BeatPain Utah: study protocol for a pragmatic randomised trial examining telehealth strategies to provide non-pharmacologic pain care for persons with chronic low back pain receiving care in federally qualified health centers

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ABSTRACT

Introduction Although evidence-based guidelines recommend non-pharmacologic treatments as first-line care for chronic low back pain (LBP), uptake has been limited, particularly in rural, low-income and ethnically diverse communities. The BeatPain study will evaluate the implementation and compare the effectiveness of two strategies to provide non-pharmacologic treatment for chronic LBP. The study will use telehealth to overcome access barriers for persons receiving care in federally qualified health centres (FQHCs) in the state of Utah.

Methods and analysis BeatPain Utah is a pragmatic randomised clinical trial with a hybrid type I design investigating different strategies to provide non-pharmacologic care for adults with chronic LBP seen in Utah FQHCs. The intervention strategies include a brief pain consult (BPC) and telehealth physical therapy (PT) component provided using either an adaptive or sequenced delivery strategy across two 12-week treatment phases. Interventions are provided via telehealth by centrally located physical therapists. The sequenced delivery strategy provides the BPC, followed by telehealth PT in the first 12 weeks for all patients. The adaptive strategy uses a stepped care approach and provides the BPC in the first 12 weeks and telehealth PT to patients who are non-responders to the BPC component. We will recruit 500 English-speaking or Spanish-speaking participants who will be individually randomised with 1:1 allocation. The primary outcome is the Pain, Enjoyment and General Activity measure of pain, with about one-third of these individuals experiencing high-impact chronic pain (HICP) with significant levels of interference in work, social and/or self-care activities. Low back pain (LBP) is the most prevalent form of chronic pain and the most common diagnosis for which opioids are prescribed despite little supporting evidence. Evidence-based guidelines specify non-pharmacologic (NP) treatments are preferred to opioids as first-line LBP care. Various evidence-based NP

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a pragmatic randomised trial comparing the effectiveness of different strategies to provide non-pharmacological care for person with chronic low back pain who receive primary care in safety-net settings.
⇒ Non-pharmacologic care is provided using telehealth delivery to overcome access barriers including geographic isolation and availability of Spanish-language services.
⇒ The trial is a hybrid type I effectiveness/implementation randomised clinical trial.
⇒ Limitations include studying primary care clinics in only one state and using a limited number of physical therapists to provide the telehealth services.

INTRODUCTION

One in three Americans lives with chronic pain, with about one-third of these individuals experiencing high-impact chronic pain (HICP) with significant levels of interference in work, social and/or self-care activities. Low back pain (LBP) is the most prevalent form of chronic pain and the most common diagnosis for which opioids are prescribed despite little supporting evidence. Evidence-based guidelines specify non-pharmacologic (NP) treatments are preferred to opioids as first-line LBP care.
treatments exist with a common goal of facilitating self-management. Increasing the use of effective NP treatment is an opportunity to prevent opioid initiation or escalation, reduce costs, limit transition to HICP and improve outcomes. Challenges with access, however, continue to limit uptake of NP care for chronic LBP.

Disparities related to chronic pain have long existed and are increasingly acknowledged. Residents in low-income and rural communities experience higher rates of HICP, are more likely to be prescribed opioids and less likely to receive NP care. Individuals of Hispanic ethnicity are more likely to be managed with medication versus NP care, particularly those with lower income levels. These disparities were exacerbated by the COVID-19 pandemic. Over-representation of HICP and over-reliance on opioids in rural, ethnically diverse and low income communities highlight the need to reduce pain management disparities, but strategies must overcome limited NP access in these communities.

Federally qualified health centres (FQHCs) are federally funded, non-profit organisations providing primary care in areas with high prevalence of medically underserved individuals. About 1 in 12 Americans including 1 in 5 residents of rural communities receive primary care in FQHC clinics. Almost 60% of patients in FQHCs are members of racial/ethnic minority groups and 68% have a household income at or below the federal poverty level. Prevalence of chronic pain is 40%–60% among adult FQHC patients. Research focused on improving primary care LBP management has typically not included FQHCs.

