBP. In addition to his clinical expertise, Dr. McLaughlin's experience conducting rehabilitation health services research has prepared him well to serve as MPI for this study. Dr. McLaughlin is a member of the Johns Hopkins study team conducting the OPTIMIZE trial, a PCORI-funded study focused on the conservative treatment of patients with chronic LBP.[101] As part of his role on this study, he is responsible for overseeing the training of all physical therapists providing care as part of the clinical trial. Dr. McLaughlin is currently serving as the principal investigator on a study examining the feasibility of telerehabilitation following surgical ankle fracture repair (NCT04235907). He has also led efforts surrounding adaptations to physical therapy services provided in non-traditional environments during the COVID-19 pandemic, including field hospitals in Baltimore City.[111] Through his research, Dr. McLaughlin has collaborated closely with researchers and clinicians in the Department of Orthopaedic Surgery and the School of Public Health.

Dr. Colantuoni is a Senior Scientist in the Department of Biostatistics at the Bloomberg School of Public Health and has been the lead Biostatistician for the Outcomes after Critical Illness or Surgery (OACIS) research group at the School of Medicine, Johns Hopkins University for over 10 years. She has extensive expertise in the design and analysis of randomized controlled trials; including work on statistical methods that utilize prognostic baseline variables to improve precision to estimate marginal treatment effects. She has received funding from AHRQ as well as the NIH and is currently the PI of a NIA-funded grant (AG061384) evaluating current and develop novel statistical methods for trials where the primary outcome is delirium. She has collaborated extensively with faculty from the School of Medicine, Johns Hopkins University including from Pediatrics, Pulmonary and Critical Care Medicine and Physical Medicine and Rehabilitation.

Dr. Wegener is a rehabilitation psychologist who has conducted several studies employing CBT in the treatment of patients with pain including low back pain.[112-114] Importantly, he has also led the training of physical therapists to provide PIPT for a previous study focused on risk-stratified physical therapy for patients with LBP.[17] He has provided clinical services and conducted research with individuals with musculoskeletal pain, disability and chronic illness for 20 years. He has led multidisciplinary research team and coordinated the ongoing quality assurance activities. He is PI of a DoD funded multisite clinical trial evaluating a collaborative care intervention to improve outcomes following orthopaedic trauma.

Dr. Ali is a health services researcher with experience and expertise in rural health quality improvement, patient safety, and quality of care implementation science, study design, and content development. Her experience includes developing, implementing, and sustaining, patient safety and quality improvement programs in US and international hospitals. Dr. Ali has led efforts to conduct assessments at rural hospitals, train public, low-resource hospitals at a system-level on using patient safety and quality improvement tools and used mixed-methods analyses to inform recommendations for improving patient care within the constraints of existing resources.[115-117] Dr. Ali currently works at MedStar Health Institute for Quality and Safety as part of a multi-disciplinary team developing patient safety and quality improvement resources, metrics, and training materials. Her current work is funded by the Agency for Healthcare Research and Quality (AHRQ).

D.3 Approach for UG3 (Planning) Phase: During the UG3 (Planning) phase, we will make all necessary preparations for transition to the UH3 (Clinical Trial) phase. Our specific aims for the UG3 phase are listed below. These aims are reflective of our UG3 milestones, 22 in total, described in the Milestone Plan (*see attachment*) section. The following sections describe our approach to accomplishing each of the following aims:

1. *Finalize risk-stratification process, intervention protocols, and treatment fidelity assessments.*
2. *Finalize clinically relevant outcome measures, data collection methods, and data analysis plan.*
3. *Finalize plans to identify patients and extract data from EHR systems and validate using preliminary data.*
4. *Refine trial design, sample size, number of recruitment sites, and implementation strategies.*

Supplementary Material

D.4 Identification of a Community-Based Partner: To aid in the completion of our aims, we will identify a community-based partner in the first 1-2 months of the UG3 (Planning) Phase. This community partner will be an organization with expertise or special interest in the delivery of healthcare for patients living in rural communities. Specifically, we will seek out a community organization or advocacy group with intimate knowledge of the barriers that patients living in rural Maryland face when seeking out physical therapy care. We will work closely with our community-based partner to identify barriers and facilitators to telerehabilitation for patients in our target population and work with them to develop innovative implementation strategies tailored to the needs of this population. We will also solicit their advice on how best to measure the impact of our intervention and evaluate our results. Lastly, we will work closely with our community-based partner to disseminate the results of our study among patients and healthcare providers in rural areas of Maryland, as to accelerate the translation of our findings into clinical practice**.**

D.5 Procedures to Finalize Risk Stratification, Intervention Protocols, and Fidelity Assessment (UG3 Aim 1) During the UG3 (Planning) Phase we will coordinate with the work groups of the NIH Pragmatic Trials Collaboratory to refine and finalize our approach to risk stratification, intervention protocols for risk-stratified telerehabilitation and the education control, and EHR-based assessment of intervention fidelity.

D.5.1 *Risk Stratification*: We will finalize our methods for risk-stratification during the planning phase of the study. We plan to use the SBST to identify patients' level of psychosocial risk for persistent disability and other poor health outcomes. The SBST was specifically developed with the intent of identifying appropriate management strategies for patients with LBP based on risk of developing more persistent or severe symptoms.[63]. The SBST includes 9 items with the first 4 questions assessing comorbid pain, disability, and referred leg pain and the remaining 5 items assessing bothersomeness, pain catastrophizing, fear avoidance, anxiety, and depression. Items are each scored dichotomously (0 or 1). The scale includes a total score from 0-9 points and a psychosocial sub-score (final 5 questions) from 0-5 points. Patients with a total score of ≤3 are considered *low-psychosocial risk*. Patients with a total score of >3 and a psychosocial sub-score of ≤3 are considered *medium-psychosocial risk*. Patients with a total score >3 and a psychosocial sub-score of ≥4 are considered *high-psychosocial risk*. The SBST has been used in several previous studies to facilitate stratified care models (see section A.8 for additional information). Based on a previous multicenter study focused on physical therapy for patients with LBP, we anticipate that 39% of patients will be classified as low-psychosocial risk, 36% as medium-psychosocial risk, and 25% as high-psychosocial risk.[18]

D.5.2 *Intervention Protocols*: The current study will compare outcomes between patients randomly assigned to one of two study interventions for the treatment of chronic LBP. Prior to their initial appointment, all participants will have completed the baseline assessment that includes SBST risk stratification and random assignment to one of the two study interventions: educational control or risk-stratified telerehabilitation. Written protocols for each intervention will be developed based on existing protocols from the literature and past work of the research team with input from patient and provider stakeholders, including our community-based partner (to be named).

Supplementary Material

To enhance treatment fidelity our written protocols will include: 1) provider training emphasizing the importance of fidelity; 2) detailed intervention manuals; and 3) on-going fidelity monitoring. We will monitor fidelity during the project and take steps to avoid contamination or bias in providing treatment. Each provider will complete a fidelity checklist for all study intervention sessions. Checklists will be embedded in EHR and include key intervention components. Researchers will review at least 25% of intervention session checklists for each study provider. Once a provider reaches 90% fidelity to key components, we will continue to monitor at least 10% of the provider's sessions. We will provide feedback to providers whose fidelity falls below 90%. To facilitate ongoing fidelity, trained providers will take part in one-hour telephone calls to review two randomly selected participant intervention sessions. Training calls will be scheduled quarterly. In-person training will be provided annually and will include competency assessments conducted by the research team.

