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Implementation of the American-College of Physicians Guideline for Low Back Pain (IMPACt-LBP): protocol for a healthcare systems embedded multisite pragmatic cluster-randomised trial

Adam P Goode ,[1,2] Christine Goertz,[1,2] Hrishikesh Chakraborty,[2,3] Stacie A Salsbury,[4] Samuel Broderick,[2] Barcey T Levy,[5,6] Kelley Ryan,[2] Sharon Settles,[2] Shoshana Hort,[7] Rowena J Dolor ,[8] Elizabeth A Chrischilles,[6] Stacie Kasper,[5] James E Stahl,[7] Chandra Almond,[2] Shelby D Reed ,[9] Zacariah Shannon ,[4] Debra Harris,[2] Jeanette Daly,[5] Patricia Winokur,[10] Jon D Lurie[11]

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For numbered affiliations see end of article.

Correspondence to
Dr Adam P Goode;
adam.goode@duke.edu

ABSTRACT

Introduction Low back pain (LBP) is a key source of medical costs and disability, impacting over 31 million Americans at any given time and resulting in US$100–US$200 billion per year in total healthcare costs. LBP is one of the leading causes of ambulatory care visits to US physicians; problematically, these visits often result in treatments such as opioids, surgery or advanced imaging that can lead to more harm than benefit. The American College of Physicians (ACP) Guideline for Low Back Pain recommends patients receive non-pharmacological interventions as a first-line treatment. Roadmaps exist for multidisciplinary collaborative care that include well-trained primary contact clinicians with specific expertise in the treatment of musculoskeletal conditions, such as physical therapists and doctors of chiropractic, as first-line providers for LBP. These clinicians, sometimes referred to as primary spine practitioners (PSPs) routinely employ many of the non-pharmacological approaches recommended by the ACP guideline, including spinal manipulation and exercise. Important foundational work has demonstrated that such care is feasible and safe, and results in improved physical function, less pain, fewer opioid prescriptions and reduced utilisation of healthcare services. However, this treatment approach for LBP has yet to be widely implemented or tested in a multisite clinical trial in real-world practice.

Methods and analysis The Implementation of the American College of Physicians Guideline for Low Back Pain trial is a health system-embedded pragmatic cluster-randomised trial that will examine the effect of offering initial contact with a PSP compared with usual primary care for LBP. Twenty-six primary care clinics within three healthcare systems were randomised 1:1 to PSP intervention or usual primary care. Primary outcomes are pain interference and physical function using the Patient-Reported Outcomes Measurement Information System Short Forms collected via patient self-report among a planned sample of 1800 participants at baseline, 1, 3 (primary end point), 6 and 12 months. A subset of participants enrolled early in the trial will also receive a 24-month assessment. An economic analysis and analysis of healthcare utilisation will be conducted as well as an evaluation of the patient, provider and policy-level barriers and facilitators to implementing the PSP model using a mixed-methods process evaluation approach.

Ethics and dissemination The study received ethics approval from Advarra, Duke University, Dartmouth Health and the University of Iowa Institutional Review Boards. Study data will be made available on completion, in compliance with National Institutes of Health data sharing policies.

Trial registration number NCT05626049.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a pragmatic cluster randomised trial with the unit of randomisation at the primary care clinic level, using 26 clinics embedded within three academic healthcare systems.
⇒ This trial will compare the effectiveness of offering non-pharmacological care options with physical therapists and doctors of chiropractic at the point of entry into the healthcare system versus usual primary care.
⇒ Patients in the intervention clinics can choose between physical therapy or chiropractic care.
⇒ Limitations include the limited number of chiropractic providers at academic health systems and potential financial and logistical barriers to implementing PSP models of care within health systems.

INTRODUCTION

Low back pain (LBP) is the leading musculoskeletal pain condition and a key source of medical costs and disability worldwide.[1–6] Up to 39% of US adults have LBP in the past 3 months, with 50%–80% reporting a significant episode in their lifetime.[7 8] LBP impacts over 619 million people globally,[9] has increased threefold in prevalence in a 10-year period[5] and results in up to US$200 billion per year in total healthcare costs.[10 11] Given the significance, it is no surprise that LBP is one of the leading causes of ambulatory care visits to US physicians.[12]

In 2018, 62% of US adults who reported seeing a healthcare provider for spine pain within the past year said they had seen a medical doctor.[13] Over half of LBP visits are made to primary care physicians (PCPs).[14] Unfortunately, it is becoming increasingly clear that the usual medical care for LBP, which commonly includes prescribed medications such as non-steroidal anti-inflammatory drugs (NSAIDs) and opioids, as well as invasive therapies like spinal fusions and epidural injections, is often ineffective or of questionable benefit.[15–17] Furthermore, many of these standard treatments impose the risk of significant harm to patients.[18–24] Over 60% of opioid-related deaths are linked to chronic pain, and consistent opioid use is found in a majority (61%) of those with chronic LBP.[25] In 2012, a prescription for opioids was received by 20% of patients who visited a medical doctor for acute or chronic pain,[26] a number that is still unacceptably high.[27] Almost half of all opioid prescriptions are written by PCPs.[28]

In 2017, the American College of Physicians (ACP) guideline for LBP recommended patients receive non-pharmacological interventions as a first-line treatment.[29] To assist in the implementation of the guideline, roadmaps have been created for multidisciplinary collaborative care that place primary spine providers (PSPs) at the forefront of patient care for those with spine-related disorders, including LBP.[30–33] The PSP model emphasises the use of doctors of chiropractic (DCs) and physical therapists (PTs) as first-line providers for LBP. These clinicians have specific expertise in treating musculoskeletal conditions and routinely employ many of the non-pharmacological approaches recommended by the ACP guideline, including spinal manipulation and exercise. Mounting evidence indicates that early treatment by DCs or PTs improves pain and functional outcomes in referral and direct-access settings.[34 35] Important foundational work has demonstrated that PSP model care is feasible, safeand results in improved physical function, less pain, fewer opioid prescriptions and reduced utilisation of healthcare services.[34 36 37] DCs and PTs are licensed as direct-access clinicians in all 50 states.[38 39] Serious adverse events from these non-pharmacological treatments are rare,[40–42] with typically minimal side effects, such as mild muscle stiffness or soreness, commonly reported.[43–50] Such care is considerably safer than taking NSAIDs over time.[51] DCs and PTs are well trained to perform a history and evidence-based examination to arrive at a diagnosis and then manage a patient's care or make an appropriate referral for co-management or specialty care. Evidence supports that both DCs and PTs effectively screen and differentially diagnose musculoskeletal disorders from other systemic conditions like cancer.[52 53] However, these studies are largely based on the use of large administrative or electronic health record (EHR) data or are observational designs. There is a need to test such models in real-world settings using rigorous randomised clinical trial designs.

