Study Title: Determining the Impact of a Physiotherapist-Led Primary Care Model For Hip and Knee Pain: Study Protocol and Analysis Plan for a Cluster Randomized Controlled Trial and Process Evaluation

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Results: Our internal pilot cluster randomized trial was registered prospectively in February 2023 (NCT05736133). Recruitment of primary care sites (clusters) was completed in June 2023 and cluster randomization was performed in July 2023. Patient recruitment began in October 2023. When progression criteria for patient participant recruitment rate, assessment completion rate, and treatment fidelity were met at the 20-week time-point; the decision was made to progress directly into the fully powered trial without performing any preliminary analysis of the outcome data collected during the pilot phase with the plan to incorporate this data in the full trial analysis. The fully powered trial was registered at ClinicalTrials.gov (NCT06358521) at the end of the pilot phase (April 2024). Participant recruitment was completed in November 2024. At the time of publishing this protocol and analysis plan, data collection is ongoing and expected to be completed by December 19, 2025. Analysis will be conducted as outlined in this pre-specified analysis plan starting after all data collection is complete. No interim analysis was planned or completed. The findings are anticipated to be published in 2026.

Introduction

Hip and knee pain are leading contributors to reduced functioning. Osteoarthritis (OA) alone is one of the leading causes of pain, disability, and reduced quality of life in patients[1], and the hip and knee are the most common body regions[2,3]. Arthritis currently affects one in five Canadians, and this is expected to rise to nine million people by 2040[2]. OA places a substantial burden on society in terms of both direct and indirect costs, including reduced work productivity and missed work[2,3].

Hip and knee pain and other musculoskeletal (MSK) conditions are among the most common reasons for a patient to access primary care[4-6]. Due to the rise in patients seeking support at the primary care level for many chronic conditions and a growing shortage of primary care providers, patients often do not receive timely access to the care they require[7-10]. Additionally, for patients without primary care providers, their first point of contact for their pain is often the emergency department (ED), which contributes to long wait times and overcrowding of the EDs[11].

There is an urgent need for evidence-informed and patient-centred interprofessional primary care models to meet the needs of patients with hip and knee pain. In Canada, federal and provincial governments have identified that interprofessional teams with complementary skillsets are required to address patients' multiple needs and to improve the effectiveness, efficiency, and sustainability of the healthcare system[12,13]. Research from other health conditions suggests that team-based primary care can improve access to appropriate care, coordination of care, and patient outcomes[14-16]. One example of such an integrated model of care is having a physiotherapist (PT) integrated within primary care teams and available as the first point of contact [17] (PT-led primary care). Physiotherapists can provide comprehensive and efficient management of patients seeking primary care for musculoskeletal conditions such as hip and knee pain, and evidence suggests that PTs are able to provide collaborative care in a primary care setting[18-21].

Previous studies on PTs working in primary care for MSK disorders have demonstrated that PTs provide equal or improved care compared to physicians or nurse practitioners (NPs) and that patient satisfaction is high when being managed by a PT[22-24]. Studies conducted in the UK concluded that PTs working in primary care resulted in freeing up primary care practitioners' time, reduced referrals to secondary and tertiary care, fewer requests for diagnostic imaging, increased patient satisfaction, and potential for cost savings[25,26]. [27,28]

The impact of a PT-led primary care model for patients with hip and knee pain has not been examined in the Canadian context. High quality evidence is needed to assess the effects of the PT-led primary care model on the following: patient health outcomes; access to care; health service utilization; and society (e.g. occupational productivity, costs). Additionally, there is a need to assess how this model of care is implemented, potential mechanisms of the model, and patients' experiences with the model of care.

The goal of publishing this protocol and analysis plan for our cluster trial and embedded process evaluation is to transparently communicate our design and methods in enough detail to be reproduced and to communicate the analytic plan in advance of analysis to reduce risk of analytic or reporting bias.

Research Objectives:

1) To determine the effectiveness of a PT-led primary care model for people with hip and knee pain at

improving function (primary outcome), pain intensity, quality of life, global rating of change, patient satisfaction, and adverse events compared to usual physician-led primary care, when evaluated over a one-year period from the initial consultation.

2) To assess the impact of a PT-led primary care model for patients with hip and knee pain on the health system and society (healthcare access, primary care physician workload, healthcare utilization, missed work, cost-effectiveness), evaluated over a one-year period from initial consultation.

Methods

Design: The trial is a parallel arm cluster randomized controlled trial (RCT) conducted across 14 primary care sites in Ontario, Canada. Participating sites were randomized 1:1 to either a PT-led primary care model or the usual physician-led primary care model for hip and knee pain. Randomizing at the practice level, rather than the patient level, enabled full integration of PTs within the primary care team and minimized the risk of contamination between providers[29]. This protocol and analysis plan is according to the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) reporting guidelines[30,31]. See Table 1 for an overview of the schedule of enrolment, interventions and assessments as recommended in the SPIRIT guidelines.

Table 1. Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD						
	Enrolment or clusters	**Allocation of clusters**	**Enrolment of patient participants**	**Post-allocation**			**Close-out**
TIMEPOINT	**Pre-intervention**	**Pre-intervention**	**0 (baseline)**	***3 mo.***	***6 mo.***	***9 mo.***	***12 mo.***
ENROLMENT OF PRIMARY CARE SITES:							
Eligibility screen	X						
Informed consent	X						
Allocation to study group		X					
ENROLMENT OF PATIENT PARTICIPANTS:							
Eligibility screen			X				
Informed consent			X				
INTERVENTIONS:							
PT-led primary care				♦—	—	—	—♦
Usual care				♦—	—	—	—♦
ASSESSMENTS:							

Participant characteristics and demographic information			X				
Participant health and experiences outcomes (LEFS, pain intensity, EQ-5D-5L, PSEQ, PCS, TSK-11, PHQ-2)			X	X	X	X	X
Participant health and experiences outcomes (GROC, satisfaction, adverse events)				X	X	X	X
Health system and societal outcomes (provider encounters, EHR utilization, healthcare utilization, missed occupational activities, assistance required)				X	X	X	X
Implementation measures (timely access, PT as first point of contact, access to PT, hip/knee management)			X	X	X	X	X
Implementation measures (patient adherence)				X			
QUALITATIVE INVERVIEWS:							
Patient participants				X			

The trial includes a multi-methods process evaluation, guided by the United Kingdom Medical Research Council (MRC) framework for developing and evaluating complex interventions[32,33]. The process evaluation is exploring how the intervention is being implemented, differences in primary care provided to people with hip and knee pain receive in the PT-led primary care model in comparison to the usual care model, potential mechanisms of the model of care, and experiences of patients with this model of care. This is essential for interpreting trial results; for example, understanding why the intervention may fail, yield unintended effects, or succeed — and can help guide future implementation of this model of care in the future if effective[33,34].