D.5.2.a Educational Control: Patients randomized to the educational control group will receive registered access to a study website with access to evidence-based education for patients with chronic LBP. Each participant will have unique login credentials to allow for tracking of individual patient use. The website will include important education on the etiology of chronic LBP and evidence-based suggestions for self-management of symptoms. Education will focus on the importance of maintaining healthy levels of physical activity and avoiding bedrest. To promote increased physical activity levels, the website will also include pictures and videos of common exercises targeting the lumbopelvic region that patients can perform independently without the need for exercise equipment. We will also provide information on physical activity guidelines and suggestions of activities that can be used to meet these guidelines. The website will also provide information on other important components of a healthy lifestyle, including diet and sleep, based on publicly available guidelines.

D.5.2.b Risk-Stratified Telerehabilitation: Our telerehabilitation protocol will begin with a physical therapy evaluation conducted via telehealth visit. This form of evaluation has been shown to be reliable compared to in-person evaluations for patients with LBP.[118] Based on prior SBST risk stratification, participants in the risk-

stratified telerehabilitation group will receive subsequent care using 1 of 3 delivery methods: **RTM (low-risk), standard physical therapy telehealth visits (medium-risk), or PIPT telehealth visits (high-risk) (Table 4)**. These approaches were chosen based on previous studies of stratified care for patients with LBP that match the intensity of physical therapy care with patients' risk of developing persistent disability.[19,20] The key components of the intervention provided to those in the risk-stratified telerehabilitation group can be tailored by the treating physical therapist based on examination findings and patient response to treatment.

Remote therapeutic monitoring (RTM), an asynchronous form of telerehabilitation, will utilize a digital treatment platform (Limber Health – see letter of support) to deliver education and exercises that can be accessed via internet or mobile application for low-risk participants. Treatment progress and engagement will be monitored by a trained physical therapist. The digital treatment platform has education modules on topics relevant to chronic LBP (i.e., pain neuroscience) that will be assigned to participants. Exercises will be assigned by the treating physical therapist and will be accompanied by pictures, videos, and written instructions on how to perform each exercise. Designed to be a more independent approach to physical therapy, this care delivery method does not include scheduled face-to-face visits with a physical therapist. However, it does require at least monthly direct communication between the physical therapist and patient per CMS guidelines.

This approach to delivery of physical therapy provides important improvements over "advice only" approaches that have been utilized for low-risk patients in previous risk-stratified approaches to LBP.[17,19,20] First, the platform allows for customized education and exercise plans to be issued to patients versus standardized one-size-fits-all material. Second, it allows participant response to and engagement with treatment to be monitored by a physical therapist. Participants will receive questionnaires following each exercise session that assess difficulty and pain experienced with each exercise. This information allows physical therapists to progress exercises as appropriate. Also, the digital platform collects weekly patient-reported outcomes from participants and displays them on a provider dashboard that allows the treating physical therapist to identify individuals not responding to this approach and to intervene. Furthermore, the digital treatment platform allows patients to directly contact the treating physical therapist with questions or concerns using a secure patient messaging system.

Standard physical therapy telehealth visits will be delivered to participants who have medium-risk for persistent disability using video-conferencing technology for real-time, interactive experiences between the treating physical therapist and participant. Like the other treatment approaches, interventions delivered to patients in the medium-risk subgroup will be guided by findings of the physical exam and individual participant needs. This approach was chosen for patients in the medium-risk group as they are likely to have slightly more severe symptoms and/or elevated psychosocial risk factors compared to those in the low-risk group and are more likely to benefit from physical therapy provided in a synchronous fashion. This is in alignment with previous stratified care models for patients with LBP that have benefited from standard physical therapy visits.[19,20,93]

Psychologically informed physical therapy (PIPT) telehealth visits will be delivered to participants with high-psychosocial risk. PIPT telehealth visits will be provided using real-time, interactive communication technologies between the physical therapist and patient. PIPT merges impairment-focused physical therapy with Cognitive Behavioral Therapy (CBT) methods as needed to reduce the risk of poor outcomes by providing targeted treatment aimed at ameliorating psychological factors linked to persistent disability. Like each of the other treatment approaches, PIPT interventions delivered by telehealth visits will be based on findings of the physical exam and individual patient needs. This approach was chosen for patients in the high-risk group as they are likely to have more severe symptoms and/or elevated psychosocial risk factors compared to those in the low- or medium-risk groups and are more likely to benefit from a physical therapy protocol that is specifically geared to psychological risk factors (i.e., fear avoidance, pain catastrophizing) using components of CBT. This is in alignment with previous studies that have found patients with high-risk SBST scores to respond more readily to PIPT compared to standard physical therapy.[19,93]

D.5.3 Physical Therapist Training: All physical therapists providing care as part of the current project will complete an in-person study training during the UG3 (Planning) Phase. Training will be led by research team members with expertise in physical therapy (Dr. McLaughlin and Ms. Stone) and pain psychology (Dr. Wegener), both of whom have experience training physical therapists to provide care for those with chronic LBP as part of previous studies.[17,101] Training for all physical therapists will include procedures related to human subjects' research, HIPAA privacy protections and procedures for adverse event reporting. Training for this study will involve approximately 10 hours of instruction including a combination of didactic learning and hands-on training. Education topics pertaining to examination and treatment are listed below.

1. ***Evaluation***: Physical therapists will be trained on how to adapt standard physical therapy examination techniques for telehealth visits. For example, physical therapists will be trained on ways to substitute observation for examination techniques that typically require hands-on techniques when performed in person. They will also be trained on effective interviewing techniques, such as the use of open-ended questions, to obtain important information from patients that may inform their treatment approach.

Supplemental Material

2. ***RTM***: Physical therapists will be trained on all technical aspects of the Limber Health platform as required to provide treatment. This includes how to access the Limber Health platform, create patient profiles, assign patient exercises, monitor patient outcomes and engagement with platform, and how to communicate with patients using the secure message system.
3. ***Standard Physical Therapy Telehealth***: Physical therapists will be trained on how to access videoconferencing tools embedded within the TidalHealth EMR. They will also receive training on best practices surrounding exercise prescription and education for patients with chronic LBP. We will also provide training on how to adapt hands-on therapy techniques (i.e., joint mobilizations) so that patients can perform themselves at home (i.e., self-mobilizations). Lastly, physical therapists will be educated on approaches to monitoring patient outcomes and adapting their interventions based on patient progress.
4. ***PIPT Telehealth***: PIPT training will utilize a training protocol developed by members of our team for a previous study focused on the treatment of LBP for patients with high psychosocial risk scores on the SBST (see section C.1).[17] The primary components of PIPT training will include patient-centered communication (e.g., motivation interviewing), pain coping skills (e.g., progressive relaxation), and patient education (e.g., therapeutic neuroscience).

D.6 Procedures to Finalize Clinically Relevant Outcome Measures, Data Collection Methods, and Data Analysis Plan (UG3 Aim 2): We will finalize the primary, key secondary, and exploratory study outcomes in collaboration with the NIH Collaboratory during the UG3 (Planning) Phase and will ensure that our outcomes are aligned with the HEAL Core Measures and the NIAMS BACPAC minimum dataset. As part of this aim, we will also finalize our data collection and analysis plans. The following sections describe our initial plans for each of these areas.

D.6.1 Outcome Measures: Outcomes are based on extensive planning with our research team, physical therapy providers, and clinical operations staff and are informed by NIH (i.e., HEAL, NIAMS BACPAC), FDA, and ICHOM standards for outcomes assessment in patients with chronic LBP (**Table 6**).

To assess the clinical effectiveness of risk-stratified telerehabilitation compared to standard education (**UH3 Aim 1**), our primary outcome will be LBP-related disability assessed using the Oswestry Disability Index (ODI) – a disease-specific instrument assessing impact of spinal disorders on ten aspects of daily living. ODI has excellent re-test reliability ($r > 0.80$) and validity.[119,120] Our key secondary outcome will be physical function, measured by the NIH Patient Reported Outcome Measurement Information System (PROMIS)-29 v2.0 Profile. Exploratory outcomes will include pain intensity measured by the PEG Scale[121] and health-related quality of life (HRQoL) measured by the PROMIS-29 v2.0 Profile.