The Implementation of the American College of Physicians Guideline for Low Back Pain (IMPACt-LBP) trial addresses gaps in prior studies of LBP care by implementing the PSP model of care for LBP in three health systems. The overall goal of this study is to compare usual primary care with the PSP model, which includes co-management between a DC or PT and a PCP. Patients seeking an LBP appointment at a clinic that has been randomised to PSP model care are asked if they would consider seeing a DC or PT first. The primary objective is to determine if patients with LBP in intervention will have improved outcomes when compared with usual care based on the change in Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference and Physical Function[54] scores from baseline to 3 months. The secondary objective is to compare the effects of PSP model care with usual care for LBP at 3, 6 and 12 months on the Pain Catastrophising Scale-4 item short form, PROMIS Global-10 (V.1.2), opioid use and LBP-associated procedures and treatments including: imaging and diagnostic testing, provider visits, surgical procedures, medication prescriptions, hospital admissions and emergency room visits. Our hypotheses are that patients with LBP asked to initiate contact with PSP clinicians will experience improved physical function, decreased pain, decreased opioid and other LBP-related medication prescriptions, improved patient satisfaction and decreased costs and utilisation of healthcare services when compared with patients with LBP who are not asked to initiate contact with a PSP first.

METHODS AND ANALYSIS

Trial overview and rationale

IMPACt-LBP is a pragmatic, multisite, two-arm, cluster-randomised trial with the unit of randomisation at the primary care clinic level initiated between February and April 2023. Twenty-six family medicine, primary care and general internal medicine clinics at three academic healthcare systems (Duke University, University of Iowa Hospitals and Clinics and Dartmouth Health) will be included in the study (figure 1). The study plans to enrol 1800 patients, at least 18 years of age, who seek care at a participating primary care clinic with a complaint of LBP.

Patients presenting for care at primary care clinics in both study arms will have full access to usual medical care as needed throughout the study. All medical care is at the discretion of the clinical care teams. Data will be acquired through direct-to-patient surveys and via the EHR from

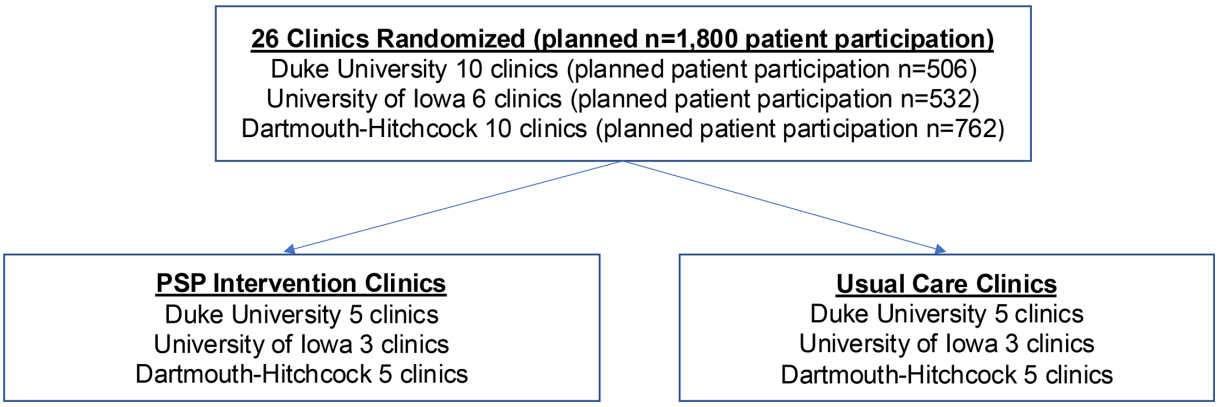

Figure 1 Number of primary care clinics per healthcare system and planned patient sample size at each site. PSP, primary spine practitioner.

each site. Patient-reported outcomes will be collected via questionnaires using a method of the patient's choice, such as a centralised data capture system, email, text, telephone interviews or paper questionnaires. All study-related data will be coordinated and analysed by investigators affiliated with the Duke Clinical Research Institute at Duke University, which serves as the Data Coordinating Centre. This study will also include a process evaluation of patient, clinician and clinic administrator perceptions of non-specific treatment factors and the effectiveness of the PSP model across the three sites to assess adoption, implementation challenges and programme acceptability.

PSP interventions

Patients seeking care at intervention clinics are asked if they are willing to see either a DC or PT as their first contact clinician for LBP care. Each participating PCP clinic has a preferred set of DCs/PTs to which patients will be offered referral; these DCs/PTs have been identified by study investigators and approved by the site PIs, agree to receive educational materials (which may include the use of existing clinical care pathways, evidence-based treatment approaches and a standardised diagnostic classification system) and agree to send clinical notes to the referring PCP clinicians. PSP educational materials recommend that if the patient is not improving as expected, the PSP refers the patient to their PCP for further evaluation. DC/PT care is presented to patients within the context of making an informed choice based on patient preference. Patients with an existing relationship with a DC or PT are encouraged to schedule with that provider or receive a referral to a study-identified PSP practice, whichever they prefer. Any patient can decline the PSP model approach, stop seeing a PSP provider at any time and all patients will have access to usual medical care throughout the study. In addition to an evaluation and treatment plan, PSPs typically provide several evidence-based treatments, including: education and counselling about the patient's condition to provide reassurance and reduce catastrophising and fear-avoidance behaviour; the application of a load (force) in the form of spinal manipulation to specific body tissues with therapeutic intent; myofascial therapies designed to stimulate sensory tissue, reduce pain, increase blood flow, relax muscle tone and break fibrous adhesions between neighbouring body tissues; therapeutic exercise, which can improve symptoms, prevent injury and encourage a team-based active treatment approach that enhances self-efficacy; proprioceptive neuromuscular facilitation, which involves specific stretching and assisted/unassisted exercise focusing on producing controlled movement to reduce abnormal muscle or joint strain; neural mobilisation, designed to improve nerve mobility and reduce tension on spinal nerves impaired by adhesions, inflammation or vascular compromise and nutritional/lifestyle and self-care strategies to reduce stress and/or change unhealthy behaviours, such as smoking. The use of these interventions is supported by numerous national guidelines.[29 55–59] It is important to note that the PSP model does not preclude additional treatments by these or other clinicians, such as psychological interventions, which are delivered as part of a multidisciplinary care approach.

