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ARBOR-Telehealth study: an examination of telerehabilitation to improve function and reduce opioid use in persons with chronic low back pain in rural communities – protocol of a pragmatic, individually randomised group treatment trial

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ABSTRACT

Introduction Chronic low back pain (LBP) imposes significant burden on patients, healthcare systems and society. Physical therapy is a cost-effective method for improving pain and disability; however, only a small number of patients (7–13%) with LBP ever receive physical therapy services. Patients report obstacles to accessing physical therapy, such as transportation, provider availability and missed work. Access is especially limited in rural communities, where approximately 40% fewer physical therapists are available per capita than in metropolitan regions. This lack of access likely contributes to the greater rates of LBP-related disability and opioid consumption in rural communities. Innovative methods for improving access to physical therapy for patients with chronic LBP are urgently needed; these can help address differences in health outcomes and mitigate opioid dependence for patients with chronic LBP living in rural communities. Telerehabilitation increases access to physical therapy, which can potentially improve health outcomes for these patients.

Methods and analysis This prospective, individually randomised group treatment trial will involve primary care clinics serving rural communities on Maryland's Eastern Shore. We will enroll 434 individuals with chronic LBP. Eligible patients will be randomised to either standardised education for back pain delivered via website or to a risk-informed telerehabilitation. Standardised education will be delivered via a study website containing information consistent with materials provided by primary care providers. Risk-informed telerehabilitation will be delivered by trained physical therapists using a web-based, video-enabled telehealth platform. The primary outcome is LBP-related disability. Secondary outcomes are opioid use, pain intensity, health-related quality of life and LBP-related healthcare use assessed using standard patient-reported outcome measures, participant self-report and medical chart abstraction. Implementation outcomes are acceptability, adoption, feasibility and fidelity of our treatment approach guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework and assessed using surveys, semi-structured interviews and key performance metrics.

Ethics and dissemination Ethics approval was obtained from the Johns Hopkins Medicine Institutional Review Boards (IRB), which serves as the single IRB for this trial. Upon completion, study data will be shared in compliance with National Institutes of Health guidelines.

Trial registration number NCT06471920.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial (N=434, 95% power) is well powered, ensuring robust and reliable results for the studied population, and includes health outcomes data for patients living with chronic low back pain.
⇒ The use of a comparison group, standardised web-based education, will provide meaningful evidence regarding the effectiveness of telehealth physical therapy for rural patients with chronic low back pain.
⇒ This study will capture key implementation outcomes that can inform the dissemination, adoption and scalability of this telehealth model to other rural healthcare settings.
⇒ Limitations of the study design include conducting the study in a single rural healthcare setting, which limits contextual generalisability to the broader population; and limitations associated with rurality, such as participants' having access to broadband internet connectivity to engage with the intervention.

INTRODUCTION

Chronic low back pain (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 two decades.[1] In the USA, approximately 80% of adults experience at least one episode of LBP during their lifetime, and 25% of adults report LBP that lasted at least 1 day during the past 3 months.[2] LBP also accounts for approximately 5% of all physician visits[3 4] and is the costliest health condition in the USA, accounting for an estimated US$135 billion in spending, exceeding diabetes, heart disease and Alzheimer disease, and increasing at the second fastest rate of any health condition during the past decade.[5] 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 USA experience chronic LBP and that this rate is steadily increasing.[6 7]

In the USA, opioids are prescribed at a higher rate per capita than in any other country in the world, accounting for 68% of opioid consumption globally.[8] From 2000 to 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.[6 9 10] Moreover, studies have shown that a diagnosis of LBP increases the likelihood that patients will receive high doses of opioids (≥180 mg morphine) compared with other conditions that are commonly treated with opioids.[11] These rates of opioid prescription for LBP continue to rise, despite a lack of evidence for long-term effectiveness.[12]

Physical therapy has been found to be effective in reducing LBP-related pain and disability and is recommended as a first-line treatment for LBP.[13] Timely access to physical therapy leads to significant decreases in pain and disability compared with usual care for patients with LBP[14] and reduces the risks of using opioids or requiring injections, surgery or advanced imaging.[15 16] Despite these benefits, only 7–13% of patients with LBP go on to receive physical therapy services.[15 16] This low rate of physical therapy utilisation by patients with LBP is likely related to obstacles surrounding access and logistics, such as transportation and missed work time.[17–21] These obstacles are amplified in rural areas of the USA. Compared with patients who live in urban areas, those in rural communities have a higher prevalence of chronic conditions, are more likely to be greater than 65 years of age, and are less likely to engage in regular physical activity.[22] Studies have found there are 40% fewer physical therapists per capita in rural geographical regions than in more urban regions.[23] These rural–urban disparities in physical therapy availability may contribute to the disproportionate amount of opioid prescriptions and use observed in rural areas of the USA.[24 25] National Veterans Health Administration data demonstrate greater opioid prescribing volume for rural versus urban residents.[24]