The BeatPain study will examine strategies to overcome access barriers and improve pain outcomes in settings that have historically experienced pain disparities. First, we are using telehealth delivery of NP care. There was pre-COVID evidence that telehealth interventions for patients with LBP can be broadly equivalent to in-person care, though evidence was limited. The uptake of telehealth during the pandemic suggests it is likely play a larger role in pain management moving forward. Expansion of telehealth provides an opportunity to reduce disparities by overcoming geographic isolation barriers to NP care.

The BeatPain study is comparing an adaptive strategy based on a stepped care model to a model that provides more intensive NP treatment to all participants. Treatments are delivered using telehealth to overcome access barriers. Our study uses a hybrid type I design focused on effectiveness while gathering implementation data to inform future efforts to scale effective strategies.

METHODS
This protocol was developed using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (online supplemental appendix 1). The manuscript and supplemental material (online supplemental appendix 2) outline the study’s alignment with the SPIRIT recommendations. The protocol was approved by the University of Utah Institutional Review Board on 14 July 2021 (IRB #00143493) and registered with Clinicaltrials.gov (NCT04923334) on 11 2021. Enrolment was planned to begin in October 2021 and end in March 2024.

Study design
BeatPain is an individually randomised, multisite, pragmatic clinical trial examining two intervention strategies (figure 1). Each intervention arm includes two treatment components (brief pain consult (BPC) and telehealth). Participants randomised to the sequenced arm receive the BPC followed by telehealth PT during phase I (figure 1). Participants randomised to the adaptive arm receive the BPC during phase I with an adaptive strategy at the 12-week follow-up to determine if participants need telehealth PT in phase II based on the response to the BPC (figure 1). All interventions are provided via telehealth by physical therapists centrally located in Salt Lake City, Utah.

Study aims
1. Compare effectiveness of a BPC with or without telehealth PT for patients with chronic LBP with pain interference as primary and opioid use as a secondary outcome.
2. Compare effectiveness of telehealth PT as a sequenced versus an adaptive strategy.
3. Examine results of aims 1 and 2 in subgroups based on gender, HICP and current opioid use.
4. Explore implementation outcomes for telehealth (acceptability, adoption, feasibility, fidelity).

Aims 1 and 2 constitute coprimary aims for comparison of effectiveness in the full study population. Aim 3 constitutes exploratory comparisons of effectiveness in subgroups, and aim 4 addresses descriptive summaries of implementation outcomes.
Table 1  Eligibility criteria

| Inclusion criteria                                                                 | Exclusion criteria                                                                 |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| ► Visit with an FQHC provider related to pain in the thoracic, lumbar and/or sacral | ► Active substance use disorder for which the individual is receiving treatment (not |
| regions of the spine with or without radiating symptoms into the leg(s) in the past | including peer-led support groups such as Alcoholics Anonymous).                   |
| 90 days.                                                                          | ► Non-musculoskeletal diagnosis causing LBP including spinal neoplasm, infection    |
| ► Meets the NIH Task Force definition\(^\text{95}\) of chronic requiring that LBP has | (osteoarthritis, discitis, etc), inflammatory disease, etc.                         |
| been a problem for >3 months and has been a problem on at least half the days in the | ► Spinal fracture diagnosis causing LBP.                                           |
| past 6 months.                                                                    | ► Presence of a comorbid condition or diagnosis that restricts ability to engage in |
| ► Age 18–70.                                                                      | physical activity including neurological disease or injury, paraplegia, wheelchair |
| ► Able to communicate in English or Spanish.                                       | dependence, etc.                                                                    |
| ► Access to resources for participating in telehealth.                            | ► Currently pregnant based on self-report.                                         |
| (phone and/or internet access)                                                     | ► Spine surgery in the past 6 months.                                              |

FQHC, federally qualified health centres; LBP, low back pain; NIH, national Institutes of Health.

Rationale for design

Brief interventions such as the BPC\(^\text{45, 46}\) and telehealth PT\(^\text{33}\) are effective for chronic LBP. We will compare effectiveness of BPC with or without telehealth PT (Aim 1). The 12-week assessment permits evaluation of waiting to provide telehealth PT in a stepped manner versus providing this treatment sequentially during phase 1 (Aim 2). We will explore heterogeneity in treatment response in prespecified subgroups (Aim 3) and explore implementation outcomes for our process of connecting patients in FQHCs to telehealth pain care (Aim 4).