Usual care

Usual care is defined as any care designated by a PCP. In most cases, this care is a combination of treatments or referrals that could consist of (1) education and counselling, (2) systemic medications (eg, NSAIDs, muscle relaxants, opioids, etc), (3) referrals for non-pharmacological interventions such as PT, DC or massage or (4) specialty care for invasive procedures such as nerve blocks, spinal injections or surgery.

Eligibility criteria—cluster and patient

Clinic (cluster) inclusion criteria

Primary care clinics: primary care clinics are eligible for study participation if they are:

1. affiliated with one of our three participating academic healthcare systems;
2. designated as a primary care, family medicine or general internal medicine clinic;
3. willing to participate in the PSP model;
4. provide a signed-site participation agreement;

5. had at least 250 unique patient visits with LBP assessed in the planning year.

Primary care clinics are not eligible for participation if they meet any of the following exclusion criteria

1. Any ongoing clinic-level study/project (research or quality improvement project) focused on LBP.
2. Designated as an urgent care or quick care clinic.

Patient inclusion criteria

Given the pragmatic approach to this study, the eligibility criteria are intentionally broad with minimal exclusion criteria to maximise the generalisability of the employed PSP model and the trial results. Patients are included if they are 18 years or older and are seeking an appointment at a participating study clinic with a complaint of LBP and agree to participate and complete the baseline questionnaire.

Patient exclusion criteria

1. Inability to provide consent or complete baseline questionnaires prior to the first PCP or PSP appointment.
2. Positive screening for cauda equina symptoms (total loss of control of bowel/bladder associated with this episode of LBP). Study personnel will screen for cauda equina symptoms and refer any patients screening positive to study personnel with a clinic background for further evaluation to consider immediate emergency department referral.

Patient eligibility

All identified patients 18 years and older seeking care at a participating clinic for a primary complaint of LBP will be offered participation. All three healthcare systems use dedicated scheduling centres for patient appointments at primary care clinics. Each scheduling centre has agreed to transfer phone calls of patients seeking care for LBP to the local study scheduling assistants. These scheduling assistants will be located at each respective healthcare system. The IMPACt-LBP scheduling assistant provides the patient with an overview of the study as detailed in the IRB-approved phone script and offers them participation in the study. If the patient agrees, they are sent an IRB-approved consent form (online supplemental appendix 1) and a baseline questionnaire to complete via the patient's preferred communication pathway. If the patient is seeking care at a primary care clinic randomised to the PSP model, the scheduling assistant offers to assist the patient with scheduling an appointment with a DC or PT. If the patient is seeking care at a primary care clinic randomised to the usual care model, the scheduling assistant assists with scheduling an appointment with their PCP at that clinic (figure 2). In addition, the first contact provider (either the PCP or PSP) will conduct additional screening to ensure that the patient does not require specialty care and/or imaging. This is part of standard clinical practice for both PCP and PSP providers. Patients with red flags (ie, severe or progressive neurological deficits, fever, trauma, serious underlying medical conditions)[53] identified by the first contact provider will continue to be followed in the trial.

Randomisation procedures

PCP clinic randomisation was stratified by health system. Primary care clinics that satisfied the clinic inclusion criteria and agreed to participate in the study were allocated 1:1 to either the intervention or control group. DCC statisticians generated the primary care clinic randomisation tables and provided a report to inform the investigators of clinic randomisation assignments before the start of patient enrolment.

Primary outcomes and secondary outcomes

Co-primary end points are changes in PROMIS Pain Interference and Physical Function scores from baseline to 3 months (table 1). The PROMIS Pain Interference instrument measures the self-reported consequences of pain across aspects of life including social, cognitive, emotional, physical and recreational activities in the past 7 days. This validated scale has five response options: not at all (1), a little bit (2), somewhat (3), quite a bit (4) or very much (5).[54] It has been shown to be a valid and reliable instrument[54] that is responsive to change in LBP status with a meaningful improvement in the total score between 3.5 and 5.5 points.[60] PROMIS Physical Function (Short Form 4a) is a valid and reliable measure of self-reported physical function that uses four items with five response options; without any difficulty (5), a little difficulty (4), some difficulty (3), much difficulty (2), unable to do (1). It performs well in multiple race-ethnicity and age groups.[61 62] It has excellent reliability, minimal ceiling/floor effects, limited item bias and is sensitive to change among patients with LBP[63] and spinal disorders.[64] We have chosen to use these co-primary end points as they represent two domains that are important factors related to patient improvement. Secondary end points collected at baseline, 3, 6 and 12 months include Pain Catastrophising Scale; 4-item short form, PROMIS Global-10 (V.1.2); opioid use; imaging and diagnostic testing; provider visits; LBP-associated procedures and treatments including: surgical procedures, medication prescriptions, hospital admissions and emergency room visits; and two items from the NIH Task Force for LBP questionnaire: how often LBP is a problem and how long it has been an ongoing problem.[65] The schedule of assessments for the primary and secondary outcomes is provided in table 2.