The COVID-19 pandemic has facilitated the rapid emergence of telerehabilitation (physical therapy delivered via a video-enabled telehealth platform), which may address obstacles to accessing physical therapy for those living in rural areas.[26–28] Early evidence suggests that patients receiving physical therapy using video visits experience meaningful reductions in LBP-related disability and pain. However, telerehabilitation studies have been limited by small sample sizes, lack of comparison arms and having been conducted outside clinical settings.[15 29–31] Larger studies embedded within clinical settings are needed to examine the effectiveness and implementation of telerehabilitation for patients with chronic LBP. The current study will address the limitations of prior telehealth physical therapy research as a large, well-powered randomised trial with an educational control comparator group conducted in a rural healthcare system (HCS).

To address this need to increase access to specialty care, reduce opioid dependence and produce reliable data with a comparison arm, the Advancing Rural Back pain Outcomes using Rehabilitation-Telehealth (ARBOR-Telehealth) study will evaluate the effectiveness of telerehabilitation compared with standard patient education, ultimately to reduce LBP-related disability and opioid use and improve health-related quality of life (HRQoL) in patients living with chronic LBP in a rural healthcare setting.

METHODS AND ANALYSIS

Study design and rationale

The ARBOR-Telehealth study is a partnership between TidalHealth and Johns Hopkins University that will compare the effectiveness of telerehabilitation for patients with chronic LBP residing in rural communities. We followed SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) reporting guidelines in the design of this protocol.[32]

We will use a type 1 hybrid design, which integrates the evaluation of both clinical effectiveness and implementation outcomes in the same study.[33] This design allows us to assess the impact of telerehabilitation on patient outcomes while simultaneously examining its feasibility and integration within a rural HCS. Telerehabilitation effectiveness will be examined using an individually randomised group treatment (IRGT) trial.[34] In the current trial, the IRGT design accounts for the fact that, although participants are individually randomised to a treatment, that treatment is provided by a limited group of physical therapists. This imparts a hierarchical data structure that must be accounted for in the analysis.[34] Implementation of telerehabilitation will be measured using the acceptability, adoption, feasibility and fidelity of our treatment approach, informed by the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework.[35]

Ethical principles

Ethical review and approval were received from the Johns Hopkins Medicine Institutional Review Boards (JHM IRB) (IRB00460142) and registered with ClinicalTrials.gov (NCT06471920). Enrolment began in January 2025

and will end in October 2027. All protocol modifications will be reviewed and approved by the JHM IRB.

Study aims

The ARBOR-Telehealth study has four broad objectives, each of which includes a set of primary, secondary and exploratory aims.

- **Aim 1 (primary):** Examine the effectiveness of risk-informed telerehabilitation in reducing LBP-related disability among patients living in rural communities with chronic LBP. We will compare 12-week changes in LBP-related disability between patients receiving telerehabilitation and those receiving web-based, standardised education.
  - **Aim 1a (secondary):** Compare the effectiveness of study treatments on 12-week, 26-week and 52-week changes in physical function.
  - **Aim 1b (secondary):** Compare the effectiveness of study treatments on 12-week, 26-week and 52-week changes in HRQoL.
- **Aim 2 (secondary):** Compare the prevalence of opioid use between patients receiving risk-informed telerehabilitation and those receiving web-based, standardised education. We will use a combination of patient surveys and electronic health record (EHR) data to assess opioid use in both groups at 12, 26 and 52 weeks.
  - **Aim 2a (secondary):** Compare the effectiveness of study treatments on non-opioid LBP-related healthcare use at 12, 26 and 52 weeks.
- **Aim 3 (exploratory):** Compare effectiveness of Aims 1 and 2 in predefined patient groups by examining heterogeneity of treatment effect in predefined groups based on sex, risk stratification and baseline opioid use.
- **Aim 4 (implementation):** Examine the implementation of risk-informed telerehabilitation at a rural HCS using a mixed-methods approach that incorporates patient and provider surveys and semi-structured interviews as key process metrics.

Participants

Potentially eligible participants will be adult patients (≥18 years) who have presented to a primary care clinic in the rural HCS in the last 90 days with a diagnosis suggestive of non-specific LBP, absent any red-flag conditions or non-musculoskeletal causes for LBP (figure 1 and table 1).