To assess the effect of risk-stratified telerehabilitation on opioid consumption (**UH3 Aim 2**), we will survey patients on opioid use over the previous 30 days at 16- and 52-weeks from enrollment. In addition, we will extract opioid prescription data from the EHR. We will use a similar approach to examine secondary outcomes focused on other LBP-related healthcare utilization.[122,123]

We will examine heterogeneity of treatment effect among pre-defined patient sub-groups defined by gender, psychosocial risk, and current opioid use (**UH3 Aim 3**) using outcomes collected in UH3 Aims 1-2.

To examine the implementation of risk-stratified telerehabilitation at our partner HSC (**UH3 Aim 4**), we will employ the RE-AIM framework[124] to examine implementation outcomes guided by Proctor's taxonomy[87]: *acceptability* (number of patients with chronic LBP who accept study participation out of those who are approached for screening), *adoption* (perceived advantages and disadvantages from a survey of physical therapists and patients), *feasibility* (number of scheduled intervention visits completed [medium, high-risk], number of sessions logged [low-risk]), and fidelity (number of key intervention components delivered out of the total number of intervention sessions provided).

We will assess participant safety through monitoring of adverse events during study participation. Adverse events will be captured using the Common Terminology Classification for Adverse Events (National Cancer Institute Updates CTCAE, to version 4.0.3). Safety comparisons between the two study groups will use Chi-square tests to test the proportion of individuals who experienced any adverse events, any related adverse events, organ system AEs, specific AEs such as falls and hospitalizations.

Supplementary Material

Variable	Suggested Measure/Source	Item[1]	Base[2]	8 wk[2]	16/52 wk[2]
Predisposing Factors					
Socio-demographic[†,‡]	Age, Gender, Race/Ethnicity	6	✓		
Social support[†]	Marital/Partner Status	2	✓		
Cognitive[†]	Psychosocial Risk (SBST)	22	✓		
Enabling Factors					
Education/Economic[†]	Education, Income, Occupation	3	✓		
Insurance[†,‡]	Coverage	2	✓		

Variable	Suggested Measure/Source	Item[1]	Base[2]	8 wk[2]	16/52 wk[2]
Need Factors					
Co-morbidities[†,‡]	Elixhauser Comorbidity Index (CCI)	19	✓		
Medical History[†,‡]	Pain Medications; Past Treatment	8	✓		
Health Habits[†]	Smoking, Alcohol Use, BMI (height & weight)	4	✓		
Effectiveness Outcomes (UG3 Aim 1)					
Disability[†]	**Oswestry Disability Index (ODI) (Primary)**	10	✓	✓	✓
Physical function[†]	PROMIS 29, v2.0 Physical Function (Secondary)	5	✓	✓	✓
Pain intensity[†]	PEG Scale (Exploratory)	3	✓	✓	✓
Quality of Life[†]	PROMIS 29, v2.0 Profile (Exploratory)	29	✓	✓	✓
Health Use Outcomes (UG3 Aim 2)					
Opioid Use[†,‡]	Recent opioid use for low back pain	2	✓	✓	✓
Health Care Use[†,‡]	Physical therapy (external to trial), Physician/ED visit, Imaging, Pain interventions, Medications, Back surgery	6	✓	✓	✓
Implementation Outcomes (UG3 Aim 4)					
Acceptability	Interest in study participation, Refusal reason	N/A	✓		
Adoption	Survey of perceived advantages/disadvantages	N/A	✓	✓	
Feasibility[‡]	Treatment initiation and retention	N/A	✓	✓	
Fidelity[‡]	Number of key components delivered	N/A		✓	
Safety					
Safety[*,**]	Adverse Events	N/A	✓	✓	✓

Table 6. Assessment Schedule

[†] Data provided through patient self-report

[‡] Data provided through passive EHR collection

[1] Number of items that participants must complete

[2] All assessments conducted over telephone or using emailed link to REDCap project

Supplementary Material

D.6.2. Data Collection Methods: We will use a data-coordinating model similar to many other clinical trials, and one that we are currently using in a PCORI-funded trial of physical therapy and pain psychology for patients with chronic LBP. JHU study team members will independently recruit participants, collect, and review data at the time of assessment, and transmit questionnaires to a central repository for quality control and creation of analytic files. This method allows for the identification and collection of missing data in real-time and review of all data. In the event of participant withdrawal, a close-out telephone assessment will include: (1) specific reason for dropout (as much detail as possible); (2) who decided the participant would drop out; and (3) whether dropout involves some or all types of participation. In addition, we will attempt to collect a final assessment of disability. A central database will be maintained to assess overall progress. We will maintain a password-protected secure linkage database containing participant protected health information and linkage to study identification number.

D.6.3 Analysis Plan: The primary outcome for **UH3 Aim 1** is 16-week change in disability measured via the ODI. The primary analysis of the primary outcome will follow the intention-to-treat principle. The marginal treatment effect for the primary outcome will be defined as the difference in the mean 16-week change comparing risk-stratified telerehabilitation to usual care (i.e., an educational control). The marginal treatment effect will be estimated using the analysis of covariance (ANCOVA) approach where we will fit a linear model for the 16-week ODI score as a function of baseline ODI, intervention group (risk-stratified telerehabilitation vs. education control, binary indicator) and adjustment for age (stratification variable, continuous) and psychosocial risk score (stratification variable, ordinal).[125] The estimated coefficient for the binary treatment group variable is the estimated marginal treatment effect. The 95% confidence interval for the marginal treatment effect will be derived using a bias-corrected and accelerated (BCa) bootstrap confidence interval (CI) based on 1000 bootstrap samples taken with replacement within intervention group. The BCa method accounts for possible bias and skew in the bootstrap distribution.[126] Risk-stratified telerehabilitation will be deemed superior to the educational control if the 95% BCa CI does not include 0 and both the upper and lower limit are below 0, i.e. the 16-week ODI change (negative change indicates improvement) is greater for risk-stratified telerehabilitation compared to the educational control group. The analysis of the key secondary outcomes, 16-week change in PROMIS physical function score and 16-week change in pain intensity (PEG Scale), as well as the exploratory outcome (16-week change in PROMIS quality of life) will be similar to that described above for the primary outcome.

Addressing missing data: We anticipate 20% attrition in the study. The methods described above will be valid under missing completely at random or missing at random where patterns of attrition are similar across the two treatment groups. We will use the observed data to explore if attrition is related to measured baseline patient and clinical characteristics as well as evaluate differences in attrition patterns across the two treatment groups.

We will conduct sensitivity analyses to account for differential attrition by multiply imputing missing outcomes as a function of baseline patient and clinical characteristics and replicating the ANCOVA procedure described above and pooling the results. Further, we will conduct a sensitivity analysis to explore missingness not at random by shifting the 8-week scores for patients with missing data by adding/subtracting a fixed constant to the patient's imputed values [127] The fixed constant will range from a minimum to maximum value that is pre-specified and represents extremes that would indicate meaningful differences between the patients who do or do not drop-out.

Per-protocol analysis: We will also evaluate primary, key secondary and exploratory outcomes in a per-protocol analysis. The analysis will be conducted using the ANCOVA approach with inverse-probability of compliance weights, which will be derived from a logistic regression model for compliance as a function of treatment group and relevant baseline patient and clinical characteristics. Compliance will be defined as completion of between 6 and 8 in-person telehealth sessions (medium- and high-risk groups) and a fixed number of logins to the digital treatment platform (low-risk group), to be determined during the planning period ahead of the trial.

Long-term outcomes: Change in ODI and secondary outcomes over 52-weeks will be analyzed separately using the same ANCOVA approach.