This cluster randomized trial is being run along-side another cluster randomized trial (clinicaltrials.gov NCT04287413) that aims to determine the impact of a PT-led primary care model for people with low back pain. The trial focused on hip and knee pain (the protocol and analysis plan presented here) is being carried out at 14 of the 20 sites participating in the low back pain trial (14 sites located in Ontario are included, six sites in BC are not included). We used the existing randomization schedule created for the low back pain trial to be able to efficiently assess the impact of a PT-led primary care model for people with hip and knee pain by leveraging the PTs and research staff already hired for the low back

pain study. The multi-methods process evaluation for the low back pain trial includes a mixed-methods exploration of how the context influences implementation of a PT-led primary care model and a qualitative exploration of the perspectives of primary care team members. These elements were intentionally not included or replicated in the process evaluation plan for the hip and knee trial in this trial. However, we anticipate findings related to the perspectives of primary care team members and contextual factors influencing implementation of the PT-led primary care model explored as part of the process evaluation in the low back pain trial will be informed by experiences implementing a PT-led primary care model for both people with low back pain and people with hip or knee pain.

The process evaluation will provide an understanding of how the PT-led primary care model for patients with hip and knee pain was implemented, explore the potential mechanisms of the interventions, and capture the experiences of patients who received care through this model.

Patient and Public Involvement: A person with lived experience was involved throughout this study, contributing to the conceptualizing the study, study design, and selection of outcomes important to people with lived experience. Their ongoing involvement included pre-testing data collection tools, supporting the interpretation of process evaluation results, and co-developing knowledge mobilization supports such as tailored summaries that will be distributed through patient organizations.

Enrollment and Randomization of Sites: We enrolled all 14 Ontario sites from the 20 sites included in our cluster-RCT testing a similar model of care for people with low back pain in Ontario and British Columbia. We used the existing randomization schedule[17], with a 1:1 ratio of the intervention and comparison arms. Covariate constrained randomization[35] was used by an independent statistician to reduce the risk of baseline imbalances across study arms; the number of active patients and rural versus urban clinic setting were used as covariates. Each cluster name was concealed with a deidentified code prior to randomization. The maximum tolerable difference for rural/urban was 1. The strata balancing criteria was 10% for number of active patients.

Strategies to Mitigate Bias: Given the nature of the trial design and the interventions being compared, blinding was not feasible for the PTs, patient participants, primary care team members, or research assistants. While this limitation is inherent to the study design, we implemented several measures recommended for cluster randomized trials to reduce potential bias[36].

A common concern in cluster RCTs is the risk of selection and recruitment bias, particularly when patient enrollment occurs after cluster assignment[37]. To address this, we took efforts to invite consecutive patients with hip or knee pain to participate in the study, to ensure RAs who handled recruitment and consent were not familiar with the patients, and to apply inclusion and exclusion criteria consistently across all sites. We also provided identical trial information to all potential participants before obtaining consent, regardless of cluster. This meant that we did not reveal which study arm participants were in until after obtaining their consent.

Patient Participant Recruitment: During patient participant recruitment, medical secretaries screened patients to be invited to participate when they booked an appointment for hip or knee pain. As an additional strategy, potential participants were also identified any healthcare provider (HCP) when they sought care for their hip or knee pain during a clinical visit. Potential participants who were agreeable to being invited to participate were contacted by a study research assistant (RA) to explain the details of the study. Those who were interested in participating were asked to complete a consent form that was built into the baseline surveys in a secure data collection platform (REDCap, Research Electronic Data

Capture). If a potential participant requested to do this in-person, arrangements were made to meet with the RA who provided detailed written and verbal information about the study and obtained consent for participation from those patients who were interested. A verbal consent process was in place for those who preferred to do this over the phone or in a virtual meeting.

Inclusion/Exclusion: All adult (≥19 years) patients who sought primary care for their hip or knee pain of any duration at participating sites were invited to meet with the RA to discuss participating in the study. Potential participants were excluded if: they reported not being able to understand, read, and write English; they had known cancer causing their hip or knee pain; or they reported being unable to complete the scheduled follow-up surveys over the one-year study period. The inclusion criteria for primary care sites were to have at least 1,500 rostered patients and two or more family physicians. Those sites that already had physiotherapy services or not enough space to include the physiotherapist were excluded.

Study Power: Participants were recruited over a 13-month period at all 14 primary care sites (7 PT-led arm, 7 usual care arm). Our power calculation is based on methods described by Hemming et al.[38] Our sample size calculation is targeted to detect a clinically meaningful mean difference of 9 points on the Lower Extremity Functional Scale (LEFS) using a two-sided alpha of 0.05, assuming a conservative standard deviation of 16, a conservative intracluster correlation coefficient of 0.1, a cluster autocorrelation coefficient of 0.5, an individual autocorrelation coefficient of 0.6, and a coefficient of variation of 0.7.[39-41] Allowing for an attrition of 20% of patient participants at the 12-month follow-up, we require a sample size of 560 participants to achieve >80% power. Pilot work for this study suggested we would recruit 1 patient per week per site; as such, we planned and prepared resources to recruit approximately 728 participants.

Interventions:
PT-Led Primary Care Model for Hip and Knee Pain: The index intervention incorporates a PT within the primary care team as an option for the first point of contact for people presenting with hip or knee pain for one year from the time of enrolment. Patients in this model are given the choice of seeing the PT or primary care provider first. There are four key components of the PT-led intervention: 1) initial assessment and screening; 2) brief individualized intervention at first visit; 3) health services navigation; 4) and providing additional PT care for people with an unmet need (e.g., no insurance coverage for PT). Physiotherapist training: During two consecutive days, seven registered physiotherapists received training on this new model of care to apply across the seven sites randomized to the PT-led primary care model for hip or knee pain.