Recruitment and randomisation

Our study team will contact potentially eligible patients for telephone-based screening of eligibility and informed consent (see Section 4 of online supplemental materials, Model Consent Form). After informed consent and baseline assessment, participants will be randomised to receive eight weekly sessions of telerehabilitation or web-based patient education. A computer-generated scheme will be used to randomise participants in a 1:1 ratio in blocks of random sizes stratified by participant gender, psychosocial risk factor using the STarT Back Screening Tool (SBST) and baseline opioid use. Randomisation will be administered centrally through the Research Electronic Data Capture (REDCap) system.[36]

Every effort will be made by the study team to ensure that participants complete each study assessment. We will follow a proactive plan for retention, including calling participants to see how they are doing, building participant relations and satisfaction with our study team members, giving participants the opportunity to ask questions and express concerns throughout the study, distributing website updates to participants and assessing each participant's drop-out potential and intervening as needed to keep participants interested in continuing to participate.

Treatments

All treatments will be provided by licensed providers who have at least 1 year of experience working with patients with chronic pain and who have been trained in study-related procedures by the investigators.

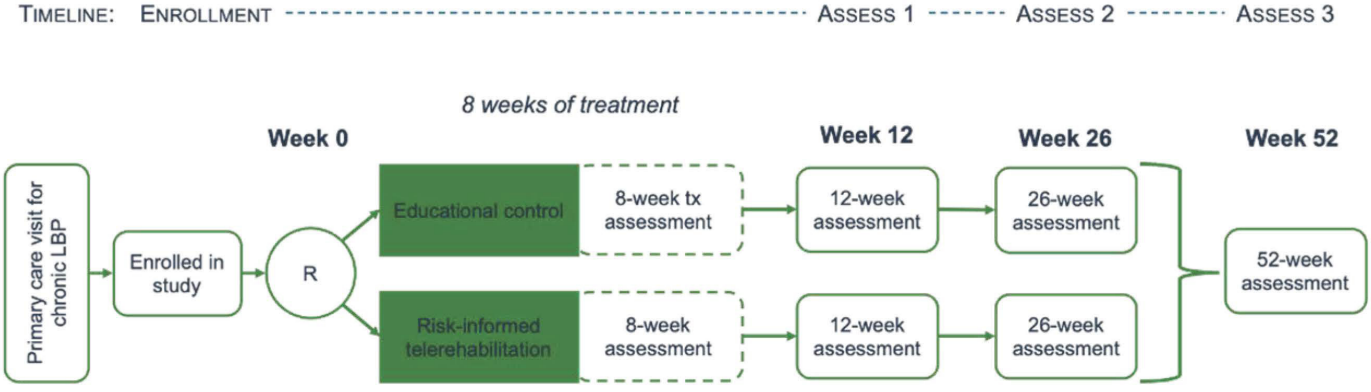

Figure 1 Intervention and assessment flow diagram for the ARBOR-Telehealth study, an individually randomised group treatment trial. ARBOR-Telehealth, Advancing Rural Back pain Outcomes using Rehabilitation-Telehealth; LBP, low back pain; R, randomise; tx, treatment.

Table 1 Eligibility criteria. Individuals will be eligible for the ARBOR-Telehealth study if they meet **ALL** of the inclusion criteria and **NONE** of the exclusion criteria

Inclusion criteria	Exclusion criteria
► Primary care visit in the past 90 days with an LBP-related ICD-10 diagnosis. ► Age 18 years or older. ► At least moderate levels of pain and disability requiring Oswestry score ≥24% and average NRS pain score ≥4/10 points. ► Meets NIH Task Force definition of chronic LBP based on two questions: (1) How long has LBP been an ongoing problem for you? and (2) How often has LBP been an ongoing problem for you over the past 6 months? Responses of 'greater than 3 months' to question 1 and 'at least half the days in the past 6 months' to question 2 are required to satisfy the NIH definition of chronic LBP. ► Can speak and understand English. ► Access to video-enabled device and internet.	► Recent history (last 6 months) of lumbar spine surgery. ► Possible non-musculoskeletal cause for low back pain symptoms (eg, pregnancy). ► Evidence of serious pathology as a cause of LBP, including neoplasm, inflammatory disease (eg, ankylosing spondylitis), vertebral osteomyelitis, etc. ► Neurological disorder resulting in severe movement disorder, or schizophrenia or other psychotic disorder. ► Knowingly pregnant.

ICD, International Classification of Diseases; LBP, low back pain; NIH, National Institutes of Health; NRS, numerical rating scale.

Web-based standardised education

Participants will receive registered access to a study website containing evidence-based standardised 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 education on the aetiology 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. We will provide information on physical activity guidelines and suggestions for 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.