The primary outcome for **UH3 Aim 2** is the binary indicator of opioid use for LBP at 16-weeks following enrollment. The difference in the proportion of patients using opioids for LBP by the 16-week assessment will be estimated using a recent extension for the ANCOVA approach for binary outcomes proposed by Rotnitzky, et. al. and described in further detail in Colantuoni and Rosenblum that can incorporate adjustment for the stratification variables, age and psychosocial risk score, as well as baseline LBP-related opioid use.[128,129] The health care use outcomes, including use of external physical therapy (binary) and number of external physical therapy sessions (count), will be analyzed using the same approach proposed by Rotnitzky *et al*. Similar analyses will be conducted for the 8-week and 52-week outcomes.

We propose examining heterogeneity of treatment effect among sub-groups defined by gender, psychosocial risk factor, and current opioid use (**UH3 Aim 3**). Differences in results for Aim 1 (LBP-related disability [primary] and physical function [key secondary]) and Aim 2 (LBP-related opioid use and healthcare utilization) will be compared through inclusion in the analytic models of a main effect term for patient-subgroup with an interaction term between intervention group and sub-group. This will allow estimation of treatment effect within a sub-group and interaction between treatment and sub-group. Results will be displayed graphically using forest plots and numerically with 95% confidence intervals for intervention comparisons by sub-group.

Descriptive statistics will be used to summarize implementation outcomes (**UH3 Aim 4**) and adverse events.

Supplementary material

D.7 Procedures to Finalize Plans for Identifying Patients and Extracting Data from the EHR (UG3 Aim 3): Potentially eligible patients for UH3 (Clinical Trial) Phase of the current project will be those individuals with a recent primary care visits (within 90 days) for a LBP-related diagnosis. TidalHealth makes use of an EHR that includes demographic (e.g., age and gender) and clinical (e.g., back pain diagnoses) information on patients and encounter (e.g., provider, location, reason for visit, and date) that will allow the research team to develop passive EHR algorithms that generate automated reporting to identify potentially eligible patients for screening and recruitment, track treatment initiation and retention for all study participants, and assess fidelity of care provided to key components of the study interventions. Plans to identify patients and extract data from the EHR will be refined during the UG3 (Planning) Phase in collaboration with the *Electronic Health Record (EHR) Working Group* of the *NIH Collaboratory* and informatics specialists at JHU and TidalHealth.

D.7.1 Identifying Patients in the EHR: The JHU research team has extensive experience in the development of passive EHR algorithms to generate automated reporting to identify potentially eligible patients for screening and recruitment. Working with the clinical data acquisition teams at TidalHealth, the research team will develop an algorithm that selects potentially eligible patients using discrete data elements based on age (18+ years) and presence of ICD-10 diagnosis codes consistent with non-specific back pain (and absent any "red flag" conditions) (*see section D.14 for more information*) with a recent (in the past 90 days) primary care visit.

Working with the Data Coordinating Center at the Biostatistics Center of the Johns Hopkins University Bloomberg School of Public Health (*see letter of support*), the research team will develop a secure file transfer protocol to population the project database running on the Research Electronic Data Capture (REDCap) platform with the results of the EHR-based algorithm. The algorithm and sFTP transfer will occur on a biweekly basis.

D.7.2 Extracting Data from the EHR: The EHR will also be leveraged to extract relevant outcomes data. All participants will be registered as research study participants in the EHR using a unique identifier in a discrete data field. Using this unique identifier, we will extract relevant data from the EHR pertaining to opioid prescriptions (UH3 Aim 2), LBP-related healthcare utilization (i.e., office visits, diagnostic imaging) (UH3 Aim 2), initiation and retention of enrolled patients (UH3 Aim 4), and fidelity to treatment protocols (UH3 Aim 4).

D.8 Procedures to Finalize Sample Size, Number of Recruitment Sites, and Implementation Strategies (UG3 Aim 4): The research team will work with the *Biostatistics and Study Design Working Group* and the *Implementation Science Working Group* at the *NIH Collaboratory* during the UG3 (Planning) Phase to finalize sample size estimates, number of clinical sites, and implementation strategies.

D.8.1 Sample Size Estimates: For **UH3 Aim 1,** LBP-related disability will be quantified using the ODI, scored from 0% (no disability) to 100% (fully disabled). The primary outcome will be the change in ODI score comparing 16-week to baseline scores. The marginal treatment effect is the difference in the mean 16-week change in ODI scores comparing the risk-stratified telerehabilitation and usual care groups. Based on historical data from the study sites and an anticipated 20% attrition rate, we will enroll 434 patients across the 30-month study, with 346 patients expected to complete the trial. The trial will randomize patients 1:1 to the risk-stratified telemedicine and usual care groups and we assume a conservative standard deviation in 16-week change in ODI scores of 25% in the telemedicine group[130] and a standard deviation of 12.5% in the usual care group, based on the assumption that the ODI scores will change less over time in the usual care group. Given the 346 trial completers and assumptions above, we will have 90% power to detect differences of at least 6.5% in the mean 16-week change in ODI scores comparing the risk-stratified telemedicine and usual care groups. This difference is consistent with findings from earlier trials.[130-134]

For **UH3 Aim 2**, the primary outcome is opioid use for chronic LBP and the marginal treatment effect is the absolute difference in the proportion of patients with opioid use at 16-weeks comparing risk-stratified telerehabilitation and educational control groups. With 346 patients completing and conservatively assuming 50% of the usual care group patients will report opioid use and a Type I error rate of 5%, we will have 90% power to detect an absolute reduction of at least 13% in the risk-stratified telemedicine group. Although there are no studies conducted in similar populations of chronic LBP patients from rural communities, this effect size is supported by studies in comparing patients with a new episode of LBP under different PT referral models.[135,136]

D.8.2 Clinical Sites: Following the finalization of our targeted sample size, we will work with our clinical and informatics partners to finalize a list of primary care clinics at TidalHealth to be included in the UH3 (Clinical Trial) Phase of the current project. This will be based on volume of unique patients evaluated for LBP diagnoses each month per clinic and the demographics of the patients seen at each clinic to ensure adequate gender, racial, and ethnic group representation in our final data set. Currently, we plan to include 5 primary care clinics across Caroline and Worcester counties to meet our target sample size of 434 patients.

D.8.3 Implementation Strategies: We will finalize our implementation strategies for the UH3 (Clinical Trial) Phase of the study during the UG3 (Planning) Phase of the current project. This will include strategies for patient identification, risk stratification, patient evaluation, and intervention delivery.

We plan to identify patients who have sought out care for chronic LBP from primary care using the EHR at TidalHealth (*see section D.8 for additional details*). Our team has successful utilized this approach to identify patients with LBP during two previous/ongoing studies focused on conservative treatment of LBP.[17,101] This approach was selected as primary care is the most common service utilized by patients with LBP and will provide us with the greatest opportunity to recruit patients in our target population.[137]

Once identified, potentially eligible patients will be approached via mail and telephone to conduct screening, obtain informed consent, and (if enrolled) complete the baseline assessment. During the baseline assessment, participants will complete the SBST risk stratification tool and be identified as high-, medium-, or low-risk for poor outcome. After completing the baseline assessment, participants will be randomly assigned to one of the two study groups (risk-stratified telerehabilitation, education control).

All patients randomly assigned to the risk-stratified telerehabilitation group will be scheduled for an initial telehealth visit with a TidalHealth physical therapist, during which an evaluation will be performed, and a plan of care will be developed, in accordance with the patient's risk category. Prior to the telehealth visit evaluation, the research coordinator will ensure that the participant has the necessary hardware and software to complete said visit. The workflow used to schedule telehealth visit evaluations for patients randomized to telerehabilitation will be finalized during the UG3 (Planning) Phase in coordination with the *Healthcare Systems and Implementation Science Works Group* at the *NIH Collaboratory*.