Additional exploratory analyses among enrolled patients will assess whether PSP care leads to long-term improvement compared with usual care using the PROMIS Pain Interference and Physical Function at 6, 12 and 24 months. Similarly, we will determine if PSP model care leads to lower healthcare utilisation and costs for LBP in enrolled patients receiving PSP versus usual care at 12 and 24 months. Only patients who are enrolled within the first 12 months after initiating recruitment will be included in the 24-month exploratory analyses.

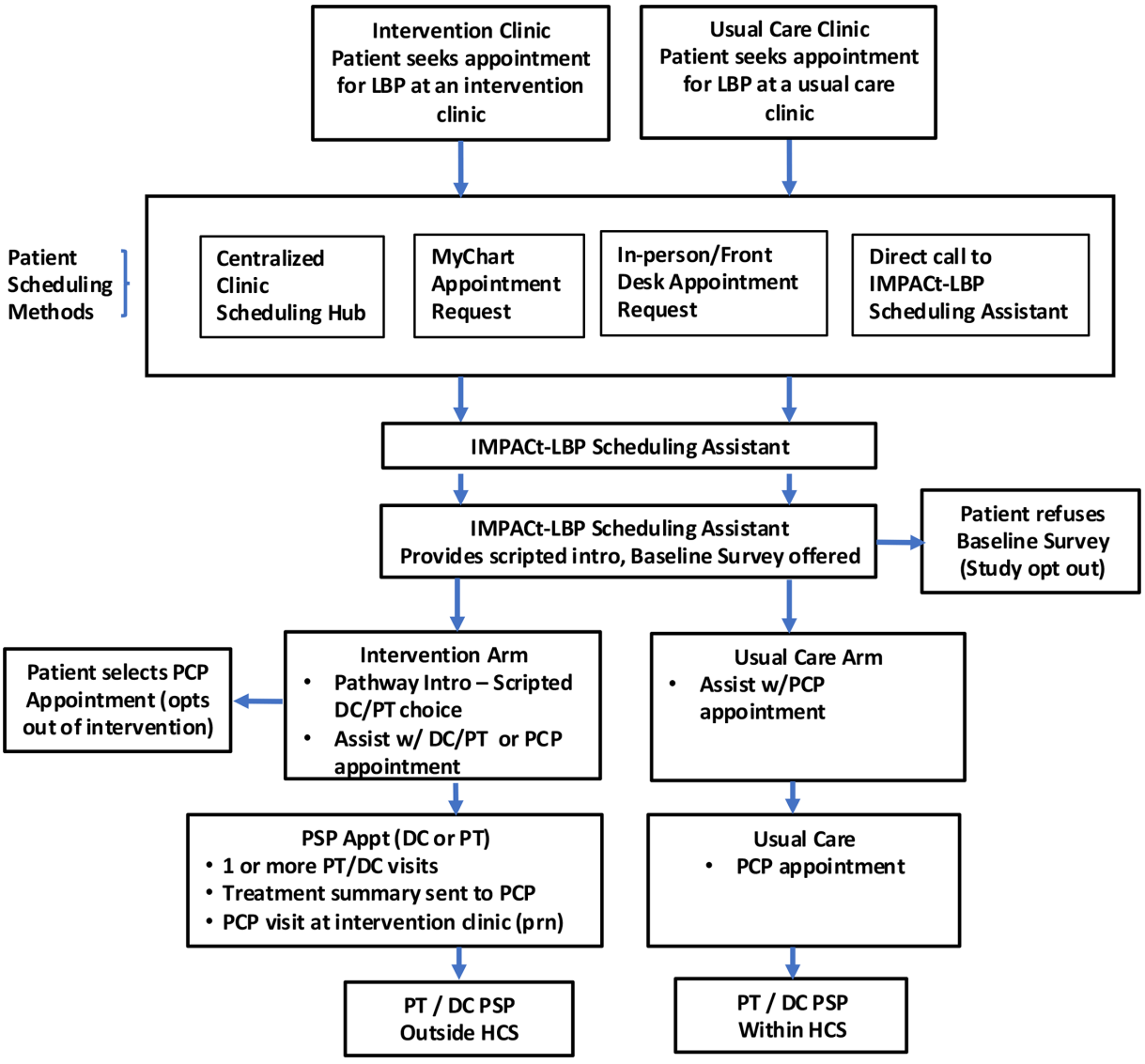

Figure 2 Patient engagement and flow for the Implementation of the American College of Physicians Guideline for Low Back Pain (IMPACt-LBP) trial. DC, doctor of chiropractic; HCS, Health Care System; PCP, primary care physician; PT, physical therapist.

Additional analyses will evaluate LBP-related utilisation within the academic healthcare systems among all patients seen in intervention versus control primary care clinics using de-identified clinic-level data extracted from the EHR and on direct to patient surveys.

Adherence

Adherence is measured in terms of the number of participants in the intervention group offered an initial visit with a PSP who see the PSP within 30 days of initial contact. Non-adherence may occur by the participant rejecting the PSP visit in favour of a visit with the PCP or by accepting the PSP appointment but then either cancelling or 'no-showing' the visit. In the usual care arm, non-adherence is similarly measured by the number of participants who cancel or do not attend their scheduled PCP visit within 30 days of initial contact. Receiving some DC or PT care in the usual care arm is an expected part of usual care. Rates will be measured and reported, although this would not be considered non-adherence nor crossover. The level of adherence is measured and reported for both groups during study execution and reviewed by the study team leadership and sponsor during monthly meetings with study team leadership and study sponsor with the Oversight Committee. The level of adherence is not included in our outcome analysis because, from a pragmatic trial point of view, the level of adherence is considered a characteristic of the intervention under 'real-world' conditions.

