

# BMJ Open Integration of musculoskeletal physical therapy care in the patient-centred medical home (IMPaC): protocol for a single-site randomised clinical trial

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## ABSTRACT

**Introduction** Annually, >50% of the US population reports musculoskeletal (MSK) pain to a provider, with direct healthcare costs exceeding \$185 billion. The number of MSK complaints and the associated costs are projected to rise, increasing demand for and burden on providers. Establishing new care models to decrease inefficiencies may lower costs and optimise care delivery. The purpose of the Integration of Musculoskeletal Physical Therapy Care in the Patient-Centred Medical Home (IMPaC) study is to compare initial evaluation by a physical therapist (PT) integrated into primary care versus initial evaluation by a primary care provider (PCP) for patients with an MSK complaint.

**Methods and analysis** This single-site, randomised clinical trial will test the hypothesis that a PT within a primary care facility as the initial evaluating provider for patients with an MSK complaint will lower costs, improve utilisation (ie, reduced opioid prescriptions, imaging, physical therapy, emergency department visits and missed appointments) and increase patient satisfaction within 90 days of the index visit compared with PCP evaluation in the same location. Participants aged ≥18 years will be randomised with equal allocation and stratified by pain site (ie, back, knee, upper extremity and other). In the initial PT evaluation arm, patients will be assessed, treated and then instructed to complete a home exercise programme. The PCP cohort will undergo a usual PCP evaluation, and if a referral to physical therapy is made, patients will be randomised to onsite versus offsite physical therapy. Differences will be calculated and tested across the two arms.

**Ethics and dissemination** Approval was received from the Duke University Institutional Review Board (01 May 2017) and the National Institutes of Health, National Centre for Advancing Translational Sciences (01 January 2017). Findings will be communicated via quarterly reports to funding bodies and disseminated through scientific publications.

**Trial registration number** NCT03110211; Pre-results.

## INTRODUCTION

Musculoskeletal (MSK) conditions are the leading cause of disability in the USA and contribute a substantial societal burden. The costs of MSK conditions comprise 5.2%

## Strengths and limitations of this study

- Physical therapists will be integrated within a primary care setting to be the initial evaluating provider for patients with musculoskeletal complaints.
- Physical therapy referral by the primary care physician is evaluated by a second level of randomisation to onsite physical therapy at the primary care location versus usual care to an offsite location.
- Qualitative feedback is gathered from various stakeholders via focus groups and individual interviews.
- Blinding of the patients and providers was not possible due to the nature of the intervention which may affect participation and outcomes.
- This is a single-site study and workflows, payer distribution and patient demographics may be different from our single site and others within our healthcare system as well as across other healthcare systems.

of the annual gross domestic product—\$796.3 billion.<sup>1</sup> In addition, opioid prescriptions for MSK pain have increased 142% from 2009 to 2011,<sup>1</sup> and there are 2.6 million annual emergency department (ED) visits for back pain alone.<sup>2</sup>

Patients with MSK complaints commonly enter the healthcare system through primary care. Nearly 31% of people with MSK conditions have at least one visit with a primary care provider (PCP) yearly, with an overall average of six visits a year.<sup>3</sup> However, clinical guidelines recommend physical therapy as front-line care for MSK conditions. Recent studies have demonstrated that early referral to a physical therapist for low back pain can decrease healthcare costs by reducing imaging, specialist referrals and opioid prescriptions.<sup>4–6</sup> Nevertheless, physical therapy referrals for MSK pain evaluation and management are disproportionately less than expected,<sup>7</sup> and the uptake of clinical guidelines has been slow.<sup>8–10</sup>

To make matters worse, referral for physical therapy at an offsite location (which is standard practice) may negatively impact care continuity, provider communication, collaboration and patient satisfaction. In contrast, coordinated care models (ie, co-location and integration) have been shown to positively impact outcomes for prevalent conditions in primary care, but data on the effectiveness of these models for MSK conditions are lacking. Co-location has proven successful for primary care and mental-health services, nearly doubling the rate of guideline-based care<sup>11</sup> and facilitating collaboration and referral due to proximity of specialised services.<sup>12</sup> We have shown that co-location of physical therapy services within primary care can help decrease opioid prescriptions and ED visits.<sup>13</sup> On the other hand, integration of services is less common and more challenging. It requires a dedicated team of providers with unified care plans and implies organisational and cultural collaboration. To our knowledge, it is unknown whether integrating physical therapy services within primary care for MSK complaints can decrease costs and utilisation of US healthcare services. Therefore, the purpose of the Integration of Musculoskeletal Physical Therapy Care in the Patient-Centred Medical Home (IMPac) study is to examine the effects of initial evaluation by an integrated physical therapist within primary care compared with usual PCP management for patients with an MSK complaint entering a primary care setting.