1) Initial assessment and screening: the PT provides a comprehensive patient assessment according to established clinical practice guidelines. The assessment includes taking a detailed clinical history; screening for potential pathology and the need to refer to another HCP; physical examination; and using a validated patient reported outcome measure (LEFS[39]) to guide clinical decision-making.
2) Brief individualized intervention at first visit: the PT intervention is at the discretion of the PT to reflect real-world PT practice.
3) Health services navigation: where applicable, patient participants are provided with options available to them in their community for rehabilitation programs or other health or social services. For example, they may be referred to community PT for ongoing management or presented with options for group exercise programs. Patients are assessed regarding the need for specialist referrals or resources available to manage complex clinical presentations such as

comorbidity, frailty, or the need for surgical consult. Patients are referred to the primary care provider if specialized services are needed or when the PT cannot provide a direct referral. In addition, patients are referred back to their primary care provider when it is deemed that their clinical needs fall outside of the PT's scope of practice (i.e., medication advice, pathology requiring medical attention) or they identify factors that require mental health intervention.

4) Providing additional PT care: patient participants who require PT but do not have the appropriate access to community-based services are managed by the PT who provided the assessment in the primary care setting. Individuals with private or government health coverage are referred to services outside of the primary care practice when they are accessible to the patient in order to avoid duplication of available services. The amount of care provided is decided on a case-by-case basis in alignment with the health needs for each individual.

Usual Care Model: The physician- or nurse practitioner -led primary care intervention is unstandardized to best reflect the usual primary care clinical practice in Ontario. Patients in the usual care group are seen by either a primary care physician or a nurse practitioner as their first point of contact, depending on the current practice at the clinic. Participants in both groups are permitted to seek additional care from interprofessional team members within their primary care team or health services outside of the primary care clinic as needed.

Duration of Treatment Period:

The intervention is being carried out over a one-year period from the time of consent. All participants in the intervention arm are offered an initial assessment with the PT. While some participants in the intervention arm may be recommended to seek community health services if they have access to comprehensive health insurance, they have access to the PT as a member of their primary care team throughout the one-year follow-up period if they require additional support for their hip or knee pain. The frequency and duration of visits is determined by the PT and patient participant. The usual care model is ongoing and involves continuing as usual, and process outcomes are being collected from the date of consent to one-year post enrollment.

Intervention Modifications:

We do not expect any safety-related issues that would necessitate removing a participant from either the PT-led or usual physician-led primary care pathway. In line with routine care practices for hip or knee pain, the primary care team will adjust the intervention as needed to prioritize participant well-being. Adjustments may be made in response to factors such as increased pain, limited mobility, poor tolerance to treatment, changes in clinical status, or adverse reactions to medications or exercises. As the risks are minimal and did not compromise participants' well-being, a data monitoring committee was not established.

Data Collection and Management:

All baseline measures have been collected from participants and follow-up data collection is ongoing. We used several approaches to support participant retention at all time points. Research assistants maintained regular contact, sending reminders every two to three days via personalized emails, phone calls, and text messages to encourage survey completion. When preferred by participants, surveys were completed in person or by phone to enhance engagement and reduce the likelihood of attrition.
All data at baseline and follow-up timepoints is being collected through online surveys using REDCap[42] (Research Electronic Data Capture), a secure online survey and data capture tool that is hosted at Queen's University.

Electronic health record (EHR) data is being extracted by trained research assistants at the end of the one-year intervention period directly into a securely stored database to capture all primary care provided related to the hip or knee pain. Unique study identifiers are used to link responses from the surveys with data obtained in the EHRs.

At the end of the study, survey responses will be exported from REDCap into encrypted, password-protected datasets and securely stored in Microsoft OneDrive. Data extracted from the EHR, as well as the master list linking participant identifiers to study IDs, will also be kept in encrypted, password-protected files on OneDrive. Audio recordings from qualitative interviews are being transcribed, de-identified, and stored in a secure OneDrive environment at Queen's University.

1. Baseline Characteristics Used to Describe the Population

We collected the following baseline information from participants through REDCap: age, sex, gender, education, duration of hip/knee pain, locations of pain, medications, comorbidities, employment status, income, rurality, and ethnicity. Comorbidities are assessed using the Functional Comorbidity Index[43-45] (a list of comorbidities that are associated with physical functioning. The presence of a comorbidity is assigned a score of 1 and the total score is the sum of the comorbidity element with a maximum score of 18).

2. Individual Health and Experience Outcomes

The following individual health and experience measures are being collected through REDCap with repeat surveys at baseline, 3-, 6-, 9-, and 12-months post enrollment. Patient satisfaction, global rating of change, and adverse events are being collected at all follow-up time points only.

- Self-reported functioning: using the LEFS[39]– a validated 20-item patient-reported outcome measure used to assess functional status related to lower extremity conditions. Each item is scored on a 5-point scale, with higher scores indicating better function.
- Pain intensity: measured using a Numeric Pain Rating Scale (NPRS)[46] where 0 is no pain and 10 is the worst possible pain.
- Health-related quality of life: using the EuroQOL-5D (EQ-5D-5L), which is suitable for economic evaluations[47,48]. The EQ-5D-5L score will also be converted to quality-adjusted life years (QALY)[47].
- Global rating of change: using an 11-point global rating of change (GROC) scale to assess perceived overall change in health status, symptoms, or function over time, with anchors of a great deal better (+5) to a great deal worse (-5).[49].
- Patient satisfaction: using an 11-point scale with anchors of very dissatisfied (-5) and very satisfied (+5).
- Adverse events: using an adverse events questionnaire aligned with reporting guidelines[27,28]. The questionnaire determines: 1) adverse events experienced as a result of any of the interventions received; 2) a description of the adverse event; 3) duration of the adverse event; and 4) severity of the adverse event. Serious adverse events are identified if the participant requires hospitalization or an emergency department as a result of the adverse event, the adverse event leads to significant and persistent disability beyond 72 hours, or the adverse event is life-threatening. The study team monitored these responses to ensure ongoing patient participant safety.
- Potential mechanisms of the intervention:

- Self-efficacy: confidence in abilities to participate in usual activities using the Pain Self-Efficacy Questionnaire (PSEQ)[50,51].
- Psychosocial risk factors for persistent pain and disability: The Pain Catastrophizing Scale (PCS)[52-54], Tampa Scale of Kinesiophobia (TSK-11) [55-57], and 2-item Patient Health Questionnaire (PHQ-2)[58] will measure psychosocial factors associated with pain-related disability.