Telerehabilitation

Participants will receive an evidence-based treatment protocol designed for video visits. Treatment will be informed by patients' baseline risk score, as measured by the SBST. Patients in the low-risk and medium-risk groups will receive standard physical therapy telehealth visits, with a focus on exercise interventions and self-management of symptoms. Patients in the high-risk category will receive these same interventions combined with components of psychologically informed physical therapy telehealth visits, such as Motivational Interviewing and pain science education.[37 38] Each patient's plan of care will be individually tailored by the treating physical therapist based on examination findings and ongoing response to treatment (table 2). Treatment is designed to be provided in weekly sessions over an 8-week period. To accommodate participants' schedules, we will allow up to two sessions to be held in the same week, but no more than eight sessions total to be received in the 8-week treatment period.[13 37 39–41]

Treatment fidelity

The study team has developed several mechanisms to enhance treatment fidelity for these study interventions. Mechanisms include provider training, structured intervention manuals and resources and ongoing monitoring using fidelity checklists embedded in the EHR.

Provider training

Study investigators developed a rigorous training schedule and materials for physical therapists providing study interventions. Providers receive 8 hours of training in study procedures and are provided manuals and online resources outlining core components for each treatment group. Physical therapists will also receive ongoing training through quarterly 1-hour telephone calls led by

Table 2 Telerehabilitation (physical therapy treatment) intervention elements

Standard telerehabilitation (low to medium risk)	Psychologically informed telerehabilitation (high risk)
► Physical therapy evaluation ► Education on benefits of exercise, increased physical activity levels and activity modifications (as appropriate) ► Therapeutic exercise – Strengthening exercise – Flexibility training – Functional movement training ► Self-management techniques for pain	► Physical therapy evaluation ► Interventions included in standard telerehabilitation ► Psychologically informed interventions – Motivational interviewing – Tailored education – Therapeutic pain neuroscience – Active pain coping techniques

members of the study team to review protocols, reinforce skills and discuss clinical issues.

Structured intervention manuals

The study team has developed structured intervention manuals that follow the eight-session format. The manuals offer guidance to treating physical therapists and include informational handouts and worksheets for participants.

Fidelity assessment

Physical therapists will complete intervention checklists built into the EHR to document treatment sessions, providing a pragmatic assessment of treatment fidelity.[42] We will use these checklists to determine whether core components of each study intervention are provided to participants. After each treatment session, the treating physical therapist will complete fidelity checklists in the EHR.

Concomitant interventions

Participants are not restricted from receiving other pain treatments outside the study. We will record the occurrence of any outside pain treatment as LBP-related healthcare use.

Study measures

Assessments will be conducted at baseline and at weeks 12, 26 and 52 after enrolment (table 3). The outcomes and instruments chosen are compliant with recommendations from the National Institutes of Health (NIH) Helping to End Addiction Long-term (HEAL) initiative.[43] All assessments will be conducted using case report forms in REDCap to minimise data missingness.

Primary outcome measure

Our primary outcome measure is LBP-related disability assessed using the Oswestry Disability Index (ODI). The ODI is a 10-item measure of LBP-related disability that assesses the current effects of a patient's symptoms on various aspects of daily living. ODI scores range from 0 to 100, with higher scores indicating greater LBP-related disability.[44]

Secondary outcome measures

Our secondary outcomes are opioid use, pain intensity, HRQoL and LBP-related healthcare use.

Opioid use will be assessed using self-report and medical record abstraction. We will ask participants to self-report opioid use at each assessment if they have used opioids for their LBP during the past 90 days. For those responding 'yes', we will ask whether the patient has used opioids for their LBP 'daily or near daily in the past 90 days'. Our research team will abstract information on LBP-related opioid use reported during the index primary care encounter to estimate the morphine milligram equivalence.[43]

Pain intensity will be assessed using the brief Pain, Enjoyment of Life and General activity (PEG) scale with scores ranging from 0 to 10, where 0 represents no pain or interference and 10 represents pain as bad as can be imagined or complete interference.[45]

HRQoL will be measured using the Patient Reported Outcome Measurement Information System (PROMIS) to assess physical, mental and social health using the PROMIS-29 short form. PROMIS is a collection of person-centred measures that assess health across three broad domains: physical, mental and social. It was established with funding from the NIH, can be used with the general population and those living with chronic conditions, and has been translated into many languages.[46 47] The health domains assessed will be pain interference, physical function, fatigue, anxiety, depression, sleep disturbance and ability to participate in social roles and activities (here, 'social roles and activities').[48] The domains are scored 0–100, with higher scores meaning more of that domain.

We will ask participants to self-report LBP-related healthcare use at each assessment, including provider visits (eg, primary care, complementary providers, emergency department or surgical consults for LBP), imaging (eg, radiographs, MRI), and procedures (eg, injections, surgery).