Participants

Eligibility criteria (Table 1) are intended to recruit adults with chronic LBP seeking care in Utah FQHCs. We will exclude individuals for whom participating may be difficult or unsafe, or for whom a different type of management may be indicated.

Recruitment

Participants are recruited from FQHC primary care clinics recruited in partnership with the Association for Utah Community Health, the federally designated Primary Care Association representing Utah’s 14 FQHC organisations. These 14 organisations operate 63 primary care clinics serving over 165,000 persons; 49% of which identify as Hispanic/Latino, 37% communicate in a language other than English and 66% have a household income at or below the federal poverty level.\(^\text{47}\)

Recruitment occurs through two methods. One uses an in-clinic provider-generated electronic referral (e-referral) placed within the clinic’s electronic health record (EHR). E-referral uses a standards-based approach, the Direct protocol for messaging and the Health Level Seven International (HL7) Consolidated Clinical Document Architecture (C-CDA), for representation of patient data. Direct is a secure email messaging protocol that is compliant with the Health Insurance Portability and Accountability Act (HIPAA) for data transmission.\(^\text{48}\) C-CDA is a document-based standard that allows sharing of a snapshot of a patient’s health record.\(^\text{49}\) Each of the three different EHR products used in Utah FQHCs support e-referrals compliant with the Direct and C-CDA standards. BeatPain uses phiMail (EMR Direct, San Diego, California, USA) as the e-referral inbox for the centrally located physical therapists. E-referrals using Direct and C-CDA are accessible from within any certified EHR in the USA and are a scalable approach that fits into existing workflows.

The second strategy uses a population health approach to offer participation following a clinic visit. Many Utah FQHC organisations adopted a population health management system (Azera Healthcare, Burlington, Massachusetts, USA). This system works via automated data interfaces with clinic EHRs to identify patients with particular criteria. An electronic dashboard provides details on the population of interest and allows for creation and management of clinic-directed messaging campaigns. Messages can be delivered by automated voice message, text message or email, per the patient’s preference recorded in the EHR. Patients who respond with interest in participating have an e-referral placed by staff assigned to monitor the messaging campaign.

Once a referral is received, a BeatPain team member reaches out to the patient by phone. Patients who wish to participate complete an oral informed consent process. Those who do not wish to participate may receive the BPC intervention with no additional research data collection.

Randomisation and blinding

Participants are randomly assigned to the adaptive or sequenced arm with a 1:1 ratio. Randomisation occurs after consent and baseline assessment using the RedCap randomisation module\(^\text{50}\) with schedules developed before enrolment by a statistician not involved in the study and stratified based on assigned physical therapist and opioid use for LBP. Randomisation assignment is revealed by the physical therapist following the first BPC session. The study is outcome assessor and investigator blinded. Physical therapists, primary care providers and participants cannot be blinded to treatment assignment.
Study interventions

The BPC and telehealth PT interventions are informed by the biopsychosocial model of pain and social cognitive theory. These models recognize that the pain experience is informed by social and economic circumstances, and may elicit powerful psychological responses that modulate behavioural responses. Both interventions use Motivation And Problem Solving (MAPS), a strategy combining motivational interviewing and social cognitive, practical problem-solving to enhance motivation and self-efficacy for behaviour change. MAPS is used to help participants set meaningful goals and develop positive coping strategies. Interventions are provided in English or Spanish based on patient preference.

The BPC component focuses on pain education from a biopsychosocial perspective to address negative pain appraisals and catastrophising thoughts, providing advice to be active and engage in exercise, and reassurance that activity is beneficial and safe. The BPC is delivered in two sessions (table 2) with a physical therapist using two-way interactive video or phone-based delivery based on patient preference and access. Sessions use MAPS techniques to help modify maladaptive beliefs about LBP and encourage positive coping through physical activity.