3. Health System Outcomes

Primary care physician or nurse practitioner visits: the total number of patient visits, both initial and follow-up, related to hip or knee pain. This metric is being used to explore whether involving PTs in care delivery helps alleviate demand on primary care providers, potentially allowing them to allocate more time to patients with other health concerns.

Healthcare utilization within the primary care team: consultations with all primary care team members (e.g., physicians, nurse practitioners, nurses, social workers, and occupational therapists), including the PT in the intervention sites, and group programming accessed within the organization. This data is being collected from the EHR abstraction process.

Healthcare utilization outside of the primary care team: medications used; walk-in clinic visits; ED visits; inpatient hospital stays; diagnostic imaging; surgeries, injections, and other interventional procedures; visits to specialist physicians; and visits to other health professionals outside the primary care team (e.g., chiropractors, massage therapists, occupational therapists, physiotherapists, chronic pain clinics). These outcomes are being collected from the self-report surveys at each follow-up assessment and verified, whenever possible, in the EHR.

Missed Occupational Activities: self-reported time lost from paid employment, volunteer, homemaking, or educational activities.

Assistance required: self-reported paid and unpaid assistance required. For example, self-care (e.g., taking medications, dressing/undressing, going to the bathroom, bathing/showering, grooming), shopping/groceries, meal preparation, housework, managing finances, or transportation (e.g., to a medical appointment).

Costs: Total per-person costs include both direct and indirect healthcare costs, with indirect costs estimated using a human capital approach based on time missed from work or other daily activities[59].

Direct costs incorporate intervention-related expenses (e.g., physiotherapist salary and training), publicly funded healthcare services (sourced from the Ontario Ministry of Health Schedule of Benefits[60]), medication costs (using the Ontario Drug Benefit formulary), and participant-reported expenses for privately funded services or out-of-pocket supports (e.g., self-care, household help, transportation). Resource use will be multiplied by relevant unit costs to estimate total expenditures, which will be summed over each follow-up interval and used to calculate both time-specific and overall costs.

Indirect costs reflect productivity losses due to time away from paid work, valued using the provincial average wage from Statistics Canada for participants not engaged in paid employment (e.g., retirees, homemakers, caregivers, students). Lost time from unpaid activities will be valued using the minimum wage in Ontario.

Implementation:
Consistent with the UK MRC guidelines[33], we are collecting the following implementation measures as part of our process evaluation:

Timely access to care: determined by the percentage of patients with hip or knee pain who are assessed within 48 hours of calling for an appointment. Only participants who were invited to participate at the time of calling for an appointment for their hip or knee pain will be included in this analysis. Participants who were invited to participate at the time of an appointment with another primary care provider will not be included.

First contact care by the PT: using the percentage of patients with hip or knee pain in the PT-led primary care arm who visited a PT as their first point of contact for the current episode of hip or knee pain.

Hip and knee pain management provided: visits to the primary care site related to hip and knee pain are being collected from the EHR, along with indicators for the following process measures: education provided; exercises prescribed; psychological interventions provided; referrals made to internal primary care team members; referrals made to external HCPs; medications prescribed, deprescribed, and suggested; diagnostic imaging ordered; notes sent to employers or insurers; messages sent to internal primary care team members; and other interventions provided.

Patient adherence to recommendations: adherence to PT activity and exercise recommendations is being collected at the 3-month follow-up survey. We will also be able to determine if participants accessed community PT as part of each follow-up survey timepoint.

Qualitative Interviews:
Qualitative interviews are being conducted with patient participants following an interpretive description approach[120] to explore their experiences with the PT-led model of care for hip and knee pain, and their perspectives towards the model of care. A purposive sampling strategy is being used[61]. We are aiming to recruit 8-12 patients representing diversity in age, gender, race, income, employment status, pain duration and intensity, baseline function, and primary care clinic. We are using the concept of information power[62] to determine sample size adequacy within each group—ending recruitment once sufficient depth and breadth of data have been obtained to meet the study objectives. During the consenting process for the main part of the study, patient participants were asked if they were willing to be contacted for qualitative interviews exploring their experiences and perspectives of the PT-led model of care. Using the purposive sampling approach, agreeable patients are being contacted, approximately 2-3 months after enrollment, to explain the purpose of the interviews, discuss the consenting process and letter of information, and schedule an interview time. At the beginning of the interview, the researcher completing the interview confirms that the participant has read the consent form and answer any questions they may have before obtaining verbal consent.

Protocol Amendments: any protocol modifications will be documented through updates to the ClinicalTrials.gov registry and described in the final trial publication. Investigators and participants will be informed as needed, depending on the nature of the changes.

Data Analysis Plan

All analyses will be by intention to treat principle. Descriptive statistics will be provided for baseline characteristics and outcomes using means (standard deviation) or medians (interquartile range) for continuous variables and frequencies (percent) for categorical variables. We will compare arms using linear mixed models and generalized estimating equations (GEE) to account for clustering and present the corresponding p-values. Analyses will be performed using SAS, version 9.4 (SAS Institute Inc; Cary, NC).

The estimand for patient health outcomes will be the time-specific patient participant treatment effect, adjusting for clustering by primary care site. The primary outcome (LEFS) will be analyzed using linear mixed regression with restricted maximum likelihood (REML) estimates under the assumption of Missing at Random (MAR), which will allow the use of all available data without the need for multiple imputation. The Kenward-Rogers degrees of freedom correction will be used to account for a small number of clusters[63]. The 12-month timepoint will provide the intervention effect as the adjusted least square mean difference between arms with 95% confidence intervals. Secondary comparisons will be made using adjusted least square mean differences between arms at all intermediate time-points. Fixed effects in the mixed model will include time, intervention group by time interaction (omitting the group main effect), pre-specified covariates associated with hip and knee function (patient participant age, sex, duration of current episode of hip or knee pain, income, highest level of education, and comorbidity score), and primary care site rurality and number of active patients (the covariates from the covariate-constrained allocation procedure). Repeated measures will be modeled using a covariance structure determined by information criteria (AIC/BIC). Clinic site will be included as a random effect to account for site clustering. We will assess for potential risk of bias associated with missing data by comparing the characteristics of those who participated. We plan to carry out a sensitivity analysis for a potential departure of our MAR assumption using a delta-adjusted imputation pattern mixture model approach[64-66]. This approach will allow us to investigate the robustness of our trial outcomes with regard to the missing values of the LEFS.