Risk for poor outcome

We will assess each patient's risk for poor outcome (ie, worsening of symptoms or non-response to treatment) at baseline (before randomisation) on the basis of psychological and physical risk factors using the SBST[49 50] to characterise participants as having high, medium or low risk for poor outcomes. Screening results from the SBST will be evaluated as a potential subgrouping variable.

Adverse events

Participants will be asked about adverse events (AEs) and unanticipated problems (UPs) during each follow-up study assessment. They will also be encouraged to report any events spontaneously to the study team. These will be recorded in REDCap and the study team will receive prompt notification. Participants will be monitored for 7 days (AEs) and 30 days (serious AEs [SAEs] and UPs) after study completion. All SAEs and UPs should be reported to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the Data Safety Monitoring Board (DSMB) (through the NIAMS Executive Secretary) within 48 hours of the study team's becoming aware of the event, whether or not considered study related. The study team will include an assessment of whether there is a reasonable possibility that the study caused the event.

Safety monitoring

A DSMB has been established based on the NIAMS guidelines and commensurate with the level of risk, size and complexity of this study. The DSMB will meet on an annual basis to review study procedures, plans for data and safety monitoring, recruitment and retention, protocol adherence, data management and the occurrence of any AEs, SAEs or UPs.

Table 3 Schedule of assessments

Domain	Instrument	Screen	Base*	12 wk†	26 wk‡	52 wk§
Demographics	Age, sex, race	x	x			
Social factors	Housing/social support		x			
Economic factors	Education, household income, work status/occupation		x			
Medical history	Comorbid conditions, height/weight/BMI		x			
Health habits	Smoking, alcohol use, physical exercise					
Psychosocial risk	SBST, Patient Activation Measure		x			
Effectiveness						
Disability	ODI	x		x	x	x
Pain	PEG-3		x	x	x	x
Chronic pain	NIH Task Force 2-questions	x				
Quality of life	PROMIS-29+2		x	x	x	x
Pain self-efficacy	PSEQ-2		x	x	x	x
Pain catastrophising	PCS-6		x	x	x	x
High-impact chronic pain	GCPS		x	x	x	x
Depression	PHQ-2		x			
Anxiety	GAD-7		x			
Substance use	TAPS-1		x			
Opioid use	EHR/self-report		x	x	x	x
Healthcare use						
Advanced imaging	Per cent of patients who received advanced spine imaging		x	x	x	x
Injections	Per cent of patients who receive spine injections		x	x	x	x
ED visits	Per cent of patients who present to the ED with back pain complaints		x	x	x	x
Specialist visits	Per cent of patients who present to specialty care with back pain complaints		x	x	x	x
Physical therapy	Per cent of patients who present to physical therapy (external to study) with back pain complaints		x	x	x	x
Back surgery	Per cent of patients who undergo back surgery		x	x	x	x
Implementation						
Acceptability	Per cent of patients approached who accept	x				
Adoption	Per cent of patients offered telerehabilitation	x				
Feasibility	Per cent of intervention sessions completed		x	x		
Fidelity	Per cent of core treatment components provided during intervention sessions		x	x		
Satisfaction	Telehealth physical therapy patient satisfaction survey					x

Continued

Table 3 Continued

Domain	Instrument	Screen	Base*	12 wk†	26 wk‡	52 wk§
Obstacles and facilitators	Semi-structured qualitative interview					x
Safety Assessment						
Safety	Adverse Events and Unanticipated Problems			x	x	x

*Baseline to occur within 14 days of screening.
†12-week assessment completed from Day 71 to Day 98.
‡26-week assessment completed from Day 162 to Day 203.
§52-week assessment completed from Day 336 to Day 392.
BMI, body mass index; ED, emergency department; EHR, electronic health record; GAD-7, General Anxiety Disorder 7-item; GCPS, Graded Chronic Pain Scale; NIH, National Institutes of Health; ODI, Oswestry Disability Index; PCS-6, Pain Catastrophizing Scale-6 item; PEG-3, Pain, Enjoyment of Life and General activity scale, 3-item; PHQ-2, Patient Health Questionnaire-2; PROMIS, Patient Reported Outcome Measurement Information System; PSEQ-2, Pain Self-Efficacy Questionnaire-2; SBST, STarT Back Screening Tool; TAPS-1, Tobacco, Alcohol, Prescription medication and other Substances-part 1; wk, weeks.

Implementation outcomes

To evaluate the implementation of risk-stratified telerehabilitation at our partner HSC, we will employ the RE-AIM framework[35] to examine implementation outcomes guided by Proctor's taxonomy[51]: acceptability (number of patients with chronic LBP who accept study participation out of those who are approached for screening), adoption (perceived advantages and disadvantages of risk-stratified telerehabilitation from a survey of physical therapists and patients), feasibility (number of scheduled intervention visits completed) and fidelity (number of key intervention components delivered out of the total number of intervention sessions provided).