Telehealth PT involves 10 weekly sessions. Key components include reinforcing biopsychosocial messages from the BPC component, exercise recommendations specific to LBP and physical activity behaviour change. Content of the 10 telehealth PT sessions is outlined in table 2. The programme includes common exercises for persons with LBP and is designed for at-home performance without specialised equipment. Review and expansion of biopsychosocial education messages designed to counter maladaptive cognitive and behavioural responses to pain are provided every other session. These messages are accompanied by solicitation of patient questions or concerns and use of active listening techniques which are components of MAPS training. Instruction is provided in a physical activity programme guided by activity goals from the BPC sessions. Telehealth PT sessions introduce additional pain coping strategies using skills such as mindful breathing, body scan and progressive muscle relaxation.

Concomitant interventions

As a pragmatic study, participants are not restricted from receiving other pain treatments or diagnostics.

Provider training

Physical therapists receive a minimum of 12 hours of training to provide study interventions. Physical therapists are trained in MAPS to help them work with patients to understand the larger context of chronic pain in their lives and enhance motivation towards the development and implementation of positive coping strategies. Training is also provided in cross-cultural communication for person-centred care. This approach encourages open, honest and non-judgemental awareness of the provider’s potential sources of bias and stereotypes that may impact communication and respect for participants’ values, preferences and needs. Physical therapist training methods

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Table 2  Content outline and core treatment components for brief pain consult

| Session topics |  |
|----------------|------------------|
| 1              | Discuss chronic pain from biopsychosocial perspective. |
|                | Explore patient’s pain experience. |
|                | Reassure that activity is safe and beneficial, introduce activity goal-setting. |
| 2              | Review activity goals, review education, solicit questions from session 1. |
|                | Consider additional pain domains and goal-setting. |
|                | Solicit and discuss any patient questions/concerns. |

Core treatment components for two-session brief pain consult:
1. Discuss chronic pain from biopsychosocial perspective.
2. Identify at least one goal for change.
3. Solicit patient input and questions.

Table 3  Content outline and core treatment components for telehealth physical therapy

| Session topics |  |
|----------------|------------------|
| 1              | Review physical activity goals from brief teleconsult and discuss any barriers to progress. Identify personalised, home-based exercise programme. |
| 2              | Review biopsychosocial education messages and physical activity goals and exercise programme. |
| 3              | Introduce pain coping strategies with mindful breathing and progressive muscle relaxation techniques. Review physical activity goals and exercise programme. |
| 4, 6, 8        | Review of biopsychosocial messages along with physical activity goals and exercise programme. |
| 5, 7, 9        | Review of pain coping strategies along with physical activity goals and exercise programme. |
| 10             | Review physical activity goals and coping strategies, transition to self-management plan |

Core treatment components for 10-session telehealth physical therapy:
1. Assign exercise for self-management in flexibility, strength and aerobic domains
2. Set at least one physical activity goal with the patient
3. Update exercise plan at least once
include didactic instruction, role-playing and simulated patient interactions and ongoing availability of the MAPS trainer on the BeatPain team (KL) for consultation.

Training is also provided on the referral process to FQHC primary care providers and staff. Training began with a sociotechnical assessment of EHR workflows conducted remotely due to COVID-19 restrictions. Sociotechnical assessments help understand technical and non-technical (eg, workflow, communication, culture) aspects of EHR use within clinics and were used to design and develop both the in-clinic and population health based approaches to referring patients to the project. Of particular interest were current practices for patients with chronic LBP, procedures for placing referrals in the EHR, and the acceptability of offering referrals using the in-clinic and population health strategies. The BeatPain team provided brief instruction to providers and staff on e-referral procedures and elicited feedback on the desired content and frequency of feedback from the BeatPain physical therapists. Occasional updates and reminders about the project are provided to clinic staff during meetings and through written communication, newsletters, etc.

**Fidelity monitoring**

Intervention fidelity is self-reported by the physical therapist using checklists in the project’s REDCap platform. Monitoring fidelity is focused on the core components of each intervention, which represent its fundamental purpose or desired effects. In pragmatic studies, fidelity monitoring focuses on core components to monitor if the intervention is provided as designed. Core components for each intervention are provided in tables 2 and 3.

**Outcome assessments**

Assessments are conducted at baseline and at 12, 26 and 52 weeks after randomisation by phone with a blinded research assistant. Outcome measures are compliant with common data elements from the National Institutes of Health Helping to End Addiction Long-term initiative which identified 9 core domains for pain assessment. The schedule of assessments is outlined in table 4. Assessments are completed by phone with a research assistant in English or Spanish based on participant preference.