## METHODS AND ANALYSIS

We followed the Standard Protocol Items: Recommendations for Interventional Trials checklist, composed of 33 items focused on the content of reporting protocols for clinical trials.<sup>14</sup>

### Study design

IMPac is a single-site, randomised clinical trial of a novel health system redesign to study the effect of an initial evaluation by a physical therapist integrated into primary care versus PCP standard evaluation for MSK conditions within the primary care setting at a large academic medical centre.

### Participant eligibility and recruitment

All existing patients (n=3918), defined as establishing care within the past 3 years and having at least one visit in the last 12 months, at the Duke Outpatient Clinic will be mailed an announcement (opt-in/opt-out) letter about the study. Existing patients, all of whom should have received an announcement letter, will be recruited in three ways: (1) patients who contact the research coordinator for eligibility screening; (2) patients who contact the main scheduling centre for an MSK complaint; and (3) patients who are on the daily schedule with an MSK complaint. All patients not meeting the definition of a current patient will be considered a *new* patient. Patients establishing care at the site for the first time will be recruited by either responding to an announcement

letter or via referral by their new provider to the study research coordinator.

### Enrolment and overview

Participants who call the scheduling centre or contact the research coordinator about the study will be screened via telephone for eligibility and asked to verbally consent to participate. Following verbal consent by the research coordinator, participants will be randomised to an intervention arm by use of a computer-generated randomisation table programmed into the study tracking database. Due to the nature of the intervention, both patients and interventionists will not be blinded to group assignment. On initial visit to the clinic, participants will provide written consent, demographic information and health status. Patients assigned to the physical therapist group will receive an evaluation for their MSK complaint(s) by a licensed physical therapist onsite and will be provided with a treatment plan that will follow usual care currently implemented in clinical practice. Patients may return to the Duke Outpatient Clinic for follow-up treatments if the physical therapist deems it medically necessary or may be referred for physical therapy offsite. Patients assigned to the PCP group will receive an initial evaluation from a licensed PCP onsite that will follow usual care. The PCP may then refer the patient for physical therapy. If so, the patient will be randomly assigned to either the physical therapist onsite or referral to an offsite physical therapy clinic of the patient's choosing, with the assistance of the research coordinator. The purpose of this second randomisation is to determine if outcomes differ based on whether participants receive physical therapy onsite at the primary care location or receive a referral to an offsite location of their choosing. If the PCP decides that physical therapy is not medically necessary, the patient will follow the PCP's usual plan of care and treatment recommendations. Following evaluation by either the physical therapist or PCP, the research coordinator will ask the patient to complete a short patient satisfaction survey about the initial visit. Participants will receive a gift worth \$20 for completing the baseline requirements. After approximately 3 months, the research coordinator will contact all enrolled patients by phone to collect health statuses and satisfaction measures. Also, at 3 months, outcomes related to total and MSK costs/charges will be collected via the Duke University Health System Department of Finance, opioid prescriptions and ED visits will be collected via electronic health records and administrative data, and offsite referrals to physical therapy will be collected via administrative data from the Department of Physical and Occupational Therapy. Investigators will also collect, via electronic health record, usual care measures of functional status. The study will end following the 3-month follow-up phone call and collection of outcomes and data.

### Inclusion/exclusion criteria

Potential participants will be considered eligible if they have an MSK pain complaint and are within the target

sample population. Based on clinical experience at the research site, any adult ( $\geq 18$  years) reporting an MSK pain complaint will be included. Patients without legal capacity (mental or psychological stability) to provide informed consent will be excluded. Patients will be withdrawn from the study if the physical therapist believes the patient may have an underlying medical condition that makes the patient inappropriate for physical therapy care.<sup>15 16</sup> In this case, the participant will be referred to a clinic PCP for further evaluation.

### Study interventions

All aspects of the physical therapy care provided for MSK complaints will be based on usual care. (Current practice at the study clinic consists of an onsite physical therapist to provide PCP referral-based examinations, onsite and home-based exercise programmes, and pain-control education.) Our study will consist of two interventions: (1) physical therapist evaluation first or (2) PCP evaluation first with possible physical therapy referral.