All participants who are randomised to the telerehabilitation group will be asked to complete a telerehabilitation satisfaction survey after their 52-week study assessment. In addition, we will randomly select 40 participants in the telerehabilitation group, whether they initiated treatment or not, for semi-structured qualitative interviews that focus on their experience with study participation, obstacles and facilitators to initiating or remaining in treatment, and recommendations to improve the care of patients with chronic LBP in rural communities. These interviews will be audio-recorded and transcribed.

Study design pragmatism

We scored the design of the ARBOR-Telehealth study using the nine domains of the PRagmatic-Explanatory Continuum Indicator Summary, V.2[52] on a scale of 1–5 and rated the study as more pragmatic than explanatory (table 4 and figure 2).

Statistical analysis

The analysis will treat the physical therapist as a random effect in the IRGT; that is, the sample of physical therapists participating in the trial represents a random sample of therapists from a larger population. The primary analysis will follow the intention-to-treat (ITT) principle and be performed on the sample of all randomised patients under the assumption of missing at random data. Secondary analyses will be performed on complete cases (ie, all patients who completed the applicable assessment) under the missing completely at random assumption and will target the per-protocol population.

The marginal treatment effect for the primary outcome is defined as the difference in the mean 12-week change in ODI scores (negative change indicates improvement) comparing telerehabilitation to web-based standardised education. The marginal treatment effect will be estimated using the doubly robust weighted least squares (DR-WLS) model standardisation approach for baseline covariate adjustment.[53] Details of the estimation procedure, including the baseline covariates that will be included in the estimation procedure, are included in Section 1 of the online supplemental materials. A bootstrap procedure that accounts for the IRGT trial design will be used to obtain 95% CIs for the marginal treatment effect. For each bootstrap replicate, we will (1) take a sample with replacement of patients in the web-based standardised education arm; (2) to maintain the clustering of patients within physical therapists administering telerehabilitation and allowing the target of inference to be the population of possible physical therapists who may have participated in the trial, take a sample with replacement of physical therapists and within each sampled physical therapist, take a sample with replacement of patients; and (3) estimate the marginal treatment effect using the DR-WLS procedure. The 95% CI will be computed using the percentile method based on 1000 bootstrap replicates. Telerehabilitation will be deemed superior to web-based standardised education if the upper bound of the 95% CI is less than 0; that is, the 12-week ODI change (negative change indicates improvement) is greater for telerehabilitation than for the web-based standardised education arm.

Secondary analyses of the primary endpoint will include estimating the marginal treatment effect within the complete-case ITT population (ie, under missingness

Table 4 Application of PRagmatic Explanatory Continuum Indicator Summary-2 criteria to the Optimized Multidisciplinary Treatment Programs for Nonspecific Chronic Low Back Pain (OPTIMIZE) study

Domain	Criteria for scoring	Score*	Rationale
Eligibility criteria	To what extent are the trial participants similar to those who would receive this intervention in usual care?	4	Eligibility criteria are similar to those that would be used in clinical decision-making; assessments and screening are clinically available and routinely used
Recruitment path	How much extra effort is made to recruit participants than what is done in usual care settings to engage patients?	3	Recruiting employs the electronic health record to identify an at-risk population; use of targeted invitation letters and telephone follow-up
Setting	How different are the resources, intervention provider expertise and organisation of care delivery in the trial from usual care?	4	Care is provided in usual care settings (eg, telerehabilitation); providers have been trained for the study protocol
Organisation of intervention	How different are the settings for the trial from usual care settings?	3	Organisation is identical to usual care; Back Pain Navigators serve a coordinating care role
Flexibility of experimental intervention delivery	How different from usual care are the resources, intervention provider expertise and organisation of care delivery in the trial?	4	There are intervention protocols, fidelity measurements and engagement activities; the protocol allows flexibility per clinical judgement;
Flexibility of experimental intervention–adherence	Is the intervention delivery in the trial more or less flexible compared with usual care?	2	Great effort is made to ensure that participants attend the first intervention appointment
Follow-up	How intense is the measurement and follow-up of trial participants compared with the typical follow-up of patients in usual care?	2	Assessments at baseline and at weeks 12, 26 and 52 are outside of usual care; incentives are offered for completion
Outcome	To what extent is the trial's primary outcome directly relevant to the participants?	5	Outcomes are highly relevant to participants and to providers
Analysis	To what extent will all data be included in the analysis of the primary outcome?	5	Intention-to-treat analysis is planned, using data from all randomised participants

*Scores of 1–5 indicate how pragmatic or explanatory the clinical trial is using the following grades: 1, very explanatory; 2, rather explanatory; 3, equally pragmatic and explanatory; 4, rather pragmatic; and 5, very pragmatic.