A different aspect of adherence is clinic-level implementation fidelity—how often a patient who called with a complaint of LBP is appropriately referred to the LBP scheduling assistant and offered a PSP appointment in the intervention clinics or a PCP appointment in the usual care clinics. Clinic-level implementation fidelity is assessed by reviewing patients scheduled for LBP visits within the participating clinics and determining how

Table 1 Summary of co-primary and secondary outcomes for the Implementation of the American College of Physicians Guideline for Low Back Pain trial

End point	Description
Co-primary end points	
PROMIS Physical Function (change from baseline to 3 months)	The PROMIS Physical Function (Short Form 4a) measures self-reported physical function that uses four items of the 29-item PROMIS Short Form.[61 72 73] This includes the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility) and central regions (neck, back), as well as instrumental activities of daily living, such as running errands with answer choices of without any difficulty (5), a little difficulty (4), some difficulty (3), much difficulty (2), unable to do (1).
PROMIS Pain Interference (change from baseline to 3 months)	The PROMIS Pain Interference Instrument (Short Form 4a)[54 72 73] measures the self-reported consequences of pain across aspects of life including social, cognitive, emotional, physical and recreational activities. This validated scale has five response options, with scores ranging from 1 to 5 (not at all (1), a little bit (2), somewhat (3), quite a bit (4), or very much (5)).
Secondary end points	
NIH LBP questions	The NIH LBP questions consist of 2-item LBP to determine patients' chronicity with LBP; how often LBP is a problem and how long it has been an ongoing problem.[65]
Patient satisfaction	We will assess patient satisfaction with care using a single-item from prior spine studies[74]: "Overall, how satisfied are you with the care you received for your back pain? Very satisfied, Somewhat satisfied, Neutral, Somewhat dissatisfied, Very dissatisfied".
Perceived improvement	Global improvement is measured using a 1-item scale: "Compared to your first visit, your low back pain is much worse, a little worse, about the same, a little better, moderately better, much better or completely gone".
Patient experience	Patient experience is compared with the clinical care between groups at 3 months using a modified 32-item satisfaction with outpatient physiotherapy instrument.[75] Domains compared will include expectations, clinician, communication, health organisation and treatment satisfaction.
Total prescribed opioid dosage	Total opioid dosage (morphine equivalents) is compared in the 12 months after baseline. To compare opioid doses across classes, we will use a standard formula to calculate morphine equivalents using Centers for Disease Control Morphine Equivalent Factors.[66] Morphine will be determined within 12 months after baseline.
PROMIS Global-10 (V.1.2)	The PROMIS Global-10[76] is a 10-item patient-reported outcome questionnaire, which has response options presented as 5-point rating scales: excellent (5), very good (4), good (3), fair (2), poor (1). Results are used to calculate a global physical health score and global mental health score with higher scores indicating better health.
LBP-related imaging and diagnostic testing	Any imaging and diagnostic tests will be collected from the time of enrolment through 24 months or study end. These measures will be extracted from the EHR using ICD, CPT codes and self-report. Imaging and diagnostics include MRI, CT, plain film X-rays, discography, electromyography and nerve conduction studies.
LBP-related injection procedures	LBP-related injection procedures conducted will be collected from the time of enrolment until 24 months or study end. These procedures will be extracted by the EHR using ICD and CPT codes. The injection procedure types include fascia, facet joint, intervertebral disc and muscle.
LBP-related surgical procedures	LBP-related surgical procedures conducted will be collected from the time of enrolment until 24 months or study end. These surgical procedures will be extracted by the EHR using ICD and CPT codes. The surgical procedure types include discectomy, fusion and decompression.
LBP-related medication prescriptions	LBP-related medication prescriptions will be collected from the time of enrolment until 24 months or study end. These medication prescriptions will be extracted from the EHR using commonly used codes during routine clinical practice. The medication types include opioids, NSAIDs, muscle relaxers, anticonvulsants and SNRIs.
LBP-related provider visits	Any provider visits from the time of enrolment until 24 months or study end will be collected. These visits will be extracted by the EHR using ICD and CPT codes.
Hospital admissions	Any hospital admissions from the time of enrolment through 24 months or study end will be collected. These admissions will be extracted by the EHR using ICD and CPT codes. The admission types include routine, emergency and elective.
Emergency room visits	Any emergency room visits from the time of enrolment until 24 months or study end will be collected. These visits will be extracted by the record EHR using ICD and CPT codes.

CDC, Centres for Disease Control and Prevention; CPT, common procedural code; EHR, electronic health record; ICD, International Classification of Disease; LBP, low back pain; NIH, National Institutes of Health; NSAIDs, non-steroidal anti-inflammatory drugs; PRO, patient-reported outcome; PROMIS, Patient-Reported Outcomes Measurement Information System; SNRI, serotonin and norepinephrine reuptake inhibitor.

Table 2 Schedule of assessments for the Implementation of the American College of Physicians Guideline for Low Back Pain clinical trial

Description				Follow-up				
Study evaluations	End point	Screening/Triage	Baseline	1 Month (±2 weeks)	3 Months (±1 month)	6 Months (±1 month)	12 Months (±3 months)	24* Months (±3 months)
Initial contact/referral to DC/PT or PCP depending on clinic randomisation		x						
PROMIS Pain Interference	Primary		x	x	x	x	x	x
PROMIS Physical Function	Primary		x	x	x	x	x	x
Pain Catastrophising Scale—4-item short form	Secondary		x		x	x	x	x
PROMIS Global-10 (V.1.2)	Secondary		x		x	x	x	x
NIH LBP questions	Secondary		x				x	
Patient satisfaction	Secondary				x			
Perceived improvement	Secondary				x			
Patient experience	Secondary				x			
Opioid use	Secondary		x	x	x	x	x	x
LBP-related imaging and diagnostic testing	Secondary			x	x	x	x	x
LBP-related injection procedures	Secondary			x	x	x	x	x
LBP-related surgical procedures	Secondary			x	x	x	x	x
LBP-related medication prescriptions	Secondary				x	x	x	x
LBP-related provider visits	Secondary			x	x	x	x	x
Hospital admissions	Secondary			x	x	x	x	x
Emergency room visits	Secondary			x	x	x	x	x

*A subset of those enrolled early in the study will have 24-month follow-up.
DC, doctor of chiropractic; LBP, low back pain; NIH, National Institutes of Health; PROMIS, Patient-Reported Outcomes Measurement Information System; PT, physical therapist.

many were routed through the LBP scheduling assistant. Implementation fidelity will be monitored closely, with feedback from the clinic/scheduling staff and refinement of the intervention workflow to maximise implementation fidelity.