D.9 Data Management and Quality Control: Data management will be overseen by the Data Coordinating Center (DCC) housed in the Biostatistics Center at the Department of Biostatistics, Bloomberg School of Public Health, Johns Hopkins University (*see letters of support*). The DCC will work in collaboration with the Steering Committee and the NIH Collaboratory. The study database will be maintained using the Research Electronic Data Capture (REDCap) platform[86,138] and reside on a secure server managed by the DCC. Dr. Colantuoni, co-investigator and study statistician, will develop plans to monitor study progress that include, but are not limited to, rates of accrual, treatment initiation and retention, follow-up assessment completion, and occurrence of adverse events. Dr. Colantuoni and the DCC have experience and expertise in data management and quality control procedures.

Supplementary Material

Study data will be obtained using both passive EHR data collection and participant self-report. Passive EHR data collection strategies will include baseline demographic data (age, gender, race/ethnicity, current opioid prescribing data, and insurance information) and data regarding treatment initiation and retention (date of scheduled, completed, or canceled visit and provider name and location). Passive EHR data collection will be verified and supplemented using participant self-report built on the REDCap platform to allow direct entry of data by participants using a computer-based web-browser or smartphone app. Baseline and follow-up data will be collected in one of two ways: 1) directly from the participant using an email or text link to our REDCap project; or 2) during telephone conversation between the participant and a member of our research team and directly entered into our REDCap project. If conducted by a member of the research team, follow-up data will be collected by a research assistant who is blinded to intervention group assignment.

Quality control procedures will be finalized during the UG3 (Planning) Phase. We developed procedures to ensure the reliability and completeness of our clinical trial data, maintain adequate regulatory compliance of our research team, and protect human research participants from risk. Reliability and completeness of the data will be addressed through automatic data verification built into REDCap to actively assess data from EHR and participant self-report. Missing data or erroneous data entry will be reported to the research team for clarification or resolution. The MPIs and Dr. Colantuoni will be responsible for ensuring that study data is stored on HIPAA compliant platforms, that access is protected through credential-based restrictions, and that all institutional, local, and federal regulations are followed. Members of the research team will be required to complete all IRB-approved training to include human subjects research, conflict of interest, and privacy for research participants. Logs of training and recertification for research teams at all sites will be maintained at JHU. The research teams at JHU and TidalHealth will hold regular meetings to review study-related protocols, accrual and retention targets, data reliability and completeness, and implementation challenges. We will work with the JHM IRB to develop plans to communicate any potential breaches of confidentiality.

D.10 Ethical and Regulatory Oversight: The Johns Hopkins University School of Medicine Institutional Review Board (hereafter, JHU IRB) will serve as the review board of record with study-related activities at TidalHealth relying on the JHU IRB. Research staff at TidalHealth will receive ongoing training in ethical conduct for human subject research, HIPAA privacy protections, and Good Clinical Practice using resources from their respective institutional review boards with certification filed with JHU IRB. Research staff will be trained on all study procedures, including data collection, entry, and reconciliation, and will participate in regularly scheduled web-based video-calls to review study activity (e.g., screening, recruitment, and retention) and to address any barriers or facilitators to study progress (e.g., data queries and IRB regulatory issue). Study data will be locally entered using the web-based REDCap platform housed at the Data Coordinating Center (DCC) at the Biostatistics Center, Johns Hopkins University Bloomberg School of Public Health (*see letter of support*) and directed by Dr. Colantuoni. All study data will be referenced with a unique study identification number. Datasets generated will not include patient identifying information. Upon study completion, de-identified datasets will be archived in coordination with NIH and local data sharing policies.

Supplementary Material

D.11 Study Timeline and Key Milestones for UG3 (Planning) Phase: Milestones for the Year 1 UG3 (Planning) Phase are comprised of quantifiable achievements required to proceed to the UH3 Phase of the proposed Project. Key milestones for the UG3 (Planning) Phase of the study will establish and the necessary study infrastructure and regulatory compliance needed before our project can transition to the UH3 (Clinical Trial) Phase of the current project. Our list of our Key Milestones (22 in total), as well as a timeline for completion can be found in the *Study Milestones* attachment.

D.12 Approach for the UH3 (Clinical Trial) Phase: Upon successful completion of the UG3 (Planning) Phase, the research team, in coordination with the NIH Pragmatic Trials Collaboratory will transition to the UH3 (Clinical Trial) Phase with the initiation of a randomized clinical trial (RCT) of risk-stratified telerehabilitation vs. educational control for the treatment of chronic LBP at a rural HCS (TidalHealth). The RCT will be a hybrid Phase IV-V study per Glasgow.[100] Under this framework, Phase IV studies focus on effectiveness outcomes while the major focus of Phase V studies is implementation. The UH3 (Clinical Trial) milestones outlined in the Human Subjects and Clinical Trials Information section are reflected in our Aims:

1. *Examine the effectiveness of risk-stratified telerehabilitation in reducing LBP-related disability*
2. *Compare the prevalence of opioid use between patients receiving risk-stratified telerehabilitation and educational control.*
3. *Compare effectiveness of Aims 1 and 2 in pre-defined patient groups by examining heterogeneity of treatment effect in pre-defined groups based on gender, risk stratification, and current opioid use.*

4. *Examine the implementation of risk-stratified telerehabilitation at a rural HCS by examining the acceptability, adoption, feasibility, and fidelity of our treatment approach guided by the RE-AIM framework.*

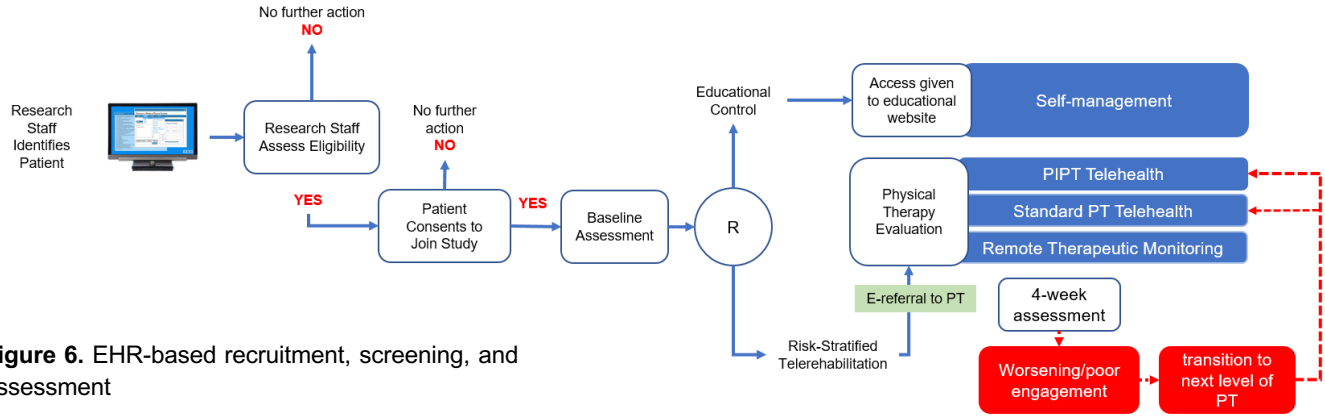

Figure 6. EHR-based recruitment, screening, and assessment

D.13 Patient Recruitment and Eligibility: Recruitment for the UH3 (Clinical Trial) Phase of the current project will leverage an EHR-based approach that has proven useful in prior and current funded work of the research team.[17,101] We will recruit patients presenting to primary care clinics associated with TidalHealth, a rural HCS on Maryland's Eastern Shore. Patients will be identified through TidalHealth's EHR (*see section D.8.1 for more information*). Leveraging the embedded clinic scheduler, the EHR will automatically generate a list of potentially eligible patients that is transferred via a secure file transfer protocol (sFTP) into a recruitment project using Research Electronic Data Capture (REDCap) on a bi-weekly schedule.