#### Physical therapist evaluation

This intervention builds on our current clinical model of a physical therapist co-located within the Duke Outpatient Clinic. The physical therapist has an assigned treatment room, is available for scheduled follow-up appointments, attends staff meetings and events, and is considered a provider within the Duke Outpatient Clinic system. Co-location is fully supported by the administration of the clinic and the Department of Physical Therapy and Occupational Therapy. The utilisation of physical therapy services is considered usual care; however, the timing of services is unique given the co-location. This allows for prompt access to not only a physical therapy evaluation (billing for services occurs), but for consultation with a PCP (a contact note for consultation is included in the patient's medical records). For IMPaC, investigators will use this co-located physical therapist as a front-line provider for patients seeking care for MSK complaints at the clinic. The physical therapy evaluation will be usual care and will not be modified in any way for the purposes of the study. If, at any time during evaluation, the physical therapist determines that the patient would benefit from an additional PCP assessment, the patient will be scheduled for one. These referrals from the physical therapist to the PCP can occur within the same day, which adds considerable efficiency.

#### PCP evaluation

In this cohort, patients will undergo initial assessment by the PCP, which is considered usual care. If the PCP deems that the patient should be referred for physical therapy for medically necessary treatment, the research coordinator will randomly assign the patient to onsite or offsite physical therapy. The research coordinator will assist with scheduling, track referrals and record outcome data for patients referred offsite. If the PCP does not refer to

physical therapy, patients will follow care recommendations provided by the PCP.

### Outcomes, data collection and storage

Our primary outcome will be total costs and charges, which will be captured by the Duke University Health System Department of Finance using individual visits and corresponding billing codes for every participant enrolled. We will review each participant visit using medical record numbers. This will occur over the 3-month study period for each instance the participant presents with a pain complaint, including but not limited to office visits, ED visits, imaging appointments and so on.

Secondary outcomes include utilisation, which will be captured through chart review of the participant's electronic medical record, monthly review of the electronic medical record for opioid prescriptions, physical therapy missed appointments and review of the number of times patients visit the ED for MSK pain. Over a 3-month study period, we will analyse the ED visits for the type of pain and medications given. We are also measuring the type, date and number of imaging referrals. Another secondary outcome will be patient and provider satisfaction, which will be evaluated via several tools: the Center for Epidemiological Studies Depression Scale (CESD; which measures depressive symptoms<sup>17</sup>), the Keele Musculoskeletal Patient Reported Outcome (MSK-PROM) survey (which asks respondents to prioritise outcomes for different MSK conditions<sup>18</sup>), the Patient Satisfaction Questionnaire Short Form (PSQ-18; which asks respondents how satisfied they are with their physical function and about their MSK function<sup>19</sup>) and the PSQ-18 satisfaction survey (which also asks the patient how they feel about the healthcare they received and about their overall socioeconomic background). Provider satisfaction will be measured with the Maslach Burnout Inventory, a psychological assessment tool used to measure occupational burnout. Adverse events will be measured by participant report and by tracking provider and ED visits in the electronic health record. Adverse events will be defined by protocol as 'any untoward physical or psychological occurrence by participating in research'. Potential adverse events will be reported in accordance with Duke University Institutional Review Board requirements.

To gain feedback from our stakeholders (ie, patients, providers, administrators and staff), we will conduct focus groups, individual interviews and satisfaction feedback via telephone. Providers and administrators will be selected to participate in the focus groups and individual interviews based on availability and experience with the model of care described in the study. The focus groups and individual interviews will be facilitated by the study team using a predetermined set of discussion questions. Sessions will be tape recorded and transcribed for further analysis. Focus groups, interviews and telephone feedback will be conducted according to the Duke University Institutional Review Board requirements. Participants in the study will also be asked, via telephone, during 3-month follow-up



about their experiences with the model of care and any feedback from this experience that can be used to refine the current model. All data collection and confidential storage will occur through Research Electronic Data Capture software, with only the research coordinator and principal investigator having access.

### Patient and public involvement

Neither patients or the public were directly involved in the study design or conduct of the study. No plans were established a-priori for sharing the results of the study with participants.

### Sample size estimates

Our sample size estimates are based on a superiority hypothesis positing that initial MSK evaluation by a physical therapist in a primary care setting will result in lower costs relative to initial MSK evaluation by a PCP. Sample size estimates for this study are based on our prior feasibility cost data, which is consistent with previous literature from 'early' versus 'late' referral to physical therapy for low back pain.<sup>6</sup> Assuming a difference in costs between arms of the study of \$2800 with a SD of \$6240, an alpha=0.05, and at 80% power we would need a total of n=150 participants, with equal allocation to one of the arms, to complete the study. Given our primary aim is based on costs related to care collected from our finance department, we anticipate few missing data. Our secondary outcomes are based on 3-month telephone follow-up data collection. To account for a potential refusal rate of 20% to complete 3-month follow-ups, we would need to enrol participants (n=195). We selected a 20% attrition rate to account for the high no-show attendance rate at this clinic that could potentially impact study follow-up.