**Primary outcome**

The primary outcome is the Pain, Enjoyment and General Activity (PEG) Scale. The PEG includes three items: (1) pain severity; (2) interference of pain with enjoyment and (3) interference of pain with general activity. Item response options range from 0 to 10. The PEG score is the mean of the item scores.

**Main secondary outcome**

Opioid use at 52-week follow-up is the main secondary outcome. Opioid use will be determined from EHR data. We will also collect self-reported opioid use. We will categorise participants as using opioids for pain management if prescriptions are available in the EHR covering at least 90 of the previous 120 days from the time of the 52-week follow-up.

**Additional secondary outcomes**

Table 4 lists additional secondary outcomes including Patient-Reported Outcomes Measurement Information Systems short forms for physical activity and sleep disturbance. A single question from the Pittsburgh Sleep Quality Index assesses sleep duration. Pain catastrophising and self-efficacy are captured using 4–6 item short forms. The General Anxiety Disorder and the Patient Health Questionnaire 2-item screeners identify generalised anxiety disorder and depressive symptoms respectively. HICP is identified using two items from the Revised Chronic Pain Scale. The Tobacco, Alcohol and Prescription Medications and other Substance tool is a four-item screening for substance misuse and illicit substance use in the past year.

**Responder status**

The single-item patient global impression of change (PGIC) is used to determine treatment response. The PGIC asks: ‘Since starting the study, my pain is...’ with Likert scale response ranging from (0) ‘very much worse’ to (6) ‘very much improved’. Responses of ‘much improved’ (5) or ‘very much improved’ (6) define a treatment responder.

**Implementation outcomes**

Selected domains from Proctor’s taxonomy of Outcomes for Implementation Research including acceptability, adoption, fidelity and feasibility for the implementation of telehealth pain care. Definitions are provided in table 4.

**Retention**

Participant retention will be supported through flexible scheduling of intervention and assessment sessions to accommodate participants’ schedules. Multiple contact methods are recorded (phone, email, text, etc) at baseline, and participants’ preferred communication method is noted. Participants who do not attend a session are sent reminders using multiple contact methods. A modest financial remuneration (US$25) is provided to compensate participants who complete assessments.

**Design pragmatism**

BeatPain is designed as a mostly pragmatic study. Ratings of the design domains with rationale based on the PRagmatic Explanatory Continuum Indicator Summary are provided in table 5. The least pragmatic domains are the organisation, intervention delivery flexibility and follow-up.

**Statistical analysis**

This trial has the primary goal of evaluating the effects of interventions implemented by the participating physical therapists. Accordingly, our primary analysis will consider the effects of treatment within therapists as fixed effects.
Under this approach, a positive result will signify that an intervention was beneficial as implemented by participating therapists. We will carry out an exploratory analysis in which the effects of the treatment within therapists are modelled as random effects. In this approach statistical inferences will apply to the average effects of the interventions across a broader population of therapists. Power is lower under the random effects versus the fixed effects approach as there is greater uncertainty when applying inferences beyond the specific participating therapists. We will provide results using both random and fixed effects approach so the distinction between the two perspectives is clear.

Analyses for aims 1–3 address intervention effectiveness and will follow the intention-to-treat principle, with all participants analysed according to their randomised assignment, irrespective of adherence. Aims 1 and 2 constitute coprimary aims for comparison of effectiveness of the study interventions. Aim 3 constitutes exploratory comparisons of effectiveness in pre-specified subgroups. Aim 4 will be addressed using descriptive summaries of implementation outcomes.

**Primary analysis for aims 1 and 2**

These analyses will be performed under a longitudinal mixed effect model for PEG scores across follow-up assessments. The model will include terms that estimate the effects of the treatment for each therapist as fixed effect; the overall effect of the treatment will be estimated as a weighted average of the therapist-specific treatment effect estimates. The model will also include predictor variables for randomisation stratification variables and will assume equal mean baseline PEG scores across groups. Comparison of adjusted mean PEG scores at 12 weeks will constitute the primary comparison for aim 1. Comparison at 52 weeks will constitute the primary comparison for aim 2. Secondary comparisons will compare PEG scores between groups across assessments and will compare phase II treatment effect at 52 weeks to the phase 1 effect at 12 weeks.
Exploratory analyses for aims 1 and 2
In exploratory analyses, the longitudinal model will be modified by considering the effects of the treatment within each therapist to be random effects. In this approach, variation in treatment effects between therapists will be an additional source of uncertainty for statistical inferences. This analysis will evaluate the extent to which the statistical inferences apply to the average effects across a broader population of therapists.