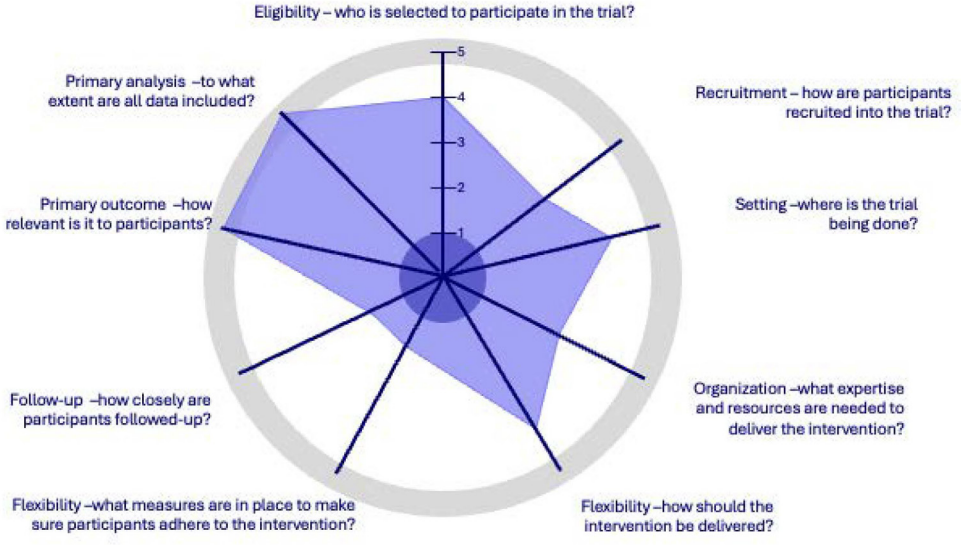

Figure 2 PRagmatic-Explanatory Continuum Indicator Summary-2 scoring wheel for the ARBOR-Telehealth study. Scores of 1–5 on each wheel spoke indicate how pragmatic or explanatory the clinical trial is using the following grades: 1, very explanatory; 2, rather explanatory; 3, equally pragmatic and explanatory; 4, rather pragmatic; and 5, very pragmatic. Figure adapted from a study by Loudon *et al*.[52] Used by permission. ARBOR-Telehealth, Advancing Rural Back pain Outcomes using Rehabilitation-Telehealth.

completely at random) and per-protocol population (see Sections 2 and 3 of the online supplemental materials).

The analysis of secondary continuous outcomes (Aims 1a and 1b); for example, 12-week change in PROMIS physical function score and 12-week change in pain intensity (PEG scale), as well as the exploratory outcomes (eg, 12-week change in PROMIS quality of life), will be similar to that described above for the primary outcome. The marginal treatment effect for secondary binary outcomes (Aims 2 and 2a); for example, opioid use and use of external physical therapy reported at 12 weeks, is defined as the absolute difference in prevalence of the binary outcome, and the marginal treatment effect for secondary count outcomes (Aim 2a); for example, number of external physical therapy sessions reported at 12 weeks, is the difference in the mean outcome. These treatment effects will also be estimated using the DR-WLS procedure (see Section 1 of the online supplemental materials), with corresponding 95% bootstrap CIs as described above.

Similar analyses will be conducted for the 26-week and 52-week outcomes. Patient-subgroup analyses (Aim 3) will use the same methods, restricting the estimation procedure to the appropriate patient subgroup.

We will evaluate the implementation of risk-informed telerehabilitation by examining the acceptability, adoption, feasibility and fidelity of our treatment approach guided by the RE-AIM framework.[35] To accomplish this aim, we will use a mixed-methods approach that incorporates patient and provider surveys, semi-structured interviews and key process metrics (Aim 4). Patient and provider surveys will assess perceptions of acceptability, ease of use and satisfaction with the telerehabilitation approach. Semi-structured interviews with key stakeholders will explore obstacles and facilitators influencing the adoption and feasibility of the intervention in real-world practice. Key process metrics, such as utilisation rates, adherence to treatment protocols and patient engagement levels, will measure implementation fidelity and overall programme effectiveness. We will employ a purposive sampling strategy to ensure our study captures differing perspectives from key stakeholders directly involved in the implementation. We will apply the trustworthiness criteria ensuring credibility, transferability, dependability and confirmability throughout the qualitative data collection and analysis to serve as a parallel to reliability and validity in quantitative research. Findings will be triangulated to develop an understanding of how risk-informed telerehabilitation is perceived, adopted and could be sustained in rural clinical settings.