Blinding

Given the pragmatic design, participants and treating providers are not blinded to study interventions. As this is a cluster randomised pragmatic trial, patients, clinicians delivering care and the LBP scheduler and research coordinators at the sites are not blinded to clinic intervention assignment. Our analysis team includes both blinded and unblinded statisticians.

Safety monitoring

This study involves clinically determined standard-of-care treatments, does not collect any sensitive study data and uses no investigational drug or device; it therefore was considered a no greater than minimal risk study. The Data and Safety Monitoring Board (DSMB) reviews our enrolment, trial conduct, adverse events and outcome data per the terms of the DSMB charter. Currently, no formal interim analyses are planned for this study. Any participant deaths that occur during study participation will be evaluated to assess whether they might be related to the study and reported to relevant entities as required. Healthcare utilisation in the form of emergency department (ED) visits and hospitalisations will be collected as secondary outcomes and reported across groups in DSMB reports but will not specifically be reported as serious adverse events. The DSMB meets at the frequency specified in the DSMB charter and may meet more frequently if circumstances warrant.

Analytical methods

Study population details will be described, including the number enrolled in each treatment arm, in each stratum and those lost to follow-up. Baseline participant characteristics will be summarised as means, SD, medians and 25th, 75th percentiles for continuous variables, and as counts and percentages for categorical variables. Model assumptions for the analysis of study data will be examined prior to analysis and transformations implemented, if necessary, to meet the assumptions more adequately.

Primary analysis

To test the primary hypothesis that participants in the PSP model care group will show greater improvements in pain interference and physical function at 3 months compared with usual care, we will compare the changes in PROMIS Pain Interference and PROMIS Physical Function scores, individually, from baseline to 3-month follow-up between usual care and intervention arms using linear mixed-effects models (LMM) with random effects to account for correlated patients within clinic using an unstructured covariance matrix. This primary analysis is unadjusted for covariates and will be conducted according to the principle of intention-to-treat with participants analysed and end points attributed according to the treatment arm, regardless of postrandomisation treatments received. Secondarily, we will repeat analyses for the primary end points to examine any effects for the adjustment of covariates known to influence functional outcomes, including, at minimum, those covariates easily obtained from the EHR, such as age, sex and race. Additional secondary analyses will assess using LMMs, similar to that described above:

1. Differences in the change in pain interference or physical function from baseline to 6 months and from baseline to 12 months between treatment arms.
2. Differences in the time trend of pain interference or physical function between treatment arms.

Differences in the change of pain interference or physical function scores from baseline to 6 months and from baseline to 12 months between treatment arms will be assessed with LMM using random effects using an unstructured covariance structure to account for repeated measurements. Differences in the time trend of pain interference or physical function between treatment arms will be assessed with repeated measures mixed-effects models accounting for clustering within clinic as well as repeated measures. For these models, we will select the appropriate covariance matrix (eg, compound symmetry, autoregressive, unstructured, etc) based on the data. This model will include pain interference or physical function outcomes at 1, 3, 6 and 12 months follow-up. Models will be repeated with adjustment for baseline covariates known to influence pain interference or physical function including age, sex, race/ethnicity and health-related quality of life. We will adjust for between-group differences in clinic-level characteristics if necessary. If we encounter high rates of non-adherence in the intervention group relative to control, we will evaluate outcomes in the adherent versus non-adherent groups separately compared with the usual care group. This method will be more informative than excluding the non-adherent as typically done in a 'per-protocol' analysis. We plan to assess the extent of non-adherence across clinic sites and ensure that the non-adherence is due to true patient needs and preferences and not a failure of implementation at the site level. Lastly, we will examine our primary outcomes stratified by sex to examine biological variabilities of interest.

Secondary analyses

For continuous secondary measures collected at baseline, 3, 6 and 12 months (ie, pain catastrophising, health-related quality of life, medical resource use and costs and opioid prescriptions), we will compare the change from baseline to 3 months, change from baseline to 6 months and change from baseline to 12 months between treatment arms using the LMMs described above. We will select the appropriate covariance matrix (eg, compound symmetry, autoregressive, unstructured, etc) based on the data. Opioid prescriptions will be captured through EHR at baseline (and in 12 months prior to baseline). We will compare total opioid dosage (morphine equivalents) in the 12 months after enrolment. In order to be able to compare opioid doses across classes, we will use a standard formula to calculate morphine equivalents from the CDC Morphine Equivalent Factors.[66] We will also compare differences in time trends for these continuous secondary end points between treatment arms with repeated measures, mixed-effects models as described above using a data-driven covariance structure.

Sample size determination

The primary end points are the PROMIS Pain Interference and Physical Function scores at 3-month follow-up between the PSP model and usual care. Because randomisation will occur at the clinic level and the enrolled patients' outcomes may be correlated within clinics, we must account for the correlated observations in sample size calculations and in analysis. We assumed intracluster correlation (ICC) of 0.03 for both of our primary outcomes. We assumed effect sizes (mean change over SD) of 0.4 based on data from the pilot study by Goode *et al*.[67] The changes in the PROMIS Physical Function were more conservative than those of the PROMIS Pain Interference. For the sample size calculation, we used a two-sided type I error of 2.5% to account for two primary outcomes with 90% power. Also, the calculations account for an assumed maximum attrition rate of 20% during the first 3 months of the trial. Table 3 presents the sample size requirements for effect sizes between 0.3 and 0.5, ICCs between 0.01 and 0.05, 80% and 90% power, a two-sided 2.5% type I error rate and a 20% dropout rate. Based on these assumptions, 1800 patients from 26 clinics (13 clinics randomised to each arm), with an average of 80 enrolled participants per clinic and an ICC of 0.03, we will have >90% power to detect a difference of differences in minimum effect sizes of 0.4 for both primary outcomes. We initiated the trial with 22 clinics. Due to slow enrolment early on in one of the health systems, we added four additional clinics from a better enrolling system for a total of 26 clinics as described above. The addition of these clinics did not materially affect the estimated total sample size of 1800 planned enrollees.