Potentially eligible patients will be approached via a recruitment letter describing the study and providing them the ability to opt out of future contact. Following this letter, the research team will contact patients by telephone to describe the study, answer questions, and conduct screening and consent, and baseline assessment (**Fig 6**).

Research coordinators at each site will track all potentially eligible patients, patients who are approached (recording demographics and reason for those who refuse), and participants who are recruited and followed. Research coordinators will track all scheduled follow-up visits to assist in our retention strategy. A centralized web-based REDCap data entry system will be employed to record study information (e.g., demographic and clinical characteristics, intervention visits, patient outcomes, and health care use). We have sought to reduce undue participant burden and will compensate participants for their time and effort of participation.

We will enroll adult patients (≥18 years) with recent (past 90 days) primary care visit and LBP-related diagnosis. Recruitment will begin in the 2nd quarter of Year 1 during the UH3 (Clinical Trial) Phase (last 30 months and average 30 patients per month). Participants will be randomized to receive care in the risk-stratified telerehabilitation or education control groups and be in the study for 12 months. Recruitment targets, treatment groups, and duration of study have been reviewed by our patient and provider stakeholders.

- Inclusion criteria: 1) Primary care visit in the past 90 days with a LBP-related ICD-10 diagnosis; 2) age 18 years or older; 3) Oswestry score > 24% and average pain rating ≥ 4/10 points; 4) Meet the NIH definition of chronic LBP 5) can speak and understand English; 6) Access to video-enabled device and Internet.
- Exclusion criteria: 7) Recent history (last 6 months) of lumbar spine surgery; 8) Possible non-musculoskeletal cause for low back pain symptoms (e.g., pregnancy); 9) "Red flags" of potentially serious cause of LBP (e.g., spinal metastasis, bone infection, etc.); 10). Neurological disorder resulting in severe movement disorder, or schizophrenia or other psychotic disorder.

We will use a mixed-mode approach to maximize retention. To achieve this, we will:

- Work closely with clinical and operations staff to develop rapport to create a sense of community.
- Mail thank you cards to participants.
- Routinely remind participants of scheduled visits and follow-up assessments. If the patient prefers a telephone interview, it will be completed at that time.
- Send hardcopy assessments used for follow-up to facilitate participant understanding.
- Call each participant at 16- and 52-weeks to collect data about co-interventions and maintain contact.
- Respect the individual's time and effort through respectful communication and flexible scheduling

Extensive efforts will be made to locate non-respondents. To prevent loss, we will maintain a contact log (telephone and email of participant and one other person) collected at baseline and reviewed at follow-up.

D.14 Randomization and Data Collection: Once a participant has been deemed eligible and provided informed consent, they will complete the baseline assessment that includes patient reported outcomes and other information not accessible from the EHR.

Supplementary Material

D.14.1 Randomization After the baseline assessment, they will be randomized to one of the two intervention groups (**Figure 6**) using stratified permuted block randomization with random block sizes and a 1:1 ratio. We will stratify randomization by age group (18-45 or 45+ years old) and STarTBack Screening Tool (SBST) psychosocial risk group (low, medium, or high). The randomization sequence will be generated using SAS version 9.4 by the Elizabeth Colantuoni, Ph.D., lead biostatistician, and automated using the REDCap randomization module. Randomization scheme will be finalized during the UG3 (Planning) Phase

For participants randomized to risk-stratified telerehabilitation, a research coordinator will contact patients to assist with scheduling their physical therapy evaluation with a TidalHealth physical therapist, conducted via telehealth visit. The research coordinator will also ensure that they have the necessary exercise equipment (e.g., exercise bands), have configured their web-based device to access the telehealth visit, and have downloaded and configured the smartphone app (for participants in the low risk [i.e., RTM] group only).

D.14.2 Data Collection: We have worked to minimize the length and number of study assessments to be consistent with a pragmatic design and to improve the ability to collect these either via email/text-based link to the REDCap project or using the telephone. Method of data collection will be in accordance with participants preferred method. When collected using the telephone, research coordinators will enter participant responses directly into REDCap. During the UH3 (Planning) Phase, data collection and management plans will be finalized with the *NIH Pragmatic Trials Collaboratory*. LBP-related opioid use and healthcare utilization will be collected using both automated (passive) EHR-based reporting and participant self-report. Treatment initiation and retention will be collected using automated (passive) EHR-based reporting. EHR-based reporting from TidalHealth will be transferred to REDCap using sFTP.

D.14.3 Follow-up: Follow-up assessments will be conducted as described (*section D.7.1 Outcome Measures*) and occur at 8-, 16-, and 52-weeks following treatment initiation. Follow-up assessments will be collected directly from the participant or conducted by a research assistant who is blinded to intervention group assignment.

D.15 Timeline and Key Milestones for UH3 Phase: Milestones for the UH3 (Clinical Trial) Phase of the current project will be finalized with *NIH Pragmatic Trials Collaboratory* in order to meet the specific aims of the clinical trial. Our list of planned milestones and timetable are available in the *Study Milestones* attachment.

D.16 Data Analysis and Sample Size Considerations: We will finalize our outcome measures, statistical analysis plan, and power calculations during the UG3 (Planning) Phase. We provide an overview of our planned analysis and sample size considerations to allow evaluation of the feasibility of the proposed UH3 (Clinical Trial) Phase of the current project (*see additional details in the Statistical Analysis Plan*).

This clinical trial is powered based on Aim 1 (*greater reduction in LBP-related disability (ODI) with risk-stratified telerehabilitation compared to an educational control*) and Aim 2 (*reduced opioid use with risk-stratified telerehabilitation compared to educational control*).

We have developed the following *a priori* plans for analysis of study data corresponding to each specific aim. Data analysis will be carried out by a master's level statistician under direction of study statistician Elizabeth Colantuoni, Ph.D.

Supplementary Material

D.17 Missing Data: Despite attempts to improve adherence, some missing data are expected. To deal with missing data, baseline characteristics between patients with and without the assessment at 8-, 16-, and 52-week follow-up will be compared to assess potential biases in the complete case analysis. We will also try to obtain reasons for study drop out to assess the missing data mechanism (missing completely at random, missing at random, non-ignorable missingness). In our previous trials among similar patient populations, greater than 84% of the participants completed follow-up assessments. In this study we estimate attrition to be 20% at 52 weeks. We will compare baseline characteristics (e.g., age, gender, SBST, and LBP-related disability) between participants with complete follow-up data to those with missing data by intervention group to assess potential bias that may exist in the complete case analysis. We will use sequential multiple imputation methods for imputing data and re-analyze using intention to treat (as randomized) to assess the impact of missing data on our conclusions as recommendations.[139] We will conduct sensitivity analyses for primary and secondary outcomes using multiple imputation (assuming missing at random), and pattern mixture models and selection models which align with non-ignorable missingness.[140,141]

D.18 Adequacy of Health System Volume: The recruitment targets in the current project can reasonably be achieved by TidalHealth, who has expressed strong support for this study (*see Letters of Support*). The volume of unique patients with LBP seen monthly at TidalHealth across five (5) primary care clinics [Berlin, Ocean Pines, Pocomoke, Snow Hill, and Federalsburg, MD] is listed below in **Figure 7**. As seen below, the total volume of unique patients with LBP across these three primary care clinics was approximately 105 per month. The proposed trial will recruit from these same five (5) primary care clinics. Based on previous experience with similar inclusion criteria, we conservatively estimate that 45% of these patients will be eligible for enrollment (N=47) each month. Conservatively estimating that 35% of these patients will consent for participation, we anticipate

enrolling 16 patients per month. At this rate, we will reach our target sample size by 27 months. We have included 30 months of recruitment to account for any periods of lower-than-expected enrollment.