Analyses of secondary outcomes
We will use similar longitudinal models with fixed and random therapist effects for analyses of secondary outcomes using generalised linear models and generalised linear mixed models, respectively, for negative binomial outcomes to estimate the effects of the intervention on count outcomes including opioid use.

Sub-group analyses
The PEG outcome will be examined in prespecified subgroups by the addition of appropriate main effect and interaction terms for the subgroup factor with treatment and follow-up time to the fixed effects model described for aims 1 and 2. Prespecified subgrouping variables are gender, the presence of HICP, and opioid use at enrolment. Other subgroups may be used for post hoc sensitivity analyses. We will use the fixed effects approach for subgroup analyses due to power constraints.

Missing data
Primary and secondary analyses of continuous variables remain asymptotically unbiased if missingness follows a missing at random (MAR) pattern. To protect against bias resulting from association of the probability of missingness on other measured factors, we will apply fully sequential multiple imputation to impute missing data, where imputation models will include all variables in the respective outcome models plus additional auxiliary variables identified as likely related to the missing mechanism. We will use Rubin’s formula to adjust SEs in final analyses to account for multiple imputation of missing data.

Sample size Justification
We based power calculations on the following assumptions: (1) 80% retention across follow-ups, based on our experience in prior trials, (2) minimum important difference (MID) for the PEG is 1.0 (SD=2.5), which translates to 40% of 1 SD change, (3) A projected sample size of 500 participants or 250 per group and (4) a conservative assumption of serial correlations R=0 for repeated PEG assessments. For exploratory analyses of treatment effects across therapists as random effects, we assume there will be a total of eight therapists who will see similar numbers of patients and we conservatively assume a denominator df of 7 (8–1) for statistical inference. Previous studies have noted variable intraclass correlation coefficients (ICCs) for outcomes across therapists providing psychological interventions with a mean around 0.08. We note that the ICC in this study may be lower because the same therapists will treat subjects in both arms, but we are not aware of previous data that would confirm this conjecture. With these assumptions, table 6 provides conservative estimates of the minimum

Table 5  PRECIS-2 domain ratings and rationale for the BeatPain study

| Domain score rationale | 1. Eligibility criteria | 4 | Broad definition of chronic low back pain with minimal exclusion criteria. |
|------------------------|------------------------|---|-------------------------------------------------------------------------|
| 2. Recruitment         | 4                      | Electronic referrals to outside providers are part of routine procedures in primary care. The population health recruitment strategy leverages tools available in routine practice, but are used less commonly. |
| 3. Setting             | 5                      | Participating primary care clinics are usual care settings. Telehealth care is now part of routine care. |
| 4. Organisation        | 3                      | Additional training is provided to physical therapists providing treatments. A minimal amount of training is provided to primary care clinic staff and providers. |
| 5. Flexibility: intervention delivery | 3 | Intervention components use specific protocols that predetermine the number of sessions while providing flexibility for delivering content within sessions. Self-report measures of provider fidelity are used. |
| 6. Flexibility: participant adherence | 5 | Participants are reminded about upcoming sessions and contacted if sessions are missed as is done in usual care. Participants are not pre-screened for likelihood of adhering or withdrawn for low adherence. |
| 7. Follow-up           | 2                      | The amount and frequency of data collection from participants is more than usual care. |
| 8. Primary outcome     | 4                      | The PEG outcome is highly patient-centred and is commonly available through EHRs for use in usual care, although routine use is not common. |
| 9. Primary analysis    | 5                      | Primary analyses use intention-to-treat principles. Participants are included regardless of compliance. |

Domains are scored from 1 (fully explanatory) to 5 (fully pragmatic). EHRs, electronic health records; PEG, pain, enjoyment and general activity.
treatments in the full cohort that are detectable with the fixed and random effects approaches with 80% or 90% power and two-sided $\alpha=0.05$. These calculations indicate excellent power to detect the MID for the PEG under a fixed effects approach. Adequate power to detect the MID is possible under a random effects approach, but is not assured with high confidence.