We plan a secondary analysis using our primary outcome (LEFS) to compare the proportion of participants who experience a meaningful improvement in each arm (responder analysis[67]). We will define a meaningful change as an improvement of greater than or equal to 9 points on the LEFS (the minimally important change[39,40]). We will present the proportion of participants who experience a meaningful improvement in each arm and compare, using relative risk, between groups using robust Poisson regression, accounting for clustering[130]. We will use empirical covariance ("sandwich") bias-adjusted (residual-based) estimators, and apply the Fay and Graubard correction for the small number of clusters[68].

Pain intensity (NPRS), quality of life (EQ-5D-5L), self-efficacy (PSEQ), catastrophic thinking (PCS), pain-related fear (TSK)-11, and depressive symptoms (PHQ-2) will be analyzed using the same analytic approach as described for our primary LEFS analysis, adjusted for the same covariates. We will use simple mean imputation to fill in missing individual items on surveys as described by Chavance[66]. Patient satisfaction and global rating of change do not include a baseline measure and will be assessed using ordinal logistic regression with random effects and adjusting for the same covariates as above.

Incidence rates for minor adverse events (yes or no) will be calculated using robust Poisson regression and compared by calculating relative risks with confidence intervals using GEE-type robust covariance estimators (PROC GLIMMIX, EMPIRICAL option in SAS) to account for clustering[69]. In our models comparing incidence rates, we will use an exchangeable working correlation matrix, empirical covariance ("sandwich") bias-adjusted (residual-based) estimators, and the Fay and Graubard correction

to account for small number of clusters[68]. Given that we have only included 14 clusters and adverse events are expected to be rare, we anticipate there may be issues of non-convergence or instability in our models. Should the model for adverse events not converge or demonstrate instability, we would attempt to fit the model using an independent working correlation matrix. If there are still issues of non-convergence or instability, we will reduce the model by removing covariates, beginning with duration of pain and income. Severity and duration of minor adverse events will be presented descriptively. We do not anticipate many, if any, serious adverse events; as such, we plan to present these data descriptively.

Visits with primary care physicians or nurse practitioners, time (days) lost from occupational activities, and assistance required (hours) will be presented as rates and compared by calculating rate ratios using GEE-type covariance estimators with an adjusted Poisson or negative binomial model, accounting for clustering, and assuming an exchangeable working correlation matrix. Incidence rates will be used to present visits to other health professionals within the primary care team, participation in group programs offered by the primary care team, and health care services received outside of the primary care team (medications, diagnostic imaging, walk-in clinic visits, ED visits, specialist physician visits, , hospital admissions, interventional procedures, surgeries, other health provider visits). Comparisons between groups for each of these variables will be made by calculating relative risk using robust Poisson regression[130]. These models will incorporate empirical covariance ("sandwich") bias-adjusted (residual-based) estimators, and the Fay and Graubard correction due to the small number of clusters[68,70,71]. These models will use time as an offset to account for variable follow-up times. All of the healthcare utilization and lost time from occupational activity models will control for the same covariates as the patient health outcomes analyses Similar to our analyses for adverse events, in the case of model non-convergence or instability, we will attempt to fit the model using an independent working correlation matrix and if the model still does not converge and demonstrate stability, we will reduce the model by removing covariates.

Our cost utility analysis will be carried out from societal (primary) and health payer (secondary) perspectives. We will calculate total costs by multiplying the quantity of resource use by the corresponding unit cost, summing the total cost over each follow-up interval to determine total costs at each follow-up time point as well as across the entire study period. Total and mean costs (overall and at each time point) will be presented by aggregated and disaggregated costs. We will estimate quality adjusted life year (QALYs) for every participant using area under the curve and assuming linear interpolation between assessment time points. Bivariate multilevel modelling, accounting for clustering, will be used to analyze the incremental cost per Quality-Adjusted Life Year (QALY) gained and describe the incremental net benefit at various values of willingness-to-pay. We will model treatment group as a fixed effect and account for site clustering. We will adjust for the same covariates as the primary analyses. We will use a probabilistic sensitivity analysis with Monte Carlo simulations to explore the uncertainty in our cost-effectiveness estimates. The results will be illustrated on cost-effectiveness planes, and cost-effectiveness acceptability curves will be presented to demonstrate the likelihood that the PT-led care model is cost-effective across various willingness-to-pay thresholds.

We also plan a subgroup analysis based on sex for each of our effectiveness outcomes, as recommended in the sex and gender equity in research (SAGER) guidelines[33.] We will include an interaction term with sex and group, and group by time in order to assess this. We will present the data using forest plots and 95% confidence intervals.

Process Evaluation

Implementation

Timely access to care: the percentage of patients with hip or knee pain who are assessed within 48 hours of calling for an appointment will be reported descriptively and compared between arms by calculating relative risks with robust Poisson regression, using GEE-type covariance estimators to account for clustering, assuming an exchangeable working correlation matrix. Empirical covariance ("sandwich") bias-adjusted (residual-based) estimators and the Fay and Graubard correction will be used[68]. We will incorporate the same covariates as with our effectiveness analysis.

First contact care by the PT: the percentage of patients with hip or knee pain in the PT-led primary care arm who visited a PT as their first point of contact for the current episode of hip or knee pain will be reported descriptively.

Hip and knee pain management provided: the proportion of patient participants who receive the following will be reported descriptively: education; exercises; psychological interventions; referrals to internal primary care team members; referrals to external HCPs; medications prescribed, deprescribed, and suggested; diagnostic imaging ordered; notes to employers or insurers; messages sent between internal primary care team members. Comparison between arms will be made using robust Poisson regression. Comparison between arms will be made using relative risks and confidence intervals using GEE-type covariance estimators, accounting for clustering, and assuming an exchangeable working correlation matrix. Empirical covariance ("sandwich") bias-adjusted (residual-based) estimators and the Fay and Graubard correction to account for small number of clusters will be used[131-133].