The main secondary outcomes are the PROMIS Pain Interference and PROMIS Physical Function scores at the 12-month follow-up visit between the intervention arm and usual care arm. With a total of 1800 patients in 26

Table 3 Required sample size for different effect sizes and ICCs with 80% and 90% power, 2.5% type I error rate for cluster size of 26 clinics (13 clinics randomised to each arm) and 20% drop out

	90% power			80% power		
	Effect size			Effect size		
ICC	0.3	0.4	0.5	0.3	0.4	0.5
0.01	1194	674	343	915	520	335
0.02	1721	972	625	1319	749	483
0.03	2248	1270	817	1723	979	631
0.04	2776	1567	1008	2127	1208	779
0.05	3303	1856	1200	2530	1437	927

ICC, intracluster correlation.

clinics with an average cluster size of 80 and ICC of 0.03, a two-sided type I error of 2.5% and 30% dropout rate during 12 months follow-up, we will be able to detect a minimum effect size of 0.4 with >80% power.

Procedures for missing data

Significant effort will be made to reduce the amount of missing data for all end points. Despite these efforts, missing data for primary and secondary end points are likely. For primary and secondary analyses that examine the change from baseline (to 3, 6 or 12 months), missing data in either baseline or the follow-up time point will lead to missing end point data for the patient. For these analyses, multiple imputation may be used for sensitivity analysis if the amount of missingness is >10% for the primary and secondary outcome variables.

Additional analyses

Exploratory analyses will include subgroup analyses, covariate-adjusted analyses and as-treated analyses. First, if the data provide evidence of an overall difference in the primary outcomes between treatment groups in the intention-to-treat analysis, we will further examine whether the therapeutic effect is similar for all participants, or whether it varies according to race (African American vs white), sex and LBP acuity (acute vs chronic) based on the NIH Task Force questions. All subgroup analyses will use LMMs or GLMMs as described above to test for interactions between treatment and subgroup variables. Effect estimates for subgroups will be assessed with formal interaction tests and, if needed, we will adjust the p values for multiple comparisons. Second, we will repeat analyses for all secondary end points with adjustments for covariates known to influence functional outcomes, including, at minimum, those covariates easily obtained from the EHR, such as age, sex and race. As an exploratory safety analysis, we will determine if there is a difference in time from enrolment to diagnosis of serious underlying medical causes of LBP (vertebral fractures, inflammatory spondyloarthropathies, malignancy, infections and aortic dissections) between the study arms by using a time-to-event analysis. Diagnoses will be identified via International Classification of Disease-10 codes in the EHR extracts related to provider visits, ED visits and hospitalisations among enrolled patients and the time between enrolment and initial diagnosis occurrence will be compared between patients from intervention versus control clinics. Finally, we will assess whether the PSP model care leads to long-term improvement compared with usual care in our primary and secondary outcomes at 24 months.

Patient and public involvement

Patient and public involvement in IMPACt-LBP first occurred during the UG3 planning phase (2021). Clinicians and healthcare administrators from all three healthcare systems, and patients from the Duke and Iowa sites were invited to take part in focused interviews designed to refine the PSP model for patients with LBP and to identify potential barriers and facilitators to implementation of the clinical trial at each site. Community-based PSP clinicians not affiliated with the three healthcare systems also were invited to complete interviews during their onboarding process to identify their specific concerns for trial implementation. While the overall research questions were not changed based on public involvement, the interview responses did lead to adaptation of outcome measures, recruitment and study implementation parameters. For example, the secondary end point, patient experience, was added based on interview feedback. Patients, clinicians and administrators noted that patients' experiences with PSPs might vary depending on their expectations for chiropractic care and physical therapy as well as contextual factors from the clinic in which care was received. These selected measures will allow our team to explore the patient experience with their PSP, treatment sessions, communication with their clinician and organisational aspects of the clinic setting. Patients also identified their typical ways of seeking care within their healthcare system, such as through phone calls or the EHR, which informed trial recruitment efforts. Patients with chronic LBP and complex comorbidities also identified their preferences for first contact with their PCP, especially when they had previously tried physical therapy or chiropractic care. This information allowed us to anticipate that this

group may decline participation, as well as to tailor study recruitment methods to address their concerns, such as adding details to the scheduler scripts. Patients were specifically asked about the potential benefits, burdens and time constraints of planned scheduling procedures and online questionnaires, as well as concerns regarding the use of EHRs, with patients generally approving the proposed methods.

DISCUSSION

LBP is a prevalent and complex condition commonly seen in primary care clinics. Although many evidence-based guidelines[68 69] recommend conservative, non-pharmacological first-line treatments, implementing these interventions has lagged.[15 16] New data support that DC and PT treatments are effective, especially when delivered early in the patient care-seeking process.[18–21 24] Challenges around guideline concordant care for LBP have increased the emphasis on pragmatic trials to examine real-world strategies to increase the use of non-pharmacological interventions. The IMPACt-LBP trial will address this high-priority musculoskeletal area as it is designed to be a multisite, healthcare system, embedded pragmatic, cluster randomised clinical trial with the unit of randomisation at the primary care clinic level. The cluster randomisation provides the IMPACt-LBP trial an opportunity to examine the early intervention of PSP care at the PCP clinic level as an effective way to address LBP within healthcare systems. A key aspect of the choice of cluster randomisation is to evaluate the change in workflow for patients entering the primary care system for LBP. Our design changes how patients schedule and receive care for LBP by providing them the option for initial DC or PT care at intervention clinics. Therefore, this choice of design allows the examination of a change in process at the primary care clinic level, which is important for the longstanding adoption of the intervention model.