### DISCUSSION

Persons living in rural or lower income communities and persons of Hispanic/Latino ethnicity experience disparities in chronic pain prevalence and management.\cite{14,50,91}

Although evidence-based guidelines recommend NP care as first-line management, implementation has lagged, particularly in these communities.\cite{19,92,93} Emerging data suggest this evidence-practice gap was exacerbated with the onset of COVID-19, which saw increased rates of opioid prescribing and decreased use of NP care for chronic pain.\cite{20} Persistent evidence-practice gaps in pain care have prompted interest in pragmatic trials examining real-world strategies to increase utilization of NP treatments.\cite{94} If pragmatic studies fail to include safety-net settings serving diverse communities it is unlikely that existing disparities will be reduced. FQHCs are key components of the nation’s primary care safety net but are rarely included in pragmatic trials.\cite{95}

Increasing access to NP care in Utah FQHC clinics required our team to overcome limited access to NP care due to geographic isolation, financial barriers and lack of Spanish-language services.\cite{10,21,22} We are using telehealth delivery by centrally-located physical therapists able to provide care in English or Spanish to overcome these barriers. Our treatments are designed with flexibility to be provided by phone or two-way video telehealth visits to overcome technology barriers.

The BeatPain study tests an adaptive treatment strategy, grounded in a stepped care model that provides a brief intervention to all patients, with a more resource-intensive treatment added only for those who do not respond. Evidence supports brief interventions focused on pain education to counter negative appraisals, advice to be physically active and engage in exercise as positive coping strategies, and reassurance that activity is beneficial and safe to build self-efficacy.\cite{45,96,97} A stepped care model has the advantage of consistently providing evidence-based first-line care and implementing more intensive treatment for patients based on clinical response, making efficient use of provider time. We are comparing this adaptive strategy to an approach that provides the brief and intensive interventions sequentially, without an intervening assessment of the clinical response, recognising that a more intensive approach may be necessary to achieve meaningful improvement for the most patients.

A key aspect of this study is use of EHRs at FQHC clinics to connect patients to telehealth NP care using two scalable strategies—point-of-care, EHR-based e-referral and a population-based approach for patients not offered an in-clinic referral. A challenge in establishing the EHR-based strategies is the variety of vendors used by FQHCs in Utah and nationwide. Our approach for implementing e-referrals is compliant with national standards required for EHR certification, allowing our e-referral strategy to be integrated with any standards-compliant EHR. Our second approach takes advantage of population health management tools that interface with EHRs and provides automated outreach to patients through widely available technology such as text messaging. Even in households with annual incomes below US$30 000, 97% own a phone that can receive text messages.\cite{98}

This study has limitations. Clinicians and patients cannot be blinded to treatment assignment. Our study takes place within one state with a limited number of physical therapists. While the demographics of persons receiving care in these clinics is diverse with respect to rurality and ethnicity, there is less diversity present on the basis of other characteristics including race. Despite these limitations, the BeatPain study will examine practical, potentially scalable strategies to reduce pain disparities in rural and ethnically diverse communities and improve outcomes for persons with chronic LBP.

### Table 6 Minimum detectable treatment effects on the primary PEG outcome—analyses of the full study cohort

| Power | Fixed effects approach | Random effects approach |
|-------|------------------------|------------------------|
|       | ICC=0.04 | ICC=0.08 | ICC=0.12 |
| 80%   | 0.70   | 0.99   | 1.14 |
| 90%   | 0.81   | 1.15   | 1.32 |

ICC, intraclass correlation coefficient; PEG, pain, enjoyment and general activity.

### Patient and public involvement

Persons with chronic LBP in the communities served by FQHC clinics in Utah contributed to development of the study protocol during the first phase of funding (1UG3NR019943-01). Specifically, the study team interviewed ethnically Hispanic or Latino community members with chronic LBP to inform the cultural adaptation of aspects of the protocol.

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