Missing data

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% by 52 weeks. Our analysis procedures described above are valid under the missing completely at random and missing at random assumptions.

Statistical power

The trial will enrol 434 patients, with 346 patients expected to complete the trial. We conservatively based our sample size on an unadjusted analysis; if there is improved precision for the marginal treatment effect with the baseline covariate adjustment, our power will be larger than estimated. Using data from a prior observational study of adults aged 18–64 years with chronic LBP who engaged in telehealth physical therapy administered by 16 physical therapists,[54] we assumed a SD in 12-week change in ODI scores of 6.5 in both treatment arms, although we expect less variation in the 12-week change in the educational control arm, and an intra-class correlation of 0.02 for 12-week change in ODI scores among patients treated by the same physical therapist. Using these assumptions and a Type I error rate of 5%, we simulated 1000 hypothetical trials under the IRGT design and estimated 95% power to detect a marginal treatment effect of 6.5 (favouring the risk-stratified telerehabilitation arm). This difference is consistent with findings from earlier trials.[55–59]

Given our target sample size, we evaluated the power to detect a clinically relevant effect on the key secondary outcome, opioid use by 12 weeks. Using the prior study data, we assumed the proportion of patients reporting opioid use by 12 weeks in the educational control arm to be 25% and the intra-class correlation of opioid use among patients treated by the same physical therapist to be 0.06. Assuming 346 patients will complete the trial, we estimate 85% power to detect a marginal treatment effect of 15%, that is, 10% of telerehabilitation patients will report opioid use by 12 weeks based on 1000 simulated hypothetical IRGT trials with the assumptions and a Type I error rate of 5%. 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 physical therapy referral models.[60 61]

Patient and public involvement

People living with chronic LBP who resided in the same rural communities included in the ARBOR-Telehealth study took part in surveys and semi-structured interviews as part of the planning phase for this clinical trial. Their participation informed the recruitment methods, study implementation and communication strategies to be employed during the clinical trial.

Ethics and dissemination

Ethics approval was obtained from the Johns Hopkins Medicine Institutional Review Boards (IRB), which serves as the single IRB for this trial. RLS, EC and KHM will be responsible for data curation and management. On completion, study data will be shared in compliance with NIH guidelines.

DISCUSSION

This study will be among the first to examine the use of telerehabilitation in a rural population. Telerehabilitation

has long been discussed as a means of improving access to physical therapy and improving health outcomes among those in rural parts of the USA, but few studies have examined the effectiveness or implementation of telerehabilitation in these areas. The current study will address the limitations of prior research by a large sample size, a protocol-driven comparison group and implementation in a rural healthcare setting. The results of this study will have important implications for the strategies used to improve health outcomes among patients with chronic LBP living in rural areas. This aligns with priorities surrounding rural health published by the Health Resources and Services Administration,[62] the Centers for Disease Control[63] and the NIH.[64]

This study will address the need for research on the effectiveness of telerehabilitation, which has been highlighted as an obstacle to greater use of telerehabilitation by patients and physical therapists.[65 66] A study examining perceptions of telerehabilitation among patients using physical therapy to manage spine pain identified 'new research supporting the effectiveness of telerehabilitation' as the factor most likely to increase their use of telerehabilitation in the future.[66] Similarly, a study examining perceptions of telerehabilitation among physical therapists found that physical therapists are sceptical about the effectiveness of telerehabilitation to treat patients with musculoskeletal pain but do think that telerehabilitation plays an important role in expanding access to physical therapy.[65] The results of this study will directly address these gaps in knowledge surrounding the effectiveness of telerehabilitation, which can be used to inform patient and provider decisions surrounding the use of telerehabilitation for patients with chronic LBP.

The study has limitations that may affect its generalisability to patients with chronic LBP who live in other rural communities. The ARBOR-Telehealth study is being conducted in a single HCS on Maryland's Eastern Shore. This may limit the contextual generalisability to the broader population. In addition, limitations associated with rurality, such as participants having access to broadband internet connectivity to engage with the intervention, may differ across rural communities. Patients in other rural areas may have unique characteristics and/or obstacles to seeking treatment and differential access to devices and internet service. Despite these limitations, the study has strengths: a large representative patient sample; use of a protocol-driven, evidence-supported comparison group; use of outcomes that are important to patients and healthcare providers; and measurement of implementation outcomes that can inform dissemination, adoption and scalability of this telehealth model. The ARBOR-Telehealth study will compare a treatment delivery strategy that has the potential to reduce the rural–urban differences gap by increasing access to physical therapy care services for patients who reside in rural communities.

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