The IMPACt-LBP trial used a 1-year planning grant period to further develop and improve the original study design. To do so, the IMPACt-LBP team worked with the NIH Pragmatic Trials Collaboratory Working Groups, a Protocol Review Committee, an insurance advisory committee, and gained patient, administrative and clinical stakeholder input on the original and proposed changes to the design. This planning process resulted in several important changes. First, our initial plan for primary outcome data collection was to rely on the EHR during the routine clinical encounter. During the assessment of the EHR at each of our three healthcare systems, we identified several inconsistencies in currently available patient-reported outcomes measures and challenges with the timely implementation of measures to ensure consistency of outcome collection across sites. In addition, several ongoing and recently completed large pragmatic trials had experienced common challenges, such as inadequate collection of measures, lack of structured data collection or standardised data and difficulties aggregating data across sites and accessing the EHR.[70] As such, we chose to use a hybrid of patient-reported outcomes and healthcare utilisation collected by direct-to-patient surveys and healthcare utilisation and safety events documented in the EHR. Similarly, our planning phase identified some advantages and disadvantages of EHR collection across the three healthcare systems. One disadvantage is that although two of our healthcare systems participated in PCORnet's common data model[71] for standardisation of EHR data, one did not. To address this challenge, our data coordinating centre mapped the required data elements from that site's EHR to the common data model to ensure consistent measures across study sites. This led to additional costs and delays in EHR data access for healthcare utilisation and safety events. In addition, delays of up to 6 months in obtaining EHR data from PCORnet resulted in challenges with scheduling and review of these data by the DSMB.

A few notable changes to the protocol also occurred following the initial start of the trial. While two of the healthcare systems implemented the protocol and enrolled close to expected numbers, one site had substantially lower-than-expected accrual. As a result, the NIH and our DSMB requested and approved a mitigation plan expected to increase enrolment at that site. One key component that influenced enrolment was efforts within this academic healthcare system to improve access to same-day/next-day primary care appointments, as this would influence the ability to complete the baseline questionnaires prior to PCP or PSP appointments. The same-day/next-day appointments limited our ability to offer PSP care before the PCP appointment. To assist in providing access to PSP care for the intervention clinics, several changes were made, including allowing same-day/next-day appointments for PSP providers, allowing MyChart self-scheduling for PSP appointments, and providing the option for PSP care for anyone making an appointment at one of the intervention clinics and then offering the option to participate in the study after the appointment was scheduled but before the visit took place. Another important component of this mitigation plan was to increase the number of primary care clinics (clusters) at one of our current sites that were meeting enrolment goals in order to increase overall enrolment. Finally, we identified that initial positive cauda equina syndrome screening was differentially higher at one site, leading to the exclusion of potentially eligible patients and high rates of referral to emergency care. We investigated those patients who screened positive for cauda equina syndrome with a chart review at all sites. None of those patients who screened positive were diagnosed with cauda equina syndrome, and the leading cause of this positive screening was due to an additional question related to progressive muscle weakness that we had initially employed. As such, we modified cauda equina syndrome screening to that described earlier in this protocol to reduce unnecessary referrals to emergency care and concern to patients.

The IMPACt-LBP study has several strengths including a pragmatic design across three different healthcare systems on an important and common condition (ie, LBP) seen in primary care but is not without limitations. Our trial includes either DC or PT care as the intervention based on patient preference. However, there is limited availability of DCs within the three healthcare systems. To overcome this problem, we partnered with chiropractic clinics within the communities around the healthcare systems. In addition, the trial is structured with the assumption that there would be no systematic difference in outcome between PT and DC care. We also identified challenges related to insurance coverage, differential copays for DC versus PT care and the perceived need for PCP referrals for PT with some insurance plans. To assist with these challenges, we formed an insurance advisory committee consisting of leaders in major payers across the country to discuss barriers and solutions to access due to insurance coverage. Patients attending academic health centres may not be representative of those who attend community-based clinics. Despite these limitations, IMPACt-LBP was designed to compare a model in which patients are offered care from a PSP before or in lieu of a PCP compared with usual primary care for LBP. As a healthcare system-embedded pragmatic clinical trial, IMPACt-LBP will provide evidence on the effectiveness of real-world care processes to inform best clinical practice for LBP.

ETHICS AND DISSEMINATION

This study received ethics approval from the following institutional review boards: Advarra, Duke University, Dartmouth Health and the University of Iowa. On completion, study data will be made available in compliance with NIH data sharing policies. Dissemination activities will include presentations at local, national and international conferences to communicate study results and prepare publications for open-access journals.

Author affiliations
[1]Duke University School of Medicine, Durham, North Carolina, USA
[2]Duke Clinical Research Institute, Duke University, Durham, North Carolina, USA
[3]Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina, USA
[4]Palmer Center for Chiropractic Research, Palmer College of Chiropractic, Davenport, Iowa, USA
[5]Family and Community Medicine, The University of Iowa Roy J and Lucille A Carver College of Medicine, Iowa City, Iowa, USA
[6]College of Public Health, Department of Epidemiology, The University of Iowa, Iowa City, Iowa, USA
[7]Department of Medicine, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, USA
[8]Department of Medicine, Duke University School of Medicine, Durham, North Carolina, USA
[9]Population Health Sciences, Duke University School of Medicine, Durham, North Carolina, USA
[10]Internal Medicine, The University of Iowa Roy J and Lucille A Carver College of Medicine, Iowa City, Iowa, USA
[11]Medicine, Orthopaedics, Health Policy, and Clinical Practice, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, USA

Contributors CG, APG and JDL conceived the study. CG, APG, JDL, HC and SS designed the trial and obtained funding for the study, and made substantial contributions to the design of the trial and the intervention protocols. SS, BTL, KR, RJD, SK, ZS, JES and JD were responsible for implementation of recruitment methods and recruitment of participants. HC and SB are responsible for designing the data analysis plan. CG, APG, JDL, HC, SB, SS, SH, EAC, CA, SDR, PW, DH, BTL, KR, RJD, SK, ZS, JES and JD provided critical review of the manuscript and approved the final manuscript. APG is the guarantor of the manuscript.

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ORCID iDs
Adam P Goode http://orcid.org/0000-0002-0793-3298
Rowena J Dolor http://orcid.org/0000-0001-7317-9468
Shelby D Reed http://orcid.org/0000-0002-7654-4464
Zacariah Shannon http://orcid.org/0000-0003-3751-5465

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