Patient adherence to recommendations: adherence to PT activity and exercise as reported at 6-week follow-up will be reported descriptively. The proportion of people accessing PT in the community will be reported descriptively and compared using robust Poisson regression, accounting for clustering.

Potential Mechanisms

If the intervention is effective (i.e., The PT-led primary care model results in greater patient functioning than the usual care group), we will carry out mediation analyses[137] to assess potential mechanisms. Specifically, we will assess whether changes in self-efficacy (PSEQ) or changes in psychosocial risk factors (PHQ-2, PCS, TSK-11) explain or partially explain changes in patient functioning (LEFS score). We will conduct a separate mediation analysis for each potential variable (PSEQ, PHQ-2, PCS, TSK-11). We will use a stepped approach proposed by Beril and colleagues[138] to investigate temporal and dynamic trends of the treatment effect across repeated measures using theoretical insights about the mediation effect to choose the appropriate mediation model. The intervention effect explained by the mediator (indirect effect) will be calculated as the difference between the total effect (the effect calculated in the primary analysis) of the PT-led primary care model on the LEFS score and the direct effect of the intervention[139,140]. We will evaluate the possibility of mediation using the significance of this effect[141,142]. We will use the LEFS outcome at the 12-month follow-up timepoint as the outcome variable[143,144]. This analysis will provide effect measures that allow us to report the proportion of the total effect that is mediated through each of the potential mediator variables.[145]. Our causal/associated conceptual model has considered, and controlled for where needed, mediation analysis assumptions that there is no intervention-outcome, mediator-outcome, or intervention-mediator confounding or mediator-outcome confounding that is influenced by the intervention itself[140,146,147]. To explore potential mechanisms of cost differences in our cost analysis, we will report the proportion of cost differences between arms that are healthcare utilization costs and the proportion of costs associated with missed occupational activities.

Patient Experiences
We will explore the experiences of patient participants with hip or knee pain who have participated in the PT-led primary care model for hip or knee pain using in-depth qualitative interviews conducted and analyzed in an interpretive description tradition[72,73]. Interpretive description is a qualitative approach that is founded on naturalistic inquiry and involves focusing on identifying applied and clinically relevant themes that can inform healthcare or health service delivery. Interpretive description, therefore, is well suited to helping us achieve our process evaluation goal to understand experiences and perspectives with the PT-led primary care model for people with hip or knee pain. The experiences and perspectives of patients are expected to lead to refinements how the model of care is implemented if effective. Strategies to support rigour will include use of two independent coders for the first two to three manuscripts to ensure reliability and consistency in coding, use of reflexive journaling and reflexive dialogue amongst team members throughout the analytic process, incorporation of detailed field notes and written memos, long and deep engagement with the qualitative interview data, and maintaining an audit trail to document the analytic decisions throughout the research process[74-78].

Ethics
Ethics approval for this study has been obtained from the Queen's University Health Science and Affiliated Teaching Hospitals Research Ethics Board (HSREB #6040471). Written consent was obtained from all participants willing to participate.

Discussion: The results of this pragmatic trial and accompanying mixed methods process evaluation will provide comprehensive evidence to guide health system leaders and primary care teams regarding the implementation of a new PT-led primary care model of hip and knee pain in Ontario, with relevance for health systems across Canada and around the world. Our approach combines quantitative analyses of patient health outcomes and healthcare costs with in-depth qualitative inquiries into how the model of care was experienced and implemented. This design allows us not only to assess effectiveness and cost implications, but also to understand contextual factors, barriers, and facilitators that shape real-world uptake. The evaluation has been co-developed with knowledge users—including individuals living with hip and knee pain and health care professionals engaged in the intervention—to ensure that study outcomes are meaningful and aligned with current health system priorities.

We will share out findings through peer-reviewed manuscripts on: the effectiveness of the PT-led primary care model for people seeking primary care with hip or knee pain, the cost-effectiveness of the model, how the model of care was implemented (including differences in care provided between arms), potential mechanisms (if the intervention is effective) and the experiences of patients.
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Competing Interest
The authors declare that they have no competing interests, including: no support from any organization for this work, no financial relationships with any organizations that might have an interest in our study

in the previous three years, no other relationships or activities that could appear to have influenced this work.

Data Availability
For access to the data, please contact the corresponding author.

Abbreviations:

CCI: Canadian Classification of Health Interventions
ED: Emergency Department
EHR: Electronic health record
GEE: Generalized estimating equation
GROC: global rating of change
HCP: healthcare provider
LEFS: Lower Extremity Functional Scale
MAR: Missing at random
MRC: Medical Research Council (UK)
MSK: musculoskeletal
NPRS: Numeric Pain Rating Scale
OA: Osteoarthritis
OHIP: Ontario Health Insurance Program
PSEQ: Pain Self-Efficacy Questionnaire
PT: Physiotherapist
QALY: Quality-adjusted life years
RA: Research assistant
REDCap: Research Electronic Data Capture
REML: Restricted maximum likelihood
RCT: Randomized controlled trial

References

1. Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet.* 2021;396(10267):2006-2017.
2. Badley EM, Wilfong JM, Zahid S, Perruccio AV. *The status of arthritis in Canada: National report.* 2019.
3. Bombardier C, Hawker G, Mosher D. *The impact of arthritis in Canada: Today and over the next 20 years.* Arthritis Alliance of Canada;2011.
4. Cote P, Cassidy JD, Carroll L. The treatment of neck and low back pain: who seeks care? who goes where? *Med Care.* 2001;39(9):956-967.
5. Stephenson E, Butt DA, Gronsbell J, et al. Changes in the top 25 reasons for primary care visits during the COVID-19 pandemic in a high-COVID region of Canada. *PLoS One.* 2021;16(8):e0255992.
6. Finley CR, Chan DS, Garrison S, et al. What are the most common conditions in primary care? Systematic review. *Can Fam Physician.* 2018;64(11):832-840.