During the UG3 (Planning) Phase, we will revisit clinic volumes and estimates of eligibility and study participation at each health system and examine the adequacy of our recruitment projections.

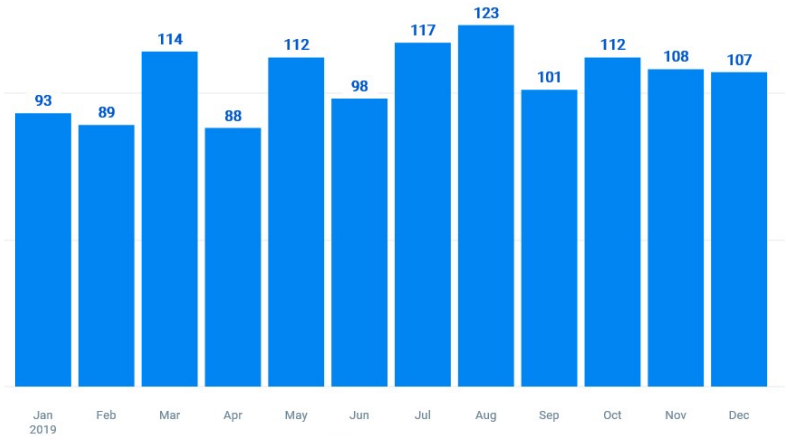

Figure 7. Volume of Discrete Patients with Low Back Pain at Included TidalHealth Primary Care Clinics

D.19 Potential Challenges and Contingencies: The hybrid effectiveness-implementation approach that we propose offers many strengths both in scientific premise and innovation. However, there are potential barriers to completing our study. We identify these barriers below, including our strategy to overcome each.

Access to broadband internet: Providing care using telehealth requires access to the internet, which if often more limited in rural parts of the country. However, the most recent census data from Caroline and Worcester Counties show that 83% and 85% of homes have a subscription to broadband internet.[142,143] This is comparable to the rate of broadband access in New York City (84%).[144] In addition, we have included a stipend for patients in the telerehabilitation group that can be used to offset the cost of a monthly broadband subscription.

Insufficient recruitment and follow up: Practical challenges may arise during the UH3 (Clinical Trial) Phase of the current project. The decision to randomize participants provides patients with two different approaches to treating chronic LBP and allows patients to make the 'real world' decision to accept randomization. Acceptability of randomization will be critical. We have identified potential recruitment barriers and solutions (**Table 11**).

Recruitment barrier	Solution
Identification of eligible patients	RC will receive electronic physical therapy clinic schedule biweekly to identify potential candidates.
Description of study/informed consent	Working with clinical partners, RC will adapt recruitment strategy to fit local norms and describe the study with patient and allow adequate time for consent.
Assessment collection	Assessments will consist of self-report measures (timing/inconvenience).
Maintain level of interest with providers	Team meets regularly with clinical and operations staff to maintain interest and assess of recruitment and retention strategies, provider satisfaction, and sharing of study findings.
Loss to follow-up	**Section D.14** details steps taken to minimize loss to follow-up
Burden of study participation	Efforts are made to minimize participant burden (e.g., reduce assessment number and frequency, developing efficient methods to collect assessments to minimize patient time).

Table 11. Anticipated recruitment barriers and solutions

Supplementary Material

We have considered the challenges to adequate recruitment, treatment initiation and retention, and assessment follow-up. During the UG3 (Planning) Phase, we will work with our health system partner to confirm participating primary care clinics and assess patient volume to ensure adequacy of recruitment goals. We will continue to work with our patient and provider stakeholders to refine our recruitment strategy to reduce respondent burden, focus on important inclusion criteria, and adequately convey the responsibilities of participation. Based on prior clinical trials, we will develop daily EHR-based reports to track treatment initiation and retention for all active participants and work closely with providers to reschedule any missed intervention appointments. Adequate collection of follow-up assessment is critical in establishing effectiveness of any intervention. We will gather preferred communication methods, schedule days/times to call for follow-up assessment, and identify a third-party (e.g., partner or friend) who can reach the participant. Our efforts to improve recruitment, treatment initiation and retention, and follow-up assessment will be ongoing and will be refined during the UG3 (Planning) Phase.

Opioid utilization data: An important effectiveness outcome in the current project is LBP-related opioid use. We will employ a two-step strategy to capture opioid use: EHR-based extraction of prescribing data and reported medication use; and participant self-reported use. There is the potential to miss non-prescription opioid use and medication that is prescribed outside of our health system. It is also possible that certain patients will underreport opioid utilization. During the UG3 (Planning) Phase, we will consider using state-based prescribing databases to augment our collection.

Data Sharing and Management Plan

The Research Team at the Johns Hopkins University and TidalHealth (sub-award) for the proposal titled "Improving Function and Reducing Opioid Use for Patients with Chronic Low Back Pain in Rural Communities through Improved Access to Physical Therapy using Telerehabilitation" (RFA-NR-23-001) agree to accept the overall governance, common protocols, publication policies, collaborative procedures, confidentiality, and data sharing plans to be developed by the HEAL Consortium. The following document exists to reflect our best practices for data acquisition, management, stewardship, and dissemination that are consistent with the HEAL Initiative Public Access and Data Sharing Policy.

DATA TYPE

Data generated by the scientific projects will include experimental and observational data, statistical and programming code, derived and compiled metadata, experimental and analytic documentation, and physical collections of specimens, images, and behavioral recordings.

Richard L. Skolasky, Sc.D. and Kevin McLaughlin, D.P.T. will work with leaders of each of the scientific projects at Johns Hopkins University (JHU) School of Medicine and TidalHealth to identify the type and amount/size of scientific data expected to be collected and used.

A description of which scientific data from the project will be preserved and shared.

The proposed project has the following aims:

1. Examine the effectiveness of risk-stratified telerehabilitation in reducing LBP-related disability among patients living in rural communities with chronic LBP. We will compare 4-month changes in LBP-related disability (measured using the Oswestry Disability Index [ODI]) between patients receiving telerehabilitation and usual care. Key secondary outcomes will include 4-month changes in physical function measured by the Patient Reported Outcome Measurement Information System (PROMIS)-29.
2. Compare the prevalence of opioid use between patients receiving risk-stratified telerehabilitation and educational control . We will use a combination of patients surveys and EHR data to assess opioid use in both groups at 4 and 12-months. Secondary outcomes will include other LBP-related healthcare utilization (e.g., physician office visits, imaging, surgery).
3. Compare effectiveness of Aims 1 and 2 in pre-defined patient groups by examining heterogeneity of treatment effect in pre-defined groups based on gender, risk stratification, and current opioid use.
4. Examine the implementation of risk-stratified telerehabilitation at a rural HCS by examining the acceptability, adoption, feasibility, and fidelity of our treatment approach guided by the RE-AIM framework. We will use a mixed-methods approach to accomplish this aim that incorporates patient and provider surveys, semi-structured interviews, focus groups, and key process metrics.

Supplementary Material

Project Aims 1, 2, and 3 will make use of data collected from the electronic medical record (EMR) at the participating health system (TidalHealth, Salisbury, MD) (e.g., diagnosis and problem list ICD10 codes and opioid prescription) and through participant self-report (e.g., LBP-related disability, opioid use). Project Aim 4 will make use of data collected from participant and provider surveys and semi-structure interviews (e.g., survey of perceived advantages/disadvantages) and from key process metrics (e.g., treatment initiation and retention and number of key components delivered). The table below details the data that will be collected in the proposed project.