### Quantitative analysis

We will calculate differences in total and MSK-specific costs and charges between the physical therapist evaluation group and the PCP group using standard analysis of variance or tests of medians, depending on the distribution of data (parametric vs non-parametric). Secondary outcomes will be analysed by analysis of variance for continuous outcomes or  $X^2$  tests for categorical outcomes. We will also calculate changes in routinely collected disease-specific measures stored in the electronic medical record. Physical therapy missed appointments and patient and provider satisfaction will be reported as descriptive data. We will explore differences in these outcomes between onsite versus offsite physical therapy. Analyses will follow intent-to-treat assumptions. All analyses will be conducted in Stata V.15.

### Qualitative analysis

Qualitative data from the focus groups and interviews will be transcribed and coded into themes. These codes will be based on the levels of influence on outcomes (patients, providers, models of care tested at the clinic, and local and national policies such as health insurance, access to providers and so on) The intent is to understand barriers

and facilitators, needs, and preferences at each level and between each level. We will use a constant comparative method to analyse the data and to identify relevant recurrent themes.

### Strengths and limitations

There are several strengths of the IMPaC study, including randomisation to decrease bias, implementation design, qualitative feedback from stakeholders and an opportunity to create a healthcare redesign important for MSK care within the primary care setting. However, this design is not without limitations. Due to the nature of interventions by providers, we are unable to blind participants or providers to the arms of the study. Therefore, we cannot rule out the potential for information bias with outcome ascertainment. This is a single-site study and therefore there is a risk of contamination between groups that would greatly be reduced with a cluster design. Also, the workflow and procedures for conducting provider examinations may differ across sites, which may impact recruitment, enrolment and exposure to physical therapy or primary care. In addition, a participant in the PCP group that is referred to physical therapy and randomised onsite or offsite may not have their location preference met which may affect multiple outcomes. This is also a single healthcare system, and there may be large variation in the way in which the healthcare process occurs between systems. Our single site is also unique in the demographic, race and insurance payer distributions across patients. This site has a higher-than-average African American population, older age and higher proportion of Medicare and Medicaid payor mix than other primary care/internal medicine clinics across our healthcare system. Therefore, results could differ in other clinics with respect to these factors. Lastly, the source population from which we are recruiting for this study includes both established patients and patients establishing care with an MSK complaint within this primary care facility. Therefore, these results may not be representative of only new patients for care of a new episode of MSK pain complaint.

### ETHICS AND DISSEMINATION

Ethics approval was obtained by both the Duke University Institutional Review Board and the National Center for Advancing Translational Sciences. Verbal and written consent will be required from participants, including verbal consent for randomisation to group assignment and written consent for participation, including randomisation to onsite or offsite physical therapy, if applicable, and collection of outcomes. This study was registered on ClinicalTrials.gov (#NCT03110211) and approved on 22 August 2017. Amendments to the protocol will be noted within any resulting publications.

The results will be disseminated via quarterly progress reports to the Duke Clinical and Translational Science Institute (home of the Clinical and Translational Agency (UL1TR001117)) and the Duke Institute for Health

Innovation. Results will be presented through institutional, local and national venues via conference presentations and publications. Findings from this study will be used to develop a larger, multisite implementation pragmatic trial.

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**Contributors** Conception and design of the work: APG, JPB, DD, EC and LB. Acquisition of data: APG, JPB, AAH and LB. Statistical analysis plans: APG, JPB, and LB. Coordinated the day-to-day management of the study: AAH, JPB, JB, MWC, MC, EC, LB and APG. Drafting and critical revision of the manuscript for important intellectual content, accountable for all aspects of the work and approval of the final manuscript: EC, JPB, MC, DD, LB, MWC, AAH, JB, APG. The entire team also meets regularly, once a month, to discuss the overall running of the study, including rates of recruitment, adherence to the protocol and safety of patients.

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**Competing interests** None declared.

**Ethics approval** Duke University Institutional Review Board.

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**Data sharing statement** No data were used for development of this protocol paper. Materials used to conduct the study may be available on reasonable request.

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