7. Muggah E, Graves E, Bennett C, Manuel DG. The impact of multiple chronic diseases on ambulatory care use; a population based study in Ontario, Canada. *BMC Health Serv Res.* 2012;12(1):452.
8. Rothman AA, Wagner EH. Chronic illness management: what is the role of primary care? *Ann Intern Med.* 2003;138(3):256-261.
9. Broemeling A-M, Watson D, Black C. *Chronic conditions and co-morbidity among residents of British Columbia.* Centre for Health Services and Policy Research, College of Health …; 2005.
10. Rahman B, Costa AP, Gayowsky A, et al. The association between patients' timely access to their usual primary care physician and use of walk-in clinics in Ontario, Canada: a cross-sectional study. *CMAJ Open.* 2023;11(5):E847-E858.
11. MacKichan F, Brangan E, Wye L, et al. Why do patients seek primary medical care in emergency departments? An ethnographic exploration of access to general practice. *BMJ Open.* 2017;7(4):e013816.
12. Health Canada. *Collaborative Care.* 2007.
13. Government of Ontario. Ontario's Primary Care Action Plan, January 2025. https://www.ontario.ca/page/ontarios-primary-care-action-plan-january-2025. Published 2025. Accessed August 2025.
14. Bastiaens F, Barten D-J, Veenhof C. Identifying goals, roles and tasks of extended scope physiotherapy in Dutch primary care- an exploratory, qualitative multi-step study. *BMC Health Serv Res.* 2021;21(1):19.
15. Samsson KS, Bernhardsson S, Larsson MEH. Perceived quality of physiotherapist-led orthopaedic triage compared with standard practice in primary care: a randomised controlled trial. *BMC Musculoskeletal Disorders.* 2016;17(1):257.
16. Sephton R, Hough E, Roberts SA, Oldham J. Evaluation of a primary care musculoskeletal clinical assessment service: a preliminary study. *Physiotherapy.* 2010;96(4):296-302.
17. Miller J, Barber D, Donnelly C, et al. Determining the impact of a new physiotherapist-led primary care model for back pain: protocol for a pilot cluster randomized controlled trial. *Trials.* 2017;18(1):526.
18. Dufour SP, Brown J, Deborah Lucy S. Integrating physiotherapists within primary health care teams: perspectives of family physicians and nurse practitioners. *Journal of Interprofessional Care.* 2014;28(5):460-465.
19. Dufour SP, Lucy SD, Brown JB. Understanding physiotherapists' roles in Ontario primary health care teams. *Physiotherapy Canada.* 2014;66(3):234-242.
20. Perreault K, Dionne CE, Rossignol M, Morin D. Interprofessional practices of physiotherapists working with adults with low back pain in Québec's private sector: results of a qualitative study. *BMC Musculoskeletal Disorders.* 2014;15(1):160.
21. Saragiotto BT, de Almeida MO, Yamato TP, Maher CG. Multidisciplinary Biopsychosocial Rehabilitation for Nonspecific Chronic Low Back Pain. *Phys Ther.* 2016;96(6):759-763.
22. Desjardins-Charbonneau A, Roy JS, Thibault J, Ciccone VT, Desmeules F. Acceptability of physiotherapists as primary care practitioners and advanced practice physiotherapists for care of patients with musculoskeletal disorders: a survey of a university community within the province of Quebec. *BMC Musculoskelet Disord.* 2016;17(1):400.
23. Moffatt F, Goodwin R, Hendrick P. Physiotherapy-as-first-point-of-contact-service for patients with musculoskeletal complaints: understanding the challenges of implementation. *Primary Health Care Research & Development.* 2018;19(2):121-130.

24. Goodwin RW, Hendrick PA. Physiotherapy as a first point of contact in general practice: a solution to a growing problem? *Primary Health Care Research & Development.* 2016;17(5):489-502.
25. Downie F, McRitchie C, Monteith W, Turner H. Physiotherapist as an alternative to a GP for musculoskeletal conditions: a 2-year service evaluation of UK primary care data. *Br J Gen Pract.* 2019;69(682):e314-e320.
26. Leach J, Lievesley K. Our experience of employing a musculoskeletal practitioner in general practice. *Br J Gen Pract.* 2020;70(692):110.
27. Bignell MscPt K, Bender MscPt C, Lichtenstein MscPt A, et al. Improving access in rheumatology: Evaluating the validity of a paper triage process involving an advanced practice physiotherapist through a retrospective chart review. *Physiotherapy Theory and Practice.* 2020;36(1):203-210.
28. Ahluwalia V, Larsen TLH, Kennedy CA, Inrig T, Lundon K. An advanced clinician practitioner in arthritis care can improve access to rheumatology care in community-based practice. *Journal of Multidisciplinary Healthcare.* 2019;12(null):63-71.
29. Eccles M, Grimshaw J, Campbell M, Ramsay C. Research designs for studies evaluating the effectiveness of change and improvement strategies. *Qual Saf Health Care.* 2003;12(1):47-52.
30. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ : British Medical Journal.* 2013;346:e7586.
31. Chan AW, Boutron I, Hopewell S, et al. SPIRIT 2025 statement: updated guideline for protocols of randomized trials. *Nat Med.* 2025;31(6):1784-1792.
32. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *Int J Nurs Stud.* 2024;154:104705.
33. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.
34. May CR, Mair FS, Dowrick CF, Finch TL. Process evaluation for complex interventions in primary care: understanding trials using the normalization process model. *BMC Fam Pract.* 2007;8:42.
35. Moulton LH. Covariate-based constrained randomization of group-randomized trials. *Clin Trials.* 2004;1(3):297-305.
36. Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. *Bmj.* 2003;327(7418):785-789.
37. Campbell MJ. Challenges of cluster randomized trials. *Journal of Comparative Effectiveness Research.* 2014;3(3):271-281.
38. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the Shiny CRT Calculator. *Int J Epidemiol.* 2020;49(3):979-995.
39. Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther.* 1999;79(4):371-383.
40. Dingemans SA, Kleipool SC, Mulders MAM, et al. Normative data for the lower extremity functional scale (LEFS). *Acta Orthop.* 2017;88(4):422-426.
41. Campbell MK, Fayers PM, Grimshaw JM. Determinants of the intracluster correlation coefficient in cluster randomized trials: the case of implementation research. *Clin Trials.* 2005;2(2):99-107.

42. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.
43. Groll DL, Heyland DK, Caeser M, Wright JG. Assessment of Long-Term Physical Function in Acute Respiratory Distress Syndrome (ARDS) Patients: Comparison of the Charlson Comorbidity Index and the Functional Comorbidity Index. *American Journal of Physical Medicine & Rehabilitation.* 2006;85(7):574-581.
44. Rundell SD, Resnik L, Heagerty PJ, Kumar A, Jarvik JG. Performance of the Functional Comorbidity Index (FCI) in Prognostic Models for Risk Adjustment in Patients With Back Pain. *PM R.* 2020;12(9):891-898.
45. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. *Journal of clinical epidemiology.* 2005;58(6):595-602.
46. Kahl C, Cleland JA. Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties. *Physical Therapy Reviews.* 2005;10(2):123-128.
47. van Reenen M, Janssen B, Stolk E, et al. EuroQol Research Foundation. EQ-5D-5L User Guide, 2019. doi:https://euroqol.org/publications/user-guides.
48. Finch AP, Dritsaki M, Jommi C. Generic Preference-based Measures for Low Back Pain: Which of Them Should Be Used? *Spine (Phila Pa 1976).* 2016;41(6):E364-374.
49. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther.* 2009;17(3):163-170.
50. Chiarotto A, Vanti C, Cedraschi C, et al. Responsiveness and Minimal Important Change of the Pain Self-Efficacy Questionnaire and Short Forms in Patients With Chronic Low Back Pain. *J Pain.* 2016;17(6):707-718.
51. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *Eur J Pain.* 2007;11(2):153-163.
52. Sullivan MJL, Bishop SR, Pivik J. The Pain Catastrophizing Scale: Development and validation. *Psychol Assess.* 1995;7(4).
53. Osman A, Barrios FX, Kopper BA, Hauptmann W, Jones J, O'Neill E. Factor structure, reliability, and validity of the Pain Catastrophizing Scale. *J Behav Med.* 1997;20(6):589-605.
54. Sullivan MJ, Thorn B, Haythornthwaite JA, et al. Theoretical perspectives on the relation between catastrophizing and pain. *The Clinical journal of pain.* 2001;17(1):52-64.
55. Roelofs J, Goubert L, Peters ML, Vlaeyen JWS, Crombez G. The Tampa Scale for Kinesiophobia: further examination of psychometric properties in patients with chronic low back pain and fibromyalgia. *European Journal of Pain.* 2004;8(5):495-502.
56. Woby SR, Roach NK, Urmston M, Watson PJ. Psychometric properties of the TSK-11: A shortened version of the Tampa Scale for Kinesiophobia. *Pain.* 2005;117(1):137-144.
57. Tkachuk GA, Harris CA. Psychometric Properties of the Tampa Scale for Kinesiophobia-11 (TSK-11). *The Journal of Pain.* 2012;13(10):970-977.
58. Thombs BD, Benedetti A, Kloda LA, et al. The diagnostic accuracy of the Patient Health Questionnaire-2 (PHQ-2), Patient Health Questionnaire-8 (PHQ-8), and Patient Health Questionnaire-9 (PHQ-9) for detecting major depression: protocol for a systematic review and individual patient data meta-analyses. *Syst Rev.* 2014;3:124.

59. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes.* Fourth edition. ed. Oxford, United Kingdom ;: Oxford University Press; 2015.
60. Ministry of Health. OHIP Schedule of Benefits and fees. https://www.ontario.ca/page/ohip-schedule-benefits-and-fees. Published 2024. Updated August 30, 2024. Accessed November 13, 2024.
61. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. *Adm Policy Ment Health.* 2015;42(5):533-544.
62. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res.* 2016;26(13):1753-1760.
63. Kenward MG, Roger JH. An improved approximation to the precision of fixed effects from restricted maximum likelihood. *Computational Statistics & Data Analysis.* 2009;53(7):2583-2595.
64. Moreno-Betancur M, Chavance M. Sensitivity analysis of incomplete longitudinal data departing from the missing at random assumption: Methodology and application in a clinical trial with drop-outs. *Statistical Methods in Medical Research.* 2016;25(4):1471-1489.
65. Troendle JF, Sur A, Leifer ES, Powell-Wiley T. Sensitivity Analyses for Missing in Repeatedly Measured Outcome Data. *Stat Med.* 2025;44(23-24):e70282.
66. Chavance M. Handling Missing Items in Quality of Life Studies. *Communications in statistics Theory and methods.* 2004;33(6):1371-1383.
67. Teirlinck CH, Verhagen AP, Reijneveld EAE, et al. Responders to Exercise Therapy in Patients with Osteoarthritis of the Hip: A Systematic Review and Meta-Analysis. *Int J Environ Res Public Health.* 2020;17(20).
68. Fay MP, Graubard BI. Small-Sample Adjustments for Wald-Type Tests Using Sandwich Estimators. *Biometrics.* 2004;57(4):1198-1206.
69. Yelland LN, Salter AB, Ryan P. Performance of the Modified Poisson Regression Approach for Estimating Relative Risks From Clustered Prospective Data. *American Journal of Epidemiology.* 2011;174(8):984-992.
70. Li P, Redden DT. Small sample performance of bias-corrected sandwich estimators for cluster-randomized trials with binary outcomes. *Statistics in medicine.* 2015;34(2):281-296.
71. Thompson JA, Leyrat C, Fielding KL, Hayes RJ. Cluster randomised trials with a binary outcome and a small number of clusters: comparison of individual and cluster level analysis method. *BMC Medical Research Methodology.* 2022;22(1):222.
72. Hunt MR. Strengths and challenges in the use of interpretive description: reflections arising from a study of the moral experience of health professionals in humanitarian work. *Qual Health Res.* 2009;19(9):1284-1292.
73. Thorne S, Kirkham SR, MacDonald-Emes J. Interpretive description: a noncategorical qualitative alternative for developing nursing knowledge. *Res Nurs Health.* 1997;20(2):169-177.
74. Morse JM, Barrett M, Mayan M, Olson K, Spiers J. Verification strategies for establishing reliability and validity in qualitative research. *International journal of qualitative methods.* 2002;1(2):13-22.
75. Holloway I, Galvin K. *Qualitative research in nursing and healthcare.* John Wiley & Sons; 2016.
76. Guba EG, Lincoln YS. *Effective evaluation: Improving the usefulness of evaluation results through responsive and naturalistic approaches.* Jossey-Bass; 1981.

77. Lincoln YS, Guba EG. But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. *New directions for program evaluation.* 1986;1986(30):73-84.
78. Guba EG. Criteria for assessing the trustworthiness of naturalistic inquiries. *Ectj.* 1981;29(2):75.