Variable	Suggested Measure/Source	Item[1]	Base[2]	8 wk[2]	16/52 wk[2]
Predisposing Factors					
Socio-demographic[†,‡]	Age, Gender, Race/Ethnicity	6	✓		
Social support[†]	Marital/Partner Status	2	✓		
Cognitive[†]	Psychosocial Risk (SBST)	22	✓		
Enabling Factors					
Education/Economic[†]	Education, Income, Occupation	3	✓		
Insurance[†,‡]	Coverage	2	✓		
Need Factors					

Variable	Suggested Measure/Source	Item[1]	Base[2]	8 wk[2]	16/52 wk[2]
Co-morbidities†,‡	Elixhauser Comorbidity Index (CCI)	19	✓		
Medical History†,‡	Pain Medications; Past Treatment	8	✓		
Health Habits†	Smoking, Alcohol Use, BMI (height & weight)	4	✓		
Effectiveness Outcomes (UG3 Aim 1)					
Disability†	**Oswestry Disability Index (ODI) (Primary)**	10	✓	✓	✓
Physical function†	PROMIS 29, v2.0 Physical Function (Secondary)	5	✓	✓	✓
Pain intensity†	Numeric Pain Rating Scale (NPRS) (Exploratory)	3	✓	✓	✓
Quality of Life†	PROMIS 29, v2.0 Profile (Exploratory)	29	✓	✓	✓
Health Use Outcomes (UG3 Aim 2)					
Opioid Use†,‡	Current opioid use for low back pain	2	✓	✓	✓
Health Care Use†,‡	Physical therapy (external to trial), Physician/ED visit, Imaging, Pain interventions, Medications, Back surgery	6	✓	✓	✓
Implementation Outcomes (UG3 Aim 4)					
Acceptability	Interest in study participation, Refusal reason	N/A	✓		
Adoption	Survey of perceived advantages/disadvantages	N/A	✓	✓	
Feasibility‡	Treatment initiation and retention	N/A	✓	✓	
Fidelity‡	Number of key components delivered	N/A		✓	
Safety					
Safety*,**	Adverse Events	N/A	✓	✓	✓

Table 1. Assessment Schedule

† Data provided through patient self-report
‡ Data provided through passive EHR collection
[1] Number of items that participants must complete
[2] All assessments conducted over telephone or using emailed link to REDCap project

Supplementary Material

A brief listing of the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Documentation will consist at the level of the project aim (e.g., research strategy and regulatory documents) and the individual experiment level (e.g., lab manual describing experimental controls, methods, and outcomes) and the analytic level (e.g., data codebook, statistical code, and generated results and figures). These will be made accessible to facilitate the interpretation and reproducibility of the scientific data.

RELATED TOOLS, SOFTWARE AND/OR CODE

Each Scientific Project will generate README files that contain documentation for all experiments to be conducted. These README files will include date, user, and detail of all activities conducted. Minimum detail included will be variable names and description, explanation of codes and classification systems, algorithms used to transform data, file format and software (including version) used.

All data and documentation will be organized into subfolders as follows:

- 'RawData': All raw data goes into this folder, with subfolders organized by date
- 'AnalyzedData': Data analysis files
- 'PaperDrafts': Draft of paper, including text, figures, outlines, reference library, etc.
- 'Documentation': Scanned copies of written research notes and other research notes
- 'Miscellaneous': Other information that relates to this project

In addition to consistent subfolder organization, the scientific projects aims will adopt a consistent naming structure.

Raw data files will be named as follows:

"YYYYMMDD_experiment_sample_ExpNum"
(ex: "20140224_UVVis_KMnO4_2.csv")

All files will be stored on the Johns Hopkins Secure Analytic Framework Environment (SAFE) desktop that is maintained (security and backup) by Johns Hopkins University IT. A staff member with expertise in data curation (see Budget Justification), working under the direction of Dr. Skolasky will ensure all data and documentation (including written research notes) are appropriately cataloged and stored in SAFE desktop on a weekly basis. In the event that data and documentation are not in SAFE desktop, Drs. Skolasky and McLaughlin will work with the co-investigators and study team to ensure compliance with this critical data management requirement.

The Johns. Hopkins SAFE Desktop provides access to Hopkins faculty and staff for analytic programs (e.g., Stata and R). Where possible, all documentation and code will be in the open-source R to allow redistribution to other investigators.

STANDARDS

We will work with the leaders of the scientific projects, the NIH program officer and staff, members of the HEAL Stewardship Group and the JHU Data Service to adhere to and/or to develop appropriate data standards for the storage and reporting of scientific data and associated metadata (e.g., data formats, dictionaries, identifiers, and definitions) as described in the principles and recommendations developed by the HEAL Data Ecosystem.

DATA PRESERVATION, ACCESS, AND ASSOCIATED TIMELINES

The name of the repository(ies) where scientific data and metadata arising from the project will be archived.

Johns Hopkins University (JHU) Data Archive

How the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

We have developed the infrastructure (e.g., Research Electronic Data Capture (REDCap) and SAFE Desktop) to implement persistent unique identifiers and other standard indexing tools to ensure that scientific data will be findable and identifiable (ICTR, see Letter).

When the scientific data will be made available to other users (i.e., the larger research community, institutions, and/or the broader public) and for how long.

Data and research materials made available for public access will be shared through the JHU Data Archive, which uses an established repository platform (Dataverse) and is supported by preservation practices, with administrative help for preparing deposits provided by Johns Hopkins Data Services. Deposited data is given standard data citations and persistent identifiers (DOIs) and will be archived for a minimum of 5 years, with the possibility of renewal.

Supplementary Material

Data will be generated, quality assured, indexed, and stored to the specified timeline for this proposal

Under this Data Sharing and Management Plan, we will comply with Data Preservation and Sharing timelines. Shared scientific data will be made accessible as soon as possible, and no later than the time of an associated publication, or the end of the performance period, whichever comes first. Therefore, data will be deposited in the JHU Data Archive and made available at the time of publication or one year after the project, whichever is sooner.

ACCESS, DISTRIBUTION, OR REUSE CONSIDERATIONS

Describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to:

- Informed consent (e.g., disease-specific limitations, particular communities' concerns).
    - The proposed study is considered human subject research.
        - Data from patients presenting to a primary care clinic serving rural communities with a diagnosis or problem list consistent with low back pain will be approached for screening, consent, and randomization following an IRB approved protocol. The participating health system will provide demographic and clinical information (e.g., name, contact information, age, gender, height, and diagnosis or problem list ICD-10 codes). The Johns Hopkins University School of Medicine IRB has review and approval authority over this activity.

- Privacy and confidentiality protections (i.e., de-identification, Certificates of Confidentiality, and other protective measures) consistent with applicable federal, Tribal, state, and local laws, regulations, and policies.
    - All data will be identified by a synthetic study identification number that is not linked to any personal health information.

OVERSIGHT OF DATA MANAGEMENT AND SHARING

Indicate how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom (e.g., titles, roles).

Compliance with the Data Sharing and Management Plan will be monitored and managed by Dr. Richard Skolasky (MPI) working in coordination with Dr. McLaughlin (MPI) and Dr. Colantuoni (Co-I) with regular quarterly reporting to the internal committee comprised of scientific project leaders and regular reporting to the NIH program officer and staff and relevant HEAL consortium members.

These reports will include description of the the type, location, and standards of experimental data (collected, analyzed, and stored), statistical and programming code, and metadata; the type, location, and standards of physical collections (samples, images, and behavioral recordings); and progress of implementation of data sharing using the FAIR principles and NIH HEAL Initiative Public Access and Data Sharing Policy.

Monitoring and management will be discussed during regular consultation with the NIH Program Officer and staff and relevant HEAL consortium members.

Supplementary Material